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

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

(submitted by the competent authority)

Drevosan family

Product type 08

Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride, Propiconazole, Tebuconazole and Cypermethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-SV017567-01

Competent Authority: Czech Republic

Date: 31/10/2023

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Changes history table

Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	CZ	BC-SV017567-01	31.10.2023	Initial assessment	

1 Conclusion

The BPF Drevosan family consists of products containing the active substances alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC), propiconazole, tebuconazole and cypermethrin. The products are soluble concentrates and ready-to-use solutions. The BPF is used for preventive treatment of timber in use classes 1 and 2 by professional and non-professional users for the control of wood rotting basidiomycetes and the house longhorn beetle (*Hylotrupes bajulus*).

The BPF consists of 6 meta-SPCs. Meta-SPCs 1 and 2 are water-based concentrates containing 20% ADBAC, 0.3% propiconazole, 0.3% tebuconazole and 0.1% cypermethrin. Meta-SPC 1 comprises of the colourless and green variants, meta-SPC 2 of the brown variant. The brown variant has to be included in a separate SPC due to presence of a skin sensitising dye (Acid Brown 282) leading to a classification different from that of the other colour variants. The remaining four meta-SPCs represent dilutions of meta-SPCs 1 and 2. Again, the brown variants are included in separate meta-SPCs. Regardless of the meta-SPC, the application rate (in terms of a.s. amount) is identical for all products and uses.

The BPF falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s).

The overall conclusion of the evaluation is that the BPF meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the uses 'automated dipping' (by industrial users), 'brush treatment – professional' and 'brush treatment – non-professional', as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended use(s) of the BPF 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 BPF 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.

Detailed information on classification and labelling is provided in section 2.9 of the PAR. The hazard and precautionary statements of the BPF according to Regulation (EC) No 1272/2008 are available in the SPC, in section 3 for each meta-SPC.

The BPF contains a non-active substance (so called "co-formulant") which is considered as a substance of concern (for human health). The assessment of the non-active substances showed that the content of Acid Brown in meta-SPCs 2 and 4 leads to the classification of the respective products as Skin Sens. 1 and labelling of meta-SPC 6 with EUH208. More detailed information on the substance(s) of concern is provided in the confidential annex.

The BPF contains the active substance propiconazole having endocrine-disrupting properties. As to the product as a whole, the draft ATP to the CLP introducing the hazard class of endocrine disruptors[1] proposes generic concentration limits of 0.1% and 1% for Category 1 and Category 2 endocrine disruptors respectively. Propiconazole is present at ≥0.1% in meta-SPCs 1 to 4 and at <0.1% in meta-SPCs 5 and 6.

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

[1] Document C/2022/9383 final; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM:C(2022)9383

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 BPF.

More information is available in section 2.8 of the PAR and in the confidential annex.

The BPF contains propiconazole and tebuconazole which meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are considered as candidates for substitution based on the following criteria: propiconazole is considered toxic for reproduction Cat. 1B and to have endocrine-disrupting properties with regard to humans and non-target organisms; tebuconazole is considered very persistent and toxic (vP and T). Therefore, a comparative assessment has been performed in accordance with Article 23(1) of Regulation (EU) No 528/2012 and following the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[2]. The assessment is presented in a separate document. In addition, it is briefly summarised under section 3.10 of the PAR. The competent authority concluded that (1) the available biocidal products not containing active substances targeted by exclusion criteria present major practical disadvantages and (2) that there is no suitable non-chemical alternative to biocidal timber treatment.

Composition

The qualitative and quantitative information on the non-confidential composition of the BPF 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 products is listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the BPF are met. More information is available in sections 2.5 and 2.6 of the PAR. The manufacturers of the active substances are listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

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

Physical, chemical and technical properties

The physico-chemical properties for biocidal products included in all meta-SPC are deemed acceptable for the appropriate use, handling, storage and transportation. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards related to products across the biocidal product family were not identified.

More information is available in section 3.3 of the PAR.

Methods for detection and identification

Fully validated analytical method for the determination of the mass concentration of the active substances in representative biocidal products is available. More information on the analytical method for the active substances is available in section 3.4 of the PAR.

[2] The document is available in CIRCABC at https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3.

Related to the analytical methods for monitoring of relevant components of the biocidal product and/or residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff – all Letters of access to the active's dossiers were submitted by the applicant. More information is available in section 3.4 of the PAR. Moreover, all products are labelled "Do not use on wood which may come into direct contact with food, feeding stuff, drinking water or livestock animals."

Efficacy against target organisms

The BPF has been shown to be efficacious against wood rotting basidiomycetes and house longhorn beetle *Hylotrupes bajulus* for all intended uses (automated dipping and brush treatment) in all Meta SPCs. 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 Acid Brown 282 has been identified as a substance of concern, the human health risk assessment is based on ADBAC, propiconazole, tebuconazole, cypermethrin and on Acid Brown 282.

Based on the risk assessment, it is unlikely that the intended uses cause 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 uses, food or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substances is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

Considering the uses, 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.

A qualitative consideration of risk was performed. The intended uses fall under use classes 1 and 2, which are characterized by negligible emissions of product residues to the environment during the service-life as the treated wood is not expected to be exposed to (significant) weathering. Additionally, risk mitigation measures were proposed for the application, storage, and disposal steps to further prevent emissions to the environment and exposure of non-target organisms. The primary recipient of emissions, air, is not considered to be at risk, owing to the non-volatile nature of the active substances and the short (< 2 d) half-lives in the air (expect for tebuconazole with a DT50 value in air of 3.8 d).

The product contains tebuconazole and propiconazole, which are considered candidates for substitution. Propiconazole is considered to have endocrine properties, nevertheless, the decision on approval for renewal has been postponed till Dec 2023, and until that time, propiconazole remains approved for use in biocidal products of product-type 8 subject to

the specifications and conditions set out in Annex I to Directive 98/8/EC.

Nevertheless, the presence of candidates for substitution in the product family triggers the need for a comparative assessment.

Based on the qualitative risk assessment, it is unlikely that the intended uses cause unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

Post-authorisation conditions

No post-authorisation conditions have been set out.

2 Information on the biocidal product family

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

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

Product type(s)	PT08
Type(s) of formulation	SL-soluble concentrate for meta-SPCs 1, 2, 3 and 4 AL-other liquids (to be applied undiluted) for meta-SPCs 5 and 6

2.2 Uses

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

Table 2.2 Overview of uses of the BPF

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (by CA)[8]	Comment[9]
1.1 and 2.1	Automated dipping	PT8	Wood-rotting basidiomycetes *Hylotrupes bajulus*	Automated dipping	15 g/m^2	Industrial	A	PPE required
1.2 and 2.2	Brush treatment – professionals			Brushing	15 g/m^2	Professional	A	PPE required
3.1 and 4.1	Automated dipping			Automated dipping	40 g/m^2	Industrial	A	PPE required
3.2 and 4.2	Brush treatment – professionals			Brushing	40 g/m^2	Professional	A	PPE required
5.1 and 6.1	Brush treatment – non-professionals			Brushing	150 g/m^2	Non-professional	A	

[1] Use number (as applied for) to be indicated together with the meta-SPC number, as in the SPC (e.g. 1.2, where "1" is the meta-SPC and "2" is the use number within the meta-SPC)
[2] Title of the specific use (as applied for), as indicated in the SPC
[3] Product type(s) of the use(s)
[4] Target organisms, group of organisms
[5] Application method for all meta-SPCs for the specific use
[6] Min-max. application rate of the product(s) for the specific use
[7] User categor(y/ies), e.g. general public, non-professional, professional, industrial
[8] eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

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

[9] If the use or meta-SPC is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

2.3 Similarity of the group of products for which the authorisation as a biocidal product family is sought

The application for authorisation as a BPF explicitly identified the maximum risks to human health, animal health, and the environment, and the minimum level of efficacy.

All the products applied for include the same active substances and are similar in composition. Information on the similarity of composition and the identified worst and best case composition are provided in the confidential annex.

Table 2.3 Overview regarding the similarity of the intended uses

Use number	Product type	Reference[1]	Use pattern[2]
1.1 and 2.1	PT8	#39	Wood preservatives
1.2 and 2.2	PT8	#39	Wood preservatives
3.1 and 4.1	PT8	#39	Wood preservatives
3.2 and 4.2	PT8	#39	Wood preservatives
5.1 and 6.1	PT8	#39	Wood preservatives

[1, 2] As indicated in the Note for Guidance "Implementing the concept of biocidal product family" (CA-July19-Doc4.2-Final).

The agreed general criteria for deciding on whether the intended uses can be considered as similar were applied, according to the document CA-July19-Doc.4.2-Final entitled "Implementing the concept of biocidal product family". In accordance with these criteria, all the intended uses are considered similar uses.

All the intended uses as applied for by the applicant have been assessed. By considering only those uses appropriate for authorisation which bear a consistent set of instructions for use, RMMs etc. (e.g. same RMMs from best to worst case composition), it was ensured that all products of the BPF have a similar level of risk and efficacy.

2.4 Identity and composition

The identity and composition of the products within the BPF are

identical ☐
not identical ☒

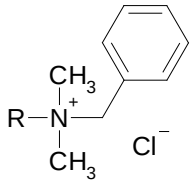
to the identity and composition of the products evaluated in connection with the approval for listing of the active substances on the Union list of approved active substances under Regulation (EU) No 528/2012.

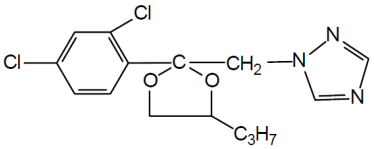
The qualitative and quantitative information on the non-confidential composition of the meta-SPCs and of the individual products is detailed in sections 2.1 and 7 of the SPC, respectively. Information on the full composition is provided in the confidential annex.

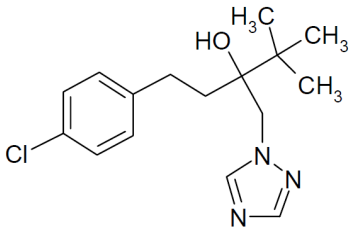
2.5 Identity of the active substances

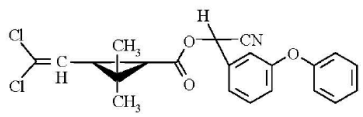
Table 2.4 Identity of the active substances

Main constituent	
Common name	Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride
Chemical name	
EC number	270-325-2
CAS number	68424-85-1
Index number in Annex VI of CLP	n.a.
Minimum purity / content	Dry weight: 940 g/kg

Structural formula	 R = $C_{12}H_{25}$, $C_{14}H_{29}$ or $C_{16}H_{33}$

Main constituent	
Common name	Propiconazole
Chemical name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
EC number	262-104-4
CAS number	60207-90-1
Index number in Annex VI of CLP	613-205-00-0
Minimum purity / content	930 g/kg
Structural formula	

Main constituent	
Common name	Tebuconazole
Chemical name	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol
EC number	403-640-2
CAS number	107534-96-3
Index number in Annex VI of CLP	603-197-00-7
Minimum purity / content	950 g/kg
Structural formula	

Main constituent	
Common name	Cypermethrin
Chemical name	Cypermethrin *cis:trans*/40:60 (RS)-α-cyano-3-phenoxybenzyl-(1RS)-*cis,trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate
EC number	257-842-9
CAS number	52315-07-8
Index number in Annex VI of CLP	607-421-00-4
Minimum purity / content	920 g/kg
Structural formula	

2.6 Information on the sources of the active substances

Is the source of alkyl (C_{12-16}) dimethylbenzyl ammonium chloride the same as the one(s) 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?

Stepan Europe SAS:

☒ Yes
☐ No

Is the source of propiconazole the same as the one(s) 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?

Syngenta Crop Protection AG:

☒ Yes
☐ No

Jiangsu Yangnong Chemical Group Co., Ltd:

☐ Yes
☒ No

The source has been subject to an assessment of technical equivalence and has been found to be technically equivalent (decision number 717/713/2011).

Jiangsu SevenContinent Green Chemical Co., Ltd:

☐ Yes
☒ No

The source has been subject to an assessment of technical equivalence and has been found to be technically equivalent (TE-APP asset number EU-0013032-0000, decision number TAP-D-1182636-27-00/F).

Is the source of tebuconazole the same as the one(s) 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?

Bayer CropScience Corp.:

☒ Yes
☐ No

Jiangsu Sword Agrochemicals Co., Ltd:

☐ Yes
☒ No

The source has been subject to an assessment of technical equivalence and has been found to be technically equivalent (TE-APP asset number EU-0016012, decision number TAP-D-1252239-29-00/F).

Is the source of cypermethrin the same as the one(s) 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?

Arysta LifeScience Benelux SPRL – Groupe UPL:

☒ Yes

☐ No

2.7 Candidate(s) for substitution

The following candidates for substitution have been identified:

- Propiconazole
- Tebuconazole

The following criteria for substitution are met:

Propiconazole:

- Toxic for reproduction Cat. 1B (existing harmonised classification)
- Endocrine-disrupting properties with regard to humans and non-target organisms (BPC opinion PT8 renewal, March 2022)
- Very persistent and Toxic (BPC opinion PT8 renewal, March 2022)

Tebuconazole:

- Very persistent and Toxic (Regulation (EU) 1038/2013)

Further, a CLH report with a proposal to classify tebuconazole as toxic for reproduction Cat. 1B was submitted to ECHA in November 2021.

2.8 Assessment of the endocrine-disrupting properties of the biocidal product family

The BPF contains the active substance propiconazole having endocrine-disrupting properties on the basis of the scientific criteria in Regulation (EU) 2017/2100. The details on the endocrine-disrupting properties are available in the CAR provided for the renewal of approval of the active substance.

The active substance alkyl (C_{12-16}) dimethylbenzyl ammonium chloride is not considered to have ED properties with respect to humans. No conclusion on ED properties with respect to non-target organisms can be drawn based on the available data (BPC opinions for PT 1 and 2, 2021).

The BPF further contains the active substances tebuconazole and cypermethrin, which have not yet been evaluated according to the scientific criteria set out in the Regulation (EU) No 2017/2100.

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

2.9 Classification and labelling

Table 2.5 Classification and labelling of the BPF

Meta-SPC 1	Classification	Labelling
Hazard Class and Category code	Acute Tox. 4 Skin Corr. 1B Eye Dam. 1 Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	
Hazard Pictograms	GHS05, GHS07, GHS08, GHS09	GHS05, GHS07, GHS08, GHS09
Signal word(s)	Danger	Danger
Hazard statements	H302 – Harmful if swallowed H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage H360D – May damage the unborn child H400 – Very toxic to aquatic life H410 – Very toxic to aquatic life with long lasting effects	H302 – Harmful if swallowed H314 – Causes severe skin burns and eye damage H360D – May damage the unborn child H410 – Very toxic to aquatic life with long lasting effects

Precautionary statements*	P201 – Obtain special instructions before use. P202 – Do not handle until all safety precautions have been read and understood. P260 – Do not breathe ~~dust/fume/gas/~~mist~~/vapours/spray.~~ P264 – Wash hands thoroughly after handling. P270 – Do not eat, drink or smoke when using this product. P273 – Avoid release to the environment. P280 – Wear protective gloves/protective clothing/eye protection/face protection. ~~P301+P312 – IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.~~ ~~P330 – Rinse mouth.~~ P301+P330+P331 – IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304+P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310 – Immediately call a POISON CENTER/doctor. P363 – Wash contaminated clothing before reuse. ~~P308+P313 – IF exposed or concerned: Get medical advice/attention.~~ ~~P321 – Specific treatment (see … on this label).~~ P391 – Collect spillage. P405 – Store locked up. P501 – Dispose of contents and container in accordance with national regulation.	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements	EUH208 - Contains propiconazole (CAS No. 60207-90-1). May produce an allergic reaction.	
Notes	P-statements P301+P312, P330 and P308+P313 have been removed to avoid redundancy. P321 has been excluded as no specific treatment is available.	

*****P-statements that are excluded based on the risk assessment or the intended use of the product(s), are indicated with a strikethrough. All P-statements listed under the first column have also been listed in the SPC.

Meta-SPC 2	Classification	Labelling
Hazard Class and Category code	Acute Tox. 4 Skin Corr. 1B Eye Dam. 1 Skin Sens. 1 Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	
Hazard Pictograms	GHS05, GHS07, GHS08, GHS09	GHS05, GHS07, GHS08, GHS09
Signal word(s)	Danger	Danger
Hazard statements	H302 – Harmful if swallowed H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage H317 – May cause an allergic skin reaction H360D – May damage the unborn child H400 – Very toxic to aquatic life H410 – Very toxic to aquatic life with long lasting effects	H302 – Harmful if swallowed H314 – Causes severe skin burns and eye damage H317 – May cause an allergic skin reaction H360D – May damage the unborn child H410 – Very toxic to aquatic life with long lasting effects

Precautionary statements*	P201 – Obtain special instructions before use. P202 – Do not handle until all safety precautions have been read and understood. P260 – Do not breathe ~~dust/fume/gas/~~mist~~/vapours/spray.~~ ~~P261 – Avoid breathing dust/fume/gas/mist/vapours/spray.~~ P264 – Wash hands thoroughly after handling. P270 – Do not eat, drink or smoke when using this product. P272 – Contaminated work clothing should not be allowed out of the workplace. P273 – Avoid release to the environment. P280 – Wear protective gloves/protective clothing/eye protection/face protection. ~~P301+P312 – IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.~~ ~~P330 – Rinse mouth.~~ P301+P330+P331 – IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. ~~P302+P352 – IF ON SKIN: Wash with plenty of water.~~ P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304+P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310 – Immediately call a POISON CENTER/doctor. P363 – Wash contaminated clothing before reuse. ~~P308+P313 – IF exposed or concerned: Get medical advice/attention.~~ ~~P321 – Specific treatment (see … on this label).~~ P333+P313 – If skin irritation or rash occurs: Get medical advice/attention. ~~P362+P364 – Take off contaminated clothing and wash it before reuse.~~ P391 – Collect spillage. P405 – Store locked up.	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.

	P501 – Dispose of contents and container in accordance with national regulation.	
Supplemental hazard statements	EUH208 - Contains propiconazole (CAS No. 60207-90-1) and Acid Brown 282 (CAS No. 70236-60-1). May produce an allergic reaction.	
Notes	P-statements P261, P301+P312, P330, P302+P352, P308+P313 and P362+P364 have been removed to avoid redundancy. P321 has been excluded as no specific treatment is available.	

*****P-statements that are excluded based on the risk assessment or the intended use of the product(s), are indicated with a strikethrough. All P-statements listed under the first column have also been listed in the SPC.

Meta-SPC 3	Classification	Labelling
Hazard Class and Category code	Skin Corr. 1B Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	
Hazard Pictograms	GHS05, GHS09	GHS05, GHS09
Signal word(s)	Danger	Danger
Hazard statements	H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage H400 – Very toxic to aquatic life H410 – Very toxic to aquatic life with long lasting effects	H314 – Causes severe skin burns and eye damage H410 – Very toxic to aquatic life with long lasting effects
Precautionary statements*	P260 – Do not breathe ~~dust/fume/gas/~~mist~~/vapours/spray.~~ P264 – Wash hands thoroughly after handling. P273 – Avoid release to the environment. P280 – Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331 – IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304+P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310 – Immediately call a POISON CENTER/doctor. P363 – Wash contaminated clothing before reuse. ~~P321 – Specific treatment (see … on this label).~~ P391 – Collect spillage. P405 – Store locked up. P501 – Dispose of contents and container in accordance with national regulation.	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements	EUH208 - Contains propiconazole (CAS No. 60207-90-1). May produce an allergic reaction.	
Notes	P321 has been excluded as no specific treatment is available.	

***P-statements that are excluded based on the risk assessment or the intended use of the product(s), are indicated with a strikethrough. All P-

statements listed under the first column have also been listed in the SPC.

Meta-SPC 4	Classification	Labelling
Hazard Class and Category code	Skin Corr. 1B Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	
Hazard Pictograms	GHS05, GHS07, GHS09	GHS05, GHS07, GHS09
Signal word(s)	Danger	Danger
Hazard statements	H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage H317 – May cause an allergic skin reaction H400 – Very toxic to aquatic life H410 – Very toxic to aquatic life with long lasting effects	H314 – Causes severe skin burns and eye damage H317 – May cause an allergic skin reaction H410 – Very toxic to aquatic life with long lasting effects

Precautionary statements*	P260 – Do not breathe ~~dust/fume/gas/~~mist~~/vapours/spray.~~ ~~P261 – Avoid breathing dust/fume/gas/mist/vapours/spray.~~ P264 – Wash hands thoroughly after handling. P272 – Contaminated work clothing should not be allowed out of the workplace. P273 – Avoid release to the environment. P280 – Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331 – IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. ~~P302+P352 – IF ON SKIN: Wash with plenty of water.~~ P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304+P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310 – Immediately call a POISON CENTER/doctor. P333+P313 – If skin irritation or rash occurs: Get medical advice/attention. ~~P362+P364 – Take off contaminated clothing and wash it before reuse.~~ P363 – Wash contaminated clothing before reuse. ~~P321 – Specific treatment (see … on this label).~~ P391 – Collect spillage. P405 – Store locked up. P501 – Dispose of contents and container in accordance with national regulation.	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements	EUH208 - Contains propiconazole (CAS No. 60207-90-1) and Acid Brown 282 (CAS No. 70236-60-1). May produce an allergic reaction.	
Notes	P-statements P261, P302+P352 and P362+P364 have been removed to avoid redundancy. P321 has been excluded as no specific treatment is available.	

***P-statements that are excluded based on the risk assessment or the intended use of the product(s), are indicated with a strikethrough. All P-statements listed under the first column have also been listed in the SPC.

Meta-SPC 5	Classification	Labelling
Hazard Class and Category code	Skin Irrit. 2 Eye Irrit. 2 Aquatic Chronic 1	
Hazard Pictograms	GHS07, GHS09	GHS07, GHS09
Signal word(s)	Warning	Warning
Hazard statements	H315 – Causes skin irritation H319 – Causes serious eye irritation H410 – Very toxic to aquatic life with long lasting effects	H315 – Causes skin irritation H319 – Causes serious eye irritation H410 – Very toxic to aquatic life with long lasting effects
Precautionary statements*	P264 – Wash hands thoroughly after handling. P273 – Avoid release to the environment. P280 – Wear protective gloves/~~protective clothing/~~eye protection~~/face protection~~. P302+P352 – IF ON SKIN: Wash with plenty of water. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332+P313 – If skin irritation occurs: Get medical advice/attention. P337+P313 – If eye irritation persists: Get medical advice/attention. P362+P364 – Take off immediately all contaminated clothing and wash it before reuse. ~~P321 – Specific treatment (see … on this label).~~ P391 – Collect spillage. P501 – Dispose of contents and container in accordance with national regulation.	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements	None	
Notes	P321 has been excluded as no specific treatment is available.	

***P-statements that are excluded based on the risk assessment or the intended use of the product(s), are indicated with a strikethrough. All P-statements listed under the first column have also been listed in the SPC.

Meta-SPC 6	Classification	Labelling
Hazard Class and Category code	Skin Irrit. 2 Eye Irrit. 2 Aquatic Chronic 1	
Hazard Pictograms	GHS07, GHS09	GHS07, GHS09
Signal word(s)	Warning	Warning
Hazard statements	H315 – Causes skin irritation H319 – Causes serious eye irritation H410 – Very toxic to aquatic life with long lasting effects	H315 – Causes skin irritation H319 – Causes serious eye irritation H410 – Very toxic to aquatic life with long lasting effects
Precautionary statements*	P264 – Wash hands thoroughly after handling. P273 – Avoid release to the environment. P280 – Wear protective gloves/~~protective clothing/~~eye protection~~/face protection~~. P302+P352 – IF ON SKIN: Wash with plenty of water. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332+P313 – If skin irritation occurs: Get medical advice/attention. P337+P313 – If eye irritation persists: Get medical advice/attention. P362+P364 – Take off immediately all contaminated clothing and wash it before reuse. ~~P321 – Specific treatment (see … on this label).~~ P391 – Collect spillage. P501 – Dispose of contents and container in accordance with national regulation.	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements	EUH208 - Contains Acid Brown 282 (CAS No. 70236-60-1). May produce an allergic reaction.	
Notes	P321 has been excluded as no specific treatment is available.	

***P-statements that are excluded based on the risk assessment or the intended use of the product(s), are indicated with a strikethrough. All P-statements listed under the first column have also been listed in the SPC.

2.10 Letter of access

The following letters of access have been submitted:

- Stepan Europe S.A.S. granted the right to access Stepan Europe's studies submitted for the purpose of approval of ADBAC (C12-16) under Directive 98/8/EC (BPD) (list of studies based on AR PT 8 dated 2012).
- Lanxes Deutschland GmbH granted the right to access the BPD dossiers of propiconazole and tebuconazole.
- Arysta LifeScience Benelux SPRL granted the right to access Arysta's studies submitted for the purpose of approval of cypermethrin under BPR.

2.11 Data submitted in relation to product authorisation

No new data on the active substances have been submitted in relation to product authorisation.

Studies on the biocidal products of Drevosan family submitted for the purpose of authorisation are listed in section 4.3.

2.12 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product family

3.1 Packaging

Table 3.1 Packaging

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)
Jerry can	1 kg to 50 kg	HDPE	Screw cap, PE	Industrial, professional	Yes
Jerry can	1 kg to 15 kg	HDPE	Screw cap, PE	Non-professional	Yes

3.2 Physical, chemical, and technical properties

Biocidal products Drevosan Profi in meta-1 (colourless and green) and meta-2 (brown) are water-based concentrates containing 20% ADBAC, 0.3% propiconazole, 0.3% tebuconazole and 0.1% cypermethrin. The remaining four meta-SPCs (3, 4, 5 and 6) represent dilutions of meta-SPCs 1 and 2. Biocidal products Drevosan in meta-SPC 3 (colourless and green) and meta-SPC 4 (brown variant) are water-based concentrates, aqueous liquids, containing 8% ADBAC, 0.12% propiconazole, 0.12% tebuconazole and 0.04% cypermethrin. Biocidal products Drevosan Optimal in meta-SPC 5 (colourless and green) and 6 (brown) are water-based concentrates containing 2% ADBAC, 0.03% propiconazole, 0.03% tebuconazole and 0.01% cypermethrin. The specifications of the pigments and their concentrations are given in the confidential annex. The pigment content does not lead to any significant change in physico-chemical properties across the biocidal product family. For this reason, relevant physico-chemical properties for Drevosan Profi (meta-SPC 1), Drevosan (meta-SPC 3) and Drevosan Optimal (meta-SPC 5) are considered as representative for all products of the BPF. All relevant physico-chemical data and justifications provided by the applicant are presented in the Table below.

More information on the choice of the worst case composition for physical, chemical, and technical properties (e.g. representative test products) and the justifications for why the chosen test products are considered sufficient to cover the whole range of variations (use / composition) in the BPF are provided in the confidential annex.

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				
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual observation	Drevosan Profi (meta-SPC 1) Drevosan (meta-SPC 3) Drevosan Optimal (meta-SPC 5)	Liquid	MSDS
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual observation	Drevosan Profi (meta-SPC 1) Drevosan (meta-SPC 3) Drevosan Optimal (meta-SPC 5)	According to the visual inspection biocidal product is colourless (or according to added pigment green or brown) liquid (aqueous solution of active substances).	MSDS
3.1.3.	Odour at 20 °C and 101.3 kPa	Organoleptic detection	Drevosan Profi (meta-SPC 1) Drevosan (meta-SPC 3) Drevosan Optimal (meta-SPC 5)	According to the olfactory inspection biocidal product is slightly aromatic liquid (aqueous solution of active substances).	MSDS
3.2.	Acidity, alkalinity, and pH value	OECD TG 122 (CIPAC MT 75.3)	Drevosan Profi (meta-SPC 1) **Batch No.:** 012/15/506 Drevosan (meta-SPC 3) **Batch No.:** 007/15/501	**pH at 20°C** Drevosan Profi (undiluted): 7.85 Drevosan (undiluted): 8.53 Drevosan Optimal (undiluted): 8.12 Due to the pH value	Šošolíková and Sysala, 2015a Metrum s.r.o. **Report no.: 101-215001**

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
			Drevosan Optimal (meta-SPC 5) **Batch No.:** 001/15/520	in the range of 4–10, the acidity/alkalinity test is not required. (rel. to stability tests)	
3.3.	Relative density / bulk density	OECD TG 109	Drevosan Profi (meta-SPC 1) **Batch No.:** 012/15/506 Drevosan (meta-SPC 3), **Batch No.:** 007/15/501 Drevosan Optimal (meta-SPC 5) **Batch No.:** 001/15/520	**Density at 20°C** Drevosan Profi: 1002 $kg.m^{-3}$ Drevosan: 1001 $kg.m^{-3}$ Drevosan Optimal: 1000 $kg.m^{-3}$ Because Drevosan profi is a water based product its relative density is assumed to be approximately one. This is confirmed by the tests performed with the product and its application solution (i.e. 10 % dilution).	Šošolíková and Sysala, 2015b Metrum s.r.o. **Report no.: 101-215002**
3.4.1.1.	Storage stability test – **accelerated storage at 40°C for 6 months**	CIPAC MT 46 Guidance on the storage stability by BPU (HSE) Dilution stability: CIPAC MT 41	Drevosan Profi (meta-SPC 1) **Batch No.:** 311018 Drevosan (meta-SPC 3) **Batch No.:** 311018	**<u>Drevosan Profi</u>** <u>Pre-storage:</u> ADBAC 20.2% Propiconazole 0.299% Tebuconazole 0.299% Cypermethrin 0.104% <u>After 3 months/40°C:</u> ADBAC 20.3%	Musálková et al., 2021-11-21 **Test Report No.: 5910/BD+D+BO/ 2018**

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
			Drevosan Optimal (meta-SPC 5) **Batch no.:** 311018 **Target values:** Drevosan Profi (meta-SPC 1) ADBAC: 20.0% PPA: 0.3% TEB: 0.3% CYP: 0.1% Drevosan (meta-SPC 3) ADBAC: 8.0% PPA: 0.12% TEB: 0.12% CYP: 0.04% Drevosan Optimal (meta-SPC 5) ADBAC: 2.0% PPA: 0.03% TEB: 0.03% CYP: 0.01%	Propiconazole 0.301% Tebuconazole 0.301% Cypermethrin 0.095% No sediment After 6 months/40°C: ADBAC 20.4% Propiconazole 0.304% Tebuconazole 0.303% Cypermethrin 0.089% **5% and 10% sol.:** (after 6 months) No sediment observed Conc. mass values deviations statistically non-significant and/or acceptable tolerance. **Drevosan** Pre-storage: ADBAC 8.2% Propiconazole 0.120% Tebuconazole 0.120% Cypermethrin 0.043% After 3 months/40°C: ADBAC 8.2% Propiconazole 0.120% Tebuconazole 0.120% Cypermethrin 0.039% No sediment After 6 months/40°C: ADBAC 8.3%	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				Propiconazole 0.122% Tebuconazole 0.121% Cypermethrin 0.036% Conc. mass values deviations statistically non-significant and/or acceptable tolerance. **<u>Drevosan Optimal</u>** <u>Pre-storage:</u> ADBAC 2.03% Propiconazole 0.030% Tebuconazole 0.030% Cypermethrin 0.010% <u>After 3 months/40°C:</u> ADBAC 2.03% Propiconazole 0.030% Tebuconazole 0.030% Cypermethrin 0.009% No sediment <u>After 6 months/40°C:</u> ADBAC 2.04% Propiconazole 0.030% Tebuconazole 0.030% Cypermethrin 0.009% Conc. mass values deviations statistically non-significant and/or acceptable tolerance.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				No significant deviations in the active's mass values within the accelerated stability testing were found. This indicates that products would be stable for at least 3 years under the ambient conditions of storage. This was confirmed within the long-term stability tests at ambient temperature of storage for 3 yrs.	
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	Determination of ADBAC: ČSN EN ISO 2871-2 Determination of: propiconazole, tebuconazole, and cypermethrin: HPLC-UV method (internal SOP) Density: OECD TG 109 pH: OECD TG 122 **Packaging:** Container: 1 LHDPE	Drevosan Profi (meta-SPC 1) **Batch No.:** 021/11/506 **Target values:** Drevosan Profi (meta-SPC 1) ADBAC: 20.0% PPA: 0.3% TEB: 0.3% CYP: 0.1%	<u>Pre-storage:</u> ADBAC 20.12% Propiconazole 0.318% Tebuconazole 0.305% Cypermethrin 0.105% pH 7.63 density 1001 kg.m^{-3} <u>After 3 years at 18°C</u> ADBAC 20.03% Propiconazole 0.315% Tebuconazole 0.305% Cypermethrin 0.103% pH 7.88 density 1001 kg.m^{-3} Conc. mass values deviations statistically non-significant and/or	Šošolíková and Sysala, 2015c **Report no.: 101-215004**

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				acceptable tolerance.	
		CIPAC MT 46 Guidance on the storage stability by BPU (HSE) Dilution stability: CIPAC MT 41 **Packaging:** Container: 1L HDPE	Drevosan Profi (meta-SPC 1) **Batch No.:** 311018 Drevosan (meta-SPC 3) **Batch No.:** 311018 Drevosan Optimal (meta-SPC 5), **Batch No.:** 311018 **Target values:** Drevosan Profi (meta-SPC 1) ADBAC: 20.0% PPA: 0.3% TEB: 0.3% CYP: 0.1% Drevosan (meta-SPC 3) ADBAC: 8.0% PPA: 0.12% TEB: 0.12%	**<u>Drevosan Profi</u>** <u>Pre-storage:</u> ADBAC 20.2% Propiconazole 0.299% Tebuconazole 0.299% Cypermethrin 0.104% <u>After 1 yr./20-25°C</u> ADBAC 20.4% Propiconazole 0.302% Tebuconazole 0.305% Cypermethrin 0.100% No sediment <u>After 2 yrs./20-25°C:</u> ADBAC 20.4% Propiconazole 0.302% Tebuconazole 0.303% Cypermethrin 0.096% No sediment <u>After 3 yrs./20-25°C:</u> ADBAC 20.5% Propiconazole 0.300% Tebuconazole 0.301% Cypermethrin 0.090% No sediment **No sediment found. Visual observation.**	Musálková et al., 2021 **Test Report No.: 5910/BD+D+BO/ 2018** Study period: from 02/11/2018 to 01/11/2021

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
			CYP: 0.04% Drevosan Optimal (meta-SPC 5) ADBAC: 2.0% PPA: 0.03% TEB: 0.03% CYP: 0.01%	Conc. mass values deviations statistically non-significant and/or acceptable tolerance. **<u>Drevosan</u>** <u>Pre-storage:</u> ADBAC 8.2% Propiconazole 0.120% Tebuconazole 0.120% Cypermethrin 0.043% <u>After 1 yr./20-25°C</u> ADBAC 8.3% Propiconazole 0.120% Tebuconazole 0.120% Cypermethrin 0.040% No sediment <u>After 2 yrs./20-25°C:</u> ADBAC 8.2% Propiconazole 0.118% Tebuconazole 0.119% Cypermethrin 0.038% No sediment <u>After 3 yrs./20-25°C:</u> ADBAC 8.3% Propiconazole 0.117% Tebuconazole 0.117% Cypermethrin 0.036% No sediment **No sediment found.**	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				Visual observation. Conc. mass values deviations statistically non-significant and/or acceptable tolerance. **<u>Drevosan Optimal</u>** <u>Pre-storage:</u> ADBAC 2.03% Propiconazole 0.030% Tebuconazole 0.030% Cypermethrin 0.010% <u>After 1 yr./20-25°C</u> ADBAC 2.03% Propiconazole 0.030% Tebuconazole 0.030% Cypermethrin 0.010% No sediment <u>After 2 yrs./20-25°C:</u> ADBAC 2.03% Propiconazole 0.029% Tebuconazole 0.030% Cypermethrin 0.009% No sediment <u>After 3 yrs./20-25°C:</u> ADBAC 2.04% Propiconazole 0.029% Tebuconazole 0.030% Cypermethrin 0.009% No sediment	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				No sediment found. Visual observation. Conc. mass values deviations statistically non-significant and/or acceptable tolerance. All the biocidal products tested are stable for 3 years. Shelf-life for this period could be granted.	
3.4.1.3.	Storage stability test – **low temperature stability test for liquids at 1°C and -18°C**	CIPAC MT 46 Guidance on the storage stability by BPU (HSE) Dilution stability: CIPAC MT 41 **Packaging:** Container: 1L HDPE	Drevosan Profi (meta-SPC 1) **Batch No.:** 311018 Drevosan (meta-SPC 3) **Batch No.:** 311018 Drevosan Optimal (meta-SPC 5) **Batch No.:** 311018 **Target values:** Drevosan Profi (meta-SPC 1) ADBAC: 20.0% PPA: 0.3% TEB: 0.3%	**<u>Drevosan Profi</u>** <u>Pre-storage:</u> ADBAC 20.2% Propiconazole 0.299% Tebuconazole 0.299% Cypermethrin 0.104% <u>After 6 months/1°C:</u> ADBAC 20.3 Propiconazole 0.303% Tebuconazole 0.302% Cypermethrin 0.101% No sediment **<u>5% and 10% sol.:</u>** (after 6 months/1°C) No sediment observed <u>After 6 months/-18°C</u> ADBAC 20.2% Propiconazole 0.304%	Musálková et al., 2021 **Test Report No.: 5910/BD+D+BO/ 2018**

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
			CYP: 0.1% Drevosan (meta-SPC 3) ADBAC: 8.0% PPA: 0.12% TEB: 0.12% CYP: 0.04% Drevosan Optimal (meta-SPC 5) ADBAC: 2.0% PPA: 0.03% TEB: 0.03% CYP: 0.01%	Tebuconazole 0.302% Cypermethrin 0.100% No sediment **5% and 10% sol.:** (after 6 months/-18°C) No sediment observed Conc. mass values deviations statistically non-significant and/or acceptable tolerance. **Drevosan** Pre-storage: ADBAC 8.2% Propiconazole 0.120% Tebuconazole 0.120% Cypermethrin 0.043% After 6 months/1°C: ADBAC 8.2% Propiconazole 0.122% Tebuconazole 0.121% Cypermethrin 0.042% No sediment After 6 months/-18°C ADBAC 8.2% Propiconazole 0.121% Tebuconazole 0.121% Cypermethrin 0.043% No sediment Conc. mass values deviations statistically	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				non-significant and/or acceptable tolerance. **<u>Drevosan Optimal</u>** <u>Pre-storage:</u> ADBAC 2.03% Propiconazole 0.030% Tebuconazole 0.030% Cypermethrin 0.010% <u>After 6 months/1°C:</u> ADBAC 2.02% Propiconazole 0.030% Tebuconazole 0.030% Cypermethrin 0.010% No sediment <u>After 6 months/-18°C</u> ADBAC 2.02% Propiconazole 0.030% Tebuconazole 0.030% Cypermethrin 0.010% No sediment Conc. mass values deviations statistically non-significant and/or acceptable tolerance. All the biocidal products tested are stable at minimum for 6 months up to -18°C	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**			Biocidal product is protected from the effects of UV light by packaging. Therefore no study is required.	
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		Drevosan Profi (meta-SPC 1) **Batch No.:** 311018 Drevosan (meta-SPC 3) **Batch No.:** 311018 Drevosan Optimal (meta-SPC 5) **Batch No.:** 311018	The stability tests performed and all data available show that biocidal product is stable within the temperature range from -18 to 40°C. Moreover, humidity could not affect the properties of products as all are aqueous solutions. All products are aqueous solutions containing ingredients and co-formulants thermally stable under the normal conditions of use, handling and/or storage.	Musálková et al., 2021 **Test Report No.: 5910/BD+D+BO/ 2018**
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		Drevosan Profi (meta-SPC 1) **Batch No.:** 311018 Drevosan (meta-SPC 3) **Batch No.:** 311018	No reactivity towards container material within the storage stability tests was observed.	Musálková et al., 2021 **Test Report No.: 5910/BD+D+BO/ 2018** **Study period:** from 02/11/2018

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
			Drevosan Optimal (meta-SPC 5) **Batch No.:** 311018		to 01/11/2021
3.5.1.	Wettability			Not applicable. The product is an aqueous solution.	
3.5.2.	Suspensibility, spontaneity, and dispersion stability			Not applicable. The product is an aqueous solution.	
3.5.3.	Wet sieve analysis and dry sieve test			Not applicable. The product is an aqueous solution.	
3.5.4.	Emulsifiability, re-emulsifiability, and emulsion stability			Not applicable. The product is an aqueous solution.	
3.5.5.	Disintegration time			Not applicable. The product is an aqueous solution.	
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability			Not applicable. The product is an aqueous solution.	
3.5.7.	Persistent foaming		Persistent foaming during the application by automated dipping or brushing is not anticipated. The product is not applied via spraying. Moreover, the efficacy of the biocidal product was confirmed by the relevant tests indicating that potential persistent foaming preventing the product penetration into the wood does not take place. However, determination of persistence foaming characteristics would provide supporting information for human risk characterization. Therefore, to confirm or declare the aforementioned assumption related to efficacy and human health, applicant will submit a study related to the persistent foaming within the biocidal product renewal.		
3.5.8.	Flowability/pourability/dustability			Not applicable.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.9.	Burning rate — smoke generators			Not applicable. The product is an aqueous solution.	
3.5.10.	Burning completeness — smoke generators			Not applicable. The product is an aqueous solution.	
3.5.11.	Composition of smoke — smoke generators			Not applicable. The product is an aqueous solution.	
3.5.12.	Spraying pattern — aerosols / spray			Not applicable. The product is an aqueous solution.	
3.6.1.	Physical compatibility			Not applicable. The product is not intended to be used or stored with other biocidal products.	
3.6.2.	Chemical compatibility			Not applicable. The product is not intended to be used or stored with other biocidal products.	
3.7.	Degree of dissolution and dilution stability	CIPAC MT 41 **Concentrations:** 5% and 10% application water based solutions. (application solutions)	Drevosan Profi (meta-SPC 1) **Batch No.:** 311018	**No sediment found.** **Visual observation.** For further details, see the relevant test reports, justifications.	Musálková et al., 2021 **Test Report No.: 5910/BD+D+BO/ 2018** Study period: from 02/11/2018 to 01/11/2021
3.8.	Surface tension	OECD 115, plate method; ISO 304 OECD Guideline 115 (Surface Tension of	Drevosan Profi (meta-SPC 1) Drevosan (meta-SPC 3)	Surface tension/20°C **Drevosan Profi:** 32 mN/m **Drevosan:**	Musilová, Mráček (2017a) Thomas Bata University in Zlín

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		Aqueous Solutions) The surface tension of samples was determined using the tensiometer KRÜSS K100 (KRÜSS, GmbH, Germany) by the Wilhelmy plate method.	Drevosan Profi 10% solution Drevosan Profi 5% solution	33 mN/m Drevosan Profi 10%: 34 mN/m Drevosan Profi 5%: 34 mN/m	
3.9.	Viscosity	OECD 114 capillary viscometer; ISO 3104 and 3105 OECD Test Guideline 114 (Viscosity of Liquids) The viscosity of samples was determined using the Viscosity Measuring Unit Visco Clock (SCHOTTGERÄTE GmbH, Germany) by the ISO Ubbelohde viscometers (type I, Oc).	Drevosan Profi (meta-SPC 1) Drevosan (meta-SPC 3) Drevosan Profi 10% solution Drevosan Profi 5% solution	**Kinematic viscosity (at 20°C):** **Drevosan Profi:** 5.5 mm^2/s **Drevosan:** 1.7 mm^2/s Drevosan Profi 10%: 1.2 mm^2/s Drevosan Profi 5%: 1.1 mm^2/s **Kinematic viscosity (at 40°C):** **Drevosan Profi:** 2.9 mm^2/s **Drevosan:** 1.1 mm^2/s Drevosan Profi 10%: 0.78 mm^2/s Drevosan Profi 5%: 0.73 mm^2/s	Musilová, Mráček (2017b) Thomas Bata University in Zlín

Czech Republic	Drevosan family	PT08

Table 3.3 Conclusion on physical, chemical and technical properties

Conclusion on physical, chemical, and technical properties
Biocidal products from the Drevosan family are water-based concentrates, aqueous liquids.
Drevosan Profi is a colourless or green variant (meta-SPC 1) and brown variant (meta-SPC 2).
Drevosan is a colourless or green variant (meta-SPC 3) and brown variant (meta-SPC 4).
Drevosan Optimal is a colourless or green variant (meta-SPC 5) and brown variant (meta-SPC 6).
Biocidal products Drevosan and Drevosan Optimal are aqueous dilutions of BP Drevosan Profi.
Relevant physico-chemical properties for Drevosan Profi (meta-SPC 1), Drevosan (meta-SPC 3) and Drevosan Optimal (meta-SPC 5) are considered as representative for all products of the BPF. All relevant physico-chemical data and justifications provided by the applicant are considered sufficient in order to cover the whole range of variations applied for. All the studies have been performed in accordance with the current requirements and all the results are acceptable.
Data on persistent foaming will be requested within the biocidal product renewal.
Based on the long-term stability tests results, **shelf-life of 3 years** for all the products is granted.
The product is also temporarily stable at elevated and decreased temperatures.
Implications for labelling for all meta-SPCs: "Store the product in tightly closed original containers. Store at temperatures not exceeding 30°C."

3.3 Physical hazards and respective characteristics

Information on the choice of the worst case composition for physical hazards and respective characteristics (e.g. representative test products) and the justification for why the chosen test products are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex. The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

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			Not explosive. There are no chemical groups present in the biocidal product formulation associated with explosive properties. If potentially any, these groups are bounded with carbon directly only. Moreover, several years experiences with manufacture, use, handling and/or storage do not show any indications bounded with explosive properties. The exact composition of the product is well known. Note also that the product contains no ingredient classified for explosiveness. No study is required.
4.2.	Flammable gases			Not applicable. Scientifically unjustified. Biocidal product is an aqueous solution.
4.3.	Flammable aerosols			Not applicable. Scientifically unjustified. Biocidal product is an aqueous solution.
4.4.	Oxidising gases			Not applicable. Scientifically unjustified. Biocidal product is an aqueous solution.
4.5.	Gases under pressure			Not applicable. Scientifically unjustified. Biocidal product is an aqueous solution.
4.6.	Flammable liquids			Biocidal product is an aqueous solution of active substances and as such can hardly be considered as flammable.
4.7.	Flammable solids			Not applicable. Biocidal product is an aqueous solution.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.8.	Self-reactive substances and mixtures			Not applicable. There are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are in the Tables A6.1 and A6.2 in Appendix 6 of the UN MTC. The experience in manufacture, use, handling and/or storage of the biocidal product shows its long-term stability at room temperature.
4.9.	Pyrophoric liquids			Based on the experience in manufacture, use, handling and/or storage no study and/or classification is required. Biocidal product does not ignite spontaneously on coming into contact with air at normal temperatures. Biocidal product is an aqueous solution of active substances. No self-ignitable or pyrophoric properties under normal conditions of use, handling and/or storage were observed. No study is required.
4.10.	Pyrophoric solids			Not applicable. Biocidal product is an aqueous solution.
4.11.	Self-heating substances and mixtures			Not applicable. There is no evidence that the product is a self-heating mixture. Biocidal product is an aqueous solution of active substances. Self-heating under normal conditions of use, handling and/or storage is not expected. Long-term stability testing results show that the biocidal product is stable. The study is scientifically unjustified.
4.12.	Substances and mixtures which in contact with water emit flammable gases			No classification required. Biocidal product is stable aqueous solution. No indications of destruction of the packaging material within the stability testing were observed.
4.13.	Oxidising liquids			The product contains no ingredients classified for oxidising properties nor does

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				the structural properties of any ingredients imply such properties. Where present, oxygen, fluorine and chlorine are chemically bonded only to carbon or hydrogen. No oxidising properties are expected. Moreover, no chemical groups suggesting an alert for oxidising properties are present in the biocidal product's mixture.
4.14.	Oxidising solids			Not applicable. Biocidal product is an aqueous solution.
4.15.	Organic peroxides			Biocidal product do not contain organic peroxides. In the BP's formulation there are no co-formulants that are classified as organic peroxides. The study is therefore scientifically unjustified.
4.16.	Corrosive to metals	UN Test C.1 Section 37, UN-MTC	Drevosan Profi (meta-SPC 1)	Report No.: M451-2 (05/06/2023) (Barák, V., Prošek, T., Technopark VTP Kralupy (UCT Prague) Determination of corrosiveness of the BP Bochemit Dřevosan Profi in accordance with UN-MTC C.1 and interpretation of results obtained with the criteria described in the Guidance on the Application of the CLP Criteria. **Specimens used/test performed with:** Three aluminium (7075-T6) and three carbon steel (grade S235JR+CR according to ISO 3574) specimens each dimensions of 50×20×1 mm. (6 specimens total). (specimens = samples tested) **Method's set-up:** The samples were hanged using PTFE threads in 2-litre Erlenmeyer flasks with

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				reflux condensers filled with 1.5 litre of the mixture to achieve the mixture volume to sample surface ratio above 20 ml/cm². For each material, one sample was completely immersed in the mixture with the distance between the upper edge of the sample and the surface of the mixture of 10 mm, the second sample was partially immersed to represent the corrosion behaviour at the mixture/air interface, and the third sample was placed above the mixture and exposed in vapours. Duration of the test/exposure was 7 days within the temperature of 55°C as prescribed. Both uniform corrosion attack and localized corrosion were investigated. **Evaluation of the data measured:** **Uniform corrosion attack** The highest mass loss value measured (taking into account all 6 specimens used/tested) was **1.20%**, corresponding corrosion rate calculated is **0.288 mm/year** (calculated from the intrusion depth value for 7 days obtained from the mass loss measured based on the presumption of constant corrosion intrusions for all 3 axes of the specimen tested). The only difference related to the UN-MTC C.1 is the thickness of specimens used, i.e. 1 mm instead of 2 mm recommended. That means the recalculation of the mass loss threshold value from approx. **13.5%** to approx. **25.2%** acceptable mass loss tolerance

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				both for 7 days of duration of the test (exposure of the specimens to the 1.5L matrix tested). In fact, this mass loss threshold recalculation is the only consequence of the thickness deviation rel. to the UN-MTC. All potential values below **25.2%** mass loss at maximum will be still acceptable for 1 mm thickness specimens and are corresponding to the intrusion depths below 120 um default (7 days) at maximum leading to 6.25 mm corrosion rate p.a. default at maximum. Intrusion depth is independent on the specimen's volume (mass) tested. As a conclusion, the highest mass loss value of **1.20%** measured for steel mixture/vapours interface is below the threshold **25.2%** as well as all 6 mass loss values measured for 2 types of specimen each in 3 positions. The test for uniform corrosion attack is **negative**. **Localized corrosion** was measured or quantified on steel samples with the maximum average intrusion depth of approx. **92 um** for specimens exposed in vapours. The highest intrusion depth measured was approx. **95 um** (for 7 days exposure, duration of the test). No intrusion was deeper/higher than the threshold for the classification as corrosive to metals, which is still **120 um** after 7 days of exposure (as written above, intrusion depth does not depend on the specimen's volume, intrusion depth threshold value does not depend on

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				the thickness reduction of the specimens tested). Test for localized corrosion is **negative** for all the specimens tested. Intrusion depth analysis for aluminium specimens did not reveal any measurable degradation. For more details and detailed specimens description, see the photo documentation in the original Test report submitted. **Overall conclusion:** Based on the results both for uniform corrosion attack (mass losses measured) and localized corrosion (intrusion depths investigated) biocidal product tested **is not classified** as corrosive to metals. All results measured or calculated from the mass loss values measured are below the relevant interpretation thresholds (cut-off/threshold values as above).
4.17.1.	Auto-ignition temperatures of products (liquids and gases)			Biocidal product is an aqueous solution of the active substances none of which self-ignitable under normal conditions of use, handling and/or storage. Experiences from the manufacture do not showed any indications bounded with auto-ignition properties. No study is required. In fact, spontaneous combustion is excluded.
4.17.2.	Relative self-ignition temperature for solids			Not applicable. Biocidal product is an aqueous solution.
4.17.3.	Dust explosion hazard			Not applicable. Biocidal product is an aqueous solution.

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
Based on the assessment of the representative products, meta-SPC 1-6 are not classified for the physical hazards. Biocidal products are aqueous solutions. No risk from physical hazards is anticipated under the normal conditions of use, handling and storage.

3.4 Methods for detection and identification

Information on the choice of the worst case composition for methods for detection and identification (e.g. representative test products) and the justification for why the chosen test products are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex. The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues, fully validated analytical method for all active substances in the biocidal product

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Determination of Tebuconazole, Propiconazole, Cypermethrin and alkyl (C12-16) dimethylbenzylammonium chloride in Drevosan											
Analyte	**Linearity**	**Specificity**	**Standard fortification level and number of measurements**		**Accuracy Recovery rate (%)**			**Precision Repeatability (%)**			**Reference**
			Result % w/w	Number of measuremn.	Result %	Mean %	RSD %	Conc. tested % w/w	Number replicates	RSDr %	
Tebuconazole (active subst.) Target value: 0.3% w/w HPLC-DAD See all details below the tab.	Range: 0.098 mg/ml 0.295 mg/ml 5 points cal. R^2 = 0.999 y=kx+q k=7919 q= -10,907	Matrix analysis Sample analysis Specificity was confirmed using in-house std. cal. solutions. Without interferences rel. to the active's RT.	0.290 0.293 0.292 0.292 0.290 Mean: **0.292**	5 samples anal.under repeatab. conditions. One day, operator, calibration.	98.4 99.4 99.0 98.9 98.3	range: 98.3-99.4 mean: **98.8**	0.46	**0.295**	5	**0.46**	Bukovská, Navrátilová, Mráčková, Hantlová 31/10/2022 Report No.: **VP-01/22**
Propiconazole (active subst.) Target value: 0.3% w/w HPLC-DAD See all details below the tab.	Range: 0.103 mg/ml 0.309 mg/ml 5 points cal. R^2 = 0.999 y=kx+q k=7710 q= +20,264	Matrix analysis Sample analysis Specificity was confirmed using in-house std. cal. solutions. Without interferences rel. to the active's RT.	0.292 0.294 0.293 0.295 0.297 Mean: **0.294**	5 samples anal.under repeatab. conditions. One day, operator, calibration.	98.8 99.6 99.2 100.1 100.6	range: 99.2-100.6 mean: **99.7**	0.71	**0.295**	5	**0.71**	Bukovská, Navrátilová, Mráčková, Hantlová 31/10/2022 Report No.: **VP-01/22**
Cypermethrin (active subst.) Target value: 0.1% w/w HPLC-DAD See all details below the tab.	Range: 0.033 mg/ml 0.099 mg/ml 5 points cal. R^2 = 0.999 y=kx+q k=15092 q= +0.53	Matrix analysis Sample analysis Specificity was confirmed using in-house std. cal. solutions. Without interferences.	0.098 0.098 0.098 0.101 0.099 Mean: **0.099**	5 samples anal.under repeatab. conditions. One day, operator, calibration.	98.1 97.8 98.3 101.2 99.0	range: 97.8-101.2 mean: **98.9**	1.39	**0.100**	5	**1.39**	Bukovská, Navrátilová, Mráčková, Hantlová 31/10/2022 Report No.: **VP-01/22**

Analyte	Linearity	Specificity	Standard fortification level and number of measurements		Accuracy Recovery rate (%)			Precision Repeatability (%)			Reference
			Result % w/w	Number of measuremn.	Result %	Mean %	RSD %	Conc. tested % w/w	Number replicates	RSDr %	
ADBAC (active subst.) Target value: 20.00% w/w Volumetric dt. cationic subst. See all details below the tab.	Range: 20.08 mg/ml 60.24 mg/ml 5 points cal. R^2 = 0.999 y=kx+q k=147.4 q= +0.06	No interferences. Visual detection. No interferences in the equivalence point.	20.86 21.36 20.88 20.98 20.88 Mean: **20.99**	5 samples anal.under repeatab. conditions. One day, operator, calibration.	99.5 101.9 99.6 100.1 99.6	range: 99.5-101.9 mean: **100.2**	1.00	**20.96**	5	**1.00**	Bukovská, Navrátilová, Mráčková, Hantlová 31/10/2022 Report No.: **VP-01/22**

Description of the method presented above

Chemicals
Standards of TBA, PPA and CYPR supplied with Certificates of analysis
Acetonitrile CHROMANORM for HPLC (gradient grade)
Methanol CHROMANORM for HPLC/UHPLC (gradient grade)
Ultra clean water prepared using ULTRAPUR 10 super system

Equipment used and analytical method's set up
Liquid chromatograph, Agilent 1100 series with Diode Array Detector (DAD)
Column: Waters Spherisorb® 5µm ODS2 125 x 4mm, No.: PSS845543
Guard column: Phenomenex SecurityGuard Cartridge C18, 4 x 3.0 mm, No.: AJO-4287
Analytical scales, Mettler Toledo XS105 DU/M, SN B222975992 (gravimetric standards preparations)
HPLC system set-up: Column temperature: 35°C
Composition of the mobile phase: methanol and ultra clean water
Setting: gradient, 0.0 – 4.0 min: 70/30 M/V, 4.5 min: 90/10 M/V
Flow of the mobile phase: 1.2 ml/min, Detection: 220 nm DAD
Dosage of the samples: 5µl, Stop time: 9 min, Post time: 3 min.

Model internal (in-house) standard
The model analytical standard was gravimetrically prepared according to the real composition of the product.
Following standards of all active substances (resulting into mass concentrations below) were used:

Tebuconazole 97% TC (ABAKAP; Batch No.: 20220227; 97.8% TBA)
Preventol A 12 (LANXESS; Batch No.: 202106032; 98.9% PPA)
CYPRESS 40/60 (ARYSTA; Batch No.: 21121469; 96.0% CYPR)
BARQUAT BAC-50 (ARXADA; Batch No.: 46187; 52.4% ADBAC)
Concentrations of actives: 0.295% TBA + 0.295% PPA + 0.100% CYPR+ 20.96% ADBAC

System suitability and set-up check using working solution was investigated
TBA; 98.4%; working standard; PPA; 98.1%, working standard; CYPR; 96.4%; working standard
Solvent: Acetonitrile for HPLC (gradient grade). For all results (RTs and peak areas) see the original Test report.

Accuracy and precision determination and evaluation
Accuracy for each active substance was evaluated as recovery. Active's mass concentration values measured to the active's reference values in the in-house standard solution were compared. This internal standard was gravimetrically prepared using starting active's reference materials supplied with Certificates of analysis. Precision of the method is represented by repeatability of the active's mass concentration values measured. Repeatability was calculated as relative standard deviation of repeatability (RSDr) of active's mass concentrations values measured under repeatability conditions, i.e. all the analyses were performed on the same day, by the same operator and under one system calibration and set-up. This procedure is in accordance with basic quality assurance requirements for analytical measurements. All the results obtained are presented in the Table above. All accuracy (presented as recovery) and precision (presented as repeatability) values for active's mass concentrations levels tested (closed to the active's mass concentrations in the real sample) are within the tolerance intervals given by the relevant Guidance. It can be concluded that the analytical method is fit for intended and given purpose, i.e. active's mass values determinations in the Drevosan's biocidal product family real samples. More justifications and details could be found in the original Test report submitted by the Analytical testing laboratory.

Linearity and specificity of the method
Linearity was verified at five concentration levels of standard solutions. Determination was monitored as the dependence of the peak area to the TBA, PPA and CYPR concentrations and was evaluated using linear regression. Correlation coefficients and parametric equations arising from the linear regression are presented in the Table above. It can be concluded that the analytical method is linear within the range of real active's mass concentration values in the real samples investigated. In order to verify the specificity of the TBA, PPA and CYPR determinations, matrix of Drevosan Profi colourless as well as colour variants was prepared. Both matrices as closed as possible to the real biocidal product's matrix. These model samples or matrices without the active substances TBA, PPA and CYPR were measured and chromatograms compared to the standard samples measurements. These measurements were performed to declare there are no interferences of the biocidal product's co-formulants with the active substances around their retention times. More justifications could be found in the original Test report. From the specificity point of view the method is fit for given purpose.

Determinaton of the content of alkylbenzyldimethylammonium chloride (ADBAC)
Method based on biphasic titration of cationic substance (AS ADBAC) in the water/chloroform system by volumetric solution of anionic substance (sodium dodecyl sulphate) in acid medium with the presence of mixed indicator comprised by cationic and anionic dye was

investigated and used for the ADBAC active determination. The method is practically based on EN ISO 2871 which was investigated by Sysala (2016), however, in this case is fully validated by the laboratory taking into account the purpose of the determination. All the details related to the method's set-up, conditions and procedure description, could be found in the original Test report. Validation parameters requested are presented in the Table above. Accuracy and precision determination and evaluation is practically of the same approach as in the case of the other actives determined using HPLC-DAD. Different aliquots of ADBAC were titrated. There is no doubt this approach is correct in the case of repeatability, which could be considered as dominant budget to the total uncertainty of the titrimetric determinations. Accuracy, evaluated as recovery again, could be considered as supporting parameter. This is due to the fact that primary methods are directly bounded with the amount of substance not depending on any comparisons with reference. However, it is also useful parameter. The similar conclusion could be made for linearity. Given amount of ADBAC is titrated. Specificity is practically shown by the sharpness of colour change in the equivalence point and, as mentioned above, also fortified with recoveries values. Method is fully acceptable.

eCA remark:
There are another methods for the active substances determination in the dossier (Smrček, Sysala, 2016). However, these were not considered sufficient for the given purpose. This was due the fact that both were investigating the determination of active substances separately, i.e. neither all active substances together in one complex matrix, nor in the real biocidal product.

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Analytical methods for the determination of tebuconazole, propiconazole, cypermethrin and alkyl (C12-16) dimethylbenzylammonium chloride in Drevosan biocidal product family products are available. Specificity, linearity, accuracy (presented as recovery) and precision (repeatability) were checked and are acceptable. Analytical method for the determination of the substance of concern "Acid Brown 282" was not investigated as this substance does not change in its concentration and is not formed during storage. Methods for the detection of active substances in soil, air, water, and animal and human body fluids and tissues were not provided. All relevant Letters of access to all the active's dossiers were submitted by the applicant. Moreover, products are not intended to be used on surface in contact with food/feed of plant and animal origin. All products are labelled "Do not use on wood which may come into direct contact with food, feeding stuff, drinking water or livestock animals."

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)

The products of Dřevosan family are a wood preservatives intended for preventive surface treatment of wood to be used in use classes 1 and 2.

The target organisms are wood rotting basidiomycetes and wood boring beetle *Hylotrupes bajulus*. The object to be protected is timber intended for use in wooden elements indoors.

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

The product prevents fungal growth by inhibition of sterol synthesis. In addition, it alters cell membranes in both fungi and insects by a surfactant mode of action. Furthermore, in insects the product causes hyper-excitation of the central nervous system. The detailed mode of action of the active substances is described below.

ADBAC (C12-16) provides fungistatic and insecticidal effects. Its insecticidal effect is enhanced by cypermethrin. ADBAC is a cationic surfactant type active substance. Via interaction with phospholipid-bilayer-based membrane structures it severely alters the membrane permeability and disturbs membrane-bound ion-translocation mechanisms and may facilitate the uptake of other biocides.

The mode of action of propiconazole and tebuconazole consists in interfering with the biosynthesis of sterols, lipids essentials for structure and function of the cell membrane of fungi. The final result is inhibition of cell growth.

Cypermethrin is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon. Typically, this intoxication results in a rapid "knockdown". The affected insect shows uncoordinated movements and finally dies.

As the product is used for preventive action, the time delay is not critical.

3.5.3 Efficacy data

Efficacy studies with Drevosan Profi are summarized in the table below. The results of the EN 46 and EN 113 tests confirm the preventive efficacy of the products from Drevosan family against wood rotting basidiomycetes and *Hylotrupes bajulus*. Tests were conducted in combination with evaporating procedures (EN 73).

Applicant in the IUCLID submitted summaries of three other tests (6.7/002, 6.7/003 and 6.7/004). The test according to EN 893 in combination with EN 73 and other two tests carried out for Drevosan Profi after preconditioning of the treated blocks by a leaching procedure according to EN 84 were not considered due to the fact that products of Drevosan family are only intended for preventive surface treatment of wood in use classes 1 and 2.

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** *[address here results related to efficacy of the test product and validity of the test]*	**Reference**	**Number in IUCLID section 6.7/Test report title**
PT8 Preventive timber treatment, Use Class 1	Drevosan Profi (meta-SPC 1)	*Hylotrupes bajulus*	EN 46-1 after EN 73 (evaporation) Wood: *Pinus sylvestris,* sapwood The product was applied by dipping Concentration: 10% Retentions: ca. 0, 15, 20, 30 g/m^2 No. of specimens: 7 per testing retention, 4 treated by diluent, 3 control (unprotected) Exposure time: 4 weeks The effect investigated is mortality of larvae	The study is valid as at least 70% of the larvae exposed to all of the controls and diluent controls survived Toxic value: <14.5 g/m^2 The toxic value of the test product Drevosan Profi for *H. bajulus* on softwood after evaporative ageing procedure is <14.5 g/m² of wood	Součková and Jiráková, 2012 study no. VZL-16/11	6.7/001
PT8 Preventive timber treatment, Use Class 2	Drevosan Profi (meta-SPC 1)	*Coniophora puteana, Poria placenta, Gloeophyllum trabeum*	EN 113 after EN 73 (evaporation) Wood: *Pinus sylvestris,* sapwood The product was applied by vacuum impregnation Retentions: ca. 0, 5, 7.5, 10, 15 kg/m^3 Concentrations: 0, 0.6, 0.9, 1.2, 1.8% 5 blocks per treatment (incl. controls) and fungal strain Exposure time: 16 weeks The effect investigated is mass loss of the test blocks, induced by the fungal development The method for recording effects is	The study is valid (more than 20% of mass loss was observed in the control) Toxic values: <4.9 kg/m^3 for *C. puteana and P. placenta* <5.2 kg/m^3 for *G. trabeum* The biological reference value of the test product Drevosan Profi for brown rot fungi on softwood after evaporative ageing procedure is 5.2 kg/m^3 or 10.4 g/m² of wood	Součková and Lišková, 2016 study no. MVZ-02/16/238	6.7/005

			the individual weighting of the test blocks at the beginning and at the end of the exposure period.			

3.5.4 Efficacy assessment

Information on the choice of the worst case composition for efficacy (e.g. representative test product(s) and expert judgement/bridging studies where applicable) and the justification for why the chosen test product(s) are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Read-across to products of Drevosan family with the brown and green dyes is in line with the EN 599, Annex A.2.3, which says that for water-soluble wood preservatives new efficacy tests are not required in the case of adding or removal of a soluble dye. For more details see the confidential annex.

Use class 1
Wood preservative products in use class 1 shall be effective against wood boring beetle *Hylotrupes bajulus.* The minimum toxic value for efficacy against this wood boring beetle for use class 1 is <14.5 g/m^2. Therefore, the toxic value 15 g/m^2 as applied for by the applicant is confirmed.

Use class 2
The minimum toxic value for efficacy against wood destroying basidiomycetes for use class 2 is <10.4 g/m^2. As the applicant intends to claim efficacy against wood boring beetles in use class 2 as well, the minimum application rate in use class 2 is 15 g/m^2.

3.5.5 Conclusion on efficacy

The efficacy data submitted by the applicant result in the following recommended application rates for softwood against wood rotting fungi and wood boring beetle *H. bajulus*.

Meta SPC 1 and 2:
Use class 1 and 2: 15 g/m^2
The retention 15 g/m^2 can be achieved even with 5% or 10 % dilution. It depends on the time of dipping. 10% solution corresponds to the intake of a 150 g/m^2 of the diluted product. In the case of 5% solution, it corresponds to the intake of 300 g/m^2 of dilution. Retention of both diluted products 150 g and 300 g per 1 m^2 can be achieved by dipping. The difference is in the dipping time, i.e. the time for which the wood is dipped in solution. The required dipping time to reach the prescribed amount of solution depends on the permeability of the wood, its moisture and the way it is processed. A dilution of 5% is suitable for dipping rather dry wood, a dilution of 10% is suitable for the treatment of moderately moist wood.

Meta-SPCs 3 to 6 represent dilutions of meta-SPCs 1 and 2. Irrespective of the meta-SPC, the target application rate is the same. It corresponds to 15 g/m^2 for meta-SPC 1 or 2 (20% ADBAC), ca. 40 g/m^2 for meta-SPC 3 or 4 (8% ADBAC) or 150 g/m^2 for meta-SPC 5 or 6 (2% ADBAC).

Efficacy tests were performed on softwood (Scots pine). It is known that wood preservatives may have lower efficacy against fungi when applied on hardwood compared to softwood. Therefore, the application rates listed above apply only to softwood.

3.5.6 Occurrence of resistance and resistance management

No development of resistance to ADBAC (12-16) has been reported.

In the BPC opinion on the renewal of the approval of the active substance propiconazole in product type 8 (2022) it is stated that products containing triazole derivatives are used as a medicine and resistance of a human pathogen *Aspergillus fumigatus* to triazole derivatives used for medical purposes has been reported (e.g. casualties due to treatment failure reported in the Netherlands). In addition, there are indications that there may be multiple sources of resistance including agricultural use of (tri)azole derivatives. The concern has further strengthened by the results from a couple of recent studies about triazole-resistance selection of fungi (*A. fumigatus*) in the environment from the Netherlands. In these studies several hotspots of azole-resistant *A. fumigatus* were identified, including flower bulb waste, green waste, and wood chip waste. Genetic analysis showed that identical resistance mechanisms were found in azole resistant strains from these hotspots and in strains isolated from patients. In samples of wood waste of type B (painted, lacquered or glued) and C (treated with wood preservatives) containing propiconazole and tebuconazole high levels of resistance were found at biomass processing facilities. The texture of the material was found to be of importance; azole-resistant *A. fumigatus* was only found in fine to semi-coarse material. Furthermore, a study showing the presence of azole-resistant *Aspergillus fumigatus* in sawmills of Eastern France processing wood treated with propiconazole and tebuconazole has recently been published. The possible role of other sources of use of triazole derivatives such as in animal health or cosmetics is not yet clear. Therefore, it is recommended to pay attention to prevention of the evolution of tolerant fungal strains and report to Competent Authorities any new information on development of fungal resistance.

Resistance to pyrethroid insecticides has been reported for a number of pests in agricultural use and in public health. If resistance to cypermethrin is observed, active substances with a different mode of action should be used.

3.5.7 Known limitations

For resistance, see the previous subsection.

No undesirable or unintended side effects have been reported.

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

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

3.6 Risk assessment for human health

Table 3.9 Overview table of the concentrations of the active substance(s) and substance(s) of concern contained in the BPF

Concentration range of the BPF (%)						
meta-SPC number	**1**	**2**	**3**	**4**	**5**	**6**
Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride	20	20	8	8	2	2
Propiconazole	0.3	0.3	0.12	0.12	0.03	0.03
Tebuconazole	0.3	0.3	0.12	0.12	0.03	0.03
Cypermethrin	0.1	0.1	0.04	0.04	0.01	0.01
Acid Brown 282	0	1	0	1	0	0.1

Information on the choice of the worst case composition for human health risk assessment (e.g. representative test product(s)) and the justification for why the chosen test product(s) are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products chosen, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

3.6.1 Assessment of effects on human health

There are no human health data available for the products. The assessment, classification, and labelling are based on the agreed endpoints for the active substances and available information for the non-active substances.

3.6.1.1 Skin corrosion and irritation

No studies with the product are available.

Table 3.10 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	See the classification below
Justification for the value/conclusion	Based on the CLP calculation rules
Classification of the product(s) according to CLP	Meta-SPCs 1, 2, 3 and 4: Skin Corr. 1B; H314 Meta-SPCs 5 and 6: Skin Irrit. 2; H315

Table 3.11 Data waiving

Data waiving	
Information requirement	Skin corrosion/irritation
Justification	Classification is based on the calculation rules

3.6.1.2 Eye irritation

No studies with the product are available.

Table 3.12 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	See the classification below
Justification for the value/conclusion	Based on the CLP calculation rules
Classification of the product(s) according to CLP	Meta-SPCs 1, 2, 3 and 4: Eye Dam. 1; H318 Meta-SPCs 5 and 6: Eye Irrit. 2; H319

Table 3.13 Data waiving

Data waiving	
Information requirement	Eye damage/irritation
Justification	Classification is based on the calculation rules

3.6.1.3 Respiratory tract irritation

No studies with the product are available.

Table 3.14 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Expected to be corrosive/irritant to the respiratory tract when inhaled as aerosol
Justification for the conclusion	As the products are corrosive/irritant to skin and eyes due to ADBAC, they are also expected to be corrosive/irritant to the respiratory tract. The potential for local effects in the respiratory tract will be taken into account in risk assessment for local effects. As to classification, ADBAC is not volatile and the potential effects on the respiratory tract are considered to be sufficiently communicated by the classification for skin and eye irritation/corrosion. Therefore, additional classification is for respiratory tract irritation/corrosion not considered necessary.
Classification of the product(s) according to CLP	No classification

Table 3.15 Data waiving

Data waiving	
Information requirement	Respiratory tract irritation
Justification	No information requirement under the BPR. The existing information on skin/eye irritation/corrosion has been taken into account.

3.6.1.4 Skin sensitization

No studies with the product are available.

Table 3.16 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	See the classification and labelling below
Justification for the value/conclusion	Based on the CLP calculation rules
Classification of the product(s) according to CLP	Meta-SPC 1: EUH208 (propiconazole) Meta-SPC 2: Skin Sens. 1; H317, EUH208 (propiconazole and Acid Brown 282) Meta-SPC 3: EUH208 (propiconazole) Meta-SPC 4: Skin Sens. 1; H317, EUH208 (propiconazole and Acid Brown 282) Meta-SPC 5: no classification or labelling for skin sensitisation Meta-SPC 6: EUH208 (Acid Brown 282)

Table 3.17 Data waiving

Data waiving	
Information requirement	Skin sensitisation
Justification	Classification is based on the calculation rules

3.6.1.5 Respiratory sensitization

No studies with the product are available.

Table 3.18 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	See the classification below
Justification for the value/conclusion	Based on the CLP calculation rules
Classification of the product(s) according to CLP	No classification

Table 3.19 Data waiving

Data waiving	
Information requirement	Respiratory sensitisation (ADS)
Justification	ADS. Classification is based on the calculation rules

3.6.1.6 Acute oral toxicity

No studies with the product are available.

Table 3.20 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	Meta-SPCs 1 and 2: ATE = 1750 mg/kg bw Meta-SPCs 3, 4, 5 and 6: ATE > 2000 mg/kg bw
Justification for the selected value	Based on the CLP calculation rules
Classification of the product(s) according to CLP	Meta-SPCs 1 and 2: Acute Tox. 4; H302 Meta-SPCs 3, 4, 5 and 6: no classification

Table 3.21 Data waiving

Data waiving	
Information requirement	Acute oral toxicity
Justification	Classification is based on the calculation rules

3.6.1.7 Acute inhalation toxicity

No studies with the product are available.

Table 3.22 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	See the classification below
Justification for the selected value	Based on the CLP calculation rules
Classification of the product(s) according to CLP	No classification

Table 3.23 Data waiving

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	Classification is based on the calculation rules

3.6.1.8 Acute dermal toxicity

No studies with the product are available.

Table 3.24 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	See the classification below
Justification for the selected value	Based on the CLP calculation rules
Classification of the product(s) according to CLP	No classification

Table 3.25 Data waiving

Data waiving	
Information requirement	Acute dermal toxicity
Justification	Classification is based on the calculation rules

3.6.2 Information on dermal absorption

No dermal absorption studies are available for the product. Default values according to the EFSA Guidance on Dermal Absorption (2017) can be used for propiconazole, tebuconazole and cypermethrin at non-corrosive concentrations.

No dermal absorption value is needed for ADBAC. During active substance evaluation it was concluded that due to lack of systemic effects in the absence of local effects, a systemic exposure assessment was not considered necessary (see Assessment Report, 2015).

Table 3.26 Value(s) used in the Risk Assessment – Dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Propiconazole Tebuconazole Cypermethrin
Value(s)	Concentrate (undiluted Meta-SPCs 1, 2, 3 and 4): 100% In-use dilution (including Meta-SPCs 5 and 6): 50%
Justification for the selected value(s)	Undiluted Meta-SPCs 1 to 4 are classified as corrosive to the skin. A default dermal absorption value of 100% applies for corrosive concentrations. According to the EFSA Guidance on Dermal Absorption (2017), a default absorption value of 50% may be applied for in-use water-based dilutions.

Table 3.27 Data waiving

Data waiving	
Information requirement	Dermal absorption
Justification	Risk assessment is based on default values according to the EFSA Guidance on Dermal Absorption (2017)

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

According to the criteria as set in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)), the following substance needs to be considered as a substance of concern regarding human health: Acid Brown 282 (CAS no. 70236-60-1).

Table 3.28 Available toxicological data relating to substance(s) of concern

Meta-SPC	Substance of concern	Criterion for the identification as a substance of concern	Band	Type of risk assessment performed
Meta-SPCs 2 and 4	Acid Brown 282 (CAS no. 70236-60-1) (max. conc. 1%)	BPR, Art. 3 (f) Acid Brown 282 is self-classified as Skin Sens. 1B; H317 (presumably based on a positive LLNA	B	Qualitative assessment based on product classification

		with an EC3 of ca. 50%). At a concentration of 1% this leads to classification of meta-SPCs 2 and 4 as Skin Sens. 1; H317.		
Meta-SPCs 1, 3, 5 and 6	No substance of concern identified	Not relevant	Not relevant	Not relevant

3.6.4 Other

Not relevant

3.6.4.1 Food and feeding stuffs studies

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

3.6.4.3 Other test(s) 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 substance(s), refer to the respective section of the confidential annex.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

Relevant guidance documents consulted for human health risk assessment

- Guidance on the BPR: Volume III Human Health, Assessment & Evaluation (Parts B+C) (version 4.0, December 2017)
- Biocides Human Health Exposure Methodology (version 1, October 2015)
- Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure: Methods and models to assess exposure to biocidal products in different product types (version 4, May 2020)
- Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure: The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling (May 2016)
- HEEG opinion 1 on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale (2008)
- Technical Notes for Guidance: Human Exposure to Biocidal Products – Guidance on Exposure Estimation (2002)
- HEEG opinion 13 Assessment of Inhalation Exposure of Volatilised Biocide Active Substance (2011)
- Technical Agreements for Biocides Human Health (TOX) (version 2.0, November 2018)
- HEEG opinion 8 Defaults and appropriate models to assess human exposure for

dipping processes (PT 8) (2009)
- HEEG opinion 18 For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping (2013)
- HEEG opinion 11 Exposure model primary exposure scenario – washing out of a brush which has been used to apply a paint (2010)

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

Exposure models used:

- Automated dipping: Handling Model 1
- Professional brush treatment: indicative values from HEAdhoc Rec. no. 6 (based on Lingk et al., 2006)
- Non-professional mixing & loading (pouring into a smaller vessel): as there is no harmonized model for non-professionals, the professional M&L model 4 has been used (HEEG Op. 1)
- Non-professional brush treatment: indicative values from HEAdhoc Rec. no. 10 (based on Austrian/BfR model)
- Sanding: TNsG 2002 'Inhalation of dust – machine sanding preserved wood-adult', 'Adult (professional) sanding wooden posts', 'Adult sanding treated wood posts – inhalation route' (TNsG 2002, part 3, p. 37, p. 50; TNsG 2002, User Guidance, p. 55-56)
- Infant chewing an off-cut: TNsG 2002 'Infant acute chewing wood off-cut – ingestion route' (TNsG 2002, part 3, p. 50)

Strategy for human health risk assessment

Type of assessment:

- ADBAC: qualitative assessment for local effects; corrosive mode of action, no systemic risk characterisation is required
- Propiconazole, tebuconazole, cypermethrin: quantitative assessment for systemic effects
- Acid Brown 282: qualitative assessment for local effects (skin sensitisation)

For scenarios involving corrosive concentrates (i.e. mixing & loading for Meta-SPC 1 to 4) only local risk assessment is needed for the dermal route (cf. TAB, TOX 19). The use of appropriate PPE and RMMs will always be required for corrosive concentrations and exposure is therefore expected to be negligible, the systemic risks are covered by local risk characterisation.

Primary exposure has been evaluated for the three intended uses: automated dipping by industrial users, brush treatment by professional uses and brush treatment by non-professional uses.

Two secondary exposure scenarios have been evaluated: sanding of treated wood by professionals and oral exposure of infants chewing a treated off-cut. Exposure of non-professionals performing sanding is covered by the professional scenario (non-professionals have shorter exposure duration, other parameters are the same).

Exposure associated with formulation and disposal of the product is addressed through other pieces of legislation than BPR. Exposure from diassembling and disposal of the wooden article at the end of their service life is covered by dermal exposure in the 'sanding' scenario.

Considerations on volatility of the active substance(s) and substance(s) of concern

All active substances are of very low volatility (vapour pressure <10 mPa). The screening criterion according to HEEG opinion no. 13 is <1 for all active substances having a systemic

AEL (propiconazole, tebuconazole, cypermethrin). Therefore, there is no need to consider exposure towards vapours of active substances.

The substance of concern Acid Brown 282 is not volatile and inhalation is not a relevant exposure route for skin sensitisation.

Strategy for livestock exposure and/or dietary risk assessment

Not relevant. Dietary exposure and livestock exposure is not anticipated as the following RMM applies:

- Do not use on wood which may come into direct contact with food, feeding stuff, drinking water or livestock animals.

Strategy for the assessment of substance(s) of concern

Undiluted products of meta-SPCs 2 and 4 are classified as Skin Sens. 1; H317 due to the presence of a sensitising substance of concern, Acid Brown 282. For SoCs of band B, a qualitative exposure and risk assessment is required to determine whether P-statements normally associated with concerned H-statements are sufficient or whether other RMMs should be applied.

Undiluted products of meta-SPCs 2 and 4 are also classified as Skin Corr. 1B; H314. Dilution of the product is an activity of a short duration and use of PPE is mandatory due to corrosive properties. The risk mitigation measures required due to corrosive properties and the P-statements associated with H317 are considered to provide sufficient protection, no further RMMs are considered necessary.

Strategy for disinfectant by-products assessment

Not relevant

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 BPF

Table 3.29 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	no	no	yes	no
Dermal	yes	yes	yes	yes	no
Inhalation	yes	yes	yes	yes	no

3.6.6.3 List of exposure scenarios

Table 3.30 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		
Scenario 1	**Professional automated dipping/immersion of wooden articles**	
Task 1	Mixing & loading (only local risk characterisation)	Professionals
Task 2	Application	Professionals
Scenario 2	**Professional brush treatment**	
Task 1	Mixing & loading (only local risk characterisation)	Professionals
Task 2	Application	Professionals
Scenario 3	**Non-professional brush treatment**	
Task 1	Mixing & loading	Non-professionals
Task 2	Application	Non-professionals
Combined primary exposure: not relevant		
Secondary exposure		
Scenario 4	**Sanding**	Professionals, non-professionals
Scenario 5	**Infant chewing an off-cut**	General public
Combined secondary exposure: not relevant		

3.6.6.4 Overview of BPF: worst case uses and corresponding exposure scenarios

Table 3.31 Overview of the BPF: worst case uses and corresponding exposure scenarios

Overview of the BPF: worst case uses and corresponding exposure scenarios						
Use number[1]	**Exposure scenarios[2]**	**Application method[3]**	**Maximum in-use concentration of the active substance(s)[4]**	**Maximum in-use concentration of substance(s) of concern[5]**	**Application frequency[6]**	**User category[7]**
1.1, 2.1, 3.1, 4.1	Scenario 1	Automated dipping	ADBAC: 1% Propiconazole: 0.015% Tebuconazole: 0.015% Cypermethrin: 0.005%	Acid Brown 282: 0.05%	Daily	Professional
1.2, 2.2, 3.2, 4.2, 5.1, 6.1	Scenario 2 Scenario 3	Brush treatment	ADBAC: 2% Propiconazole: 0.03% Tebuconazole: 0.03% Cypermethrin: 0.01%	Acid Brown 282: 0.1%	Daily	Professional Non-professional

[1] Use numbers in accordance with the list of all uses indicated under section 2.2, where further details are described.
[2] Indicate the number of the scenarios according to section 3.6.6.3.
[3] Indicate the worst case application method or n/a if not relevant.
[4] For the respective use indicate the maximum concentration for all active substances. Add or delete rows according to the number of active substances.
[5] Maximum concentration of the substance(s) of concern if relevant for the use. Add more columns for other substances of concern, if needed.
[6] Worst case application frequency for exposure assessment.
[7] Worst case user category for the exposure assessment.

3.6.6.5 Reference values to be used in risk characterisation

Table 3.32 Reference values to be used in risk characterisation: ADBAC (from the Assessment Report for PT 4, 2020)

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
Dermal NOAEC	2-week skin irritation study in rats with DDAC	0.6%	n.a.	n.r.	0.6%
Oral NOAEC	1-year gavage study in dogs with DDAC	0.03%	n.a.	n.r.	0.03%

Table 3.33 Reference values to be used in risk characterisation: propiconazole (from the Assessment Report for PT 7, 2015)

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	Developmental study in rats	30 mg/kg bw/d	100	No	0.3 mg/kg bw/d
AELmedium-term	2-generation study in rats	8 mg/kg bw/d	100	No	0.08 mg/kg bw/d
AELlong-term	2-year study in rats	3.6 mg/kg bw/d	100	No	0.04 mg/kg bw/d

Table 3.34 Reference values to be used in risk characterisation: tebuconazole (from the Assessment Report for PT 7, 2013)

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	Developmental study in mice	10 mg/kg bw/d	300	No	0.03 mg/kg bw/d
AELmedium-term	1-year study in dogs	3 mg/kg bw/d	100	No	0.03 mg/kg bw/d
AELlong-term	1-year study in dogs	3 mg/kg bw/d	100	No	0.03 mg/kg bw/d

Table 3.35 Reference values to be used in risk characterisation: cypermethrin

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	90-day study in rats	20 mg/kg bw/d	100	44%	0.088 mg/kg bw/d
AELmedium-term	90-day oral study in dogs	12.5 mg/kg bw/d	100	44%	0.055 mg/kg bw/d
AELlong-term	2-year oral study in rats	5 mg/kg bw/d	100	44%	0.022 mg/kg bw/d

3.6.6.6 Specific reference value for groundwater

No specific reference value has been derived for the active substances contained in the product, the limit of 0.1 µg/l set by Directive 98/83/EC applies.

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

Scenario 1: Professional automated dipping

Description and input parameters

Table 3.36 Description and input parameters

Description of Scenario 1
Task description (based on HEEG opinion 8): An operator uses a fork-lift truck or similar equipment to lower the wood into the dipping tank or transfers the wood to a bathing tray. The wood stays in the wood preservative for an appropriate time (few minutes to a few hours). Then it is lifted out of the tank by the fork-lift truck. The wood is then transferred by the fork-lift truck to a storage area where it is placed to dry. Model: according to HEAdhoc rec. no. 6, TNsG Handling Model 1 is to be used, giving the following indicative values for water-based products: Hands (inside used gloves) 1080 mg/cycle Body (potential) 8570 mg/cycle Inhalation exposure from dipping is considered negligible. A 5% application solution of meta-SPCs 1 or 2 is used. The concentrations of the active substances in the application solution are as follows: ADBAC: 1% Propiconazole: 0.015% Tebuconazole: 0.015% Cypermethrin: 0.005% Dermal absorption values (default values): Propiconazole: 50% Tebuconazole: 50% Cypermethrin: 50% Due to the content of ADBAC, the application solution is considered a skin irritant. Therefore, in the industrial setting the use of gloves is required. Besides this, HEAdhoc rec. no. 6 only provides harmonised indicative values for gloved hands. Therefore, only Tier 2 exposure estimates with gloves will be presented here. As to protective clothing, values both with and without coated coverall will be calculated (Tier 2b and 2a respectively). Note: This scenario also covers professional fully automated dipping since the exposure from fully automated dipping is lower than from automated dipping. Other operations associated with automated dipping: • Dilution of the concentrate (mixing & loading) – the concentrate is corrosive to the skin, systemic effects are covered by local risk characterisation (TAB, TOX 19) • Re-stacking of fallen wood – covered by automated dipping as in any particular day re-stacking will normally be done by a person other than the person undertaking the dipping of wood (HEEG opinion 18) • Cleaning of the dipping tank – done infrequently (usually once per several years); no data available to define the exposure model (HEEG opinion 18)

Input parameters for Scenario 1			
Dermal			
	Parameters[1]	Value	Reference and justification[3]
Tier 2a[2] (gloves, no protection by clothing)	Number of cycles per day	4	HEAdhoc rec. no. 6
Tier 2b (gloves and coated coverall)	Coated coverall – protection factor	90%	Biocides Human Health Exposure Methodology

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and

protection/penetration rates for PPE.
[2] Only include the parameters changed with respect to the previous Tier. Tier 1 assessments should reflect the exposure for an unprotected person, normally only in higher tier assessments the use of PPE and/or RPE may be included as a refinement.
[3] Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).

Scenario 2: Professional brush treatment

Description and input parameters

Table 3.37 Description and input parameters

Description of Scenario 2
Task description: Manual brushing is small scale application usually used in-situ to treat small areas of wood. Before application, the application solution is to be prepared by diluting the required amount of concentrate with water. The application should be performed twice to achieve the target application rate. Model: according to HEAdhoc rec. no. 6, the following indicative values normalized to 1% active substance should be used (m^2 refers to application area): Hands (potential) 0.5417 mg/m^2 Body (potential) 0.2382 mg/m^2 Inhalation 0.0016 mg/m^2 Application area is 31.6 m^2, exposure duration is 240 min. A 10% application solution of meta-SPC 1 or 2 is used (roughly corresponding to a 20% solution of meta-SPC 3 or 4). The concentrations of the active substances in the application solution are as follows: ADBAC: 2% Propiconazole: 0.03% Tebuconazole: 0.03% Cypermethrin: 0.01% Dermal absorption values (default values): Propiconazole: 50% Tebuconazole: 50% Cypermethrin: 50% Due to the content of ADBAC, the application solution is considered a skin irritant. Therefore, use of gloves is required for professionals and only Tier 2 exposure estimates will be presented. Other operations associated with professional brush treatment: • Dilution of the concentrate (mixing & loading) – the concentrate is corrosive to the skin, systemic effects are covered by local risk characterisation • Cleaning the brush (post-application) – exposure is very low for water-based paints as the running water used for washing washes both the paint from the brush and the contamination from the hands (HEEG opinion 11)

Input parameters for Scenario 2			
Dermal			
	Parameters	Value	Reference and justification
Tier 2a (gloves, no protection by clothing)	Application area	31.6 m^2	HEAdhoc rec. no. 6
	Gloves – protection factor	90%	Biocides Human Health Exposure Methodology
Tier 2b (gloves and coated coverall)	Coated coverall – protection factor	90%	Biocides Human Health Exposure Methodology
Inhalation			
	Parameters	Value	Reference and justification
Tier 2 (gloves with or without coated coverall, no RPE)	Application area	31.6 m^2	HEAdhoc rec. no. 6

Outcome of systemic exposure and risk characterisation

Table 3.38 Summary table: estimated systemic exposure and risk characterisation for professional users

Summary table: estimated systemic exposure and risk characterisation for professional users							
Exposure 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 (%)** AEL (prop.) = 0.04 mg/kg bw/d AEL (teb.) = 0.03 mg/kg bw/d AEL (cyp.) = 0.022 mg/kg bw/d	**Acceptable** for individual a.s. **(Yes/No)**
Scenario 1	2a/gloves	0	Prop.: 0.0483 Teb.: 0.0483 Cyp.: 0.0161	0	Prop.: 0.0483 Teb.: 0.0483 Cyp.: 0.0161	Prop.: 121 Teb.: 161 Cyp.: 73	No
	2b/gloves and coated coverall	0	Prop.: 0.00969 Teb.: 0.00969 Cyp.: 0.00323	0	Prop.: 0.00969 Teb.: 0.00969 Cyp.: 0.00323	Prop.: 24 Teb.: 32 Cyp.: 15	Yes
Scenario 2	2/gloves	0	Prop.: 0.00231 Teb.: 0.00231 Cyp.: 0.000770	Prop.: $2.53 \cdot 10^{-5}$ Teb.: $2.53 \cdot 10^{-5}$ Cyp.: $8.43 \cdot 10^{-6}$	Prop.: 0.00234 Teb.: 0.00234 Cyp.: 0.000778	Prop.: 5.8 Teb.: 7.8 Cyp.: 3.5	Yes

prop. = propiconazole, teb. = tebuconazole, cyp. = cypermethrin

Combined scenarios

Not relevant. It is unlikely that the same person would perform automated dipping (full shift) and brush treatment (full shift).

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

ADBAC triggers classification of the products and in-use dilutions for skin/eye irritation/corrosion. ADBAC is classified as Skin Corr. 1B without specific concentration limits. The generic concentration limits for skin irritation and corrosion are 1% and 5% respectively; the generic concentration limits for eye irritation and eye damage are 1% and 3% respectively. The dermal NOAEC from a 2-week rat dermal irritation study of 0.6% is in line with the generic limit for skin irritation (1%). No AEC for inhalation is available. Although

a semi-quantitative risk characterisation could be attempted, it would not provide any additional information compared to a purely qualitative risk characterisation. Therefore, a qualitative risk characterisation is considered sufficient (see next section).

Acid Brown 282 triggers classification of some of the concentrates as Skin Sens. 1. Only qualitative risk assessment is required for this substance of concern.

Outcome of qualitative local risk assessment

Table 3.39 Outcome of qualitative local risk assessment

Hazard	**Exposure information**						**Risk**	
Hazard category	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMMs & PPE**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
Skin Corr. 1B, Eye Dam. 1, Skin Sens. 1	8	Automated dipping – dilution of the product	Skin, eye	few minutes, <1/week	No significant exposure expected (except accidental splashes)	Labelling Automated or semi-automated process Gloves, eye protection	Acceptable: No significant exposure expected due to the RMMs and PPE Low frequency, short duration Trained workers	Level of automation
Skin Corr. 1B, Eye Dam. 1, Skin Sens. 1	8	Professional brush treatment – dilution of the product	Skin, eye	few minutes, daily	Small splashes	Labelling Gloves, eye protection	Acceptable: Use of PPE Short duration	Behaviour of the worker

							Experienced workers	
Skin Irrit. 2, Eye Irrit. 2	8	Automated dipping – application (handling of treated wood, mainly using a fork-lift truck; restacking fallen wood)	Skin, eye	<1 h/day, daily	≈40 ml/day	Transfer using a fork-lift truck Gloves, coated coverall	Acceptable: Reversible effect Automated transfer, use of PPE	
Skin Irrit. 2, Eye Irrit. 2	8	Professional brush treatment – application	Skin, eye	≈4 h/day, ≤daily	Several ml/day	Gloves	Acceptable: Reversible effect Use of gloves	

Conclusion

Scenario 1: Professional automated dipping

Dilution of the product:

- The risk is considered acceptable
- PPE required: gloves, eye protection
- An automated or semi-automated mixing and loading process is assumed

Application:

- The risk is considered acceptable
- PPE required: gloves, coated coverall

Scenario 2: Professional brush treatment

Dilution of the product:

- The risk is considered acceptable
- PPE required: gloves, eye protection

Application:

- The risk is considered acceptable
- PPE required: gloves

3.6.6.8 Non-professional users

Scenario 3: Non-professional brush treatment

Description and input parameters

Table 3.40 Description and input parameters

Description of Scenario 3
Task description: In-situ brush treatment of small areas of timber. The products (meta-SPCs 5 and 6) are ready-to-use. Although no mixing step is needed, pouring from the original container (jerry can) into a smaller vessel has to be assumed. The size of the worst-case consumer packaging is 15 kg. Model – pouring: according to the Mixing and loading model 4, the following indicative value should be used for a 10L or 20L container: Hands (potential) 0.5 ml/loading As the density of the product (meta-SPC 5) is 1.00 g/cm^3 (see section 3.2), ml is equivalent to g in this case. Two pouring events per day will be assumed. Model - application: according to HEAdhoc rec. no. 10, the following indicative values should be used for water-based products: Hands (potential) 4.07 µl/min Body (potential) 1.7 µl/min Inhalation 1.63 mg/m^3 As the density of the product is 1.00 g/cm^3, µl/min is equivalent to mg/min in this case. No exposure duration is specified for non-professional brush treatment in the Biocides Human Health Exposure Methodology nor in HEAdhoc recommendation 10. The value for professionals according to HEAdhoc rec. 6 will be used. The concentrations of the active substances in the ready-to-use products (meta-SPCs 5 and 6) are as follows: ADBAC: 2% Propiconazole: 0.03% Tebuconazole: 0.03% Cypermethrin: 0.01% Dermal absorption values (default values): Propiconazole: 50% Tebuconazole: 50% Cypermethrin: 50% Due to the content of ADBAC, the application solution is considered a skin irritant. Although use of gloves is recommended, use of PPE cannot be assumed in exposure calculations for non-professionals except for antifouling paints (Biocides Human Health Exposure Methodology, p. 152). Exposure from cleaning the brush after application is considered negligible for water-based products (HEEG opinion 11).

Input parameters for Scenario 3			
Mixing and loading			
Dermal			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Number of events per day	2	Expert judgment (in the absence of a harmonized value)
Application			
Dermal			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Exposure duration	240 min	HEAdhoc rec. 6
	Clothing penetration	100%	Uncoated clothing, challenge by wet substance (cf. Biocides Human Health Exposure Methodology, p. 156)
Inhalation			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Exposure duration	240 min	HEAdhoc rec. 6
	Inhalation rate	1.25 m^3/h	HEAdhoc rec. 14

Outcome of systemic exposure and risk characterisation

Table 3.41 Summary table: estimated systemic exposure and risk characterisation for non-professional users

Summary table: estimated systemic exposure and risk characterisation for non-professional users							
Exposure 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 (%)** AEL (prop.) = 0.3 mg/kg bw/d AEL (teb.) = 0.03 mg/kg bw/d AEL (cyp.) = 0.088 mg/kg bw/d	**Acceptable** for individual a.s. **(Yes/No)**
Scenario 3 – mixing and loading	1/no PPE	0	Prop.: 0.00250 Teb.: 0.00250 Cyp.: 0.00083	0	Prop.: 0.00250 Teb.: 0.00250 Cyp.: 0.00083	Prop.: 0.8 Teb.: 8.3 Cyp.: 0.9	
Scenario 3 – application	1/no PPE	0	Prop.: 0.00346 Teb.: 0.00346 Cyp.: 0.00115	Prop.: $4.08 \cdot 10^{-5}$ Teb.: $4.08 \cdot 10^{-5}$ Cyp.: $1.36 \cdot 10^{-5}$	Prop.: 0.00350 Teb.: 0.00350 Cyp.: 0.00117	Prop.: 1.2 Teb.: 11.7 Cyp.: 1.3	
Scenario 3 – total exposure	1/no PPE	0	Prop.: 0.00596 Teb.: 0.00596 Cyp.: 0.00198	Prop.: $4.08 \cdot 10^{-5}$ Teb.: $4.08 \cdot 10^{-5}$ Cyp.: $1.36 \cdot 10^{-5}$	Prop.: 0.00600 Teb.: 0.00600 Cyp.: 0.00199	Prop.: 2.0 Teb.: 20.0 Cyp.: 2.3	Yes

prop. = propiconazole, teb. = tebuconazole, cyp. = cypermethrin

Combined scenarios

Not relevant

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

Not performed, qualitative risk characterisation for local effects (below) is considered sufficient.

Outcome of qualitative local risk assessment

Table 3.42 Outcome of qualitative local risk assessment

Hazard	**Exposure information**						**Risk**	
Hazard category	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMMs & PPE**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
Skin Irrit. 2, Eye Irrit. 2	8	Non-professional brush treatment	Skin, eye	≈4 h/day, 1-2 times per year	Several ml	Labelling Instructions: avoid skin and eye exposure, wash hands after use Gloves recommended	Acceptable: Reversible effect Low frequency Instructions for use	Adherence to instructions

Conclusion

Scenario 3: Non-professional brush treatment

- The risk is considered acceptable
- Instructions for use: Avoid exposure of skin and eyes. Wash hands after use. It is recommended to wear gloves during application.

3.6.6.9 Secondary exposure to professional bystanders and non-professional bystanders/general public

Scenario 4: Sanding

Description and input parameters

Table 3.43 Description and input parameters

Description of Scenario 4
Task description: (machine) sanding of treated wood Model: • Inhalation: 'Inhalation of dust – machine sanding preserved wood – adult' (TNsG 2002, part 3, p. 37) • Dermal: 'Adult (professional) sanding wooden posts' (TNsG 2002, User Guidance, p. 56) The professional model also covers non-professional exposure. Non-professionals are exposed for a shorter duration (1 h instead of 6 h; TNsG 2002, part 3, p. 50; User guidance, p. 55) and the exposure is acute rather than chronic (corresponding to a higher AEL for propiconazole a cypermethrin). Dermal absorption values (default values): Propiconazole: 50% Tebuconazole: 50% Cypermethrin: 50%

Input parameters for Scenario 4			
Inhalation			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Airborne concentration of wood dust	5 mg/m^3	TNsG 2002, part 3, p. 37
	Exposure duration	6 hours	TNsG 2002, part 3, p. 37
	Inhalation rate	1.25 m^3/h	HEAdhoc rec. 14
	Application rate	15 g/m^2	Instructions for use
	Penetration depth	0,2 cm	Expert judgment. The default for vacuum pressure treatment according to TNsG 2002 (User guidance, p. 55-56) is 1 cm, penetration depth after treatment by dipping or brushing is assumed to be lower.
	Wood density	0.4 g/cm^3	TAB TOX
Dermal			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Application rate	15 g/m^2	Instructions for use
	Hand surface area contaminated	84 cm^2	TNsG 2002, User guidance, p. 56
	Transfer coefficient	2%	Biocides Human Health Exposure Methodology (rough sawn wood, dried fluid)

Scenario 5: Infant chewing an off-cut

Description and input parameters

Table 3.44 Description and input parameters

Description of Scenario 5
Scenario description: an infant chewing a treated wood off-cut (oral exposure) Model: 'Infant acute chewing wood off-cut – ingestion route' (TNsG 2002, part 3, p. 50) Absorption from the gastrointestinal tract: Propiconazole: 100% Tebuconazole: 100% Cypermethrin: 57%

Input parameters for Scenario 5			
Oral			
	Parameters	Value	Reference and justification
Tier 1	Application rate	15 g/m^2	Instructions for use
	Surface area treated	32 cm^2	TNsG 2002, part 3, p. 50; the front and back side of the 4 x 4 x 1 cm off-cut assumed to be treated
	Fraction of the biocidal product extracted by chewing	10%	TNsG 2002, part 3, p. 50
	Body weight	10 kg	TNsG 2002, part 3, p. 50

Outcome of systemic exposure and risk characterisation

Table 3.45 Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public							
Exposure 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[#] (%)** $AEL_{long-term}$ (prop.) = 0.04 mg/kg bw/d $AEL_{long-term}$ (teb.) = 0.03 mg/kg bw/d $AEL_{long-term}$ (cyp.) = 0.022 mg/kg bw/d $AEL_{short-term}$ (prop.) = 0.3 mg/kg bw/d $AEL_{short-term}$ (teb.) = 0.03 mg/kg bw/d $AEL_{short-term}$ (cyp.) = 0.088 mg/kg bw/d	**Acceptable** for individual a.s. **(Yes/No)**
Scenario 4	1/no PPE	0	Prop.: $6.30 \cdot 10^{-5}$ Teb.: $6.30 \cdot 10^{-5}$ Cyp.: $2.10 \cdot 10^{-5}$	Prop.: $3.52 \cdot 10^{-5}$ Teb.: $3.52 \cdot 10^{-5}$ Cyp.: $1.17 \cdot 10^{-5}$	Prop.: $9.82 \cdot 10^{-5}$ Teb.: $9.82 \cdot 10^{-5}$ Cyp.: $3.27 \cdot 10^{-5}$	Prop.: 0.24 Teb.: 0.33 Cyp.: 0.15	Yes
Scenario 5	1/no PPE	Prop.: 0.00144 Teb.: 0.00144 Cyp.: 0.000274	0	0	Prop.: 0.00144 Teb.: 0.00144 Cyp.: 0.000274	Prop.: 0.48 Teb.: 4.8 Cyp.: 0.31	Yes

prop. = propiconazole, teb. = tebuconazole, cyp. = cypermethrin

[#] $AEL_{long-term}$ for Scenario 4 (professional exposure), $AEL_{short-term}$ for Scenario 5 (general public)

Combined scenarios

Not relevant

Outcome of qualitative local risk assessment

No local effects are expected from sanding and other processing of treated wood.

Slight transient irritation of oral mucosa cannot be excluded from chewing of treated wood by toddlers. However, this effect is of minor importance given the low severity and rare occurrence.

Conclusion

Risk from secondary exposure (dermal and inhalation exposure of professionals and non-professionals from sanding of treated wood, oral exposure of toddlers from accidental chewing of a treated off-cut) is considered acceptable.

3.6.7 Monitoring data

No monitoring data is available.

3.6.8 Dietary risk assessment

Not relevant. No food, drinking water or livestock exposure is foreseen.

The following RMM applies:

- Do not use on wood which may come into direct contact with food, feeding stuff, drinking water or livestock animals.

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

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

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

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

3.6.8.5 Maximum residue limits or equivalent

3.6.9 Aggregated exposure and risk characterisation

Guidance on aggregated exposure is currently not available.

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

Tier 1 and tier 2

Table 3.46 Tier 1 and tier 2

Scenario 1 Primary exposure	Propiconazole	Tebuconazole	Cypermethrin	Conclusions
With gloves and coated coverall during application				
Tier 1	24% AEL	32% AEL	15% AEL	Acceptable

Tier 2	0.24	0.32	0.15	Acceptable
	HI = 0.71			
Scenario 2 Primary exposure	**Propiconazole**	**Tebuconazole**	**Cypermethrin**	**Conclusions**
With gloves during application				
Tier 1	6% AEL	8% AEL	4% AEL	Acceptable
Tier 2	0.06	0.08	0.04	Acceptable
	HI = 0.18			
Scenario 3 Primary exposure	**Propiconazole**	**Tebuconazole**	**Cypermethrin**	**Conclusions**
No PPE				
Tier 1	2% AEL	20% AEL	2% AEL	Acceptable
Tier 2	0.02	0.20	0.02	Acceptable
	HI = 0.24			
Scenario 4 Secondary exposure	**Propiconazole**	**Tebuconazole**	**Cypermethrin**	**Conclusions**
Tier 1	0.2% AEL	0.3% AEL	0.2% AEL	Acceptable
Tier 2	0.002	0.003	0.002	Acceptable
	HI = 0.01			
Scenario 5 Secondary exposure	**Propiconazole**	**Tebuconazole**	**Cypermethrin**	**Conclusions**
Tier 1	0.5% AEL	4.8% AEL	0.3% AEL	Acceptable
Tier 2	0.005	0.048	0.003	Acceptable
	HI = 0.06			

Tier 3: not needed

3.6.11 Overall conclusion on risk assessment for human health

Table 3.47 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[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]** (details below the table)
1.1 and 2.1	Automated dipping	Acceptable with risk mitigation measures	PPE required
1.2 and 2.2	Brush treatment – professionals	Acceptable with risk mitigation measures	PPE required
3.1 and 4.1	Automated dipping	Acceptable with risk mitigation measures	PPE required
3.2 and 4.2	Brush treatment – professionals	Acceptable with risk mitigation measures	PPE required
5.1 and 6.1	Brush treatment – non-professionals	Acceptable with risk mitigation measures	Instructions

[1] Use numbers in accordance with the list of all uses indicated under section 2.2, where further details are described.
[2] Title of the specific use, as indicated in the SPC
[3] For the wording of the RMMs, refer to the "Frequently used sentences in the SPC and translations" available at https://echa.europa.eu/support/dossier-submission-tools/spc-editor. The conclusion and

set RMMs should be in alignment with the overall conclusion under section 2.2

RMMs (HH) for all uses:

- Do not use on wood which may come into direct contact with food, feeding stuff, drinking water or livestock animals.

RMMs (HH) for meta-SPCs 1, 2, 3 and 4:

Automated dipping, brush treatment:

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- The use of eye protection during handling of the undiluted product is mandatory.

Automated dipping:

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

RMMs (HH) for meta-SPCs 5 and 6:

- Avoid exposure of skin and eyes.
- Wash hands after use.
- It is recommended to wear gloves during application

3.7 Risk assessment for animal health

Exposure of companion or livestock animals is not foreseen.

The following RMMs apply:

- Do not use on wood which may come into direct contact with food, feeding stuff, or drinking water or livestock animals.
- Do not use the product for wood, which is foreseen as part of structures (e.g. flooring, furniture), to which persons of the general public and pets may have prolonged contact.
- Do not use the wood waste from the treated wood (e.g. shavings, sawdust etc.) as a bedding for animals.

3.7.1 Risk for companion animals

Not relevant

3.7.2 Risk for livestock animals

Not relevant

3.8 Risk assessment for the environment

Information on the choice of the worst-case composition for environmental risk assessment (e.g. representative test product(s)) and the justification for why the chosen test product(s) is/are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test product(s) chosen, the corresponding justification and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance(s), metabolite(s), and transformation product(s)

No new endpoint studies have been submitted since the approval of the active substance. Therefore, the risk assessment has been driven by endpoints published in the assessment reports of the active substances:

i) Assessment report for ADBAC, PT08 (June 2015, IT)
ii) Assessment report for cypermethrin cis:trans (40:60), PT08 (July 2013, BE)
iii) Assessment report for propiconazole, PT08 (January 2015, FI)
iv) Assessment report for tebuconazole, PT08 (2007, DK) and PT07 (September 2013, DK)

The assessment reports are available on the ECHA website.

The products in the product family contain four active substances, a brief summary on the active substances and relevant metabolites was derived from the respective assessment reports and is provided below:
ADBAC is not volatile (vapour pressure < 1 x 10-5 Pa at 20°C). It is readily biodegradable with the 10-day window criterion met. ADBAC is hydrolytically stable (at pH 5, 7, and 9 at 25°C). The mean atmospheric half-live is 0.368 d. ADBAC can be considered immobile in soil with a Koc value of 1640329 L/kg, and thus, is unlikely to leach into groundwater and contaminate groundwater. With regard to bioaccumulation, the BCF (fish) for ADBAC was determined to be 79 L/kg, indicating a low potential for bioaccumulation. No data are available on the BCF (earthworm).
Tebuconazole is stable to hydrolysis. Direct photodegradation of tebuconazole in water is low and the substance may be considered photolytically stable in both water and on soil. the calculated DT50 of tebuconazole in air is more than 2 days. Based on the modified MITI test, tebuconazole is concluded to be not ready biodegradable. The biodegradation half-life in surface water is estimated to be 198 days. Tebuconazole is not metabolised rapidly in soil in laboratory experiments, the half-life for primary degradation is greater than one year. In field studies the dissipation half-life period is 77 days. Accumulation of tebuconazole in soil is not anticipated. organic carbon adsorption coefficients of 800-1250 L/kg indicate a moderate to high adsorption of tebuconazole to soil and thus a low mobility potential in soil. In the risk assessment, an adsorption coefficient Ka arithmetic mean value of 12.7 L/kg and a KaOC of 992 L/kg (arithmetic mean) are used. The BCF value (fish) used in the risk assessment is 78 L/kg.
1,2,4-Triazole is the primary metabolite from the degradation of tebuconazole (max 9%). The dissipation half-life of this metabolite in aerobic soil is estimated to be about 10 days. The ecotoxicity of the metabolite is significantly lower than that found for tebuconazole for both the aquatic and terrestrial environment.

Propiconazole is not readily biodegradable and is hydrolytically and photolytically stable. Propiconazole adsorbs to soil and sediment (arithmetic mean Koc of 944 from 9 soils). The dissipation half-life of propiconazole is around 6.4 days in water and degradation half-life 636 days in the whole water-sediment system at 20 °C ± 2 °C. The degradation half-life of 636 days in the water/sediment system at 20 °C corresponds to 1206 days at 12 °C. In the bioaccumulation study the mean steady-state BCF of propiconazole was 180 and depuration half-life 0.4 days for the whole fish. The estimated BCF of propiconazole for bioconcentration to soil dwelling species is 64.
In the soil laboratory studies there were two degradation products of propiconazole accounting more than 10% of the active substance in the laboratory studies (CGA 118 245 and 1,2,4-triazole). Both are degraded in soil faster than the parent substance CGA 118 245 having DT 50 of around 1 day and 1,2,4-triazole having DT50 of around 9.3 days at 20 °C. Both degradation products are also more mobile in soil than propiconazole CGA 118 245 having the arithmetic mean Koc of 129 from 3 soils and 1,2,4-triazole having the arithmetic mean Koc of 69 from 10 soils.
Cypermethrin degrades under alkaline conditions in water. The DT50 values at 12°C for pH7 and pH 4 are 98.8 days and > 7630 days, respectively. The DT50 value for the photolysis in air is 0.749 day (17.990 hr). The degradation of cypermethrin was effective in the water/sediment systems (DT50 values in the whole systems: 3.5-9.8 days and 6.6-18.5 days at 12°C). The two main degradation products identified in the water/sediment system, TDCVC and CDCVC, are considered persistent with typical DT50 values > 40 days. The DT50 values for the degradation of cypermethrin (cis:trans/40:60) in the four soils tested were within the range of 6-24 days following incubation at 20 ± 2°C. These results of the soil adsorption/desorption study provided minimum Koc values ranging from 80653 to 574360 for the soil and is minimum 527972 for the sediment. The result of a QSAR provided a Koc of 2676776 for a log Pow of 5.3 and a Koc of 574360. These values are indicative of a strong adsorption to the soil particles and sediment. Cypermethrin (cis:trans/40:60) tends to bioaccumulate in water organism with a typical bioaccumulation factor (fish) of 374.4 (±45.35) and a depuration rate of 0.00158 l/h. A QSAR (BCFwin; EPISUITE) provided a BCF value of 417 L/Kg (Log P_{OW} = 5.45).

PBT assessment

None of the active substances is considered to be PBT or vPvB.

Cypermethrin is considered toxic (T). Tebuconazole is considered persistent (P) as well as meets the criteria for classification as toxic (T) for reproduction, category 2 according to the CLP Regulation (AR, PT07, Denmark, 2013). Propiconazole fulfilled the criteria for being classified as vP and T, but is not considered to be B. Therefore, tebuconazole and propiconazole meets the conditions laid down in Article 10(1)(a), (d) and (e) of Regulation (EU) No 528/2012, and are considered as candidates for substitution.
In addition, propiconazole (in PT08) has been assessed for endocrine disrupting properties. According to the Biocidal Products Committee (BPC) Opinion from March 2022 (ECHA/BPC/324/2022; https://echa.europa.eu/documents/10162/2b615a3d-38d2-0087-31b6-dda6cfea6902, accessed 14 Dec 2022), propiconazole has an endocrine mode of action as it shows endocrine activity by interfering steroidogenesis. There is a biologically plausible link between the endocrine mode of action (activity on steroidogenesis by aromatase enzyme inhibition) and the adverse effects (reduced number of eggs). Thus, propiconazole is considered to have endocrine disrupting properties according to Section B of Regulation (EU) 2017/2100 and meets the exclusion criteria laid down in Article 5(1)(c) and (d) of Regulation (EU) No 528/2012. However, no conclusion on the level of risks of using propiconazole considering its endocrine disrupting properties can currently be drawn, as neither guidance nor a harmonised understanding on the principles of an ED risk assessment is available.

Further on, in view of the fact that the examination of approval of propiconazole renewal will not be possible to complete before the current expiry date (31 Dec 2022), the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 set out in Implementing Decision (EU) 2021/354 was postponed to 31 December 2023.

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

Table 3.48 Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment

Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment						
	Value				**Unit**	**Remarks**
	ADBAC	**Tebu-conazole**	**Propi-conazole**	**Cypermethrin**		
Fate and behaviour in the environment						
Molecular weight	340.0 – 396.1	307.8	342.2	416.3	g/mol	
Melting point	-	105ºC	-	47.3	°C	
Vapour pressure (at X°C)	US ISC: **6.03E-04 Pa at 20°C,** 8.57E-04 Pa @ 25°C, 4.22E-03 Pa at 50°C EQC: < 1.5E-03 Pa at 20°C, < 5.8E-03 Pa at 25°C	1.7 × 10-6 Pa at 20ºC	5.6 x10-5 Pa at 25°C	2.3x10-7 Pa at 20 °C, 6x10-7 Pa at 25°C	Pa	
Water solubility (at X°C)	US ISC: pH 5.5: 409 g/l at 20°C **pH 6.5: 431 g/l** at 20°C pH 8.2: 379 g/l at 20°C EQC: 455 g/l in doubled distilled water at 20.0 ± 0.5 °C 444 g/l in acidic or basic solution at 20.0 ± 0.5 °C Solubility was found to be independent of Temperature.	pH 5: 0.027 g/l at 20ºC; **pH 7: 0.029 g/l at 20ºC;** pH 9: 0.032 g/l at 20ºC	pH 6.9 at 20ºC: 100 mg/l	< 9 µg/L at 20°C (99.5% pure) (4µg/L used for the environmental risk assessment)	mg/l	
Log Octanol/water partition coefficient (K_{ow})	EQC: 0.004 at 20°C	3.53 at 10°C, 3.4 at 20°C, 3.47 at 30°C	pH 6.6 at 25ºC: 3.72	5.45 (mean)	Log 10	

Organic carbon/water partition coefficient (K_{oc})	US ISC: 2658607.75 L/kg (mean, 4 soils) EQC: 282624.3 L/kg (mean, 3 soils)	992 (arithmetic mean)	944 (arithmentic mean, 9 soils)	Freundlich adsorption coefficients (K) values could not be determined. Minimum Kd values ranges from 3871 to 8976. Minimum Koc values were between 80653 and 574360 mL/g. QSARkoc: 2.676.776-4.586.002 (log Pow 5.3-5.6)	L/kg	
Henry's Law Constant (at X C)*[if measured data available]*	US ISC: 5.03E-07 Pa m3 mol -1 at 20°C EQC: < 1.15E-06 Pa m3 mol -1 at 20°C	1 × 10-5	9.2 x10-5	0.024 Pa.m³.mol-1 at 20°C	Pa/m^3 /mol	
Characterisation of biodegradability	*Ready biodegradable, the 10-d window met*	*Not readily biodegradable*	*Not readily biodegradable*	*Not inherently biodegradable*	-	
Rate constant for STP					h^{-1}	
Transformation fraction and maximum radioactivity	-				- %	
DT_{50} for biodegradation in surface water		43 d	6.4 d	0.948 d (12°C)	d or hr (at 12ºC)	
Transformation fraction and maximum radioactivity	-				- %	
DT_{50} for hydrolysis in surface water	stable, > 30 days	stable	stable	98.9 d (pH 7, 12°C)	d or hr (at 12ºC /pH)	
DT_{50} for degradation in soil	-	77 d (field study)	137 d (lab, worst-case, at 12°C) 16-129 d (field)	17.2 days at 12°C (based on the geom.mean)	d or hr (at 12ºC)	
Transformation fraction and maximum radioactivity	-				- %	
DT_{50} for degradation in air	8.3 hr (AOPWIN)	3.8 d	10.2-42 h	17.990 hr (EPIWIN AOP)	d or hr	
DT_{50} for degradation in the sewer system					d or hr (at 12ºC)	
DT_{50} for degradation in manure	-	-	-	-	d or hr (at 12ºC)	

Predicted no effect concentrations (PNEC) ***[highlight in bold PNEC values derived from new endpoints]***						
Sewage treatment plant	0.0775	0.32	1.0 (AR – PT8, 2007, FI), 100 (AR, PT7, 2015, FI)	1.63	mg/L	
Surface water	0.000415	1.0×10^{-3}	1.6×10^{-3} (AR – PT8, 2007, FI) based on NOEC for algae, 6.8×10^{-3} (AR, PT7, 2015, FI) based on NOEC for marine fish	1×10^{-6}	mg/L	
Marine water	-	-		-	mg/L	
Sediment	3.57 (5.20 mg/kg dw)	O.55 mg/kg wwt	0.054 ok	0.125 (EqP)	mg/kg wwt	*EqP = PNEC was calculated from the PNEC for surface water using the equilibrium partitioning approach*
Marine sediment	-	-		-	mg/kg wwt	
Soil	0.70	0.10	0.02 (AR – PT8, 2007, FI), 0.1 (AR, PT7, 2015, FI)	0.1	mg/kg wwt	
Bird	0.821	Dietary toxicity: Bobwhite quail, LC50 (5 day): >5000 mg a.s./kg feed; Mallard duck, LC50 (5 day): >4816 mg a.s./kg feed		Dietary toxicity to brids LC50 (Colinus virginianus, 5d) > 5620 mg a.s./Kg feed or > 1376 mg a.s./Kg bw/d, Reproductive toxicity to birds: NOEC (Colinus virginianus, 21 weeks) = 1000 mg a.s./Kg feed or 92.0 mg a.s./Kg bw/d	mg/kg food	*ADBAC: Acute and short-term toxicity dta on birds are available only in the US ISC dossider: LC50 > 2463 mg a.s./kg food (mallard duck)*
Mammals	4.4			Acute toxicity to mammals: LD50 (rat, oral) = 1945 mg/Kg	mg/kg food	

Table 3.49 Endpoints and PNEC or effect values for the metabolite(s) and transformation product(s) 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**
	1,2,4-Triazole	**Transformation product 1**		
Fate and behaviour in the environment				
Molecular weight	69.06		g/mol	*CLH report for 1,2,4-triazole, Feb 2018 (https://echa.europa.eu/documents/10162/7374c035-9145-ff17-42b7-781efb2ddf07)*
Melting point	120-121°C		°C	*CLH report for 1,2,4-triazole, Feb 2018 (https://echa.europa.eu/documents/10162/7374c035-9145-ff17-42b7-781efb2ddf07)*
Vapour pressure (at X°C)	0.22 Pa (20°C), 80.4 Pa (25°C)		Pa	*CLH report for 1,2,4-triazole, Feb 2018 (https://echa.europa.eu/documents/10162/7374c035-9145-ff17-42b7-781efb2ddf07)*
Water solubility (at X°C)	730 g/L (25°C), 4244 g(L (25°C)		mg/l	*CLH report for 1,2,4-triazole, Feb 2018 (https://echa.europa.eu/documents/10162/7374c035-9145-ff17-42b7-781efb2ddf07)*
Log Octanol/water partition coefficient (K_{ow})	25° C, pH 5: log Pow = -0.62; 25°C, pH 7: log Pow = -0.71; 25° C, pH 9: log Pow = -0.68; -0.58.		Log 10	*CLH report for 1,2,4-triazole, Feb 2018 (https://echa.europa.eu/documents/10162/7374c035-9145-ff17-42b7-781efb2ddf07)*
Organic carbon/water partition coefficient (K_{oc})	69 (10 soils)		L/kg	*(AR-propiconazole, PT08, Finland, 2007)*
Henry's Law Constant (at X C)*[if measured data available]*	-		$Pa/m^3/mol$	
Characterisation of biodegradability	*not readily biodegradable*		-	
Rate constant for STP	-		h^{-1}	
Transformation fraction and maximum radioactivity	-		- %	
DT_{50} for biodegradation in surface water	-		d or hr (at 12ºC)	

Endpoints and PNEC values for the metabolite(s) and transformation product(s) applied in the environmental risk assessment				
	Value		**Unit**	**Remarks**
	1,2,4-Triazole	**Transformation product 1**		
Transformation fraction and maximum radioactivity	-		- %	
DT_{50} for hydrolysis in surface water	-		d or hr (at 12ºC /pH)	
DT_{50} for degradation in soil	9.3 d at 12°C		d or hr (at 12ºC)	
Transformation fraction and maximum radioactivity	-		- %	
DT_{50} for degradation in air	-		d or hr	
DT_{50} for degradation in the sewer system	-		d or hr (at 12ºC)	
DT_{50} for degradation in manure	-		d or hr (at 12ºC)	
Predicted no effect concentrations (PNEC) ***[highlight in bold PNEC values derived from new endpoints]***				
Sewage treatment plant	-		mg/L	
Surface water			mg/L	*LC50 = 498 mg/L (fish)* *EC50 > 100.0 mg/L (invertebrates)* *ErC50 > 31.0 mg/L (algae)* *(AR-tebuconazole, PT08, Denmark, 2007)*
Marine water	-		mg/L	
Sediment	-		mg/kg wwt	
Marine sediment	-		mg/kg wwt	
Soil			mg/kg wwt	*LC50 > 1000 m/kg dw, 299 mg/kg ww (earthworms)* *EC > 0.33 mg/kg dw, 0.82 mg/kg ww (nitrogen mineralization) (AR-propiconazole, PT08, Finland, 2007)*
Bird	-			
Mammals	-			

For ABAC, no PNEC is available for sediment and were therefore derived from the PNEC for surface water. No PNECs are available for the marine ecosystem.

3.8.1.2 Endpoints for the products

There are no new additional data available for the products. 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.

The leaching behaviour is not considered in the PAR. The products from the Drevosan family are intended for the treatment of wood in use classes 1 and 2. For those use classes, no emission due to leaching are expected. Leaching during the application and storage is prevented by the requirements listed in the respective inclusion directives, which states: „that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water."

3.8.1.3 Substance(s) of concern

Regarding co-formulants (see the whole composition of the products in the Confidential Annex), no non-active substances have been identified to be of concern.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of non-active substances, refer to the respective section of the confidential annex.

3.8.2 Emission estimation

3.8.2.1 General information

Predicted Environmental Concentrations (PECs) are calculated according to the relevant exposure scenario documents (ESD-PT08), the Guidance on the BPR: Volume IV Environment (Parts B+C) (distribution in the environment), and the Technical Agreement on Biocides (TAB) by using the default values for parameters, unless otherwise noted. Distribution in the STP is calculated using SimpleTreat version 4.0 in which the concentration of suspended solids in the effluent should be set to 30 mg/L in accordance with the TAB. Distribution in the STP and the environment is driven by the physical-chemical properties of the active substances and metabolites as listed in section 3.2.

Various phases in the life cycle of a product may cause emissions and environmental exposure. Significant release to the environment will therefore occur during the application of products holding the biocide.
The emissions of active substances may occur in the following stages of the product life:

a) during the application
b) during the storage of treated wood prior to its sale
c) during the mechanical processing and handling with treated wood
d) during usage of the treated wood
e) during the disposal of the treated wood.

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.

The table below summarises the receiving environmental compartments that have been identified as potentially exposed during the use of the product for the different applications.

Compartments highlighted in bold are directly exposed.

Emission should be calculated for each intended use based on the worst-case composition that results in the highest emission to the environment which depends on the highest concentration (which must be at the same time efficacious), application rate and frequency.

The risk assessment approach applied for this product family is summarised below.

Table 3.50 Environmental risk assessment

Environmental risk assessment						
Use number[1]	**Scenario assessed**	**ESD applied[2]**	**Maximum in-use concentration of the active substance(s)[3]**	**Maximum in-use concentration of substance(s) of concern[4]**		**Receiving compartments[5]**
1.1 and 2.1	*Life cycle stage: Product application, Industrial preventive processes and storage of treated wood - Dipping (professional)*	*ESD for PT 8: Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013)*	*Application rate 15 g of product/m2:* *ADBAC: 20%* *Tebuconazole: 0.3%* *Propiconazole: 0.3%* *Cypermethrin: 0.1%*	*Corresponds to the concentration of the active substance (previous column)*	*UC 1,2*	***Air*** *STP* *Soil* *Groundwater (leaching from soil)* *Freshwater/sediment*
3.1 and 4.1	*Life cycle stage: Product application, Industrial preventive processes and storage of treated wood - Dipping (professional)*		*Application rate 40 g of product/m2:* *ADBAC: 8%* *Tebuconazole: 0.12%* *Propiconazole: 0.12%* *Cypermethrin: 0.04%*	*Corresponds to the concentration of the active substance (previous column)*	*UC 1,2*	***Air*** *STP* *Soil* *Groundwater (leaching from soil)* *Freshwater/sediment*
1.2 and 2.2	*Life cycle stage: Product application, In-situ treatment (curative, preventive) – brushing (professional)*	*ESD for PT 8: Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013)*	*Application rate 15 g of product/m2:* *ADBAC: 20%* *Tebuconazole: 0.3%* *Propiconazole: 0.3%* *Cypermethrin: 0.1%*	*Corresponds to the concentration of the active substance (previous column)*	*UC 1,2*	***Air*** *STP* ***Soil*** *Groundwater (leaching from soil)* *Freshwater/sediment*

Environmental risk assessment						
Use number[1]	**Scenario assessed**	**ESD applied[2]**	**Maximum in-use concentration of the active substance(s)[3]**	**Maximum in-use concentration of substance(s) of concern[4]**		**Receiving compartments[5]**
3.2 and 4.2	*Life cycle stage: Product application, In-situ treatment (curative, preventive) – brushing (professional)*	*ESD for PT 8: Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013)*	*Application rate 40 g of product/m2:* *ADBAC: 8%* *Tebuconazole: 0.12%* *Propiconazole: 0.12%* *Cypermethrin: 0.04%*	*Corresponds to the concentration of the active substance (previous column)*	*UC 1,2*	***Air*** *STP* ***Soil*** *Groundwater (leaching from soil)* *Freshwater/sediment*
5.1 and 6.1	*Life cycle stage: Product application, In-situ treatment (curative, preventive) – brushing (amateur)*	*ESD for PT 8: Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013)*	*Application rate 150 g of product/m2:* *ADBAC: 2%* *Tebuconazole: 0.03%* *Propiconazole: 0.03%* *Cypermethrin: 0.01%*	*Corresponds to the concentration of the active substance (previous column)*	*UC 1,2*	***Air*** *STP* ***Soil*** *Groundwater (leaching from soil)* *Freshwater/sediment*

[1] Use numbers in accordance with the list of all uses indicated under section 2.2, where further details are described.
[2] Refer to the ESD or TAB-agreement that is applied in the risk assessment. Indicate if the assessment is covered by another use.
[3] For the respective use indicated the maximum concentration for all active substances.
[4] Maximum concentration of the substance(s) of concern if relevant for the use.
[5] Only relevant receiving compartments based on the exposure pathway are listed and the compartment receiving the direct emissions is highlighted in bold. Include sediment and groundwater if applicable.
[6] The applied scenario is based on tonnage data which are confidential. The risk assessment is consequently included in the confidential annex of the PAR.

3.8.2.2 Emission estimation for the scenario(s)

In Table 3.50 Environmental risk assessment, the relevant scenarios are outlined and include the use of the product by professionals and amateurs, with the application method of automated dipping/spraying and/or brushing.

The production is automated and designed so as to ensure that the individual ingredients are used up in the product formulation. If any remnants occur, these are re-used in the manufacture. Remnants that cannot be reused are disposed of in compliance with the national regulations. Thus, the emissions of the product to the environment during the manufacture are not quantified.

Further to that, additional information on the application, storage, handling, use and disposal are provided below, which affects emissions of the residues of the product to the environment.

Application:
According to Annex I to Directive 98/8/EC (ADBAC (C12-16) and cypermethrin):
„Labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding" and that *„any losses from the application of the product shall be collected for reuse or disposal."*
And ESD (p. 46) notes that "*The release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries*."

Storage:
Annex I to Directive 98/8/EC (all four active substances) states:
„Labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water."

Mechanical processing and handling with treated wood:
"*During mechanical processing of the treated wood all the remains should be collected and disposed of as waste."*

Use:
The product family is intended to be used in line with the descriptions of use classes 1 and 2, which specify the main uses of treated wood materials to be as follows:
Use class 1: Situation in which the wood or wood-based product is under cover, fully protected from the weather and not exposed to wetting.
Use class 2: Situation in which the wood or wood-based product is under cover and fully protected from the weather but where occasional but not persistent wetting may occur.

Disposal of the treated wood:
Disposal of the treated wood is performed by burning or storing in landfills. Direct discharging of the wood waste into the environment is prohibited.

It is anticipated that the emissions to the environment can be considered negligible if the information above are fully integrated and followed during the whole life cycle of the products.
During application and during the service life of the treated wood, the emission to the environment can be effectively prevented, leaving air as the only primary receiving environmental compartment. However, since the active substances are non-volatile, and a

sufficient dilution can be achieved during outdoor applications, the emissions to the air can be reasonably assumed to be negligible.

As such, the emissions are not addressed quantitatively, as they are expected to be negligible, but a qualitative assessment has been performed for environmental compartments that may be exposed to residues of the products as primary or secondary recipients.

Atmosphere

Environmental risk assessment for air was based on qualitative evaluation. The vapour pressures of the active substances as well instructions for application, storage/handling, use, and disposal were brought together to justify that emissions to the environment from those processes will be generally low.
The active substances in the product are not volatile and will therefore not evaporate from the wood during treatment and during use of the treated wood. Emissions during the outdoor use can generally be considered negligible because of instant dilution and turbulence in air. In addition, there are no indications that the active substances contribute to depletion of the ozone layer as the compounds are not listed as 'controlled substances' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Moreover, AOPWIN calculates for three (ADBAC, propiconazole, and cypermethrin) out of the four active substances, the half-lives are < 2 days (OH timeframe 24 hrs/day, 0.5×10^6 OH radicals/cm³). Thus, the calculated half-lives are below the trigger of 2 days, which is used as cut-off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. For tebuconazole, a half-live of 3.8 day was calculated, however, since the very low vapour pressure of this compound, air will not be an environmental compartment of concern for tebuconazole used in wood preservatives. In conclusion, the environmental risk to air arising from the use of the product family Drevosan can be considered acceptable.

Conclusion: Following the qualitative assessment, the risk to the air compartment is considered acceptable on the basis of negligible emissions and short half-lives of the active substances in the air.

Sewage treatment plant (STP)

Direct emissions to an STP are not foreseen as product applications "*shall be conducted within a contained area or on impermeable hard standing with bunding*" and *„any losses from the application of the product shall be collected for reuse or disposal.", where in many EU countries (ESD-PT08, p. 46),"the release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore".*
In addition, the use classes 1 and 2 describe situations in which the wood or wood-based product is under cover and fully protected from the weather (but where occasional but not persistent wetting may occur), and therefore, emission during the service life also are not expected. The proposed instructions for use (risk mitigation measures) and specification of use classes implies negligible emission to STPs. Based on the qualitative consideration, the risk to the STP compartment is expected to be acceptable.

Conclusion: Following the qualitative assessment, the risk to the STP compartment is considered acceptable on the basis of negligible emissions.

Aquatic compartment

The risk to the marine compartment was not considered following the proposed uses of the product family.

For the freshwater compartment during the application, direct emissions to an STP are prevented by appropriate risk mitigation measures, where the industrial application *"shall be conducted within a contained area or on impermeable hard standing with bunding*" and *„any losses from the application of the product shall be collected for reuse or disposal."*, where in many EU countries (ESD-PT08, p. 46)," the release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore". Therefore, it follows that indirect emissions to surface water are not likely.
In addition, the intended uses (use classes 1 and 2) encompass situations where the wood or wood-based product are protected from weather and persistent wetting, and therefore, direct emissions of product residues during service life are foreseen to be negligible.

Conclusion: Following the qualitative assessment, the risk to the aquatic compartment is considered acceptable on the basis of negligible emissions.

Terrestrial compartment

For the application step, the instructions specify that the application of the product *"shall be conducted within a contained area or on impermeable hard standing with bunding*" and *„any losses from the application of the product shall be collected for reuse or disposal."* Therefore, direct emissions during application of the product will be prevented.
Indirect emissions during the service life the treated wood are unlikely in use classes 1 and 2, where the treated wood is protected from weathering.

Conclusion: Following the qualitative assessment, the risk to the terrestrial compartment is considered acceptable on the basis of negligible emissions.

Groundwater

Groundwater is unlikely to be exposed to residues of the product. Following the instructions for use and the respective risk mitigation measures, the application of the product, storage/handling, use and disposal of the treated wood are not likely to give rise to significant emissions to the environment. Since emissions to an STP, soil and surface water will be prevented, no significant emissions to groundwater are foreseen for the proposed uses of the product family.

Conclusion: Following the qualitative assessment, the risk to the groundwater compartment is considered acceptable on the basis of negligible emissions.

3.8.3 Exposure calculation and risk characterisation

See the qualitative assessment above

3.8.4 Primary and secondary poisoning

3.8.4.1 Primary poisoning

For PT08-wood preservatives, primary poisoning is not considered relevant.

3.8.4.2 Secondary poisoning

For ADBAC, the BCF amounted to 79 L/kg for fish. No data are available on the

BCFearthworm for this compound. For tebuconazole, the BCF was 78 (fish) and 28 (earthworm). For propiconazole, the BCF values were reported to be 180 (fish) and 64 (soil dwelling species), which indicates slight potential for bioaccumulation.
Cypemethrin cis:trans/40:60 is characterized by Log Kow values ranging from 5.3-5.6, which indicates a potentially high potential for bioaccumulation. The results of an experimental BCF test tends to impair this assumption, although it should be noted that the deviation in the test protocol lowered the relevance of the study results. Subsequently, a QSAR (BCFwin; EPISUIT) confirmed a low potential for bioaccumulation, providing a BCF of 417 L/Kgwwt. Both results suffer from uncertainty. As a consequence, bioaccumulation of the active substance should not be completely excluded. Regarding the terrestrial compartment, cypermethrin cis:trans/40:60 is characterised by a Koc value ranging from 80653 to 574360, indicating a high potential to adsorb to the soil particles, reducing the bioavailability. Conversely, the active substance may also adsorb to biological surfaces such as skin which may lead to toxic effect in higher organisms after biomagnification.

Generally, a risk for secondary poisoning is to be performed at product authorisation based on the formulation and the envisaged used. For the product family Drevosan, the proposed instructions and risk mitigations measures minimize emissions to the environment. In addition, as shown above, the reported BCF values were all below 2000. Therefore, it can be assumed that the potential for secondary poisoning is low.

Following the proposed uses of the product family (use class 1 and 2) and the proposed risk mitigation measures, the emissions to the environment during product application and from the treated wood in service, are considered negligible. As a consequence, exposure to bees via contaminated pollen can be considered unlikely and no specific warning in relation to bees is deemed necessary.

For indoor treatments by spraying, brushing and injection, emissions to the environment are considered to be negligible. Nevertheless, indoor treatments may need to be considered in the exposure assessment for bats in countries where bats are protected animals (e.g., in most European countries) [Chadwick J et al., 1992; Mitchell-Jones AJ et al., 1989]. Bats may be exposed to treated wood via contact. As the product contains cypermethrin, it is appropriate to include the following risk mitigation measure for uses 1 and 2 (indoor treatment):

Can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary.

Conclusion: Due to the expected low exposure and the BCF values of the active substances being all below 2000, the risk of secondary poisoning is considered negligible. Exposure to bees is not expected. For the indoor treatment, the possible exposure of bats, hornets, and birds should be considered, and appropriate protective measures should be applied, if needed.

3.8.5 Mixture toxicity

The product family Drevosan contains four active substances, where both propiconazole and tebuconazole are azole compounds acting via the same mode of action. Mixture toxicity assessment would therefore normally have been needed for these two compounds. Nevertheless, given that the exposure of the environment is expected to be low/negligible for use classes 1 and 2, and additional risk mitigation measures were proposed to minimize emissions to the environment, the mixture assessment has not been performed. This assumption of negligible emissions is true also for the other active substances present in the product.

3.8.6 Aggregated exposure (combined for relevant emission sources)

Aggregated exposure is not considered relevant.

3.8.7 Overall conclusion on the risk assessment for the environment

The quantitative environmental risk assessment was not performed as there are several indices that exposure of the environment due to application of the product and during the treated wood in-service life can be expected to be negligible. A qualitative environmental risk assessment was performed instead, which revealed that according to the current standards, the risk can be considered acceptable.

The product family Drevosan is intended to be used as a wood preservative by both professionals and the public in outdoor and indoor applications. The considered uses fall under use classes 1 and 2, for which the exposure to the environment from the treated wood in service is considered negligible. Emissions during industrial application are prevented by appropriate risk mitigation measures specifying that all industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g., sump). In addition, freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal. For indoor applications, exposure to bats, hornets, and birds should be prevented.

It should however be noted that tebuconazole and propiconazole are considered as candidates for substitution, and propiconazole is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council, and therefore meets the exclusion criterion set out in point (c) of Article 5(1) of Regulation (EU) No 528/2012. Furthermore, propiconazole is considered having endocrine disrupting properties that may cause adverse effects in humans, and therefore meets the exclusion criterion set out in point (d) of Article 5(1) of Regulation (EU) No 528/2012. While the examination to decide whether at least one of the conditions of the first subparagraph of Article 5(2) of that Regulation is fulfilled, and whether the approval of propiconazole may therefore be renewed, is ongoing, it will not be possible to complete this examination before the current expiry of approval. The expiry date was postponed to 31 December 2023, and thus, propiconazole remains approved for use in biocidal products of product-type 8 subject to the requirements set out in Annex I to Directive 98/8/EC (Commission Implementing Decision (EU) 2022/2298 of 23 November 2022 postponing the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council).

Table 3.51 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
1.1 and 2.1	Automated dipping – professionals, application rate: 15 g/m^2	Acceptable risk, providing the instructions for use and the proposed risk mitigation measures are applied	Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump). Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal.
1.2 and 2.2	Brush treatment – professionals, application rate: 15 g/m^2	Acceptable risk, providing the instructions for use and the proposed risk mitigation measures are applied	Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer. All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump). Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal. Can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary.
3.1 and 4.1	Automated dipping – professionals, application rate: 40 g/m^2	Acceptable risk, providing the instructions for use and the proposed risk mitigation measures are applied	Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump). Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal.

Overall conclusion on the risk assessment for the environment			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
3.2 and 4.2	Brush treatment – professionals , application rate: 40 g/m^2	Acceptable risk, providing the instructions for use and the proposed risk mitigation measures are applied	Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump). Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal. Can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary.
5.1 and 6.1	Brush treatment – non-professionals, application rate: 150 g/m^2	Acceptable risk, providing the instructions for use and the proposed risk mitigation measures are applied	Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal. Can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary.

[1] Use numbers in accordance with the list of all uses indicated under section 2.2, where further details are described.
[2] Title of the specific use, as indicated in the SPC
[3] The conclusion and set RMMs should be in alignment with the overall conclusion under section 2.2.

3.9 Assessment of a combination of biocidal products

Not relevant. The products of Drevosan product family are not intended to be authorised for use with other biocidal products.

3.10 Comparative assessment

The full comparative assessment report covering the situation in the Czech Republic can be found in the R4BP as a separate document. A brief summary is presented below.

The products of Drevosan family contain propiconazole and tebuconazole. Propiconazole meets exclusion and substitution criteria (Repr. 1B; vP and T; proposed to be ED to humans and non-target organisms). Tebuconazole meets a substitution criterion (vP and T) and a proposal has recently been made to classify the substance as Repr. 1B and to consider it ED (not evaluated yet).

3.10.1 Screening phase

- The existing chemical diversity in authorised biocidal products to minimise the occurrence of resistance is considered relatively low. This is partly due to the fact that propiconazole is a broad-spectrum fungicide and therefore its substitution normally requires more than one active substance.
- Consideration on whether propiconazole can benefit from derogation in accordance with Article 5(2) of the BPR is currently ongoing at EU level (see the Commission Implementing decision (EU) 2022/2298).
- Conclusion of the screening phase: Tier IB

3.10.2 Tier IA

Not relevant

3.10.3 Tier IB

- Main outcome of the comparison for:
  - Risk for human health, animal health, and the environment: Two products authorised for use against wood rotting fungi and *H. bajulus* and not containing active substances targeted by exclusion or substitution criteria have been identified: Tanasote S40 and Wolmanit CX-8WB family.
  - Significant economic or practical disadvantages: Neither of the two alternative products is authorised for superficial treatment, which is considered a major practical disadvantage.
- Conclusion of Tier IB: Tier II

3.10.4 Tier II

No suitable non-chemical alternative to biocidal timber treatment has been identified.

3.10.5 Overall conclusion

The CZ CA concludes that (1) the available biocidal products not containing active substances targeted by exclusion or substitution criteria present major practical disadvantages and (2) that there is no suitable non-chemical alternative to biocidal timber treatment.

It is noted that the Commission decision on the renewal of approval of propiconazole and the condition of the potential renewal is still pending, as is the conclusion on whether propiconazole can benefit from derogation in accordance with Article 5(2) of the BPR.

Therefore, at this stage Drevosan family shall be authorised for a period not exceeding 5 years in accordance with Article 23(6).

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Task/scenario: Scenario 1, Automated dipping

Scenario **Active substance**	Automated dipping Propiconazole Tebuconazole		
	Units	**Tier 2a**	**Tier 2b**
Active substance concentration	%	0,015	0,015
Body exposure			
Clothing type		no protection	coated coverall
Indicative value	mg/cycle	8570	8570
Duration	cycles/day	4	4
Potential body deposit	mg/day	34280	34280
Clothing penetration	%	100	10
Actual dermal deposit (product)	mg/day	34280	3428
Hand exposure			
Gloves worn		yes	yes
Indicative value	mg/cycle	1080	1080
Duration	cycles/day	4	4
Actual hand deposit (product)	mg/day	4320	4320
Total dermal exposure			
Product	mg/day	38600	7748
Active substance	mg/day	5,79	1,1622
Dermal absorption			
Dermal penetration	%	50	50
Absorbed dose (dermal)	mg/day	2,895	0,5811
Systemic dose			
Total absorbed dose	mg/day	2,895	0,5811
Body weight	kg	60	60
Total systemic dose	mg/kg bw/day	**4,83E-02**	**9,69E-03**

Scenario **Active substance**	Automated dipping Cypermethrin		
	Units	**Tier 2a**	**Tier 2b**
Active substance concentration	%	0,005	0,005
Body exposure			
Clothing type		no protection	coated coverall
Indicative value	mg/cycle	8570	8570
Duration	cycles/day	4	4
Potential body deposit	mg/day	34280	34280
Clothing penetration	%	100	10
Actual dermal deposit (product)	mg/day	34280	3428
Hand exposure			
Gloves worn		yes	yes
Indicative value	mg/cycle	1080	1080
Duration	cycles/day	4	4
Actual hand deposit (product)	mg/day	4320	4320
Total dermal exposure			
Product	mg/day	38600	7748
Active substance	mg/day	1,93	0,3874
Dermal absorption			
Dermal penetration	%	50	50
Absorbed dose (dermal)	mg/day	0,965	0,1937
Systemic dose			
Total absorbed dose	mg/day	0,965	0,1937
Body weight	kg	60	60
Total systemic dose	mg/kg bw/day	**1,61E-02**	**3,23E-03**

Task/scenario: Scenario 2, Professional brush treatment

Scenario **Active substance**	Brush treatment (professional) Propiconazole Tebuconazole		
	Units	**Tier 2a**	**Tier 2b**
Active substance concentration	%	0,03	0,03
Body exposure			
Clothing type		no protection	coated coverall
Indicative value (pot., for 1% a.s.)	mg/m^2	0,2382	0,2382
Indicative value (for a.s. content in the product)	mg/m^2	0,007146	0,007146
Application area	m^2/day	31,6	31,6
Potential body deposit	mg/day	0,2258136	0,2258136
Clothing penetration	%	100	10
Actual dermal deposit (a.s.)	mg/day	0,2258136	0,02258136
Hand exposure			
Gloves worn		yes	yes
Indicative value (pot., for 1% a.s.)	mg/m^2	0,5417	0,5417
Indicative value (for a.s. content in the product)	mg/m^2	0,016251	0,016251
Application area	m^2/day	31,6	31,6
Potential hand deposit	mg/day	0,5135316	0,5135316
Penetration of gloves	%	10	10
Actual hand deposit (a.s.)	mg/day	0,05135316	0,05135316
Total dermal exposure			
Active substance	mg/day	0,27716676	0,07393452
Dermal absorption			
Dermal penetration	%	50	50
Absorbed dose (dermal)	mg/day	0,13858338	0,03696726
Inhalation exposure			
Indicative value (pot., for 1% a.s.)	mg/m^2	0,0016	0,0016
Indicative value (for a.s. content in the product)	mg/m^2	0,000048	0,000048
Application area	m^2/day	31,6	31,6
Mitigation by RPE		none	none
Inhaled (a.s.)	mg/day	0,0015168	0,0015168
Systemic dose			
Total absorbed dose	mg/day	0,14010018	0,03848406
Body weight	kg	60	60
Total systemic dose	mg/kg bw/day	**2,34E-03**	**6,41E-04**

Scenario **Active substance**	Brush treatment (professional) Cypermethrin		
	Units	**Tier 2a**	**Tier 2b**
Active substance concentration	%	0,01	0,01
Body exposure			
Clothing type		no protection	coated coverall
Indicative value (pot., for 1% a.s.)	mg/m^2	0,2382	0,2382
Indicative value (for a.s. content in the product)	mg/m^2	0,002382	0,002382
Application area	m^2/day	31,6	31,6
Potential body deposit	mg/day	0,0752712	0,0752712
Clothing penetration	%	100	10
Actual dermal deposit (a.s.)	mg/day	0,0752712	0,00752712
Hand exposure			
Gloves worn		yes	yes
Indicative value (pot., for 1% a.s.)	mg/m^2	0,5417	0,5417
Indicative value (for a.s. content in the product)	mg/m^2	0,005417	0,005417
Application area	m^2/day	31,6	31,6
Potential hand deposit	mg/day	0,1711772	0,1711772
Penetration of gloves	%	10	10
Actual hand deposit (a.s.)	mg/day	0,01711772	0,01711772
Total dermal exposure			
Active substance	mg/day	0,09238892	0,02464484
Dermal absorption			
Dermal penetration	%	50	50
Absorbed dose (dermal)	mg/day	0,04619446	0,01232242
Inhalation exposure			
Indicative value (pot., for 1% a.s.)	mg/m^2	0,0016	0,0016
Indicative value (for a.s. content in the product)	mg/m^2	0,000016	0,000016
Application area	m^2/day	31,6	31,6
Mitigation by RPE		none	none
Inhaled (a.s.)	mg/day	0,0005056	0,0005056
Systemic dose			
Total absorbed dose	mg/day	0,04670006	0,01282802
Body weight	kg	60	60
Total systemic dose	mg/kg bw/day	**7,78E-04**	**2,14E-04**

Task/scenario: Scenario 3, Non-professional brush treatment – mixing & loading

Scenario **Active substance**	Brush treatment (non-professional) – mixing & loading Propiconazole Tebuconazole	
	Units	**Tier 1**
Active substance concentration	%	0,03
Dermal (hand) exposure		
Gloves worn		no
Indicative value (potential)	mg/event	500
Events per day	event/day	2
Potential hand deposit	mg/day	1000
Penetration of gloves	%	100
Actual hand deposit (product)	mg/day	1000
Actual hand deposit (a.s.)	mg/day	0,3
Dermal absorption		
Dermal penetration	%	50
Absorbed dose (dermal)	mg/day	0,15
Systemic dose		
Total absorbed dose	mg/day	0,15
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**2,50E-03**

Scenario **Active substance**	Brush treatment (non-professional) – mixing & loading Cypermethrin	
	Units	**Tier 1**
Active substance concentration	%	0,01
Dermal (hand) exposure		
Gloves worn		no
Indicative value (potential)	mg/event	500
Events per day	event/day	2
Potential hand deposit	mg/day	1000
Penetration of gloves	%	100
Actual hand deposit (product)	mg/day	1000
Actual hand deposit (a.s.)	mg/day	0,1
Dermal absorption		
Dermal penetration	%	50
Absorbed dose (dermal)	mg/day	0,05
Systemic dose		
Total absorbed dose	mg/day	0,05
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**8,33E-04**

Task/scenario: Scenario 3, Non-professional brush treatment – application

Scenario **Active substance**	Brush treatment (non-professional) – application Propiconazole Tebuconazole	
	Units	**Tier 1**
Active substance concentration	%	0,03
Body exposure		
Clothing type		no protection
Indicative value	mg/min	1,7
Duration	min/day	240
Potential body deposit	mg/day	408
Clothing penetration	%	100
Actual dermal deposit (product)	mg/day	408
Hand exposure		
Gloves worn		no
Indicative value (potential)	mg/min	4,07
Duration	min/day	240
Potential hand deposit	mg/day	976,8
Penetration of gloves	%	100
Actual hand deposit (product)	mg/day	976,8
Total dermal exposure		
Product	mg/day	1384,8
Active substance	mg/day	0,41544
Dermal absorption		
Dermal penetration	%	50
Absorbed dose (dermal)	mg/day	0,20772
Inhalation exposure		
Indicative value	mg/m^3	1,63
Duration	min/day	240
Inhalation rate	m^3/min	0,020833333
Mitigation by RPE		none
Inhaled (product)	mg/day	8,15
Inhaled (active substance)	mg/day	0,002445
Systemic dose		
Total absorbed dose	mg/day	0,210165
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**3,50E-03**

Scenario **Active substance**	Brush treatment (non-professional) – application Cypermethrin	
	Units	**Tier 1**
Active substance concentration	%	0,01
Body exposure		
Clothing type		no protection
Indicative value	mg/min	1,7
Duration	min/day	240
Potential body deposit	mg/day	408
Clothing penetration	%	100
Actual dermal deposit (product)	mg/day	408
Hand exposure		
Gloves worn		no
Indicative value (potential)	mg/min	4,07
Duration	min/day	240
Potential hand deposit	mg/day	976,8
Penetration of gloves	%	100
Actual hand deposit (product)	mg/day	976,8
Total dermal exposure		
Product	mg/day	1384,8
Active substance	mg/day	0,13848
Dermal absorption		
Dermal penetration	%	50
Absorbed dose (dermal)	mg/day	0,06924
Inhalation exposure		
Indicative value	mg/m^3	1,63
Duration	hr/day	240
Inhalation rate	m^3/hr	0,020833333
Mitigation by RPE		none
Inhaled (product)	mg/day	8,15
Inhaled (active substance)	mg/day	0,000815
Systemic dose		
Total absorbed dose	mg/day	0,070055
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**1,17E-03**

Task/scenario: Scenario 4, Sanding

Scenario **Active substance**	Sanding (professional) Propiconazole Tebuconazole	
	Units	**Tier 1**
Active substance concentration	%	0,3
Hand exposure		
Application rate (g/m^2)	g/m^2	15
Application rate (mg/cm^2)	mg/cm^2	1,5
Hand surface area contaminated	cm^2	84
Transfer coefficient	%	2
Amount on hands (product)	mg	2,52
Amount on hands (a.s.)	mg	0,00756
Dermal absorption		
Dermal penetration	%	50
Absorbed dose (dermal)	mg	0,00378
Inhalation exposure		
Indicative value	mg/m^3	5
Duration	hr/day	6
Inhalation rate	m^3/hr	1,25
Inhaled (wood dust)	mg/day	37,5
Product fraction in the wood		
Application rate (g/cm^2)	$g_{product}$/cm^2	0,0015
Penetration depth	cm	0,2
Product concentration in the penetrated layer	$g_{product}$/cm_{wood}^3	0,0075
Wood density	g_{wood}/cm_{wood}^3	0,4
Weight fraction of the product in the wood	-	0,01875
Inhaled (product)	mg/day	0,703125
Inhaled (active substance)	mg/day	0,002109375
Systemic dose		
Total absorbed dose	mg/day	0,005889375
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**9,82E-05**

Scenario **Active substance**	Sanding (professional) Cypermethrin	
	Units	**Tier 1**
Active substance concentration	%	0,1
Hand exposure		
Application rate (g/m^2)	g/m^2	15
Application rate (mg/cm^2)	mg/cm^2	1,5
Hand surface area contaminated	cm^2	84
Transfer coefficient	%	2
Amount on hands (product)	mg	2,52
Amount on hands (a.s.)	mg	0,00252
Dermal absorption		
Dermal penetration	%	50
Absorbed dose (dermal)	mg	0,00126
Inhalation exposure		
Indicative value	mg/m^3	5
Duration	hr/day	6
Inhalation rate	m^3/hr	1,25
Inhaled (wood dust)	mg/day	37,5
Product fraction in the wood		
Application rate (g/cm^2)	$g_{product}$/cm^2	0,0015
Penetration depth	cm	0,2
Product concentration in the penetrated layer	$g_{product}$/cm_{wood}^3	0,0075
Wood density	g_{wood}/cm_{wood}^3	0,4
Weight fraction of the product in the wood	-	0,01875
Inhaled (product)	mg/day	0,703125
Inhaled (active substance)	mg/day	0,000703125
Systemic dose		
Total absorbed dose	mg/day	0,001963125
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**3,27E-05**

Task/scenario: Scenario 5, Infant chewing and off-cut

Scenario **Active substance**	Infant chewing an off-cut Propiconazole Tebuconazole	
	Units	**Tier 1**
Active substance concentration	%	0,3
Oral exposure		
Application rate (g/m^2)	g/m^2	15
Application rate (mg/cm^2)	mg/cm^2	1,5
Treated surface	cm^2	32
Amount of product in the off-cut	mg	48
Fraction extracted by chewing	%	10
Amount ingested (product)	mg	4,8
Amount ingested (active substance)	mg	0,0144
Absorption		
Absorption from GIT	%	100
Absorbed dose	mg	0,0144
Systemic dose		
Total absorbed dose	mg/day	0,0144
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**1,44E-03**

Scenario **Active substance**	Infant chewing an off-cut Cypermethrin	
	Units	**Tier 1**
Active substance concentration	%	0,1
Oral exposure		
Application rate (g/m^2)	g/m^2	15
Application rate (mg/cm^2)	mg/cm^2	1,5
Treated surface	cm^2	32
Amount of product in the off-cut	mg	48
Fraction extracted by chewing	%	10
Amount ingested (product)	mg	4,8
Amount ingested (active substance)	mg	0,0048
Absorption		
Absorption from GIT	%	57
Absorbed dose	mg	0,002736
Systemic dose		
Total absorbed dose	mg/day	0,002736
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**2,74E-04**

4.1.2 Dietary assessment

Not relevant

4.1.3 Environment

The environmental risk was based on qualitative consideration of risks.

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

No new information on the active substances and the substance of concern is available.

4.3 List of studies for the biocidal product family

Table 4.1 List of studies for the biocidal product family

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Testing laboratory	Study sponsor
Šošolíková, Sysala	2015a 24/03/2015	3.2./3.2.	Protokol o zkoušce 101-2015001-pH	Protokol o zkoušce č. 101-215001	Test report	Metrum s.r.o.	Metrum s.r.o.
Šošolíková, Sysala	2015b 27/03/2015	3.3./3.3	Protokol o zkoušce 101-2015002-h	Protokol o zkoušce č. 101-215002	Test report	Metrum s.r.o.	Metrum s.r.o.
Musálková, Szyroká, Mráčková, Navrátilová	2021 21/11/2021	3.4.1.1. 3.4.1.2. 3.4.1.3. 3.7.	Not yet in IUCLID	Storage stability test report for Dřevosan Profi, Dřevosan and Dřevosan Optimal Study No.: 5910/BD+D +DO/2018	Test report	Bochemie a.s.	Bochemie a.s.
Šošolíková, Sysala	2015c 22/04/2015	3.4.1.2./3.4.1	Protokol o zkoušce 101-2015004 - storage stability	Protokol o zkoušce č. 101-215004	Test report	Metrum s.r.o.	Metrum s.r.o.
Musilová, Mráček	2017a 01/06/2017	3.8./3.8	SV_Metrum _SFT_1.6. 2017_EN	Surface tension determination of DŘEVOSAN-PROFI 100%, DŘEVOSAN 40%, DŘEVOSAN-PROFI 10% and DŘEVOSAN-	Test report	Tomas Bata University in Zlín	Metrum s.r.o.

				PROFI 5%.			
Musilová, Mráček	2017b 01/06/2017	3.9./3.9	SV_Metrum _Visco_1.6. 2017_EN	Kinematic viscosity determination of DŘEVOSAN-PROFI 100%, DŘEVOSAN 40%, DŘEVOSAN-PROFI 10% and DŘEVOSAN-PROFI 5%.	Test report	Tomas Bata University in Zlín	Metrum s.r.o.
Barák, Prošek	2023 05/06/2023	4.16	Not yet in IUCLID	Determination of corrosivity of "Bochemit Dřevosan Profi" to metals according to CLP – UN Test C.1, Report No.: M451-2	Test report	Technopark Kralupy, VŠCHT Praha	Bochemie a.s.
Bukovská, Navrátilová, Mráčková, Hantlová	2022 31/10/2022	5.1.	Not yet in IUCLID	Validation of determination of Tebuconazole, Propiconazole, Cypermethrin and alkyl (C12-16)dimethyl-benzylammonium chloride method Test report No.: VP-01/22	Validation report	Bochemie a.s.	Bochemie a.s.
Součková, Jiráková	2012 11/01/2012	6.7./6.7	Dřevosan_Profi -hmyz EN46+73 AJ	Test report no. VZL-16/11	Test report	Timber-wood research and development institute, Praha	Metrum s.r.o.
Součková, Lišková	2016 01/02/2016	6.7./6.7	Dřevosan Profi-protokol	Protokol o zkoušce č.	Test report	Timber-wood research and	Metrum s.r.o.

			113+73	MVZ-02/16/238		development institute, Praha	

4.4 References

4.4.1 References other than list of studies for the BPF

Assessment report – ADBAC (PT8, 2015, Italy)

Assessment report – Tebuconazole (PT8, 2007, Denmark)

Assessment report – Propiconazole (PT8, 2007, Finland)

Assessment report – Propiconazole (PT7, 2015, Finland)

Assessment report – Cypermethrin (PT8, 2013, Finland)

Biocidal Products Committee (BPC): Opinion on the application for approval of the active substance: Propiconazole Product type: 8 (ECHA/BPC/324/2022)

Biocidal Products Committee (BPC): Opinion on the application for approval of the active substance: Alkyl (C12-16) dimethylbenzyl ammonium chloride Product type: 1 (ECHA/BPC/309/2021)

Biocidal Products Committee (BPC): Opinion on the application for approval of the active substance: Alkyl (C12-16) dimethylbenzyl ammonium chloride Product type: 2 (ECHA/BPC/310/2021)

4.4.2 Guidance documents

Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0, October 2017

OECD Emission Scenario Document for Wood Preservatives (PT08)

Technical agreements for Biocides (TAB) - ENV (October 2022)

4.4.3 Legal texts

Commission Implementing Decision (EU) 2022/2298 of 23 November 2022 postponing the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

Commission Implementing Regulation (EU) No 1038/2013 of of 24 October 2013 approving tebuconazole as an existing active substance for use in biocidal products for product- types 7 and 10

4.5 Confidential information

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