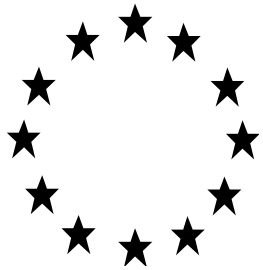
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the Competent Authority)



TWP 094i

Product type PT 8

3-Iodo-2-propynyl butylcarbamate (IPBC) and 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Permethrin) as included in the Union list of approved active substances

Case Number in R4BP: BC-NK049947-14

Evaluating Competent Authority: Denmark

Date: 29 June 2023

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1 CONCLUSION

TWP 094i is an 'AL – Any other liquid and SL – soluble concentrate' single biocidal product containing 0.75% (w/w) 3-iodo-2-propynyl butylcarbamate (IPBC) and 0.25% (w/w) Permethrin as active substances. The product does not contain any non-active substances (co-formulants) considered as substances of concern (SoC). TWP 094i is a wood preservative (PT8) for the control of blue stain fungi and brown rot fungi, and insects (House longhorn beetle (*Hylotrupes bajulus*, larvae) and termites (*Reticulitermes spp.*) in Use class 2 and 3.

The overall conclusion of the evaluation is that TWP 094i meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 (BPR) and therefore can be authorised for the uses: brushing and rolling by non-professionals and professionals (Use #1), manual dipping by professionals (Use #2), fully-automated dipping, automated flow-coating/deluging and automated spraying by industrial users (Use #3), and double vacuum/low pressure process by industrial users (Use #4), 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 uses of TWP 094i as applied for (15.03.2019) by the applicant, and proposed for authorisation, is provided in Section 2.2.1 and Section 2.1.4, respectively, of the PAR.

TWP 094i is ready-to use (RTU) (formulation type AL) for all applications except double vacuum/low pressure process, for which it is applied to wood as a dilution (formulation type SL). When used for vacuum pressure impregnation, the RTU product is loaded into the application equipment via a fully-automated pumping/transfer system. Dilution of the product with water to yield a ~ 10% in-use solution occurs within the application equipment prior to treatment of wood. Use of a ~ 10% dilution of TWP 094i for vacuum pressure impregnation, and use of the undiluted (RTU) product for all other application methods is supported by the effectivity data presented for TWP 094i.

Use-specific instructions 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 Section 2.1 Summary of the product assessment, Section 2.2.6 Risk assessment for human health, Section 2.2.7 Risk assessment for animal health, and Section 2.2.8 Risk assessment for the environment, and in Sections 4 and 5 of the SPC.

Classification of TWP 094i according to Regulation (EC) No 1272/2008 (CLP)[1] is necessary. Detailed information on classification and labelling is provided in Section 2.1.3 of the PAR. The product does not require classification for physico-chemical- or human health end-points, though due to the concentrations of the active substances IPBC and Permethrin it requires labelling with 'EUH 208 – Contains permethrin and 3-iodo-2-propynyl butylcarbamate (IPBC). May produce an allergic reaction'. The product requires

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

classification for the environmental end-points Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) based on the active substances alone. No other substance in the product is present in great enough concentration to contribute to environmental classification. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

TWP 094i does not contain any non-active substances (so called "co-formulants") which are considered as substances of concern (SoC).

TWP 094i contains the active substance(s) IPBC and Permethrin, which have not yet been evaluated according to the scientific criteria set out in Regulation (EU) 2017/2100[2]. The two active substances are currently not considered to have endocrine-disrupting properties according to Regulation (EU) 528/2012 (BPR). Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product. More information is available in Section 2.1.2.3 of the PAR, and in Section 3.7.5 of the Confidential annex.

TWP 094i contains the active substance Permethrin, which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 for a candidate for substitution based on the following criteria: meets two of the criteria (Persistence (P) and Toxicity (T)) for being a PBT substance. Permethrin is included in the list active substances meeting the exclusion/substitution criteria maintained by ECHA[3]. According to Point 1.3 of the document '*CA-June22-Doc.4.2 - Consequences for biocidal products authorisations procedures of relevant information becoming available*', a Comparative assessment in accordance with Article 23 should be carried out only when the active substance is identified as meeting the substitution criteria in the renewal of approval Regulation in accordance with Article 10(5) of the BPR. As Permethrin has not undergone renewal of approval, a Comparative Assessment of the biocidal product TWP 094i is not required at this time. Also according to Point 1.3 of the aforementioned document, TWP 094i can be granted authorisation for up to 10 years, as the status of the active substance Permethrin has not been identified as meeting the substitution criteria in the renewal of approval Regulation in accordance with Article 10(5) of the BPR.

Composition

The qualitative and quantitative information on the non-confidential composition of TWP 094i is detailed in Section 2.1.2.4 of the PAR. Information on the full composition is provided in the Confidential annex. The manufacturers of the biocidal product are listed in Section 2.1.1.3 of the PAR.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in Section 2.1.2.5 of the PAR. The manufacturers of the active substances are listed in Section 1.5 of the SPC.

[2] Commission Delegated Regulation (EU) 2017/2100 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012.

[3] This is list is updated and communicated to the Coordination Group. It is also made public on circabc: https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d

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 are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in Section 2.2.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in Section 2.2.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substances are available. More information on the analytical methods for the active substances is available in Section 2.2.4 of the PAR.

Validated analytical methods for monitoring of relevant components of the biocidal product and residues thereof in soil, air, water, animal, and human body fluids are available in the PT8 CAR for IPBC (CA DK, 2008) and PT8 CAR for Permethrin (CA IE, 2014).

Analytical method for monitoring in/on food and feeding stuff was waived as the biocidal product is not intended to come into contact with food and feeding stuff when applied according to the instructions.

More information is available in Section 2.2.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against blue stain fungi (*Sydowia polyspora*, *Aureobasidium pullulans spp.*), brown rot fungi (*Gloeophyllum trabeum*, *Poria placenta*, *Coniophora puteana*), House longhorn beetle (*Hylotrupes bajulus*), and termites (*Reticulitermes spp.*) for all intended uses except vacuum pressure, for which effectivity against brown rot fungi only has been shown. As a consequence, only a claim against brown rot fungi will be authorised for penetrative (vacuum impregnation) processes. The risk of development of resistance to carbamates used in wood preservation is considered low, as the number of treatments is generally low (in many cases, only one application is made per lifetime of timber structures), resulting in a low selection pressure. More information is available in Section 2.2.5 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 (see Section 2.2.6 of the PAR).

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

Human health risk assessment (HHRA) was carried out for all intended uses of TWP 094i as applied for by the Applicant. The HHRA was carried out according to ECHA's *Guidance on the BPR, Volume III Humana Health – Assessment & Evaluation (Parts B+C)*, Version 4.0, December 2017, with consideration of other applicable guidance documents.

Based on the risk assessment, it is unlikely that the intended uses brushing and rolling by non-professionals and professionals, manual dipping by professionals, and fully-automated dipping and double vacuum/low pressure process by industrial users cause any unacceptable acute or chronic risk to users, or to professional bystanders or non-professional bystanders/general public, if the directions for use as specified in the SPC are followed. The following risk mitigation measures are considered relevant for the use of TWP 094i:

Industrial use

When TWP 094i is applied by fully-automated dipping, automated flow-coating/deluging or automated spraying the following RMMs should be implemented:

- The product must only be loaded into industrial application equipment via a fully-automated pumping/transfer system.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within product information).
- Wear a protective coverall (type 6, EN 14605).
- The product must only be used in fully-automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry.
- The product shall only be used with flow-coating/deluging and spray tunnels equipped with a device for automated transport of the freshly treated wood to automated stacking or to a drying plant, so that manual contact with the freshly treated wood is avoided.

When TWP 094i is applied by vacuum pressure impregnation the following RMMs should be implemented:

- The product must only be loaded into industrial application equipment via a fully-automated pumping/transfer system.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within product information).
- Wear a protective coverall (type 6, EN 13034).

Professional use

When TWP 094i is applied by manual dipping the following RMMs should be implemented:

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within product information).
- Wear a protective coverall (type 6, EN 13034).

When TWP 094i is applied by brushing and rolling:

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within product information).
- Wear a protective coverall (type 6, EN 13034).

Non-professional use

No unacceptable risk was identified for non-professional users applying the product by brushing and rolling.

General public

No unacceptable risk for the general public (all age-groups) was identified in connection with the industrial, professional, and non-professional uses of TWP 094i.

Dietary risk assessment

Considering the uses of TWP 094i, food, feed or drinking water contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance(s) is considered as negligible, and no dietary risk assessment has been performed. Three risk mitigation measures are applied to help minimise the risk of dietary exposure:

- Do not use near domestic animals or livestock. (Use 1 and 2)
- Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets, particularly cats. (Use 1 and 2)
- Do not use on wood which may come in direct contact with food, feed and livestock.

Risk assessment for animal health

Exposure of animals (pets/companion animals and livestock) directly, or via their food or drinking water, is not expected when TWP 094i is applied according to the authorised uses. Therefore, no formal risk assessment for animal health has been performed. However as it cannot be excluded that pets/companion animals may be exposed to wet and/or dried paint, screening of their risk was performed by considering the human exposure scenarios most relevant for assessing animal exposure (see Section 2.2.7 of the PAR). Based on the risk assessment, risk to pets/companion animals in general with the intended uses is considered acceptable if the directions for use, as specified in the SPC, are followed. However, as cats are particularly sensitive to permethrin, they are addressed in a specific General instruction for use. Four risk mitigation measures and a General instruction for use are applied to help minimise the risk to pets/companion animals and livestock:

- Do not use near domestic animals or livestock. (Use 1 and 2)
- Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets, particularly cats. (Use 1 and 2)
- Keep uninvolved persons, children and pets (particularly cats) away from treated surfaces/areas until dried. (Use 1 and 2)
- Do not use on wood which may come in direct contact with food, feed and livestock.
- Due to the particular sensitivity of cats to permethrin, the product shall only be applied on wood which is applied in areas where contact of cats to treated wood can be excluded.

Risk assessment for the environment

Environmental risk assessment covers all the intended uses as applied for by the applicant (see Section 2.2.8 of the PAR).

Since no substance of concern for the environment has been identified, the environmental risk assessment was performed for the active substances and their metabolites only.

The ERA was carried out according to the Emission Scenario Document for PT8 (OECD, 2013), the Technical Agreements for Biocides (ENV) (ECHA, July 2021) and the Guidance on the BPR, Vol. IV, part B+C (ECHA, 2017).

The environmental risk assessment showed unacceptable risk for in-situ brushing and rolling by professionals and amateurs in both the soil, surface water and groundwater compartment. The following risk mitigation measures were applied to cover the risk:

- Do not apply near bodies of surface water.
- During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

For the professional use by manual dipping the following risk mitigation measures were applied:

- Do not apply near bodies of surface water.
- During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.
- Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer, and water.
- Any losses should be collected for re-use or disposal.

Industrial application processes showed risk in all relevant compartments and therefore the following risk mitigation measures were applied to cover the risks:

- Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer and water.
- 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).
- Any losses should be collected for re-use or disposal.

For all uses the following risk mitigation measure were applied: "*A topcoat must be applied. The topcoat cannot contain a film- or wood preservative. The topcoat should be maintained.*", since the leaching studies used as the basis for the risk assessment are based on the product with an applied topcoat.

The conclusion to the environmental risk assessment is that there are no unacceptable risk from the use of product.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[4]	**Country (if relevant)**
TWP 094i Osmo Træimprægnering WR Aqua 4018 Induline SW-906 IT Aqua IG-17 OWATROL TMU94i OWATROL SANIXYL NT Valtti Plus Guard Pinja Priming Combi IM151AI Woodmark Fondo Protector Insecticida al Agua PROTECSAM IF Barpixyl 100 WB MACYFOND ANTICARCOMA AL AGUA SERPOL AQUA XILODEX FONDO Devacide Plus Aqua Klearxyl Aqua 3 LASURTEX AQUA Fagoxil AQ Aqua Madeiras Protect Plus Decorxyl AQ CIN Imunizador para Madeiras Xylazel Woodprotec Aqua Xylazel Woodshield Aqua Xylazel Woodseal Aqua Max-Mat anti-carunchos para madeiras Aqua FR 6287 Froxynol 750 Iruxyl Aqua 13 Fustaxyl Aqua Klassikxyl Aqua Protekxyl Aqua Fustasol Aqua OBBIATEX ACE PROTEGEBOIS ProtectBois Protector fungicida Promade WOODCONTROL IP-20 YM---M122/-----	Denmark For trade names in other european countries please refer to the document "TWP 094i list_of_existing_new products_for_na_processes _en" in IUCLID chapter 13.

[4] Please fill in here the identifying product name from R4BP.

Identifier[4]	Country (if relevant)
RA2300 674810 HF ACTIVE PRIMER W CEDRIA IMPRIMACIÓN TRATANTE EXTRA Sigma WoodProtect Impregnate DK-22 GORI Transparent Trægrunder 11.1 Xtra Proff Vandig Grundingsolie Udendørs v.1 RUM Farveløs Grundings olie Udendørs v.1 Gori Transparent Træimprægnering v.1 AM0573/00 Hydroplus protettivo per legno insetticida 458-0005/2 Idro Ceopren protettivo per legno Insetticida KK2150/00 Protettivo per Legno Insetticida AM0573/00 Hydroplus Wood protection insectiside 458-0005/2 IDRO CEOPREN Wood protection Insecticide KK2150/00 Wood Protection insecticide AA1961 Laqvin Seal Insecticide Imunizador Acqua Imunizador Acqua CR Imunizador aquoso para madeira Imunizador aquoso para madeira CR KRAFT WOOD CARE AQUA AQUA STAIN PRIME 2030-25 DUROXYL AQUA WOOD PROTECTION/CONDITIONER SILAK Smaltoxyl Hydro Wood Care Praktiker Mega Hydro Wood Care Aqualasur Guard Silicon PF XYLOPHARMAKON Woodcare 94i Wood Protect 94i Holzschutz WB 94i Altax Multi-Purpose Wood Treatment (SW) Altax Pro Multi-Purpose Wood Treatment (SW) GoodHome Multi-Purpose Wood Treatment GoodHome Pro Multi-Purpose Wood Treatment GoodHome Trade Multi-Purpose Wood Treatment Ronseal Multi-Purpose Wood Treatment (SW) Ronseal Trade Multi-Purpose Wood Treatment (SW) Sherwin Williams Multi-Purpose Wood Treatment Sherwin Williams Pro Multi-Purpose Wood Treatment Sherwin Williams Trade Multi-Purpose Wood Treatment	

2.1.1.2 **Authorisation holder**

Name and address of the authorisation holder	**Name**	TROY CHEMICAL COMPANY B.V.
	Address	Poortweg 4C, 2612 PA Delft, The Netherlands
Authorisation number	DK-0031245-0000	
Date of the authorisation	08.08.2023	
Expiry date of the authorisation	08.08.2033	

2.1.1.3 **Manufacturers of the product**

Name of manufacturer	Troy Chemical Company B.V.
Address of manufacturer	Poortweg 4C, 2612 PA Delft, The Netherlands
Location of manufacturing sites	Westelijke Randweg 9, 4791 RT Klundert, The Netherlands
	Industriepark 23, 56593 Horhausen, Germany
	Geschwister-Scholl-Straße 127, 39218 Schönebeck/Elbe, Germany
	Mecklenburger Str. 229, 23568 Lübeck, Germany
	Halchtersche Str. 33, 38304 Wolfenbüttel, Germany
	Am Nordturm 5, 46562 Voerde, Germany
	Am Alten Galgen 14, 56410 Montabaur, Germany

Name of manufacturer	Tikkurila Oyj
Address of manufacturer	Kuninkaalantie 1, FI-01301 Vantaa, Finland
Location of manufacturing sites	Kuninkaalantie 1, FI-01301 Vantaa, Finland
	uL.Mościckiego 23, 39-200 DĘBICA, Poland

Name of manufacturer	Remmers GmbH
Address of manufacturer	Bernhard-Remmers-Straße 13, 49624 Löningen, Germany
Location of manufacturing sites	Bernhard-Remmers-Straße 13, 49624 Löningen, Germany

Name of manufacturer	Remmers Industrielacke GmbH
Address of manufacturer	Füllenbruchstr. 13, 32120 Hiddenhausen, Germany
Location of manufacturing sites	Füllenbruchstr. 13, 32120 Hiddenhausen, Germany

Name of manufacturer	Sherwin Williams
Address of manufacturer	Thorncliffe Park Estate, Thorncliffe Rd, Chapeltown, Sheffield S35 2YP, United Kingdom
Location of manufacturing sites	Thorncliffe Park Estate, Thorncliffe Rd, Chapeltown, Sheffield S35 2YP, United Kingdom
	Altax. Sp.Zo.o - Kopanińska 7, 60-119 Brodziszewo, Poland

Name of manufacturer	Sherwin-Williams Italy S.r.l.
Address of manufacturer	Via Del Fiffo 12 – 40065 Pianoro (BO) Italy
Location of manufacturing sites	Via Del Fiffo 12 – 40065 Pianoro (BO) Italy

Name of manufacturer	Sherwin-Williams Sweden AB

Address of manufacturer	Bellö, 570 32 Hjältevad, Sweden
Location of manufacturing sites	Bellö, 570 32 Hjältevad, Sweden
	Industrigatan 5, 195 60, Arlandastad, Sweden

Name of manufacturer	PPG Industries (Dyrup A/S)
Address of manufacturer	Gladsaxevej 300, Søborg, 2860 Gladsaxe, Denmark
Location of manufacturing sites	Gladsaxevej 300, Søborg, 2860 Gladsaxe, Denmark

2.1.1.4 **Manufacturers of the active substances**

Active substance	3-Iodo-2-propynyl butylcarbamate (IPBC)
Name of manufacturer	Troy Chemical Corporation
Address of manufacturer	8 Vreeland Road, 07932 Florham Park, New Jersey United States
Location of manufacturing sites	One Avenue L, 07105 Newark, New Jersey United States

Active substance	3-Iodo-2-propynyl butylcarbamate (IPBC)
Name of manufacturer	Troy Chemical Company B.V.
Address of manufacturer	Poortweg 4C, 2612 PA Delft, The Netherlands
Location of manufacturing sites	Industriepark 23, 56593 Horhausen, Germany

Active substance	3-Phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Permethrin)
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1, 50679 Köln, Germany
Location of manufacturing sites	Bayer Vapi Private Limited Plot # 306/3 II Phase, GIDC Vapi – 396 195 Gujarat India

Active substance	3-Phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Permethrin)
Name of manufacturer	Caldic Denmark A/S (Acting for Tagros Chemicals India Limited)
Address of manufacturer	Tagros Chemicals India Limited: "Jhaver Centre", Rajah Annamalai Building, IV Floor, 72, Marshalls Road Egmore – 600008 Chennai Tamil Nadu India Represented in the EU by:

	Caldic Denmark A/S: Odinsvej 23, DK-8722 Hedensted, Denmark.
Location of manufacturing sites	Tagros Chemicals India Limited A4/1&2, SIPCOT Industrial Complex, Kudikadu, 607 005 Cuddalore, Tamil Nadu, India

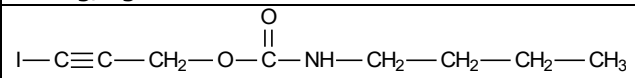
2.1.2 Product composition and formulation

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

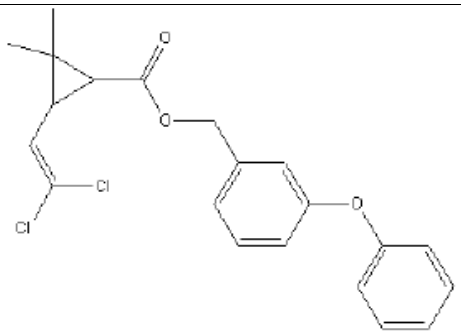
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substances

Main constituent(s)	
ISO name	IPBC, 3-Iodo-2-propynyl butylcarbamate
IUPAC or EC name	3-Iodo-2-propynyl butylcarbamate
EC number	259-627-5
CAS number	55406-53-6
Index number in Annex VI of CLP	616-212-00-7
Minimum purity / content	980 g/kg
Structural formula	

Main constituent(s)	
ISO name	Permethrin
IUPAC or EC name	3-Phenoxybenzyl(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or 3-Phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	
Minimum purity / content	≥ 93% w/w sum of all permethrin isomers Cis:trans permethrin % ratio = 22-28:72-78 cis:trans. 1Rcis permethrin content = 5.0 – 10.0% w/w. 1Scis permethrin content = 15.0 – 20.0% w/w. 1Rtrans permethrin content = 45.0 – 55.0% w/w. 1Strans permethrin content = 17.0 – 27.0% w/w.

Structural formula	

2.1.2.2 **Candidate(s) for substitution**

The active substance Permethrin is a Candidate for substitution. Permethrin meets two of the criteria (Persistence (P) and Toxicity (T)) for being a PBT[5] substance and thus is considered Candidate for substitution according to Article 10(1)d of Regulation (EU) No 528/2012 (BPR). Permethrin is included in the list active substances meeting the exclusion/substitution criteria maintained by ECHA[6]. Under Article 23(1) of the BPR, Member States evaluating biocidal products containing an active substance that is a Candidate for substitution in accordance with article 10(1) (or article 5(1)) are required to perform a Comparative Assessment. However, according to Point 1.3 of the document '*CA-June22-Doc.4.2 - Consequences for biocidal products authorisations procedures of relevant information becoming available*', a Comparative Assessment in accordance with Article 23 of the BPR should be carried out only when the active substance is identified as meeting the substitution criteria in the renewal of approval Regulation in accordance with Article 10(5) of the BPR. As Permethrin has not undergone renewal of approval, a Comparative Assessment of the biocidal product TWP 094i is not required at this time.

2.1.2.3 **Assessment of the endocrine-disrupting properties of the biocidal product**

TWP 094i contains the active substances IPBC and Permethrin, which have not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100. The two active substances are currently not considered to have endocrine-disrupting properties according to Regulation (EU) 528/2012 (BPR).

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

For further information, refer to Section 3.7.5 of the Confidential annex of the PAR.

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[5] The three BPT criteria are Persistence (P), Bioavailability (B), and Toxicity (T).

[6] This is list is updated and communicated to the Coordination Group. It is also made public on circabc: https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d

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

Common name	IUPAC name	Function	CAS number	EC number	Content TC (%)
IPBC	3-Iodo-2-propynyl butylcarbamate	Active substance	55406-53-6	259-627-5	0.75
Permethrin (ISO)	3-Phenoxybenzyl(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or 3-Phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.25

2.1.2.5 Information on technical equivalence

Information on technical equivalence is not required since all sources of the substances active substances IPBC and Permethrin used in formulation of the biocidal product are included in the Union list of approved active substances. In relation to the IPBC active substance manufacturer Troy Chemical Corporation, the 'Location of the manufacturing site' at One Avenue L, 07105 Newark, New Jersey United States has been confirmed in correspondence with the eCA (the 'Address of the manufacturer' (8 Vreeland Road, 07932 Florham Park, New Jersey United States) was incorrectly given as the location of the manufacturing site in the CAR (DK CA, 2008) for IPBC in PT8). The aforementioned correspondence can be found in Section 13 of the IUCLID dossier for TWP 094i.

2.1.2.6 Information on the substance(s) of concern

The product does not contain any substances of concern (SoC) for human health according to Article 3(f) of Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR) and to Commission document CA-Nov14-Doc.5.11, or any SoC for the environment according to Article 3(f) of Regulation (EU) No. 528/2012, and Annex A of the Guidance on the BPR: Volume IV Environment – Assessment & Evaluation, Parts B+C (Version 2.0, October 2017). A co-formulant is also considered a SoC if it has known or possible endocrine-disrupting properties; these criteria are not met by any of the co-formulants. Refer to Section 3.7.4 of the Confidential annex for further details.

2.1.2.7 Type of formulation

Other: Any other liquid (AL) and Soluble concentrate (SL)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H400 - Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning
Hazard statements	H410 - Very toxic to aquatic life with long lasting effects
Precautionary statements	P273 - Avoid release to the environment. P391 - Collect spillage. P501 - Dispose of contents and container in accordance with local/regional/national/international regulations (to be specified).
Note	EUH 208 – Contains permethrin (ISO) and 3-iodo-2-propynyl butylcarbamate (IPBC). May produce an allergic reaction.

2.1.4 Authorised uses

2.1.4.1 Use description

Table 1. Use # 1 – Brushing and rolling (non-professional and professional users)

Product Type	**Wood preservative PT8**	**Product code**
Where relevant, an exact description of the authorised use	Fungicide and insecticide	
Target organism (including development stage)	Fungi: Blue stain fungi (no data) Basidiomycetes - brown rot fungi (no data) Insects: House longhorn beetle (*Hylotrupes bajulus*) (larvae) Termites (*Reticulitermes spp*.) (no data) Note: Since termites of the genus *Reticulitermes* mainly occur in the southern part of Europe, use against termites will not be relevant in all Member States. It is up to each Member State to decide whether use against termites should be authorised. In Denmark, termites are not present in harmful quantities and thus are not considered a pest problem. Consequently, use against termites is eligible for exclusion from approval in Denmark in	 G.21.2 G.10 G.31 G.50

	accordance with Article 37(1)e of Regulation (EU) No 528/2012 (BPR). The biocidal product can be authorised in Denmark for use against termites but only when the treated wood (article) is to be exported.	
Field of use	Softwood Solid wood Preventative treatment Use class 2 as described in EN standard 335:2013 (situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and wind-driven rain) but where occasional, but not persistent, wetting can occur) Use class 3 as described in EN standard 335:2013 (situation in which the wood or wood-based product is above ground and exposed to the weather (particularly rain) See section 6 for the full titles of the EN standards Indoor and Outdoor use	B.10 C.10 D.30, D.40 E.20, E.30
Application method(s)	Brush/roller treatment Superficial treatment	F.10
Application rate(s) and frequency	100 mL/m^2 (against blue stain fungi, House longhorn beetle, and termites) 130 - 140 mL/m^2 (against wood-rotting fungi) 1 application Note: It is up to each Member State to decide if use against termites is relevant.	
Category(ies) of users	General public (non-professional) Professional	A.10 A.30
Pack sizes and packaging material	Can: PET lined metal (tinplate) or polyolefin (HDPE, PE or PP) Bottle: polyolefin (HDPE, PE or PP) Can/bottle: 0.375 L, 0.75 L, 1.0 L, 2.5 L, 5.0 L For professional use only: Can, HDPE : 10 L, 20 L, 25 L	

2.1.4.2 **Use-specific instructions for use**

Do not dilute (ready-to-use). Apply the product to wood with a brush or roller. Cleaning of tools: Use water and mild soap. Drying time: Dry to handle and ready for topcoat after approximately 24 hours. At the application rate of 100 mL/m^2, the product protects the wood surface against blue stain fungi on wood that is minimum 'moderately to slightly durable to fungi' according to EN 350:2016: Durability Class (DC) 3-4. See section 6 for the full title of the EN standards.

2.1.4.3 Use-specific risk mitigation measures

Do not use near domestic animals or livestock. Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets, particularly cats. Keep uninvolved persons, children and pets (particularly cats) away from treated surfaces/areas until dried. Do not apply near bodies of surface water. During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way. Information for professionals Wear protective chemical resistant gloves during product handling phase classified under the European Standard EN 374 or equivalent. Glove material to be specified by the authorisation holder within product information. Wear a protective coverall (type 6, EN 13034 or equivalent). This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for full titles of the EN standards and legislation.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.4.7 Use description

Table 2. Use # 2 – Manual dipping (professional use)

Product Type	**Wood preservative PT8**	
Where relevant, an exact description of the authorised use	Fungicide and insecticide	

Target organism (including development stage)	Fungi: Blue stain fungi (no data) Basidiomycetes - brown rot fungi (no data) Insects House longhorn beetle (*Hylotrupes bajulus*) (larvae) Termites (*Reticulitermes spp.*) (no data) Note: Since termites of the genus *Reticulitermes* mainly occur in the southern part of Europe, use against termites will not be relevant in all Member States. It is up to each Member State to decide whether use against termites should be authorised. In Denmark, termites are not present in harmful quantities and thus are not considered a pest problem. Consequently, use against termites is eligible for exclusion from approval in Denmark in accordance with Article 37(1)e of Regulation (EU) No 528/2012 (BPR). The biocidal product can be authorised in Denmark for use against termites but only when the treated wood (article) is to be exported.	 G.21.2 G.10 G.31 G.50
Field of use	Softwood Solid wood Preventative treatment Use class 2 and 3 Indoor use	B.10 C.10 D.30, D.40 E.20, E.30
Application method(s)	Manual dipping Superficial treatment	F.14
Application rate(s) and frequency	100 mL/m^2 (against blue stain fungi, House longhorn beetle, and termites) 130 – 140 mL/m^2 (against wood destroying fungi) 1 application Note: It is up to each Member State to decide if use against termites is relevant.	
Category(ies) of users	Professional	A.30
Pack sizes and packaging material	Can: PET lined metal (tinplate) or polyolefin (HDPE, PE or PP) Bottle: polyolefin (HDPE, PE or PP) Can/bottle: 0.375 L, 0.75 L, 1.0 L, 2.5 L, 5.0 L Can, HDPE: 10 L, 20 L, 25 L	

2.1.4.8 **Use-specific instructions for use**

Do not dilute (ready-to-use). Drying time: Dry to handle and ready for topcoat after approximately 24 hours. Cleaning of tools: Use water and mild soap.

At the application rate of 100 mL/m^2, the product protects the wood surface against blue stain fungi on wood that is minimum 'moderately to slightly durable to fungi' according to EN 350:2016: Durability Class (DC) 3-4.

See section 6 for the full title of the EN standards.

2.1.4.9 **Use-specific risk mitigation measures**

Wear protective chemical resistant gloves during product handling phase classified under the European Standard EN 374 or equivalent. Glove material to be specified by the authorisation holder within product information.

Wear a protective coverall (type 6, EN 13034 or equivalent).

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

See section 6 for full titles of the EN standards and legislation.

Do not use near domestic animals or livestock.

Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets, particularly cats.

Keep uninvolved persons, children and pets (particularly cats) away from treated surfaces/areas until dried.

Do not apply near bodies of surface water.

During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer and water.

Any losses of the product should be collected for re-use or disposal.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.4.13 **Use description**

Table 3. Use # 3 – Fully-automated dipping, automated flow-coating/deluging, and automated spraying (industrial)

Product Type	**Wood preservative PT8**	**Product code**
Where relevant, an exact description of the authorised use	Fungicide and insecticide	
Target organism (including development stage)	Fungi: Blue stain fungi (no data) Basidiomycetes - brown rot fungi (no data) Insects: House longhorn beetle (*Hylotrupes bajulus*) (larvae) Termites (*Reticulitermes spp*.) (no data) Note: Since termites of the genus *Reticulitermes* mainly occur in the southern part of Europe, use against termites will not be relevant in all Member States. It is up to each Member State to decide whether use against termites should be authorised. In Denmark, termites are not present in harmful quantities and thus are not considered a pest problem. Consequently, use against termites is eligible for exclusion from approval in Denmark in accordance with Article 37(1)e of Regulation (EU) No 528/2012 (BPR). The biocidal product can be authorised in Denmark for use against termites but only when the treated wood (article) is to be exported.	 G.21.2 G.10 G.31 G.50
Field of use	Softwood Solid wood Preventative treatment Use class 2 and 3 Indoor use	B.10 C.10 D.30, D.40 E.20, E.30
Application method(s)	Fully-automated dipping, automated flow-coating/deluging, automated spraying. Similar to automated flow-coating/deluging, automated spraying is assumed to be an essentially fully enclosed processes, whereby operator exposure occurs mainly by handling treated wet wood. Superficial treatment	F.14, F.11, F.12
Application rate(s) and frequency	100 mL/m^2 (against blue stain fungi, House longhorn beetle, and termites) 130 – 140 mL/m^2 (against wood-rotting fungi) 1 application	

	Note: It is up to each Member State to decide if use against termites is relevant.	
Category(ies) of users	Industrial	A.20
Pack sizes and packaging material	Drum/intermediate bulk container (IBC), HDPE: 120 L, 220 L, 1000 L	

2.1.4.14 **Use-specific instructions for use**

Do not dilute (ready-to-use).

Drying time: until dry to touch.

At the application rate of 100 mL/m^2, the product protects the wood surface against blue stain fungi on wood that is minimum 'moderately to slightly durable to fungi' according to EN 350:2016: Durability Class (DC) 3-4.

See section 6 for the full title of the EN standards.

2.1.4.15 **Use-specific risk mitigation measures**

The product must only be loaded into industrial application equipment via a fully-automated pumping/transfer system.

All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).

Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer and water.

Any losses of the product should be collected for re-use or disposal.

Fully automated dipping

Wear protective chemical resistant gloves during product handling phase classified under the European Standard EN 374 or equivalent. Glove material to be specified by the authorisation holder within product information.

If new gloves are worn for each treatment cycle, wear a protective coverall (type 6, EN 13034 or equivalent).

If gloves are not replaced after each treatment cycle, wear a protective coverall (type 3, EN 14605 or equivalent).

The protective equipment specified above must be worn during cleaning/maintenance of application equipment.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

See section 6 for full titles of the EN standards and legislation.

The product must only be used in fully-automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry.

Automated flow-coating/deluging, and automated spraying Wear protective chemical resistant gloves during product handling phase classified under the European Standard EN 374 or equivalent. Glove material to be specified by the authorisation holder within product information. Wear a protective coverall (type 3, EN 14605 or equivalent). The protective equipment specified above must be worn during cleaning/maintenance of application equipment. This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for full titles of the EN standards and legislation. The product shall only be used with flow coating/deluging and spray tunnels equipped with a device for automated transport of the freshly treated wood to automated stacking or to a drying plant, so that manual contact with the freshly treated wood is avoided.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.4.19 Use description

Table 4. Use # 4 – Double vacuum/low pressure process (Industrial)

Product Type	**Wood preservative PT8**	**Product code**
Where relevant, an exact description of the authorised use	Fungicide	
Target organism (including development stage)	Fungi: Basidiomycetes - brown rot fungi (no data)	 G.10
Field of use	Softwood Solid wood	B.10 C.10

	Preventative treatment Use class 2 and 3 Indoor use	D.30, D.40 E.20, E.30
Application method(s)	Double vacuum/low pressure process Penetrative treatment	F.32
Application rate(s) and frequency	65.8 – 70.6 kg/m^3 TWP 094i 10% in-use solution (1 part product: 9 parts water) 1 application	
Category(ies) of users	Industrial	A.20
Pack sizes and packaging material	Drum/IBC, HDPE: 120 L, 220 L, 1000 L	

2.1.4.20 **Use-specific instructions for use**

Drying time: until dry to touch.

2.1.4.21 **Use-specific risk mitigation measures**

The product must only be loaded into industrial application equipment via a fully-automated pumping/transfer system. Wear protective chemical resistant gloves during product handling phase classified under the European Standard EN 374 or equivalent. Glove material to be specified by the authorisation holder within product information. Wear a protective coverall (type 6, EN 13034 or equivalent). The protective equipment specified above must be worn during cleaning/maintenance of application equipment. This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for full titles of the EN standards and legislation. All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump). Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer and water. Any losses of the product should be collected for re-use or disposal.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Comply with the instructions for use. Do not use product on wood or wooden structures intended for use indoors, except for external window frames and external doors/door frames. Due to the particular sensitivity of cats to permethrin, the product shall only be applied on wood which is applied in areas where contact of cats to treated wood can be excluded. The temperature must be above 5°C and relative humidity below 80% during application and drying. Stir product before use. Avoid contact with skin and eyes. Wash hands and face after application and use of the product, and before eating, drinking or smoking.

2.1.5.2 Risk mitigation measures

Do not use on wood which may come in direct contact with food, feed, and livestock. A topcoat must be applied. The topcoat cannot contain a film- or wood preservative. The topcoat should be maintained.

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

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor. IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor. Permethrin may cause paraesthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice. IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor. IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. When seeking medical advice, have the product container or label at hand. This product contains permethrin which is dangerous for bees.

2.1.5.4 Instructions for safe disposal of the product and its packaging

This product and its container must be disposed of safely as hazardous waste. Any product collected during application that is not reused must be disposed of safely as hazardous waste.

Dispose of packaging and of unused product in accordance with local regulations. If required, consult a professional waste operator or local authority.

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

Keep out of reach of children and non-target animals/pets. Do not store near food, drink and animal feeding stuff. Shelf life: 18 months. Store below 35°C. Store in a cool, dry, well-ventilated place. Protect from frost. Protect from light. Opened containers must be carefully resealed and kept upright to prevent leakage.

2.1.6 Other information

Regarding Use 1 and Use 2: Professionals and/or trained professionals if required by national legislation. Full titles of EN standards and legislation mentioned in earlier sections: EN 335:2013 – Durability of wood and wood-based products - Use classes: definitions, application to solid wood and wood-based products EN 350:2016 – Durability of wood and wood-based products - Testing and classification of the durability to biological agents of wood and wood-based materials EN 374 – Protective gloves against dangerous chemicals and micro-organisms. Part 1: terminology and performance requirements for chemical risks. EN 13034 – Protective clothing against liquid chemicals. Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment). EN 14605 – Protective clothing against liquid chemicals. Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4]). Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11). Should the authorisation holder become aware of reports of resistance this should be reported to the competent authorities.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed

					packaging materials (Yes/No)
Can/bottle	0.375 L, 0.75 L, 1.0 L, 2.5 L, 5.0 L	Can: PET lined metal (tinplate) or polyolefin (HDPE, PE or PP) Bottle: polyolefin (HDPE, PE or PP)	Can lid: PET lined metal (tinplate) or polyolefin (HDPE, PE or PP) Bottle lid: polyolefin (HDPE, PE or PP)	Professional and non-professional use	Yes
Can	10 L, 20 L, 25 L	HDPE	Lid: HDPE	Professional use	Yes
Drum/IBC	120 L, 220 L, 1000 L	HDPE	Lid/top: HDPE	Industrial use	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Data on TWP 094i (see Annex 3.1 'List of studies for the biocidal product').

2.1.8.2 Access to documentation

The applicant itself, Troy Chemical Company B.V., is included on the 'Article 95 List' as a supplier of IPBC. Thus, for IPBC the submission of a Letter of Access is not required.

For Permethrin, refer to Section 13 of the IUCLID dossier.

2.2 Assessment of the biocidal product

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

Table 2. Use # 1 – Brushing and rolling

Product Type	PT8
Where relevant, an exact description of the authorised use	Brushing and rolling
Target organism (including development stage)	Blue stain: *Sydowia pithyophilia* (spores and spore producing structures, hyphae) *Aureobasidium pullulans spp.* (spores and spore producing structures, hyphae) Brown rot fungi: *Gloeophyllum trabeum* (spores and spore producing structures, hyphae) *Poria placenta* (spores and spore producing structures, hyphae) *Coniophora puteana* (spores and spore producing structures, hyphae) Insects: *Hylotrupes bajulus* (larvae) *Reticulitermes santonensis* (workers, soldiers, nymphs)
Field of use	Outdoor use
Application method(s)	Open system: brush treatment, brushing, rolling
Application rate(s) and frequency	100ml/m^2 TWP 094i (against blue stain fungi and insects and termites) 140-160 ml/m^2 TWP 094i (against wood destroying fungi)
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Can/Tin Metal/HDPE: 0,375 l; 0,75 l; 1,0 l; 2,5 l; 5,0 l.

Table 2. Use # 2 – Brushing and rolling, manual dipping

Product Type	PT8
Where relevant, an exact description of the authorised use	Brushing and rolling, manual dipping
Target organism (including development stage)	Blue stain: *Sydowia pithyophilia* (spores and spore producing structures, hyphae) *Aureobasidium pullulans spp.* (spores and spore producing structures, hyphae) Brown rot fungi: *Gloeophyllum trabeum* (spores and spore producing structures, hyphae) *Poria placenta* (spores and spore producing structures, hyphae) *Coniophora puteana* (spores and spore producing structures, hyphae) Insects *Hylotrupes bajulus* (larvae) *Reticulitermes santonensis* (workers, soldiers, nymphs)
Field of use	Outdoor use
Application method(s)	Brushing and rolling, manual dipping
Application rate(s) and frequency	100ml/m^2 TWP 094i (against blue stain fungi and termites and insects) 140-160 ml/m^2 TWP 094i (against wood destroying fungi)
Category(ies) of users	Professional, trained professional
Pack sizes and packaging material	Can/Tin Metal/HDPE: 0,375 l; 0,75 l; 1,0 l; 2,5 l; 5,0 l. Can/Tin HDPE: 10l; 20l; 25l (professional use only).

Table 3. Use # 3 – Automated dipping, automated spraying, double vacuum/low pressure process, flow coating/deluging

Product Type	PT8
Where relevant, an exact description of the authorised use	Automated dipping, automated spraying, double vacuum/low pressure process, flow coating/deluging
Target organism (including development stage)	Blue stain: *Sydowia pithyophilia* (spores and spore producing structures, hyphae) *Aureobasidium pullulans spp.* (spores and spore producing structures, hyphae) Brown rot fungi: *Gloeophyllum trabeum* (spores and spore producing structures, hyphae) *Poria placenta* (spores and spore producing structures, hyphae) *Coniophora puteana* (spores and spore producing structures, hyphae) Insects *Hylotrupes bajulus* (larvae) *Reticulitermes santonensis* (workers, soldiers, nymphs)
Field of use	Outdoor use
Application method(s)	Automated dipping, automated spraying, double vacuum/low pressure process, flow coating/deluging
Application rate(s) and frequency	Superficial application: 100ml/m^2 TWP 094i (against blue stain fungi) 140-160ml/m^2 TWP 094i (against wood destroying fungi) Pressure treatment: 69.7-79.5 kg/m^3 TWP 094i
Category(ies) of users	Industrial
Pack sizes and packaging material	Can/Tin Metal/HDPE: 0,375 l; 0,75 l; 1,0 l; 2,5 l; 5,0 l. Can/Tin HDPE: 10l;20 l; 25l (professional and industrial use only). Can/Tin/IBC HDPE: 220 l, 1000 l (industrial use only).

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	Test item: TWP 094i IPBC: 0.77% Permethrin: 0.25% Batch No.: SK17096	Liquid	[redacted], 2018a Report No. MG09NQ
Colour at 20 °C and 101.3 kPa	Visual inspection	Test item: TWP 094i IPBC: 0.77% Permethrin: 0.25% Batch No.: SK17096	White Colour assignment by Munsell colour system: N 9.25/84.2% R	[redacted], 2018a Report No. MG09NQ
Odour at 20 °C and 101.3 kPa	Visual inspection	Test item: TWP 094i IPBC: 0.77% Permethrin: 0.25% Batch No.: SK17096	No discernible odour was noted whilst working with the product.	[redacted], 2018a Report No. MG09NQ
Acidity / alkalinity	CIPAC MT 75.3 (Determination of pH values)	Test item: TWP 094i IPBC: 0.77% Permethrin: 0.25% Batch No.: SK17096	pH (diluted to 1% w/v): 7.6 pH (neat): 7.5 The acidity / alkalinity was not determined as the pH value is between 4 and 10.	[redacted], 2018a Report No. MG09NQ
Relative density / bulk density	EC Method A.3 (Relative Density) and OECD Guideline 109 (Density of Liquids and Solids) using a pycnometer.	Test item: TWP 094i IPBC: 0.77% Permethrin: 0.25% Batch No.: SK17096	1.01 at 20 °C	[redacted], 2018b Report No. GS55VM
Storage stability test – **accelerated storage**	Similar to CIPAC MT 46.3 Sample stored at 35°C for 12	Test item: TWP 094i Nominal AS content: IPBC: 0.75% Permethrin: 0.25%	*Supplementary data – Study not considered acceptable by rMS, for new study; see entry below.*	[redacted], 2018a Report No. MG09NQ

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	weeks in commercial packaging (HDPE bottle and epoxy-phenolic lined metal can). Deviation from guideline: The temperature dropped to 30.5 °C covering a 3 days period during the test.	AS content: See results. Batch number: SK17096.	<u>AS content (HPLC-UV method, method validation: [redacted] (2018c, XR46VD)):</u> <u>IPBC:</u> T_0: 0.77% $T_{12\ weeks}$: HDPE: 0.70% (variation: -9.1%) Metal: 0.70% (variation: -9.1%) <u>Permethrin:</u> T_0: 0.25% $T_{12\ weeks}$: HDPE: 0.25% (variation: 0%) Metal: 0.25% (variation: 0%) <u>Product appearance:</u> T_0: White liquid $T_{12\ weeks}$ (HDPE/metal): Off-white liquid <u>pH (CIPAC MT 75.3):</u> T_0 (*1% w/v*): 7.6 T_0 (*neat*): 7.5 $T_{12\ weeks}$ (*1% w/v*): HDPE: 7.5 Metal: 7.6 $T_{12\ weeks}$ (*neat*): HDPE: 7.2 Metal: 7.3 <u>Packaging, after storage:</u> HDPE bottle: Slight panelling, no evidence of damage, discolouration or permeation of the	*Supplementary data – Study not considered acceptable by rMS, for new study; see entry below.*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			packaging. Metal can: Large number of small blisters in the inner lining of the metal wall. The blisters were intact. The lining on the lid and base were unaffected. **rMS remark:** Since the study was not performed in accordance with the requirements of the guideline (i.e. the temperature deviation exceeded ± 2°C), the study was not accepted for this endpoint. A new study has been performed, see entry below.	
Storage stability test – **accelerated storage**	CIPAC MT 46.3 Samples stored at 35 ± 2 °C for 12 weeks in commercial packaging (0.5 L HDPE bottle and 0.75 L PET lined metal can).	Test item: TWP 094i Nominal content: IPBC: 0.75% Permethrin: 0.25% AS content: See results. Batch number: SK21002	<u>AS content (HPLC-UV method, method validation: [redacted] (2021, TROY2021-01-9802)):</u> <u>IPBC:</u> T_0: 0.76% $T_{12\ weeks}$: HDPE: 0.73% (variation: - 3.9%) PET lined metal: 0.73% (variation: - 3.9%) <u>Permethrin:</u> T_0: 0.25% $T_{12\ weeks}$: HDPE: 0.24% (variation: - 4.0%) PET lined metal: 0.24% (variation: - 4.0%) <u>Product appearance:</u> T_0: Off-white (milky turbid) liquid with a mild pleasant odour.	[redacted], 2021 Report No. TROY2021-01-9801

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			$T_{12\ weeks}$ (HDPE/metal): No change in the appearance of the test item after storage. pH (CIPAC MT 75.3): T_0 (*neat*): 7.7 $T_{12\ weeks}$ (*neat*): HDPE: 7.4 PET lined metal: 7.4 Packaging material: No relevant change on the packaging observed after storage: No bulking or shrinking, no visible damage on the internal coating, no leakage. A slight loss of test item occurred after storage (weight variation of -0.01%), which is probably due to evaporation. The product was stable when stored at 35 °C for 12 weeks in the commercial packaging. The product should not be stored at temperatures exceeding 35 °C	
Storage stability test – **long term storage at ambient temperature**	Samples stored in commercial packaging (HDPE bottle and epoxy-phenolic lined metal can) at ambient warehouse conditions at 4 - 28 °C for 24 months.	Test item: TWP 094i Nominal content: IPBC: 0.75% Permethrin: 0.25% AS content: See results. Batch number: SK17096.	*Supplementary data – Study not considered acceptable by rMS, for new study; see entry below* Physico-chemical properties after storage for 2 years: AS content (HPLC-UV method, method validation: [redacted] (2018c, XR46VD)): IPBC:	[redacted], 2020a Report No. LX46NV *Supplementary data – Study not considered acceptable by rMS, for new study; see entry below.*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Interim results can be found in the report.		T_0: 0.77% w/w. $T_{24\ months}$: HDPE: 0.73% w/w (variation: -5%). Metal: 0.72% w/w (variation: -6%). <u>Permethrin:</u> T_0: 0.25% w/w $T_{24\ months}$: HDPE: 0.24% w/w (variation: - 4%) Metal: 0.24% w/w (variation: - 4%) <u>Product appearance:</u> Assessed using the Munsell colour system. T_0: White liquid, colour N 9.25/84.2% R. $T_{24\ months}$ (HDPE and metal): Off-white liquid 5Y 9/1, which indicates development of a yellow hue. No discernible odour was noted whilst working with the product. The product was a homogeneous liquid both before and after storage, no sedimentation or top-clearing was observed during storage. <u>pH (CIPAC MT 75.3):</u> T_0 (*1% v/w*): 7.6 T_0 (*neat*): 7.5 $T_{24\ months}$ (*1% v/w*): HDPE: 7.2. Metal: 7.2 $T_{24\ months}$ (*neat*):	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			HDPE: 7.0. Metal: 7.4. <u>Packaging after storage:</u> HDPE: Slight panelling observed. No evidence of damage or permeation to the packaging. Metal: Blistering to the lining. A small number of blisters had burst resulting in evidence of rust at these points. No leakage observed. **rMS remark:** According to the leading guidance, GIFAP monograph No. 17, the temperature during ambient storage stability studies must be held at t ± 2°C (t = 20, 25 or 30°C). The temperature of this study varies from 4-28 °C during the study with mean temperatures of 10-19 °C (mean min. temperature – mean max temperature). Furthermore, observations of panelling and discolouration of the packaging materials were observed after storage. Since the mean temperature is significantly lower than the requirements and lower temperature generally results in lower reactivity (i.e. lower AS degradation, lower reactivity towards packaging material etc.), this deviation is not considered as acceptable when combined with indications of damage to the packaging material. Consequently, a new storage stability study at ambient temperature has been initiated. See below.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**	GIFAP (Croplife International) Monograph No. 17. Samples stored in commercial packaging (0.5 L HDPE bottle, 0.75 L PET lined metal can and 27 L HDPE canister) at 25 ± 2°C for 18 months	Test item: TWP 094i Nominal content: IPBC: 0.75% Permethrin: 0.25% AS content: See results. Batch number: B1042C	AS content (HPLC-UV method, method validation: [redacted] (2018c, XR46VD)): <u>IPBC:</u> T_0: 0.73% $T_{1\ month}$: HDPE, 0.5 L: 0.74% (variation: + 1.4%) PET lined metal: 0.74% (variation: + 1.4%) HDPE, 27 L: 0.73% (variation: 0%) $T_{6\ months}$: HDPE, 0.5 L: 0.68% (variation: - 6.8%) PET lined metal: 0.68% (variation: - 6.8%) HDPE, 27 L: 0.68% (variation: - 6.8%) <u>Permethrin:</u> T_0: 0.26% $T_{1\ month}$: HDPE, 0.5 L: 0.25% (variation: - 3.8%) PET lined metal: 0.25% (variation: - 3.8%) HDPE, 27 L: 0.25% (variation: - 3.8%) $T_{6\ months}$: HDPE, 0.5 L: 0.26% (variation: 0%) PET lined metal: 0.26% (variation: 0%) HDPE, 27 L: 0.26% (variation: 0%) <u>Product appearance:</u> T_0: Free flowing, opaque off-white liquid. Munsell* colour code: 5Y 9/1. No discernible odour noted whilst working with the test item.	[redacted], 2022 Report no. 8465684 (This version of Report (Study) no. 8465684 contains results for T_0 to T_{18}.)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			After storage (HDPE or PET lined metal): No change in appearance of the test item after storage. Test item was homogeneous and no evidence of top-clearing observed. <u>pH (CIPAC MT 75.3):</u> T_0 (*1% v/w*): 7.4 T_0 (*neat*): 7.6 $T_{1\ month}$ (*1% v/w*): HDPE, 0.5 L: 7.3 PET lined metal: 7.4 HDPE, 27 L: 7.2 $T_{1\ month}$ (*neat*): HDPE, 0.5 L: 7.5 PET lined metal: 7.6 HDPE, 27 L: 7.4 $T_{6\ months}$ (1% v/w): HDPE, 0.5 L: 7.0 PET lined metal: 7.1 HDPE, 27 L: 7.0 $T_{6\ months}$ (*neat*): HDPE, 0.5 L: 7.2 PET lined metal: 7.3 HDPE, 27 L: 7.3 <u>Relative Density (EC method A.3 - pycnometer)</u> T_0: 1.01 $T_{1\ month}/T_{6\ months}$:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			HDPE, 0.5 L: 1.01 PET lined metal: 1.01 HDPE, 27 L: 1.01 T_6 Packaging, after storage: No leakage, ballooning or panelling observed. A number of small areas of discolouration were noted on the inside edge of the 0.75 L can lid and the internal seam of the can. Some off-white particles at the base of the can was observed. No evidence of blistering, lining was intact. No significant weight change was observed for either container material. IPBC: $T_{12\ months}$: HDPE, 0.5 L: 0.70% (variation: - 4.1%) PET lined metal, 0.75 L: 0.71% (variation: – 2.7%) HDPE, 27 L: 0.70% (variation: – 4.1%) $T_{18\ months}$: HDPE, 0.5 L: 0.69% (variation: - 5.5%) PET lined metal, 0.75 L: 0.70% (variation: – 4.1%) HDPE, 27 L: 0.70% (variation: – 4.1%) Permethrin: $T_{12\ months}$:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			HDPE, 0.5 L: 0.25% (variation: – 3.8%) PET lined metal, 0.75 L: 0.26% (variation: – 0%) HDPE, 27 L: 0.25 % (variation: – 3.8%) $T_{18\ months}$: HDPE, 0.5 L: 0.25% (variation: – 3.8%) PET lined metal, 0.75 L: 0.25% (variation: – 3.8 %) HDPE, 27 L: 0.25 % (variation: – 3.8%) <u>Product appearance:</u> T_{18}: Free flowing, opaque, off-white liquid prior to and following storage. Munsell* colour code: 5Y 9/1. No discernible odour noted whilst working with the test item. After storage (HDPE or PET lined metal): The test item was observed to remain homogenous over the 18 months storage period with no evidence of top-clearing or sedimentation. Small off-white, soft particles present in the test item of all pack types. No significant change in the chemical and physical parameters was found after assessment. Occurrence of particles are not deemed to not affect the stability of the test item. <u>pH (CIPAC MT 75.3):</u> $T_{12\ months}$ (1% v/w): HDPE, 0.5 L: 7.3 PET lined metal, 0.75 L: 7.4	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			HDPE, 27 L: 7.2 $T_{12\ months}$ (neat): HDPE, 0.5 L: 7.0 PET lined metal, 0.75 L: 7.3 HDPE, 27 L: 7.2 $T_{18\ months}$ (1% v/w): HDPE, 0.5 L: 6.5 PET lined metal, 0.75 L: 6.7 HDPE, 27 L: 6.6 $T_{18\ months}$ (neat): HDPE, 0.5 L: 6.8 PET lined metal, 0.75 L: 7.1 HDPE, 27 L: 7.0 <u>Relative Density (EC method A.3 – pycnometer)</u> $T_{12}/T_{18\ months}$: HDPE, 0.5 L: 1.01 PET lined metal, 0.75 L: 1.01 HDPE, 27 L: 1.01 <u>T_{18} Packaging, after storage:</u> No leakage, ballooning or panelling observed. A number of small areas of discolouration were noted on the inside edge of the 0.75 L can lid and the internal seam of the can. Some off-white particles at the base of the can were observed, which are not deemed to affect the stability of the test item. No	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			evidence of blistering, lining was intact. No significant weight change was observed for either container material. T_{18} Dilution stability: HDPE, 0.5 L: Initial observation: Semi-translucent, off- white, homogeneous liquid. Approx. 10 mL of foam. After 24 hours: Semi-translucent, off- white, homogeneous liquid. No separated material. PET lined metal, 0.75 L: Initial observation: Semi-translucent, off- white, homogeneous liquid. Approx. 10 mL of foam. After 24 hours: Semi-translucent, off- white, homogeneous liquid. No separated material. HDPE, 27 L: Initial observation: Semi-translucent, off- white, homogeneous liquid. Approx. 10 mL of foam. After 24 hours: Semi-translucent, off- white, homogeneous liquid. No separated material. **rMS remark:** The interim results of this study indicates that the product is stable for storage at ambient temperature. The packaging material PET lined metal can and HDPE was stable for storage of the product for 18 months. Authorisation of the biocidal product of this storage stability can be given.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **low temperature stability test for liquids**	-	-	No study has been submitted since the product should be stored at a temperature above 0°C. The phrase 'protect from frost' is included as a storage condition.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Not tested as the packaging protects the products from light. The phrase 'protect from light' is included as a storage condition.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Not tested as the packaging protects the product from humidity. Furthermore, the product is a water-based formulation. Influence of temperature on the product is covered by the accelerated storage study ([redacted], 2021). This study was performed at 35°C. Therefore the phrase 'Store below 35°C' is included as a storage condition.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	Test item: TWP 094i AS content: IPBC: 0.76% Permethrin: 0.25% Batch number: SK21002 *and* Test item: TWP 094i	TWP 094i and the commercial packaging materials HDPE and PET lined metal were stable during the 12 weeks storage stability study at 35°C. **rMS remark:** The interim results of this study indicates that the product is stable for storage at ambient temperature. Supporting that the packaging material PET lined metal can and HDPE was stable for storage of the product	[redacted], 2021 Report No. TROY2021-01-9801 *and* [redacted] 2021a/ [redacted], 2022 Report No. 8465684

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		AS content: IPBC: 0.73% Permethrin: 0.26% Batch number: B1042C	for 18 months. Therefore, authorisation can be granted for packaging materials PET lined metal cans and polyolefin material (HDPE, PE or PP).	
Wettability	-	-	Not applicable as the product is a liquid formulation.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable as the product is a liquid formulation which is not to be suspended or dispersed before use.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable as the product is a liquid formulation which is not to be suspended or dispersed before use.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable as the product is a liquid formulation which is not an emulsion.	-
Disintegration time	-	-	Not applicable as the product is a liquid formulation.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not applicable as the product is a liquid formulation.	-
Persistent foaming	CIPAC MT 47.2	10%	No foaming had been observed.	[redacted], 2022 Report No. TROY2022-06-9815
Flowability/Pourability/Dustability	-	-	Not applicable as the product is a solution. Ready-to-use liquid formulation.	-
Burning rate — smoke generators	-	-	Not applicable as the product is not applied as a smoke generator.	-
Burning completeness — smoke generators	-	-	Not applicable as the product is not applied as a smoke generator.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Composition of smoke — smoke generators	-	-	Not applicable as the product is not applied as a smoke generator.	-
Spraying pattern — aerosols	-	-	Not applicable as the product is not applied as an aerosol.	-
Physical compatibility	-	-	Not applicable as TWP 094i is not to be applied together with other products.	-
Chemical compatibility	-	-	Not applicable as TWP 094i is not to be applied together with other products.	-
Degree of dissolution and dilution stability	CIPAC 46.4 and 41.1	10%	No separation	[redacted], 2022 Report No. TROY-2022-06-9816 [redacted], 2022 Report No. 8465684
Surface tension	EC Method A.5 (Surface Tension) and OECD Method 115 (Surface Tension of Aqueous Solutions) using the OECD harmonised ring method	Test item: TWP 094i IPBC: 0.77% Permethrin: 0.25% Batch No.: SK17096	30.0 mN/m at 25°C 29.0 mN/m at 40°C The product is regarded as surface-active, since the surface tension is < 60 mM/m.	[redacted], 2018b Report No. GS55VM
Viscosity	CIPAC MT 22 and OECD Method 114 using a reverse flow viscometer	Test item: TWP 094i IPBC: 0.77% Permethrin: 0.25% Batch No.: SK17096	Kinematic viscosity: 1.9 mm^2/s at 20°C 1.2 mm^2/s at 40°C Dynamic viscosity: 1.9 mPa.s at 20°C 1.2 mPa.s at 40°C	[redacted], 2018b Report No. GS55VM

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

All accepted studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The product is a water-based white liquid with no discernible odour.

The accelerated storage stability study by [redacted] (2018a, MG09NQ) was considered as not acceptable, as the variation in temperature during the test was not in compliance with the guideline. The results from the accelerated storage stability study by [redacted] (2021, TROY2021-01-9801) demonstrated acceptable variation for the parameters active substance content, pH and appearance of the product and packaging material after storage at 35 °C for 12 weeks.

The results from the persistent foaming study and degree of dissolution and dilution stability by [redacted] (2022, TROY2022-06-9815 and TROY2022-06-9816) were assessed and concluded acceptable.

The submitted storage stability study at ambient temperature by [redacted] (2020a, LX46NV) is not acceptable, as the temperature during the study was significantly lower than the requirements of the leading guidance and panelling and discolouration of the packaging material was observed after storage at ambient warehouse conditions for 2 years. Consequently, a new storage stability study has been initiated by the applicant. The submitted interim results for the long term storage stability study by Smith (2022, 846584) demonstrated acceptable variation in active substance content and that the packaging material PET lined metal can and HDPE was stable after storage for 18 months at 25 ± 2 °C.
Prior to storage and at the 18 month timepoint, the containers were inspected for any evidence of damage and for permeation of the test item through the containers. On inspection of the test item containers, they were found to be in good condition with no significant signs of damage or product permeation. Very small indentations/scratches were observed on some of the metal cans at the initial timepoint which can be attributed to transportation of this pack type. These areas were recorded at the initial timepoint with hand drawn diagrams in order to monitor any deterioration. No further deterioration was observed following the 18 month storage period.

A number of small areas of discolouration were noted on the inside edge of the 0.75 L can lid and the internal seam of the can. These assessed as a sign of significant deterioration of the packaging type. Small off-white, soft particles present in the test item of all pack types. No significant change in the chemical and physical parameters was found after assessment. Occurrence of particles are not deemed a problem.
Based on these results, PET lined metal cans and polyolefin material (HDPE, PE or PP) are considered as acceptable packaging material to be used for the biocidal product TWP094i upon authorisation.

The surface tension of TWP 094i is 30.0 mN/m at 25°C, and the product is therefore regarded as surface active. The kinematic

viscosity was determined to be 1.9 mm^2/s at 20°C and 1.2 mm^2/s at 40°C. As the content of hydrocarbons in the product is < 10%, the kinematic viscosity is not required for the toxicological risk assessment of the product.

Based on the submitted storage stability tests, a shelf-life of 18 months in the packaging material PET lined can and polyolefin material (HDPE, PE or PP) can be authorised.

Implications for labelling:

The following storage conditions must be included on the product label:

- Store below 35°C.
- Protect from frost.
- Protect from light.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	According to the UN-MTC, explosive properties are associated with certain chemical groups in a molecule. The chemical structure of IPBC contains an unsaturated C–C bond, however, according to the PT8 CAR (CA DK, 2008), IPBC is not explosive. The active substance Permethrin contains an unsaturated C-C functionality. According to literature lists of molecular structural features that are associated with instability, unusual reactivity or explosive properties,	[redacted], 2018b Report No. GS55VM

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			simple alkenes and/or aromatic rings are not included.[7] Additionally, Permethrin was found to be not explosive according to the PT8 CAR (CA IE, 2014). The remaining ingredients do not contain functional groups characteristic of explosive properties. Therefore, it was concluded that the test item, TWP 094i, does not have explosive properties. Additional rationale for the waiver can be found within section 4.1 of IUCLID regarding explosivesness	
Flammable gases	-	-	Not applicable as the product is a liquid formulation.	-
Flammable aerosols	-	-	Not applicable as the product is not used as an aerosol.	-
Oxidising gases	-	-	Not applicable as the product is a liquid formulation.	-
Gases under pressure	-	-	Not applicable as the product is a liquid formulation.	-
Flammable liquids	EC Method A.9 and BS EN ISO 2719:2002 (Determination of flash point – Pensky-Martens	Test item: TWP 094i IPBC: 0.75 Permethrin: 0.25 Batch number: SK17096.	TWP 094i was found not to have a flash point below boiling point of the product (approx. 99°C). Since no flash point was observed at < 60°C, TWP 094i is not a flammable liquid.	[redacted], 2018b Report No. GS55VM

[7] Literature sources such as: "Hazards in the Chemical Laboratory" or "Hazardous Chemicals handbooks."

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	closed cup method)			
Flammable solids	-	-	Not applicable as the product is a liquid formulation.	-
Self-reactive substances and mixtures	-	-	The active substances are not explosive or contain functional groups associated with self-reactive properties. The co-formulants do not bear any chemical groups which are associated with explosive or self-reactive properties. Therefore it was assessed that TWP 094i does not have self-reactive properties. Additional rationale for the waiver can be found within section 4.8 of IUCLID regarding self-reactive substances and mixtures.	-
Pyrophoric liquids	-	-		-
Pyrophoric solids	-	-	Not applicable as the product is a liquid formulation.	-
Self-heating substances and mixtures	-	-	Test not required. Self-heating properties only apply to solids or liquids adsorbed to a large surface. Since the product is a liquid that is not adsorbed to a surface, TWP 094i is not considered as self-heating.	-
Substances and mixtures which in contact with water emit flammable gases	-	-	Test not required since TWP 094i is a water-based formulation.	-
Oxidising liquids	-	-	An assessment of the structure of the active substances and the inert ingredients established that TWP 094i does contain oxygen and chlorine atoms but these are bonded only to carbon or hydrogen atoms.	[redacted], 2018b Report No. GS55VM

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Therefore, TWP 094i does not have oxidising properties.	
Oxidising solids	-	-	Not applicable as the product is a liquid formulation.	-
Organic peroxides	-	-	From the assessment of the active substances and the inert ingredients it was established that TWP 094i does not contain organic peroxides.	-
Corrosive to metals	UN test C.1 (Section 37.4, UN-MTC)	Test item: TWP 094i IPBC: 0.74 Permethrin: 0.25 Batch number: B1042C	Test duration: 7 days Uniform corrosion: Aluminium (7075-T6) 20 mm x 50 mm x 2 mm: Up to 0.06% Fully immersed: N/A Partially immersed:+0.02% Headspace:-0.03% Steel (S235JR) 20 mm x 50 mm x 2 mm: Up to 0.36% Fully immersed:-0.23% Partially immersed:-0.19% Headspace:-0.04% Localised corrosion: Aluminium: Not observed Steel: Up to 0.05 mm Deviation from guideline: Use of steel type S235JR (also called S235JRG2-NF) instead of S235JR+CR. Justification: The chemical composition of the metal types is comparable. CR indicates controlled rolling, whilst the delivery condition of S235JR is not specified but can be either normalised rolling (+NR) or as-rolled (+AR). As CR includes NR and AR is considered inferior to NR with respect to corrosion resistance,	[redacted], 2021b Report No. 8465686

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the metal will either demonstrate equal or lower corrosion resistance in comparison with S235JR+CR. Additionally the NF notation refer to the method of deoxidation which is optional for S235JR+CR and thus comparable (Please refer to annex 2 of the study report for further details). Since the uniform corrosion resulted in a maximum mass loss of < 13.5% and the localised corrosion resulted in a maximum intrusion depth < 0.12 mm, TWP 094i is not corrosive to metals.	
Auto-ignition temperatures of products (liquids and gases)	EC Method A.15 and BS EN 14522:2005 (Determination of the Auto Ignition Temperature of Gases and Vapours)	Test item: TWP 094i IPBC: 0.75 Permethrin: 0.25 Batch number: SK17096.	TWP 094i was found not to have an auto-ignition temperature below 400°C.	[redacted], 2018b Report No. GS55VM
Relative self-ignition temperature for solids	-	-	Not applicable as the product is a liquid formulation.	-
Dust explosion hazard	-	-	Not applicable as the product is a liquid formulation.	-

Conclusion on the physical hazards and respective characteristics of the product
All accepted studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The product is not classified for physical hazards according to Regulation (EC) No. 1272/2008 (CLP regulation).

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues								
Principle of method in Cowlyn, 2018c Report No. XR46VD: Approximately 250 mg of TWP 094i was weighed into individual 10 mL volumetric flasks, diluted with methanol to the desired volume. The samples were then sonicated for 10 minutes and filtered using a 0.2 µm PTFE filter. The resulting filtrates were analyzed using the HPLC analytical method at 220 nm with a Betasil C18 column (15 cm x 4.6 mm internal diameter) Principle of method in Rössler, 2021 Report No. TROY2021-01-9802: Aproximately 1000 mg of TWP 094i were precisely weighed into individual 25 mL volumetric flasks and had the weight noted. The samples were diluted using methanol to the desired volume of 25 mL. To ensure homogeneity, the samples were shaken for a duration of 10 minutes and then filtered using Ultrafiltration. The resulting filtrates were analyzed using the HPLC analytical method at 200 nm for IPBC and 220 nm for permethrin with a Betasil C18 column (15 cm x 4.6 mm internal diameter)								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / number of measure-ments**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IPBC (active substance)	HPLC-UV	Fortified at 187.4-192.8 mg/L n = 4 *Repeatability:* Nominal value: 0.75% w/w n = 10 Measured range: 0.7517-0.7781% w/w	54 to 270 mg/L, n = 5, y = 0.9448x + 0.6804 r = 0.9999 (y = peak area, x = concentration in mg/L) *Range of method:*	No interferences were found in the analytical procedure. Identities of active substance peaks were confirmed by diode array analysis.	100.0-102.9	101.3	1.0	Not available	[redacted], 2018c Report No. XR46VD

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
		Mean: 0.7571% w/w RSD: 1.0%	75% nominal content (n = 2): Recovery: 100.1% 125% nominal content (n = 2): Recovery: 99.3%						
Permethrin[8] (active substance)	HPLC-UV	Fortified at 62.8-63.2 mg/L n = 4 *Repeatability* Nominal value: 0.25% w/w n = 10 Measured range: 0.2488-0.2537% w/w Mean: 0.2525% w/w RSD: 0.6%	19 to 96 mg/L, n = 5, y = 39.58x + 9.793 r = 0.9999 (y = peak area, x = concentration in mg/L) *Range of method:* 75% nominal content (n = 2): Recovery: 101.1% 125% nominal content (n = 2): Recovery: 100.2%		98.9-99.5	99.2	0.6	Not available	

[8] Permethrin eluates as two peaks using the developed HPLC-UV method. Consequently, the sum of peak areas was used to determine the content of the active substance.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
IPBC	HPLC-UV	Fortified at 299.5 – 304.1 mg/L n = 4 *Repeatability:* Nominal value: 0.75% w/w n = 10 Measured range: 0.7586 – 0.7816% w/w Mean: 0.7674% w/w RSD: 0.95%	129.7 to 518.9 mg/L n = 4 (triplicates), y = 5408x – 6370 r = 0.9999 (y = peak area, x = concentration in mg/L) *Range of method:* 60% of nominal content (n = 2): Recovery: 98.8% 120% of nominal content (n = 2): Recovery: 99.2%	No interferences were found in the analytical procedure. Identities of active substance peaks were confirmed by diode array analysis.	99.5-99.8	99.6	0.13	Not available	[redacted], 2021 Report No. TROY2021-01-9802
Permethrin[9]	HPLC-UV	Fortified at 102.1-118.0 mg/L n = 4 *Repeatability:*	13.5 to 143.2 mg/L, n = 5 (triplicates) y = 28440x + 6784		101.9-103.0	102.4	0.47	Not available	

[9] Permethrin eluates as two peaks using the developed HPLC-UV method. Consequently, the sum of peak areas was used to determine the content of the active substance.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
		Nominal value: 0.25% w/w n = 10 Measured range: 0.2502 – 0.2529% w/w Mean: 0.2516% w/w RSD: 0.35%	r = 0.9999 (y = peak area, x = concentration in mg/L) *Range of method:* 60% of nominal content (n = 2): Recovery: 100.4% 120% of nominal content (n = 2): Recovery: 98.9%						

Analytical methods for monitoring:

New analytical methods for monitoring, soil, air, water, animal and human body fluids were not developed for analysis of the biocidal product since these analytical methods are covered in the PT8 CAR for IPBC (CA DK, 2008) and the PT8 CAR for Permethrin (CA IE, 2014); for further information on the analytical methods please refer to the CARs of IPBC and Permethrine. In summary the principle analytical method utilized for the monitoring of both active substances in soil, air, and water is HPLC-MS/MS.

Analytical methods for the determination of the active substance and residues thereof in/on food or feedstuffs are required if the active substance or material treated with it is to be used in a manner which may cause contact with food or feedstuffs, or is intended to be placed on, in or near soils in agricultural and horticultural use. The product and active substance is intended to be used as a wood preservative and the applied risk mitigation measures "Do not use on wood which may come in direct contact with food, feeding stuff or livestock animals" and "Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock" requires that the product is not to be used on wood that will come into contact with food or feedstuff. Therefore exposure of the active substance to food and feedstuff can be excluded when applied according to the instructions. Consequently, analytical methods for determining the active substance in/on food or feeding stuffs are not necessary.

Conclusion on the methods for detection and identification of the product
Analytical methods by [redacted] (2018c, XR46VD) and by [redacted] (2021, TROY2021-01-9802) for the determination of IPBC (2-iodo-2-propynyl butylcarbamate) and permethrin in the biocidal product are available. Specificity, linearity, accuracy and precision were checked and found acceptable. No substances of concern are present in the product. Methods for the detection of IPBC and permethrin in soil, air, water, and animal and human body fluids and tissues were provided and deemed acceptable at EU level. No additional data is required. The product is not intended to be used on surface in contact with food/feed of plant and animal origin; therefore, analytical method for the determination of active substance in food/feed of plant and animal origin is not required. **Implications for labelling:** The following Risk Mitigation Measures (RMMs) are identified: • Do not use on wood which may come in direct contact with food, feeding stuff or livestock. • Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to come in direct contact with food, feed, drinks and livestock/pets.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Wood preservative with fungicidal and insecticidal function. See below an overview of uses and more detailed information:

PT	Field of use envisaged	Likely concentration at which a.s. will be used
PT 8 – Wood preservatives	Water-based wood preservative for non-professional, professional and industrial use for outdoor* applications such as windows, exterior doors, cladding, fences, eaves and carports. (* The product should not be used indoors, except for the internal surfaces of external window frames and of external doors/door frames.) TWP 094i can be applied as follows: • Industrial use: fully-automated dipping, automated flow-coating/ deluging, automated spraying, and double vacuum/low pressure process • Professional use: brushing, rolling, and manual dipping • Non-professional use: brushing and rolling • On superficial application, a topcoat has to be applied. Type of topcoat and maintenance intervals must be in accordance with recommendations from the approval holder.	Concentration of a.s. in TWP 094i: IPBC: 0.75% w/w Permethrin: 0.25% w/w The product is ready-to use (RTU) for all applications except low pressure impregnation, for which it is applied as a ~ 10% in-use solution. Concentration at which the product will be used: Industrial use (fully-automated dipping, automated flow-coating/deluging, automated spraying, and double vacuum/low pressure process): The product is applied at a rate of 100 mL product/m^2 wood (blue stain fungi, wood destroying insects) or 130 – 140 mL product/m^2 wood (wood-rotting fungi) for superficial treatment, or at a rate of 65.8 – 70.6 kg product/m^3 wood (wood-rotting fungi) for penetrative treatment. Professional use (brushing, rolling and manual dipping): The product is applied at a rate of 100 mL product/m^2 wood (blue stain fungi, wood-destroying insects) or 130 – 140 mL product/m^2 wood (wood-rotting fungi) for superficial treatment. Non-professional use (brushing and rolling): The product is applied at a rate of 100 mL product/m^2 wood (blue stain fungi, wood-destroying insects) or 130 - 140 mL product/m^2 wood (wood-rotting fungi) for superficial treatment.

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

Control of wood rotting and wood staining fungi.

Blue stain:
Sydowia polyspora
Aureobasidium pullulans spp.

Brown rot fungi:
Gloeophyllum trabeum
Poria placenta
Coniophora puteana

Wood-destroying insects:
House longhorn beetle, *Hylotrupes bajulus* (L.)
Termites, *Reticulitermes spp.*

2.2.5.3 **Effects on target organisms, including unacceptable suffering**

TWP 094i contains two active substances - IPBC and Permethrin – which have different target organisms. IPBC exerts fungitoxic or fungistatic effects on a broad range of wood-damaging fungi. Permethrin is a synthetic pyrethroid with insecticidal effects (contact and stomach action).

2.2.5.4 **Mode of action, including time delay**

The product is applied preventively.

IPBC exerts fungitoxic or fungistatic effects and controls wood-rotting (destroying) fungi (basidiomycetes) and wood disfiguring (discolouring) fungi (blue stain, mould and sapstain). IPBC has a carbamate structure. The target sites of carbamates in fungi are cell membrane permeability and fatty acids.

Permethrin 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.

2.2.5.5 **Efficacy data**

The following efficacy studies are available to support the label claims:

- Test report No 32/17/10057/14 (EN 152 - blue stain after 6 months of field testing)
- Test report No 32/17/10057/19 (EN113/EN84 - fungi – leaching)
- Test report No 32/17/10057/20 (EN113/EN73 - fungi – evaporative ageing)
- Test report No 32/17/10057/21 (EN46-1/EN84 - house longhorn beetle [*Hylotrupes bajulus*] – leaching)
- Test report No 32/17/10057/26 (EN46-1/EN73 - house longhorn beetle [*Hylotrupes bajulus*] – evaporative ageing)
- Test report No 32/17/10057/31 (EN118/EN84 - termites [*Reticulitermes santonensis*] – leaching)
- Test report No 32/17/10057/36 (EN118/EN73 - termites [*Reticulitermes santonensis*] – evaporative ageing)

These studies are summarized in the Table below and in IUCLID section 6.7.

The efficacy evaluation gives a positive evaluation of the efficacy of the product towards blue stain fungi, brown rot fungi, the wood-boring beetle *Hylotrupes bajulus*, and the termite *Reticulitermes santonensis*.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Protection of timber against blue stain	Water-based wood preservative for non-professional, professional, and industrial use on new and used wood components such as windows, exterior doors, cladding, fences, eaves and carports.	TWP 094i	*Aureobasidium pullulans* and *Sydowia polyspora*	EN152 (2011)	TWP 094i was tested according to EN152 (2011) after 6 months of ageing (natural weathering). The application target rate of 100 mL/m^2 was on target (99.7 to 100.4 mL/m^2). An acrylic standard topcoat was applied.	For product treatment the average score for blue stained surface was 0.5 and the blue stain free zone was on average 1.8 mm width (range between 1.0 and 2.5 mm width). Visual evaluation of the test block on the surface of the products treated blocks showed no to insignificant infestation with blue stain. All nine untreated controls and the controls which are only treated with alkyd standard topcoat are well stained in the interior and on the surface. Therefore, the test is valid.	[redacted] (2018a); Report no. 32/17/10057/14
Protection of timber against wood destroying fungi	See above	TWP 094i	*Coniophora puteana*, *Poria placenta* and *Gloeophyllum trabeum*	EN in 113 (1996) in combination with EN84 (1997)	TWP 094i was tested according to EN113 after leaching (EN84). There was a dose-dependent application rate (50, 60, 70, 80 and 90 kg/m^3 (corresponding to ~ 100 to 180 mL/m^2; refer to footnote 1 to this table, and considering a product density of 1.01 g/cm^3).	For product treatment the average corrected mass loss was dose-dependent: 1.1 to 2.7% for *Coniophora puteana*, 1.1 to 3.4 % for *Poria placenta,* and 2.6 % for *Gloeophyllum trabeum*. The corresponding untreated test blocks had a mass loss: 45.8 to 46.5% for *Coniophora puteana*, 55.0 to 55.3 for *Poria placenta*, and 42.9% for *Gloeophyllum trabeum* compared to untreated controls, demonstrating the virulence of the fungi. Therefore, the test is valid. Result: b.r.v. = 65.8 kg/m^3 (refer to footnote 2 of this table) (equivalent to a b.r.v. for superficial treatment of ~ 132 g/m^2; refer to footnote 1 to this table)	[redacted] (2017a); Report no. 32/17/10057/19

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Protection of timber against wood destroying fungi	See above	TWP 094i	*Coniophora puteana, Poria placenta* and *Gloeophyllum trabeum*	EN 113 (1996) in combination with EN73 (2014)	TWP 094i was tested according to EN113 after ageing (EN73). There was a dose-dependent application rate (50, 60, 70, 80 and 90 kg/m^3 (corresponding to ~ 100 to 180 mL/m^2; refer to footnote 1 to this table, and considering a product density of 1.01 g/cm^3).	For product treatment the average corrected mass loss was dose-dependent: 0.2% for *Coniophora puteana*, 0.2% for *Poria placenta*, and 0.1% for *Gloeophyllum trabeum*. The corresponding untreated test blocks had a mass loss of 25.6% for *Coniophora puteana*, 36.5% for *Poria placenta,* and 45.8 % for *Gloeophyllum trabeum* compared to untreated controls, demonstrating the virulence of the fungi. Therefore, the test is valid. Result: b.r.v. < 50.9 kg/m^3 (refer to footnote 2 of this table) (equivalent to a b.r.v. for superficial treatment of < 102 g/m^2; refer to footnote 1 to this table)	[redacted] (2018b); Report no. 32/17/10057/20
Protection of timber against wood destroying insects	See above	TWP 094i	*Hylotrupes bajulus* - larvae	EN46-1 (2009) in combination with EN84 (1997)	TWP 094i was tested according to EN46-1 after leaching (EN84). The application target rate of 100 mL/m^2 was on target (98.2 mL/m^2 and 99.8 mL/m^2).	All larvae in the product treatments were dead (without hints of gnawing activity). All three untreated controls showed vital larvae. Therefore, the test is valid.	[redacted] (2017b); Report no. 32/17/10057/21
Protection of timber against wood destroying insects	See above	TWP 094i	*Hylotrupes bajulus* - larvae	EN46-1 (2009) in combination with EN73 (2014)	TWP 094i was tested according to EN46-1 after ageing (EN73). The application target rate of 100 mL/m^2 was on target	All larvae in the product treatments were dead (without hints of gnawing activity). All three untreated controls showed vital larvae. Only one larvae could not be recovered. Therefore, the test is valid.	[redacted] (2017c); Report no. 32/17/10057/26

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					(99.0 mL/m^2 and 99.8 mL/m^2).		
Protection of timber against termites	See above	TWP 094i	*Reticulitermes santonensis* (workers, soldiers, nymphs)	EN118 (2013) in combination with EN84 (1997)	TWP 094i was tested according to EN118 after leaching (EN84). The application target rate of 100 mL/m2 was on target (99.4 mL/m^2 and 99.8 mL/m^2).	All workers, soldiers and nymphs in the product treatments were dead. In all except one samples traces of gnawing were found. Two of the three untreated controls showed survival of workers (53 to 55%), soldiers (1/3) and nymphs (3 to 5/5). One control was infested with mould. In all controls there were found heavy attacks of the test blocks. Therefore, the test is valid.	[redacted] (2017d); Report no. 32/17/10057/31
Protection of timber against termites	See above	TWP 094i	*Reticulitermes santonensis* (workers, soldiers, nymphs)	EN118 (2013) in combination with EN73 (2014)	TWP 094i was tested according to EN118 after ageing (EN73). The application target rate of 100 mL/m^2 was on target (99.4 mL/m^2 and 99.8 mL/m^2).	All workers, soldiers and most of the nymphs in the product treatments were dead. In all samples traces of gnawing were found. All three untreated controls showed survival of workers (63 to 66%), soldiers (3/3) and nymphs (2 to 3/5). In all controls there were found heavy attacks of the test blocks. Therefore, the test is valid.	[redacted] (2017e); Report no. 32/17/10057/36

[1] According to EN 599-1:2009+A1:2013, §5.2.15, the biological reference value (b.r.v.) in g/m^2 (i.e. for superficial treatment) shall be deemed to be twice the b.r.v. established in kg/m^3 (i.e. for penetrative treatment).

[2] According to EN599-1:2009+A1:2013, §5.1.3, the b.r.v. shall be equivalent to the mid toxic value (m.t.v.). For Report no. 32/17/10057/19, the m.t.v. for the least sensitive fungal species (*Coniophora puteana*) = (60.9 + 70.6)/2 = 65.8 kg/m^3. For Report no. 32/17/10057/20, the m.t.v. for the least sensitive fungal species (*Gloeophyllum trabeum*) = < 50.9 kg/m^3 (the lowest concentration tested).

Conclusion on the efficacy of the product
Protection of softwood against blue stain fungi, the House longhorn beetle (*Hylotrupes bajulus*, and termites, *Reticulitermes spp.*, is achieved with superficial treatment (brushing and rolling, manual- and fully-automated dipping, automated flow-coating/ deluging, automated spraying) at an application rate of 100 mL/m^2 TWP 094i. Protection of softwood against wood-rotting fungi (specifically brown rot fungi) is achieved at an application rate of 130 - 140 mL/m^2 TWP 094i with superficial treatment (brushing and rolling, manual- and fully-automated dipping, automated flow-coating/deluging, and automated spraying), and at an application rate of 65.8 – 70.6 kg/m^3 TWP 094i with penetrative treatment (double vacuum/low pressure process). A topcoat is required with superficial and penetrative application. The topcoat should be maintained. TWP 094i is for use in Use class (UC) 2 and 3.

2.2.5.6 **Occurrence of resistance and resistance management**

IPBC

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

The risk of resistance formation against carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee). This applies to the use of carbamate fungicides in agriculture, where yearly applications to the same fields are possible (even more than one application per season is possible).

With regard to the use of carbamates in wood preservation, resistance formation constitutes an even smaller problem: The number of treatments to wooden structures is generally low (in many cases, only one application is made per lifetime of timber structures), resulting in a low selection pressure.

IPBC has been used for many years in wood preservation without the reporting of cases of resistance.

Permethrin

Resistance to pyrethroid insecticides has been reported for a number of pests both in agriculture and public health. Strategies such as alteration of insecticides with different modes of action and avoidance of over frequent use are standard practices in agriculture and should be applied also to biocidal uses of Permethrin.

With regard to the use of permethrin in wood preservation, resistance formation constitutes a smaller problem as the number of treatments to wooden structures is generally low (in many cases, only one application per lifetime of timber structures).

2.2.5.7 Known limitations

There are no limitations known.

2.2.5.8 Evaluation of the label claims

Label claims of protection of softwood against blue stain fungi, the House longhorn beetle (*Hylotrupes bajulus)*, and termites (*Reticulitermes spp.)* at an application rate of 100 mL/m^2 TWP 094i with superficial treatment, and protection of softwood against wood-rotting fungi (basidiomycetes – brown rot fungi) at an application rate of 130 – 140 mL/m^2 TWP 094i with superficial treatment, or at a retention of 65.8 – 70.6 kg/m^3 TWP 094i with penetrative treatment, are supported by the results of efficacy tests performed with the product.

The authorised label claims can be derived from the table below.

Categories	**Use #**			
	1	**2**	**3**	**4**
User category	A.10, A.30	A.30	A.20	
Wood category	B.10, C.10			
Application aim & Field of use	D.30, D.40, E.20, E.30			D.40, E.20, E.30
Method of application	F.10	F.14	F.11, F.12, F.14	F.32
Target organisms	G.10, G.21.2, G.31, G.50			G.10

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

Not applicable - product is not intended to be authorised for use with other biocidal product(s).

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

The toxicology of the active substance IPBC and Permethrin was examined according to standard requirements in the review programme under the Biocidal Product Directive (BPD) 98/8/EC. The toxicological properties of IPBC are summarised in its Assessment Report (CAR) (DK CA, 2008 (PT8); most recent 2015 (PT13)). The toxicological properties of Permethrin are summarised in its Assessment Report (CAR, PT8) (CA IE, 2014).

Tests for acute toxicity, skin- or eye irritation, and skin sensitisation have not been performed for TWP 094i. The criteria for classification of mixtures according to Regulation (EC) No 1272/2008 (CLP) were followed and, accordingly, TWP 094i does not need to be classified for acute toxicity, skin irritation, eye irritation, or skin sensitisation, or for respiratory tract irritation or respiratory tract sensitisation.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	TWP 094i is not skin corrosive or irritating.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product TWP 094i. Testing of the active substances IPBC and Permethrin revealed no skin corrosion/irritation potential. One co-formulant is classified for skin irritation (Skin Irrit. 2, H315), however its concentration in TWP 094i is not sufficient to trigger classification of the product for skin irritation. Refer to Section 3.7.3 of the Confidential annex for further information on classification of the biocidal product.
Classification of the product according to CLP	TWP 094i does not require classification and labelling for skin corrosion and irritation according to Regulation (EC) No 1272/2008 (CLP).

Data waiving	
Information requirement	Annex III of BPR, point 8.1 'Skin corrosion or skin irritation'
IUCLID data point	Section 8.1.1, Skin irritation/corrosion
Justification	According to Annex III, Title 1, Point 8 of the BPR (Regulation (EU) 528/2012) and Section 3.1.1 'Skin corrosion or skin irritation' of the 'Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health' (version 1.2, May 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For the biocidal product TWP 094i, the exact composition is known. For each of the individual components in the biocidal product, valid

	data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.

Eye damage and irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	TWP 094i is not eye irritating.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product TWP 094i. The active substance IPBC has a Harmonised Classification for eye damage (Eye Dam. 1, H318). As its concentration (0.75% w/w) in TWP 094i is below the GCL (C ≥ 1%) for consideration for this end-point when classifying, and there is no information suggesting that it may have eye damaging/irritating effects at concentrations < 1%, it is not considered when classifying the product for eye damage/irritation. One co-formulant is classified Eye Irrit. 2 (H319) however its concentration in TWP 094i is insufficient to trigger classification of the product for eye irritation. Refer to Section 3.7.3 of the Confidential annex for further information on classification of the biocidal product.
Classification of the product according to CLP	TWP 094i does not require classification and labelling for eye irritation according to Regulation (EC) No 1272/2008 (CLP).

Data waiving	
Information requirement	Annex III of BPR, point 8.2 'Eye irritation'
IUCLID data point	Section 8.1.2, Eye irritation
Justification	According to Annex III, Title 1, Point 8 of the BPR (Regulation (EU) 528/2012) and Section 3.1.2 'Eye irritation' of the 'Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health' (version 1.2, May 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For the biocidal product TWP 094i, the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No

	1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	TWP 094i is not irritating to the respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product TWP 094i. The active substance IPBC has a Harmonised Classification for organ damage (larynx) on repeated exposure (STOT RE 1, H372). The concentration of IPBC (0.75%) in TWP 094i is below the GCL (C ≥ 10%) for STOT RE 1 (H372) and below the GCL (C ≥ 1%) for STOT RE 2 (H373), and thus does not trigger classification of the product for respiratory tract irritation. No co-formulant is relevant for classification of the product for respiratory tract irritation. Refer to Section 3.7.3 of the Confidential annex for further information on classification of the biocidal product.
Classification of the product according to CLP	TWP 094i does not require classification and labelling for respiratory tract irritation according to Regulation (EC) No 1272/2008 (CLP).

Data waiving	
Information requirement	Not a data requirement according to the BPR.
IUCLID data point	Section 8.7.1, other endpoints
Justification	Respiratory tract irritation is not a data requirement according to the BPR (Regulation (EU) No 528/2012). There are no testing requirements for respiratory irritation under the BPR (see point 'Respiratory irritation' under Section 2.1.2 'Point 8.2 Eye irritation' of the 'Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health' (version 1.2, May 2018). Nevertheless, Annex I, chapter 3.8.3.4.5 of Regulation (EC) No 1272/2008 (CLP) allows for extrapolation of the toxicity of a mixture that contains substances classified with respect to specific target organ toxicity after single exposure category 3 (STOT SE 3; H335) based on valid data on all components in the mixtures classified with STOT SE 3; H335. TWP 094i does not contain any substances or mixtures classified H335 (or H336). For the biocidal product TWP 094i, the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.

Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	TWP 094i is not skin sensitising. However, the following sentence shall be stated on the label: *Contains Permethrin and 3-iodo-2-propynyl butylcarbamate. May produce an allergic reaction.*
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product TWP 094i. IPBC and Permethrin have a Harmonised Classification for skin sensitisation (Skin Sens. 1, H317). The concentration of IPBC (0.75%) and of Permethrin (0.25%) in TWP 094i is below the GCL (C ≥ 1%) for this end-point and thus does not trigger classification for skin sensitisation. However, IPBC an Permethrin are present at a concentration greater than one-tenth of the GCL. Consequently, according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), TWP 094i should be labelled with the appropriate EUH 208 statement. No co-formulant is relevant in relation to classification of the product for skin sensitisation. Refer to Section 3.7.3 of the Confidential annex for further information on classification of the biocidal product.
Classification of the product according to CLP	TWP 094i does not require classification and labelling for skin sensitisation according to Regulation (EC) No 1272/2008 (CLP) however an EUH 208 statement is required.

Data waiving	
Information requirement	Annex III of BPR, point 8.3 'Skin sensitisation'.
IUCLID data point	Section 8.3.1, Skin sensitisation
Justification	According to Annex III, Title 1, Point 8 of the BPR (Regulation (EU) 528/2012) and Section 3.1.3 'Skin sensitisation' of the 'Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health' (version 1.2, May 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For the biocidal product TWP 094i, the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.

Respiratory sensitisation (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	TWP 094i is not a respiratory sensitiser.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product TWP 094i. There are no validated predictive animal tests for respiratory tract sensitisers, though according to the BPR guidance on human health risk assessment[10], it is plausible to suspect skin sensitisers for also being respiratory tract sensitisers. IPBC and Permethrin both have a Harmonised Classification for skin sensitisation (Skin Sens. 1, H317), with no SCL. The concentration of IPBC (0.75%) and of Permethrin (0.25%) in TWP 094i is below the GCL (C ≥ 1%) for respiratory sensitisation and thus does not trigger classification for this end-point. No co-formulant is relevant in relation to classification of the product for respiratory sensitisation. Refer to Section 3.7.3 of the Confidential annex for further information on classification of the biocidal product.
Classification of the product according to CLP	TWP 094i does not require classification and labelling for respiratory sensitisation according to Regulation (EC) No 1272/2008 (CLP).

Data waiving	
Information requirement	Annex III of BPR, point 8.4 'Respiratory sensitisation' (ADS)
IUCLID data point	Section 8.3.2, Respiratory sensitisation
Justification	According to Annex III, Title 1 Point 8 of the BPR (Regulation (EU) 528/2012) and Section 3.1.4 'Respiratory sensitisation (ADS)' of the 'Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health' (version 1.2, May 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For the biocidal product TWP 094i, the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.

Acute toxicity

10 See Section 1.6.7. *Additional considerations [sensitisation]* of Guidance on the BPR: Volume III Human Health – Assessment & Evaluation (Parts B+C), Version 4.0, December 2017.

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	TWP 094i is not acute toxic by the oral route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal product TWP 094i. IPBC and Permethrin have a Harmonised Classification for acute oral toxicity (Acute Tox. 4, H302). The concentration of IPBC (0.75%) and of Permethrin (0.25%) in TWP 094i is below GCL (C ≥ 1%) for this end-point, thus IPBC and Permethrin do not need to be considered in relation to classification of the product for acute oral toxicity. No co-formulant is relevant in relation to classification of the product for acute oral toxicity. Refer to Section 3.7.3 of the Confidential annex for further information on classification of the biocidal product.
Classification of the product according to CLP	TWP 094i does not require classification and labelling for acute oral toxicity according to Regulation (EC) No 1272/2008 (CLP).

Data waiving	
Information requirement	Annex III of BPR, point 8.5.1 'Acute toxicity by oral route'
IUCLID data point	Section 8.5.1, Acute toxicity: oral
Justification	According to Annex III, Title 1, Point 8 of the BPR (Regulation (EU) 528/2012) and Section 3.1.5 'Acute toxicity' of the 'Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health' (version 1.2, May 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For the biocidal product TWP 094i, the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	TWP 094i is not acute toxic by the inhalation route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal product TWP 094i.

	IPBC has a Harmonised Classification for acute inhalation toxicity (Acute Tox. 3, H331). Its concentration (0.75%) in the biocidal product is above the GCL (C ≥ 0.1%) for this end-point. Permethrin has a Harmonised Classification for acute inhalation toxicity: Acute Tox. 4 (H332). As the concentration of Permethrin (0.25%) in the biocidal product is below the GCL (C ≥ 1%) for this end-point, Permethrin does not need to be considered in relation to classification for this end-point. No co-formulant is relevant in relation to classification of the product for inhalation toxicity. As the application methods for the biocidal product include spraying, the inhalation LC_{50} value for IPBC of 0.67 mg/L/4h for exposure via dusts/mists is considered most appropriate, and the inhalation toxicity of TWP 094i is calculated (according to the Additivity Method of Regulation (EC) No 1272/2008 (CLP)) as follows: $ATE_{mix} = 100/(C\ i/ATE\ i)_n$ $ATE_{mix} = 100/(0.75/0.67) = 89.3$ mg/L/4h This value greatly exceeds the threshold (5 mg/L/4h, dusts/mists) for classification for acute inhalation toxicity. Refer to Section 3.7.3 of the Confidential annex for further information on classification of the biocidal product.
Classification of the product according to CLP	TWP 094i does not require classification and labelling for acute inhalation toxicity according to Regulation (EC) No 1272/2008 (CLP).

Data waiving	
Information requirement	Annex III of BPR, point 8.5.2 'Acute toxicity by inhalation'
IUCLID data point	Section 8.5.2, Acute toxicity: inhalation
Justification	According to Annex III, Title 1, Point 8 of the BPR (Regulation (EU) 528/2012) and Section 8.5 'Acute toxicity' of the 'Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health' (version 1.2, may 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For the biocidal product TWP 094i, the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	TWP 094i is not acute toxic by the dermal route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal product TWP 094i. Testing of the active substances IPBC and Permethrin revealed no acute dermal toxicity. No co-formulant is relevant in relation to classification of the product for acute dermal toxicity. Refer to Section 3.7.3 of the Confidential annex for further information on classification of the biocidal product.
Classification of the product according to CLP	TWP 094i does not require classification and labelling for acute dermal toxicity according to Regulation (EC) No 1272/2008 (CLP).

Data waiving	
Information requirement	Annex III of BPR, point 8.5.3 'Acute toxicity by dermal route'
IUCLID data point	Section 8.5.3, Acute toxicity: dermal
Justification	According to Annex III, Title 1, Point 8 of the BPR (Regulation (EU) 528/2012) and Section 3.1.5 'Acute toxicity' of the 'Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health' (version 1.2, May 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For the biocidal product TWP 094i, the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.

Other toxicological end-points

No relevant endpoints for the active substances or co-formulant substances/mixtures.

Information on dermal absorption

According to Point 8.6 of Annex III to the BPR, identification of relevant information for determination of dermal absorption should follow a tiered approach. The approach is described in the Guidance on the Biocidal Product Regulation, Volume III Human Health, Part A (Version 2 April 2022), p. 114. The document CG-50-2022-07 AP 16.2 'Dermal

absorption value in product authorisations' provides guidance on identification of dermal absorption values for use in the authorisation of a biocidal product in the context of the Mutual Recognition Process (MRP). The approach described in 'Case 4' under the heading 'Proposed Way Forward' is considered to apply to the identification of dermal absorption values for the active substances IPBC and Permethrin from the biocidal product TWP 094i. This is based on the applicant having submitted additional (i.e. non product-specific) studies relevant for identification of dermal absorption values which the Competent Authority is required to assess.

In relation to the dermal absorption of IPBC, the applicant submitted an *in vitro* dermal absorption study for the related formulation TWP 094. DK CA has evaluated the study, which was performed according to OECD TG 428 and considers it to meet the requirements of that guidance. DK CA also considers the study to meet the requirements of EFSAs 'Guidance on dermal absorption' (EFSA Journal 2017; 15(6): 4873) for studies performed according to TG 428, and agrees with the dermal absorption value of 29% for IPBC from the formulation TWP 094 derived by the applicant (see the table 'Value(s) used in the Risk Assessment – Dermal absorption - IPBC' below). In addition, DK CA considers that the requirements of the 'Guidance on dermal absorption' (EFSA 2017) applicable to read-across of data from the formulation TWP 094 to the biocidal product TWP 094i are met, such that the dermal absorption value (29%) identified for IPBC for TWP 094 is applicable to TWP 094i. Refer to Section 3.7.2 of the Confidential annex for justification for the read-across of dermal absorption data for IPBC.

In relation to the dermal absorption of Permethrin, the applicant's initial submission referred to several reports in the open literature presenting the findings of an *in vitro* human percutaneous absorption study, an *in vivo* human volunteer study, an *in vitro* guinea pig percutaneous absorption study, and *in vivo* studies of the dermal penetration of radiolabelled permethrin in the rabbit and dog. The studies are summarised in the table below, which also includes DK CA's comments on the studies. Copies of the studies are included in Section 13 of the IUCLID dossier. Based on the available data and weight-of-evidence approach, the applicant considered a dermal absorption value for Permethrin of 30% to be justifiable. As note in the aforementioned CG document (CG-50-2022-07 AP 16.2), the Competent Authority needs to determine if additional studies submitted for identification of a dermal absorption value are sufficiently robust (and relevant) for this purpose. None of the studies were conducted according to a relevant guideline (e.g. OECD, US EPA) or performed according to GLP. DK CA did not consider the human *in vitro* study and *in vivo* study sufficiently robust for use in identifying a human dermal absorption value for Permethrin from TWP 094i. Likewise, the *in vitro* and *in vivo* animal studies were not considered robust. Consequently, the applicant was informed that unless additional information/data to support a dermal absorption value of 30% was provided, the default dermal absorption value of 50% for a water-based 'dilution' (i.e. < 5% active substance) identified in Table 2 in Section 6.1 of EFSA 'Guidance on dermal absorption' (2017) would be applied in line with the document CG-50-2022-07 AP 16.2.

In response to the DK CA's request for additional information/data to support a dermal absorption value of 30% for Permethrin, the applicant submitted the document 'WoE Dermal absorption of Permethrin for TWP 094i'. New data presented in the document comprised the human *in vivo* study used to set a dermal absorption value of 3% for Permethrin in the PT8 AR (IE CA, April 2014), and four *in vitro* human percutaneous absorption studies: one with ^{14}C-permethrin in ethanol; one with radiolabelled cis-permethrin in acetone, and two with water-based formulations containing Permethrin (conducted according to OECD TG 428). The new studies are summarised in the table below, which also includes DK CA's comments on the studies. The applicant considered the available information (i.e. in its initial submission and its follow-up) to demonstrate that the human dermal absorption of permethrin from alcohol- and water-based

formulations is very low, and considered a value of 3% to be justified with reference to the multi-to-one approach described in Section 6.2 'Use of data on similar formulations' of ECHAs 'Guideline on dermal absorption' (2017). The applicant proposed a dermal absorption value of 30% (worst-case estimate) be used in the human health risk assessment TWP 094i, in line with the initial submission. DK CA notes that the multi-to-one approach is described as being acceptable in exception circumstances, with specific conditions applying to its use. Based on the data presented by the applicant, supported by additional data on dermal absorption of permethrin from biocidal products in PT8 (and relevant products in PT18), DK CA does not consider the available data adequate to determine an overall dermal absorption value for permethrin via the 'multi-to-one approach', to identify a value to be used as a point-of-departure for setting a dermal absorption value (e.g. of 30%) for TWP 094i. DK CA considers the default dermal absorption value of 50% for a water-based 'dilution' (i.e. < 5% active substance) identified in line with Table 2 in Section 6.1 of EFSA 'Guidance on dermal absorption' to be applicable to TWP 094i and the in-use solution of the product.

Summary table of *in vitro* and *in vivo* studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks**	**Reference**
<u>Dermal absorption IPBC</u>					
In vitro percutaneous absorption through human skin, OECD TG 428, GLP certified, reliable without restrictions	Human skin membranes, n = 8 (2 samples from 4 donors) per concentration	Test formulation: TWP 094 (0.75% IPBC w/w), Lot no.: SK17097 Radiolabelled test substance: Iodocarb (IPBC), [carbamate-^{14}C], batch no. XXV/5/A/1, radiochemical purity: 99.93%, specific activity: 7.314 MBq/mg Target dose IPBC: 75.8 µg/cm^2	The mean absorbed dose (excluding tape strips) was 23.6 ± 4.5% of the applied dose. The mean potentially absorbed dose, (except for the first 2 tape strips) was 24.3 ± 4.7% of the applied dose. Mean values: Receptor fluid: 21.5% Receptor compartment wash: 0.115% Stripped skin: 2.0% Tape strips 1+2: 16.0% Tape strips 3-last: 0.8% *Stratum corneum*: 16.8% Skin wash: 52.6% Donor compartment	None	[redacted] (2018) Study Report: V21130/29

			wash: 4.8%		
Dermal absorption Permethrin (initial data submission)					
Dermal absorption of permethrin following topical administration, *in vivo* human volunteer study. The study was approved by the ethics committee of the University of Cologne and carried out in accordance with the Declaration of Helsinki and corresponding European and International Guidelines, not GLP, reliable with restrictions	6 young healthy males in Parts 1 and 2. 3 male and female patients (infested with scabies) in Part 3.	Part 1: Hair rinse solution (Infectopedicul) containing 4.3% Permethrin (*cis/trans* 25/75), 50 mL was administered onto wet hair. Urine was collected 0–8, 8–16, 16–24, 40–48, 88–96 and 160–168 h post-dose. Parts 2 and 3: Cream (Infectoscab) containing 5% Permethrin (cis/trans 25/75), 60 g was applied on the skin of the whole body (except the head and genital mucosa). Urine was collected 0–6, 6–12, 12–18, 18–24, 40–48, 88–96 and 160–168 h post dose.	The absorbed fraction of the permethrin dose and the elimination rate of permethrin was similar in all study parts. Mean estimated excreted amount of the Permethrin dose up to infinity was **0.347**%**, 0.468**% and **0.515**%, respectively, in Parts 1, 2 and 3. As for most study volunteers, the estimated excreted amount of permethrin extrapolated to infinity was nearly identical to the estimated amount up to 168 h.	Report from the open literature	Tomalik-Sharte et al. (2005)
Competent Authority comments: The studies were not conducted according to a relevant guideline nor according to GLP. The compositions of the test solution and test cream containing permethrin are not known. The hair of the subjects treated with the solution was rinsed with water 45 minutes after application. Clothing was worn over the skin to which the cream was applied. The absorbed fraction was determined based on the dose applied, however for the above reasons, the fraction of the dose applied that was available for absorption is unknown. The absorbed fraction of permethrin is based alone on quantification of urinary excretion of the main metabolites of permethrin.					
In vitro percutaneous absorption study of 5% permethrin cream in human and guinea pigs and *in vivo*	*In vitro*: Dermatomed human skin and guinea pig back skin, shave within 1 mm. Skin	*In vitro*: Permethrin cream (5% Elimite), receptor fluid: fresh-buffered saline containing 0.5% Volpo-20. Dose level 10 µL/cm^2 (overuse	*In vitro* human: Total absorption at 48 hours for permethrin was **0.77**%, total recovery was 102.6%. *In vitro* guinea pig: Total absorption at 48	Report from open literature, dermal absorption of lindane and	Franz, J.T. et al. (1996)

dermal absorption in guinea pigs. No guideline, not GLP, reliable with restrictions	integrity was assessed, only skins with a permeability less than 1.25 µL of tritiated water were used. *In vivo*: 6 Hartley male guinea pigs (total of 15, 3 controls and 6 received lindane lotion) weighing 264 to 393 g (Charles River) were dosed three times (1/day) without washing. The back was clipped to 1 mm	dose, equivalent to a dose of 465 µg Permethrin after weight correction) over 48-hours. Samples of the receptor fluid (taken at several intervals) and minced skin sample extracts were analysed by gas chromatography/ mass spectrometry. *In vivo*: Permethrin cream (5% Elimite), 2 mL at 48 cm^2 at 0 h, 24 h and 48 h. Animals were anaesthetized and blood was collected before euthanisation, brain tissues and skin samples were taken. Samples were analysed by gas chromatography/ mass spectrometry after extraction	hours for permethrin was **4.7**%, total recovery was 96.5%. *In vivo* guinea pig: Total absorption at 48 hours for permethrin was **0.73**%, total recovery was 100.7%.	permethrin creams or lotions that are used for human scabies treatment was assessed.	

Competent Authority comments:

The studies were not conducted according to a relevant guideline nor according to GLP. The composition of the test cream containing permethrin is not known. Regarding the human *in vitro* study, the following points are highlighted in relation to the requirements of the EFSA 'Guidance on dermal absorption' (EFSA 2017): The body location of the human skin samples (from 3 donors) is not stated. The human skin tested appears to be full thickness as opposed to split-thickness. Information confirming solubility of permethrin in the receptor fluid was not presented. It is not stated if the receptor chamber was washed. Tape stripping was not performed; the skins samples tested were divided (method not described) into dermis and epidermis. The presentation of the data does not allow determination of whether at least 75% of absorption of the test substance occurred with half the duration of the study. If this cannot be confirmed, absorption is calculated as the sum of the test material in the receptor fluid, receptor chamber washes, and skin sample. If tape stripping has been performed with the strips being pooled, all tape strips should be included in the absorbed material. Thus the quantity of permethrin in the dermis and epidermis fractions (1.35%) should be added to that in the receptor fluid (0.77%), yielding 2.12% (excluding an unknown fraction potentially bound to the

receptor chamber).					
Dermal penetration and distribution of 14C-labelled Permethrin Isomers *in vivo*, no Guidelines, not GLP, reliable with restrictions	Animals: 3 male albino rabbits (1.8 – 2.8 kg bw) and 3 male purebred beagle dogs (8 – 14 months old).	*Cis* and *trans* permethrin, 14C-labelled, administered as mixture only for dogs or solely for rabbits and dogs, radiochemical purity > 98%, vehicle: ethyl alcohol For topical application, 4 µg/cm^2 test substance was applied to the clipped mid-lumber area of rabbits (application are 8.2 cm^2) or dogs (16.4 cm^2). 3 rabbits received 4 µg/cm^2 *cis* or *trans* permethrin topically applied to 8.2 cm^2. Urine and faecal collections were measured daily for 7 days in rabbits and 14 days in dogs.	Dermal absorption in rabbits was 28.1% or *cis* isomer and 30.7% of *trans* Permethrin isomers through the 7-day study period. Within the first 24 h, the absorption of *cis* isomer was 12.8 and 14.7% of the *trans* isomer. Total recovery of *cis* isomer was 83.2% and 67.2% of *trans* isomer. About half of all radiochemical absorption occurred during the first 24-hours and was recovered primarily in urine. Dermal absorption in beagle dogs was less than 12% (*Cis*: 9.7%, *trans*: 11.8% and *cis/trans*: 8.9%) through the 7-day or 14-day study period independent of isomer or combination. Within the first 24 h hours, dermal absorption was < 2% (*Cis*: 0.9%, *trans*: 1.6% and *cis/trans*: 0.7%). Maximum radiocarbon recovery was observed on days 2 to 3 after application. Total recovery was 76.4% (*cis*), 77.1% (*trans*) and 73.1 (*cis/trans*).	Report from the open literature. In parallel, animals received Permethrin by injection for evaluation of the metabolism profile (ADME)	Snodgrass, H.L., Nelson, D.C. (1982)
Competent Authority comments: The studies were not conducted according to a relevant guideline nor according to GLP. A small number of animals (3) per treatment group were used. In the rabbit study, unrecovered radiolabel was 16.8% for the *cis* isomer and 32.8% for the *trans* isomers. If the unrecovered fraction is considered potentially absorbed (see Section 5.2 of the EFSA 'Guidance on dermal absorption' (EFSA, 2017)), potential dermal absorption values of 44.9% (28.1% absorbed + 16.8% unrecovered) for the *cis* isomer, and 63.5% (30.7% absorbed + 32.8% unrecovered) for *trans* isomers are obtained. In the dog study, unrecovered radiolabel was 23.6%, 22.9%, and 26.9% for the *cis*, *trans*, and *cis*/*trans* isomers, respectively, yielding potential dermal absorption values (absorbed +					

unrecovered) of 33.6%, 34.7%, and 35.8% for the *cis*, *trans*, and *cis*/*trans* isomers, respectively.

Dermal absorption Permethrin (follow-up data submission)

The applicant submitted the document 'WoE Dermal absorption of Permethrin for TWP 094i' (see Section 3.7.6 of the Confidential annex) presenting new data comprising the human *in vivo* study used to set a dermal absorption value of 3% for Permethrin (0.30 – 2.08% w/w in an isopropanol solution) in the PT8 AR (IE CA, April 2014), and four *in vitro* human percutaneous absorption studies: one with ^{14}C-permethrin in an ethanol solution at 0.05, 0.4 and 4.1% w/w (Reifenrath et al. 2011); one with radiolabelled cis-permethrin in acetone (Hughes & Edwards, 2010), and two unpublished studies with water-based formulations containing 0.1% or 0.4% Permethrin (conducted according to OECD TG 428). The human *in vivo* study of Tomalik-Sharte et al. (2005) included in the initial submission was also cited. The applicant considered the available information (i.e. in its initial submission and its follow-up) to demonstrate that the human dermal absorption of permethrin from alcohol- and water-based formulations is very low, and considered a value of 3% to be justified with reference to the multi-to-one approach described in Section 6.2 'Use of data on similar formulations' of ECHAs 'Guideline on dermal absorption' (2017). The applicant proposed a dermal absorption value of 30% (worst-case estimate) be used in the human health risk assessment TWP 094i, in line with the initial submission.

Competent Authority comments:

The two unpublished *in vitro* human percutaneous absorption studies were listed as being according to OECD TG 428, though compliance with the guideline was not addressed. No information on the composition of the two water-based formulations (other than their permethrin content) was provided. No information on the guideline status of the two published *in vitro* human percutaneous absorption studies was provided. The exposure levels in the study of Reifenrath et al. (2011) were not expressed as % w/w, while neither permethrin exposure levels or dermal absorption values found were provided for the study of Hughes & Edwards (2010). The dermal absorption values obtained in the studies were not re-calculated to account for variability within the results and outliers according to Section 5.3 of EFSAs 'Guidance on dermal absorption' (2017); i.e. dermal absorption should be calculated as: Absorption = mean value + ks, where ks is the sample standard deviation (s) adjusted by a multiplication factor (k) based on the number of replicated.

Read-across, as described in Section 6.2 of EFSAs 'Guidance on dermal absorption' (2017) between the formulations tested and in the human *in vitro* and *in vivo* studies and TWP 094i was not addressed, though is not possible due to the difference in the concentration of permethrin and/or co-formulants (or lack of information on the latter) in the tested formulations compared to TWP 094i. The applicant proposed to use the multi-to-one approach described in Section 6.2 of EFSAs 'Guidance on dermal absorption' (2017) to set a dermal absorption value for permethrin. DK CA notes that in order to accept an overall value based on a multi-to-one approach, the guidance states that the "*dermal absorption of a variety of products is always in the same range and that the formulation of the product under evaluation is covered by the tested formulations*". Due to the general lack of information on the composition of the tested formulations, the latter requirement is not considered to be met by the information submitted by the applicant. Regarding the former requirement, while the studies submitted by the applicant do show a consistently low dermal absorption value for permethrin, data available for other biocidal products in PT8 (and relevant (i.e. liquid) products in PT18) indicate variation in dermal absorption that appears to be related to differences in formulation. Table 6 in a BPC Opinion (ECHA/BPC/284/2021) on a PT 18 biocidal product summarises data for permethrin biocidal products in PT 18 and PT 8 tested for dermal absorption. The Opinion noted (p. 30): "*The results show considerable differences in the dermal absorption values of*

permethrin even for very close or identical concentrations of the active substance. Although for some of the tested products a degree of similarity in their composition is found, it seems that the remaining differences in their ingredients lead to different dermal absorption values … ." DK CA also notes that the concentration of permethrin (0.025%) in the in-use solution of TWP 094i is below the concentrations of the 'tested formulations' included in the applicant's 'multi-to-one' evaluation. In Table 6 of the afore mentioned BPC Opinion the dermal absorption values for water- or solvent-based PT 8 or PT18 products with permethrin concentrations in the range 0.018 to 0.091% w/w were in the range 12 to 28%. Based on the above, DK CA does not consider the data presented by the applicant adequate to determine an overall dermal absorption value for permethrin via the 'multi-to-one approach', or to identify a value to be used as a point-of-departure for setting a dermal absorption value (e.g. of 30%) for TWP 094i as the ready-to-use product (for superficial treatment) or as a 10% dilution (for penetrative treatment).

Value(s) used in the Risk Assessment – Dermal absorption of IPBC	
Substance	***IPBC (from TWP 094i undiluted product)***
Value	Point of departure value: 27% (for 7.91 g/L IPBC, the total concentration used in the applicable *in vitro* dermal absorption study) <u>Applicable value: 29%</u> (after correction for variability, pro-rata correction for the concentration (7.58 g/L) of IPBC in TWP 094i, and final rounding-up; all according to EFSA's 'Guidance on dermal absorption' (EFSA 2017))
Justification for the selected value	The value of 29% is based on read-across to an *in vitro* dermal absorption study of IPBC from a similar formulation (TWP 094) containing 0.75% w/w of the active substance IPBC). The dermal absorption value of 29% derived in the study is considered applicable to TWP 094i since the conditions for using data on similar formulations as described in EFSA's 'Guidance on dermal absorption' (EFSA 2017) are met (refer to Section 3.7.2 of the Confidential annex for justification for the read-across of dermal absorption data for IPBC). <u>Further information regarding the *in vitro* dermal absorption study and calculation of the dermal absorption value</u>: The following deviations the *in vitro* dermal absorption study were noted in relation to EFSA's 'Guidance on dermal absorption' (EFSA 2017): 1) The thickness of 2 of the skin replicates from 1 of the 4 donors is slightly over 400 µm (417 and 418 µm), representing an excess of max. 4.5%. The deviation from the EFSA guidance is considered acceptable. 2) In relation to the dermal integrity test, one replicate had a Kp value 2.75×10^{-3} cm/h, which is above the stated cut-off value of 2.5×10^{-3} cm/h. The mean of the 2 replicates from the same donor is 2.50 (2.25 and 2.75). The mean absorbed dose for the donor is within the range of the means of the other 3 donors. Based on this information, the apparent deviation is considered acceptable. *Basis for dermal absorption calculation*:

	More than 75% (86 ± 4%) of the absorption of IPBC in the receptor fluid over 24 hours occurred within half of the study duration. For risk assessment, in agreement with EFSA's 'Guidance on dermal absorption' (EFSA 2017), it is considered appropriate to exclude all tape strips in the calculations of the total absorption values. Based on the same EFSA guidance, the absorption values should be corrected (k) to account for variability. Based on the number of replicates, a multiple of the standard deviation is added to the mean value (a value of 0.84 is applied to a SD for 8 replicates). Moreover, pro-rata correction of the dermal absorption value for the minor deviation of the concentration is required (7.91 g/L IPBC used in the study, 7.58 g/L in-use concentration of IPBC). The calculated dermal absorption values for IPBC in TWP 094 would then be **29%** (rounded to two significant figures as per the aforementioned EFSA guidance. *Calculation*: DA = Absorbed dose + (SD * k) * pro-rata correction DA = 23.6% + (4.5% * 0.84) * (7.91 g/L / 7.58 g/L) = 28.58% (rounded to 29%) **DA = 29%**
Substance	***IPBC (from TWP 094i diluted to ~ 10% in-use solution[1])***
Value	50%
Justification for the selected value	According to EFSA's *Guidance on dermal absorption* (2017). As the ~ 10% in-use solution is a dilution of TWP 094i, pro-rata correction of the dermal absorption value (29%) for the product TWP 094i can be performed according to the procedure described in Section 5.5 of the aforementioned EFSA guidance. Pro-rata calculation: 29% x 10/1 = 290% Section 5.5 of the guidance notes that if pro rata correction yields a dermal absorption value above the default value for dilutions given in Section 6.1 of the document, the relevant default value should apply. As TWP 094i is a water-based product and contains < 5% active substance (i.e. 0.075%) when diluted to a ~ 10% in-use solution using water as the dilutant, the default value for dermal absorption of 50% for a water-based dilution is the applicable value to selected from Table 2 in Section 6.1 of the EFSA (2017) guidance.

[1] TWP 094i is diluted to a ~ 10% in-use for solution for use in low pressure impregnation.

Value(s) used in the Risk Assessment – Dermal absorption of Permethrin	
Substance	***Permethrin (from TWP 094i undiluted product; 0.25% w/w permethrin)***
Value	As proposed by the applicant: 30%

	As set by the Competent Authority: 50%
Justification for the selected value	Applicant's justification (initial data submission) No new study of the dermal absorption of Permethrin has been conducted. However, there are numerous reports available in the open literature evaluating the dermal absorption in humans, rats, rabbits or dogs, *in vitro* or *in vivo.* In the reports evaluated within this assessment (Tomalik-Sharte et al (2005), Franz, J.T. et al. (1996), Snodgrass, H.L. and Nelson, D.C. (1982), dermal absorption in humans was < 1% of the applied dose in all investigations. In a human volunteer study, dermal absorption of Permethrin from air hair rinse solution containing 4.3% Permethrin, dermal absorption ranged between 0.347% and 0.515%. In an *in vitro* dermal absorption study of Permethrin from a scabies cream (Elimite) containing 5% Permethrin through human dermatomes skin membranes, total absorption over a 48 h exposure period was 0.77%. In an *in vitro* dermal absorption study of Permethrin from a scabies cream (Elimite) containing 5% Permethrin through guinea pig skin membranes, total absorption over a 48 h exposure period was 4.7%. In an *in vivo* dermal absorption study of Permethrin from a scabies cream (Elimite) containing 5% Permethrin through the skin of guinea pigs, total absorption over a 48 h exposure period was 0.73%. There are further reports available in the open literature, indicating a very low dermal absorption study which had also been concluded during the evaluation of Permethrin used as an active substance in pesticide or biocide formulations. In is therefore concluded that using the default value for dermal absorption (50%) according to the EFSA *Guidance on dermal Absorption* (EFSA, 2017) would be a very conservative overestimation. A dermal absorption of Permethrin of 30% is therefore considered to be justified following a weight of evidence approach based on all available data, representing a worst case. Competent Authority's opinion on Applicant's initial justification The studies supporting a dermal absorption value of 30% were not conducted according to a relevant guideline (e.g. OECD, US EPA) nor according to GLP. Concerns regarding lack of information on the formulation of the test items, and the performance, findings, and/or reporting of experiments are identified for each of the studies. The Applicant was informed that unless additional information/data to support a dermal absorption value of 30% was provided, the default dermal absorption value of 50% for a water-based 'dilution' (i.e. < 5% active substance) identified in Table 2 in Section 6.1 of EFSA 'Guidance on dermal absorption' would be set for Permethrin in TWP 094i, in line with the document CG-50-2022-07 AP 16.2. ----------

	Applicant's revised justification (follow-up data submission) There is sufficient information available to demonstrate that the human dermal absorption of permethrin from alcohol- and water-based formulations is very low. The EFSA guidance provides several considerations for use of data on similar formulations. This includes a consideration of the relative differences of components and similarity of local effects on skin. TWP 094i and Preventol are both water-based PT08 products containing permethrin and IPBC. The product TWP 094i and the in-use dilutions contain > 85% water. The content of permethrin in the [redacted] products is 0.1% and 0.4%, which is similar to the range for in-use concentrations of TWP 094i (0.25% for undiluted/ ready to use and 0.025% diluted for pressure treatment). The 2017 EFSA guidance additionally allows for a multi-to-one approach in the cases that dermal absorption is consistently in the same range (Section 6.2). This has been shown here. The human *in-vitro* dermal absorption of permethrin formulated into similar water-based PT08 formulations is well-supported by the human *in vivo* studies, which also show low absorption (< 3%). A similar read across approach for dermal absorption of permethrin was used in the recently authorized PT8 product Korasit NG. This is an aqueous wood preservation product containing similar concentrations of Permethrin when in use (2.5, 1.25, 0.25 and 0.0125%). The publicly available Product Authorisation Report (RMS NL, September 2020) cites an agreed dermal absorption value of 3% based on a read-across and publicly available data. In conclusion the provided data would justify a dermal adsorption value of 3%. A dermal absorption value of 30% (worst-case estimate) is used in the draft risk assessment submitted for TWP 094i. Therefore dermal absorption value of 30% is a highly conservative approach already. There is no need to apply the default of 50 % in any scenario including the use where TWP 094i is diluted (vacuum/low pressure process). Competent Authority's opinion on Applicant's revised justification DK CA does not consider the data presented by the applicant adequate to determine an overall dermal absorption value for permethrin via the 'multi-to-one approach', or to identify a value to be used as a point-of-departure for setting a dermal absorption value (e.g. of 30%) for TWP 094i (see the table below for details). DK CA considers the default dermal absorption value of 50% for a water-based 'dilution' (i.e. < 5% active substance) identified in line with Table 2 in Section 6.1 of EFSA 'Guidance on dermal absorption' to be applicable to TWP 094i and the in-use solution of the product.
Substance	***Permethrin (from TWP 094i diluted to ~ 10% in-use solution[1]; 0.025% w/w permethrin)***
Value	As proposed by the applicant: 30%

	As identified by the Competent Authority: 50%
Justification for the selected value	Applicant's justification (initial data submission) A dermal absorption of Permethrin of 30% is therefore considered to be justified following a weight of evidence approach based on all available data, representing a worst case. Competent Authority's opinion on Applicant's initial justification The appropriate dermal absorption value for the in-use solution was not specifically addressed in the initial data submission. CA DK's opinion on the Applicant's justification for the dermal absorption value applicable to the in-use solution was as given in its opinion on the Applicant's initial justification for the dermal absorption value for Permethrin applicable to the undiluted product. ---------- Applicant's revised justification (follow-up data submission) Refer to the justification for TWP 094i (undiluted product). Competent Authority's opinion on Applicant's revised justification Refer to the justification for TWP 094i (undiluted product).

[1] TWP 094i is diluted to a ~ 10% in-use for solution for use in low pressure impregnation.

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

The biocidal product TWP 094i does not contain any substances of concern (SoC).

TWP 094i contains a co-formulant identified as a possible substance of concern (SoC) as it is a classified substance (Skin Irrit. 2 (H315), Eye Irrit. 2 (H319)), and is present at a level that requires it to be taken into consideration when classifying the product according to CLP[11]. However, based on the guidance for the identification and evaluation of SoCs (Commission document CA-Nov14-Doc.5.11[12]) the co-formulant is not considered a SoC. For the full assessment of components considered a potential substance of concern, refer to Section 3.7.4 of the Confidential annex.

Available toxicological data relating to a mixture

[11] See Criterion 1 of Commission document CA-Nov14-Doc.5.11.

[12] Document entitled *Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products*. See also the associated document *Annex A: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products (Guidance on the BPR, Volume III Humana Health)* – Assessment & Evaluation (Parts B+C), Version 4.0, December 2017).

TWP 094i includes 2 mixtures that contain substances that are identified as possible SoCs as they are an active substance in another PT[13]. However, based on Commission document CA-Nov14-Doc.5.11 the substances in question are not considered SoCs. See Section 3.8.2.1 of the Authority Confidential annex for further information.

TWP 094i includes 2 mixtures that contain substances that are identified as possible SoCs as they have a European Union Indicative Occupational Exposure Limit Value (EU-IOELV)[14]. According to the document CG-45-2021-20 AP 16.4 e-c 'SoC and workplace exposure limits'[15], Union OEL values of co-formulants must be indicated in the Confidential Annex of the PAR. See Section 3.7.4.1 of the Confidential annex for further information. Based on the approach proposed in CG-45-2021-20 AP 16.4 e-c, the substances in question are not considered SoCs. See Section 3.8.2.1 of the Authority Confidential annex for further information.

[13] See Criterion 2 of Commission document CA-Nov14-Doc.5.11.

[14] See Criterion 5 of Commission document CA-Nov14-Doc.5.11.

[15] e-Consultation 'Harmonized approach to consider a co-formulant as a substance of concern (SoC) based on its workplace exposure limits', ES CA, 29 January 2021.

2.2.6.2 **Exposure assessment**

TWP 094i is a water-based product for the preservation of wood (PT8) – prevention of fungal and insect attack. The product is applied to wood *in situ* outdoors or prior to its use outdoors, though it may be applied to the internal surfaces of external window frames and of external door/door frames. Application of an appropriate topcoat is mandatory with superficial and penetrative application; the topcoat should be maintained. The product is intended for industrial-, professional-, and non-professional (general public) use. It is to be applied by fully-automated dipping, automated flow-coating/deluging, automated spraying, and double vacuum/low pressure process (industrial use); brushing and rolling, and manual dipping (professional use); and brushing and rolling (non-professional use). The product is ready-to use (RTU) for all applications except low pressure impregnation, for which it is applied as a ~ 10% in-use solution.

TWP 094i contains 0.75% IPBC and 0.25% Permethrin as active substances. The human exposure assessment relates to the use phases of the product and covers primary and secondary exposure.

The workplace risk for industrial- and professional users will be controlled through observance of statutory requirements such as formal control measures (i.e. engineering controls). Industrial users and professional users have access to Material Safety Data Sheets (MSDS) and may have some basic knowledge about classification and labelling. They are trained and skilled in the main objectives of their occupation and may have some experience and skill in the use of personal protective equipment (PPE) if that is necessary for their normal work.

Non-professional users may or may not read a product label. Although they may not have access to formal PPE, it is expected that they will follow some basic recommendation such as do not eat, drink or smoke when working with wood preservatives, avoid contact with the eyes and skin, and to avoid inhaling vapour.

Exposure of the general public considers exposure of adults, children, toddlers, and infants. Relevant general public (adult) exposures are considered in the respective worst-case exposure scenario for industrial-, professional-, and non-professional users.

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
Primary exposure of industrial users			
1.1	Mixing and loading by industrial users	Mixing and loading not relevant as the product is RTU for industrial applications 1.2 and 1.3 while mixing for application 1.4 occurs within the automated treatment equipment, and loading is expected to be fully automated for all industrial applications.	No exposure
1.2	Application – automated industrial application by dipping	Fully-automated dipping (chronic exposure)	Industrial users
1.3	Application – industrial use – Automated flow-coating/deluging or automated spraying	Automated flow-coating/deluging or automated spraying (chronic exposure)	Industrial users
1.4	Application – Industrial use – Double vacuum/low pressure process	Double vacuum/low pressure process (chronic exposure)	Industrial users
1.5	Post-application – Handling of treated articles	Contact with the treated timber (water-wet or solvent damp wood) (chronic exposure)	Industrial users
1.6	Post-application – maintenance/cleaning of the system	Exposure during cleaning and/or maintenance of the system (intermittent exposure)	Industrial users
Primary exposure of professionals			
2.0	Mixing and loading by professionals	Mixing and loading prior to manual dipping (chronic exposure)	Professionals
2.1	Mixing and loading by professionals	Mixing and loading prior to brushing and rolling (chronic exposure)	Professionals
2.2	Application – manual dipping by professionals	Application of wood preservative by manual dipping (chronic exposure)	Professionals
2.3	Application – Brushing and rolling by professionals	Outdoor and indoor application of wood preservative by brushing and rolling (chronic exposure)	Professionals
2.4	Post-application – Drainage and reloading of the manual dipping tank	Drainage and reloading of the manual dipping tank (intermittent exposure)	Professionals
Primary exposure of non-professionals			
3.1	Mixing and loading by non-professionals	Mixing and loading not relevant the product is RTU for non-professional application and is applied direct from can	No exposure

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
3.2	Application – Brushing and rolling by non-professionals	Outdoor and indoor application of wood preservative by brushing and rolling (acute exposure)	Non-professionals
Secondary exposure of professionals, non-professionals and general public			
4.1	Cutting and sanding treated wood by professionals	Cutting and sanding treated wood by professional (chronic exposure)	Professionals
4.2	Cutting and sanding treated wood by non-professionals	Cutting and sanding treated wood by non-professional (acute exposure)	Non-professionals
4.3	Handling treated wood	Handling of treated wood once dry by non-professional (acute exposure)	Non-professionals
5	Chewing wood off-cut by infant	Infant picks up and chews wood off-cut, which has been treated with wood preservative (acute exposure, incidental)	General public (infant)
6	Playing on playground structure outdoors and mouthing by infant	Playing on treated playground structure outdoors and mouthing (chronic exposure)	General public (infant)
7	Contact to wet wood by toddler	Accidental dermal contact to freshly treated wood by toddler and hand to mouth transfer (acute exposure, incidental)	General public (toddler)
8	Inhalation of volatilised residues	Inhalation of volatilised residues indoors from treated wood (chronic exposure)	General public (adult, child, toddler, infant)
9	Laundering work clothes at home	Acute intermediary secondary exposure, Contaminated work clothing is handled during laundry (intermittent exposure)	Professionals, General public (adult)

Industrial exposure

TWP 094i may be applied in an industrial setting by fully-automated dipping, automated flow-coating/deluging, and automated spraying, and the double vacuum/low pressure process.

Scenario [1.1]: Mixing and loading by industrial users

TWP 094i is a ready-to use (RTU) for the industrial processes fully-automated dipping, automated flow-coating/deluging, and automated spraying; for use in low pressure impregnation the product is diluted (with water to a ~ 10% in-use solution) in the automated treatment equipment. For industrial use, the product is supplied in 120 L, 200 L and 1000 L containers with a standardised screw cap to allow a tight seal with connecting lines to application equipment. It is expected that the mixing/loading (transfer/pumping) process is a fully automated procedure in a closed system. The descriptions of 'Dipping and deluging', and of 'Vacuum-pressure and double-vacuum impregnation' in TNsG, Part 2 (June 2002), p. 44 and 41, respectively, note that exposure during connection and disconnection of transfer lines would be incidental. Consequently, exposure associated with the mixing and loading task is considered negligible (or accidental) compared to other related tasks (i.e. the application phase), and thus does not need to be included as a source of exposure according to the 'Comments: For automated transfer/pumping' of HEEG Opinion 1, p. 8 ('HEEG Opinion 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'). The following RMM is applicable to the industrial Mixing and loading task: TWP 094i must only be loaded into industrial application equipment via a fully-automated pumping/transfer system.

Scenario [1.2]: Application – Fully-automated dipping

TWP 094i is ready-to-use for application by industrial users by fully-automated dipping. The fully-automated dipping process includes the following operations according to HEEG Opinion 18 ('For exposure assessment for professional operators undertaking industrial treatment of wood by fully-automated dipping'): wooden articles are treated in a batch process or as a continuous process (conveyor belt/rack treatment). In a batch process, prior to dipping, the untreated wooden articles are bundled into piles held together by tension straps. The untreated wood is placed by a forklift onto a hydraulic lifting/lowering devise which is an integral part of the dip tank. This hydraulic devise lowers – and as necessary holds – the timber below the fluid in the dip tank. After a predetermined period in the dip tank, the wood is raised and excess preservative fluid is allowed to drain back into the dip tank. The wet/damp treated wood is then transferred using the forklift to a storage area to dry.

The most appropriate model available is Handling Model 1, which is for the professional intermittently handling of water-wet or solvent-damp wood and associated equipment [TNsG, Part 2 (June 2002), pp. 160 - 161 – updated by User Guidance version 1 (2002), page 26]. In fully-automated dipping, wet treated timber is not normally handled manually, though as a worse case for fully-automated dipping HEEG Opinion 18 assumes that once per day (i.e. 1 of four treatment cycles), the wet treated has to be manually handled/re-stacked/re-positioned. On automated dipping, exposure is expected to occur during every cycle.

Description of Scenario [1.2]: Application by fully-automated dipping

The ready-to-use (RTU) product containing 0.75% w/w IPBC and 0.25% Permethrin is used for wood preservation by fully-automated dipping in an industrial setting (chronic exposure).

Automated dipping includes the following operations: an operator using a fork-lift truck or similar equipment lowers the wood into the dipping tank or transfers the wood to a bathing tray. The wood stays in the wood preservative for a few minutes or for a few hours before being lifted out of the tank by the fork-lift truck (or similar). The wood is then transferred by the fork-lift truck (or similar) to a storage area where it is placed to dry. The operator exposure arises from handling of the treated wood.

Model: According to HEAdhoc Recommendation no. 6 'Methods and models to assess exposure to biocidal products in different product types, version 4' (2020), Handling model 1, TNsG Part 2, pp. 160 - 161 (intermittent manual handling by professionals of water-wet wood and associated equipment in an industrial setting) has been considered. The model includes application and post-application exposures. The duration default value of exposure for automated dipping is 4 cycles of several minutes to 60 minutes pr. day (HEEG Opinion 8 'Defaults and appropriate models to assess human exposure for dipping processes (PT8)', 2009). As a relative worse case for fully-automated dipping it is assumed that once per day wet treated wood has to be manually handled/re-stacked/re-positioned (HEEG Opinion 18 'For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping', compared to automated processes in which exposure is expected to occur during every cycle. The total exposure is thus reduced by a factor of 4. The indicative values used in the scenario calculations are from HEAdhoc Recommendation no. 6; the indicative value for hand exposure is an 'inside glove' value. An indicative value is available for 'used gloves' and for 'new gloves'; HEAdhoc Recommendation no. 6 defines new gloves as gloves that are replaced in (i.e. after) every cycle. Tier 1 and 2a of this scenario consider 'new gloves', while Tier 2b considers used gloves.

According to HEEG Opinion 9 (TM I, 2010) it is assumed that industrial operators a wear coated coverall when handling wet wood preservatives, however use of a coated coverall is first included in Tier 2.

Professionals working in industrial plants are expected to wear impermeable footwear.

HEEG Opinion 8 states that for fully-automated dipping, inhalation exposure resulting from aerosol formation should be negligible. When the low vapour pressure of IPBC and Permethrin are also considered (IPBC: 0.0045 Pa at 25°C; PT13 CAR, CA DK, 2013 (equivalent to 0.0032 Pa at 20°C); Permethrin: 2.2 x 10^{-6} Pa at 20°C; PT8 CAR, CA IE, 2014), exposure due to inhalation is considered negligible.

Tier	Parameters	Value
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Dermal penetration of IPBC	29% (based on read-across to a similar formulation containing 0.75% IPBC)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight of user [1]	60 kg
	Vapour pressure of IPBC	3.2 × 10^{-3} Pa (at 20°C)
	Vapour pressure of Permethrin	2.2 x 10^{-6} Pa (at 20°C)
	Cycles (for fully-automated dipping): data from HEEG Opinion 8, Defaults and appropriate models to assess human exposure for dipping processes (PT 8).	4 cycles/day, with exposure during 1 cycle (i.e. total exposure reduced by a factor of 4).

	Number of cycles during which exposure would occur: data from HEEG Opinion 18, For exposure assessment for professional operators undertaking industrial treatment of wood by fully-automated dipping.	
	Indicative values [2, 4]	Hands: 1080 mg/cycle (inside used gloves); 540 mg/cycle (inside new gloves) [5]. Value for new gloves selected for Tier 1 Body: 8570 mg/cycle
Tier 2a	New gloves Clothing penetration factor (coated coverall) [3]	540 mg/cycle 10%
Tier 2b	Used gloves Clothing penetration factor (impermeable coverall) [3]	1080 mg/cycle 5%

[1] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG-III-2017).

[2] Handling model 1, water-based product, TNsG 2002, part 2, pp. 160 - 161.

[3] HEEG Opinion 9, Default protection factors for protective clothing and gloves (TM I, 2010).

[4] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types, version 4, 2020.

[5] 'New gloves' are defined (in HEAdhoc Recommendation no. 6) as gloves that are replaced in (after) every cycle.

Calculations for Scenario [1.2]: Application by fully-automated dipping

(The calculation sheets is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure from application by fully-automated dipping					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [1.2]	Tier 1 / New gloves*	-	0.3302	-	0.3302
Scenario [1.2]	Tier 2a / New gloves, coated coverall	-	0.0506	-	0.0506
Scenario [1.2]	Tier 2b / Used gloves, imperm-eable coverall	-	0.0547	-	0.0547
Permethrin					
Scenario [1.2]	Tier 1 / New gloves*	-	0.1898	-	0.1898
Scenario [1.2]	Tier 2a / New gloves, coated coverall	-	0.0291	-	0.0291
Scenario [1.2]	Tier b / Used gloves, imperm-eable coverall	-	0.0314	-	0.0314

* The model used provides an indicative value for hands is 'inside gloves', thus use of gloves is considered at Tier 1.

Scenario [1.3]: Application – Automated flow-coating/deluging and automated spraying

Description of Scenario [1.3]: Automated flow-coating/deluging and automated spraying
During automated flow-coating/deluging, wood passes through an enclosed tunnel in which a wood preservative is poured/flooded onto the wood, or sprayed in the case of automated spraying. Due to its contained nature, operator exposure is expected to be low, and mainly constitutes handling of freshly treated wood as it leaves the treatment tunnel. The exposure is chronic. Although there is no generic model available for automated flow-coating, the professional dipping model is considered a good approximation for assessing exposure from the deluging process according to TNsG User Guidance, version 1, 2002, p. 44. Dipping Model 1 is the proposed exposure model for professional deluging in HEAdhoc Recommendation no. 6, version 4, May 2020, p. 26. Dipping Model 1 covers exposure of industrial users and considers exposure associated with dipping wooden articles, mixing/loading, handling wet articles and loading/unloading. Deluging processes are operated on a batch basis, assuming as a worst case one batch per day, with a duration of 60 minutes per event. The indicative values used in the scenario calculations are from HEAdhoc Recommendation no. 6; the indicative value for hand exposure is an 'inside glove' value. Although Dipping Model 1 is stated to be a good approximation for assessing exposure from the deluging process, the fact that it incorporates a mixing and loading task, and includes manual tasks that can be expected to result in more frequent contact with freshly treated wood compared to automated flow-coating/deluging, suggests that the model may overestimate exposure associated with automated flow-coating/deluging.

According to HEEG Opinion 9 (TM I, 2010) it is assumed that industrial operators a wear coated coverall when handling wet wood preservatives, however use of a coated coverall is first included in Tier 2a. Professionals working in industrial plants are expected to wear impermeable footwear. Similar to automated flow-coating/deluging, automated spraying is assumed to be an essentially fully enclosed process during wood is sprayed with a wood preservative as it passes through an enclosed tunnel. Due to its contained nature, operator exposure is expected to be low, and mainly constitutes handling freshly treated wood as it leaves the treatment tunnel. The description of the deluging process in TNsG User Guidance, version 1, 2002, p. 44, describes application of wood preservative via various types of spray jet as timber passes through an enclosed tunnel. Consequently, the model (Dipping Model 1) used to calculate exposure associated with flow-coating/deluging is considered applicable to automated spraying.		
Tier	**Parameters**	**Value**
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Dermal penetration of IPBC	29% (based on read-across to a similar formulation containing 0.75% IPBC)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight of user [1]	60 kg
	Inhalation rate [1]	1.25 m^3/h
	Number of treatment cycles [2]	1/day
	Duration of treatment cycle [2]	60
	Indicative values: [2]	Hands inside gloves: 25.7 mg/min Body:178 mg/min Inhalation < 1 mg/m^3
Tier 2a	Clothing penetration factor (coated coverall) [3]	10%
Tier 2b	Clothing penetration factor (impermeable coverall) [3]	5%

[1] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG-III-2017).

[2] HEAdhoc Recommendation no. 6, Methods and models to assess exposure to biocidal products in different product types, p. 22 (version 4, 2020).

[3] HEEG Opinion 9, Default protection factors for protective clothing and gloves (TM I, 2010).

Calculations for Scenario [1.3]: Application by automated flow-coating/ deluging or automated spraying

(The calculation sheet is provided in Annex 3.2.1)

Summary table: estimated systemic exposure from application by automated flow-coating/deluging or automated spraying					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [1.3]	Tier 1 / Gloves*	0.0002	0.4430	-	0.4432
Scenario [1.3]	Tier 2a / Gloves, coated coverall	0.0002	0.0946	-	0.0948
Scenario [1.3]	Tier 2b / Gloves, imperm-eable coverall	0.0002	0.0753	-	0.0754
Permethrin					
Scenario [1.3]	Tier 1 / Gloves*	0.0001	0.2546	-	0.2547
Scenario [1.3]	Tier 2a / Gloves, coated coverall	0.0001	0.0544	-	0.0544
Scenario [1.3]	Tier 2b / Gloves, imperm-eable coverall	0.0001	0.0433	-	0.0433

* The model considered provides an indicative value for hands is 'inside gloves', thus use of gloves is considered at Tier 1.

Scenario [1.4]: Application: Double vacuum/low pressure process

Description of Scenario [1.4]: Double vacuum/low pressure process
In the double vacuum/low pressure process, wood absorbs preservative solution under pressure. The wood is moved into and out of the treatment vessels using lift trucks or flatbeds on rails, however operators can be involved manually, for example when handling restraining straps and treatment machinery, and retrieving fallen wood. The exposure is chronic. Dermal contamination occurs through direct contact with surface of treated timber and through contact with ancillary equipment and contaminated process plant. Handling model 1 is used to model exposure (TNsG 2002, part 2, pp. 161 - 162; HEAdhoc Recommendation no. 6, version 4.0, May 2020, pp. 19-20). Hand exposure is dependent on how gloves are used and the degree of contamination. The model's tier I takes into consideration that product will come inside the gloves and act as a potential source of exposure. Inhalation exposure time is assumed to be 60 minutes, which is the time spent with the door of the treatment chamber open for 6 cycles (the values of 60 minutes is twice that given for 3 cycles of vacuum pressure impregnation in Biocides Human Health Exposure Methodology (BHHEM), 2015, p. 120; HEAdhoc Recommendation no. 6, p. 20). The indicative values used in the scenario calculations are from HEAdhoc Recommendation no. 6; the indicative value for hand exposure is an 'inside glove' value. According to HEEG Opinion 9 (TM I, 2010) it is assumed that industrial operators wear a coated coverall when handling wet wood preservatives, however, use of a coated coverall is first included in Tier 2.

Professionals working in industrial plants are expected to wear impermeable footwear. When used for the double vacuum/low pressure process, TWP 094i is diluted with water to a ~ 10% in use solution, thus an IPBC concentration of 0.075% w/w and a Permethrin concentration of 0.025% w/w are used in the exposure calculations for Scenario 1.4.		
Tier	**Parameters**	**Value**
Tier 1	IPBC concentration (in-use solution of TWP 094i)	0.075% (w/w)
	Permethrin concentration (in-use solution of TWP 094i)	0.025% (w/w)
	Dermal penetration of IPBC	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight of user [1]	60 kg
	Vapour pressure of IPBC	3.2×10^{-3} Pa (at 20°C)
	Vapour pressure of Permethrin	2.2×10^{-6} Pa (at 20°C)
	Cycles [2, 4]	3 cycles/day for vacuum pressure impregnation 6 cycles/day for double vacuum pressure impregnation (used as the worst case)
	Indicative values [3, 4]	Hands: 1080 mg/cycle (inside used gloves) Body: 8570 mg/cycle
	Inhalation exposure time (opening the door, for 3 cycles) [4]	30 min for 3 cycles Hence 60 minutes for 6 cycles
	Inhalation rate [1]	1.25 m^3/hour
Tier 2	Clothing penetration factor (coated coverall) [5]	10%

[1] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[2] TNsG 2002, part 2, p. 75.

[3] Handling model 1, water-based product, TNsG 2002, part 2, pp. 160-161.

[4] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types, version 4, 2020.

[5] TNsG 2007, Table 2, p. 19, in HEEG Opinion 9, Default protection factors for protective clothing and gloves (TM I, 2010).

Calculations for Scenario [1.4]: Application by double vacuum/low pressure process

(The calculation sheet is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure from application by double vacuum/low pressure process					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [1.4]	Tier 1 / Gloves*	0.0003	0.3619	-	0.3622
Scenario [1.4]	Tier 2 / Gloves, coated coverall	0.0003	0.0726	-	0.0729
Permethrin					
Scenario [1.4]	Tier 1 / Gloves*	0.0001	0.1206	-	0.1207
Scenario [1.4]	Tier 2 / Gloves, coated coverall	0.0001	0.0242	-	0.0243

* The model considered provides an indicative value for hands is 'inside gloves', thus use of gloves is considered at Tier 1.

Scenario [1.5]: Post-application – Handling of treated articles

Exposure from handling of treated articles (water wet or solvent damp) may occur after the application process. This scenario is covered by the calculations as presented for Scenario [1.2], which covers application and post application processes (Handling model 1 for water-based products, TNsG Part 2, p. 160).

Scenario [1.6]: Post-application – maintenance/cleaning of the system

Potential exposure may occur during maintenance, testing/repair of the automated application system (hoses, valves, connecting lines, etc.). In these cases, contamination could occur by the dermal route. However, such tasks are expected to be rare and of short duration, and that the pumping/transfer system is decontaminated before maintenance work is performed. The rationale for not considered eventual exposure during the Mixing and loading task is considered applicable to the tasks in this scenario.

Cleaning of application systems is also a potential source of exposure, and varies between industries/automated processes. According to HEEG Opinion no. 8 (TM III, 2009), a survey of 24 companies found that dipping tanks were cleaned with frequencies ranging from twice a year (only one company) to every fifth year, and thus is considered an acute exposure. At 19 companies, the cleaning was performed by in-house workers, thus this task can be considered relevant. There is no generic model for cleaning of industrial dipping tanks, though Handling Model 1 (identified in HEAdhoc Recommendation no. 6, version 4, May 2020, as an appropriate model for intermittent handling of water-wet wood and associated equipment), can be used as a surrogate. As it can be expected that the use of PPE is mandatory during such tasks, and that the task is a single event, the Tier 2a exposure value (i.e. 0.0506 mg/kg bw/day for IPBC and 0.0291 mg/kg bw/day for Permethrin) from Scenario [1.2] Application by fully-automated dipping (in which Handling Model 1 was used) can be considered applicable.

Combined scenarios

No relevant combined scenarios are identified for industrial uses on the basis that: a) chronic exposure from two or more sources is not expected to occur (it is assumed that only a single application task will be performed daily, b) that Mixing and loading (transfer form product packs to application equipment) is fully automated, resulting in negligible exposure, and c) occasional exposure during maintenance/testing of the application system is considered negligible compared to that during the application phase, such that occasional (~ once-yearly) cleaning of the dipping tank is the only relevant acute exposure. Theoretically, automated dipping (a chronic exposure) and cleaning of the dipping tank (an acute exposure) could be performed by the same worker on the same day. In this regard, Point 'TOX 37' for PT8 of the Technical Agreements for Biocides (TAB) – TOX v.2.0 (of 09.11.2018) states: "*exposure during the application and post-application tasks should be assessed but not combined in those cases where the post-application scenario is not a long-term scenario"*. As the cleaning task is a rare event, the combination of the two tasks can be evaluated as an acute exposure. The Tier 2a exposure value for Scenario [1.2] 'Application by fully-automated dipping' was used for both the application task (as the Tier 1 exposure was unacceptable) and for the cleaning task (as it was assumed that PPE equal to that in Tier 2a of the application task was used, and that the cleaning task is a rare event, such that the reduction factor in Tier 2a of the application task is also applicable to the cleaning task). Consequently in the risk characterisation, an exposure twice the Tier 2a value for Scenario [1.2] (i.e. 2 x 0.0506 mg/kg bw/day for IPBC and 2 x 0.0291) was compared to the short-term AEL.

Although there are potential sources of secondary exposure for an industrial user (i.e. touching treated dry wood at their workplace, exposure from volatilised residues indoors), the exposure is considered to be negligible (please refer to the calculations performed for Scenario 4.1[16] and Scenario 8, respectively). Secondary exposure from laundering work clothing at home (Scenario 9 for professional and general public) is not applicable for industrial users as they would not clean their work clothing (coated coverall).

Professional exposure

TWP 094i may be applied by professionals by manual dipping and brushing/rolling.

Scenario [2.0]: Mixing and loading by professional users prior to manual dipping

The description of Manual Dipping Model 1 (TNsG part 2, p. 167; Biocides Human Health Exposure Methodology document, version 1 (2015), p. 199) used to model exposure on professional manual dipping considers a worker carrying out a range of dipping activities (including mixing/diluting formulations, handling wet articles, machine minding and loading/unloading) involving a variety of articles. While the scenario can be considered quite extensive in its coverage of potential situations in which the professional worker

[16] Exposure of industrial users at Tier 2 (it is assumed that industrial workers use gloves when handling treated wood) is 0.2% and 0.34% of the long-term AEL for IPBC and Permethrin, respectively.

may be exposed to a biocidal product when performing manual dipping, it does not cover filling and topping-up of the dipping tank, or drainage and refilling. Models for identifying exposure when performing such tasks have been included in HEAdhoc Recommendation no. 6, version 4, May 2020.

According to Recommendation no. 6 (p. 20), Option 1: Manual mixing and loading (based on Mixing and loading model 4) is the recommended approach for repeated manual loading of small quantities of a biocidal product. Option 2: Semi-automated Mixing and loading (based on the RISKOFDERM Potential Dermal Exposure Model) may be considered for loading using a hand-operated pump, especially in the case of drums < 20 L, if manual pouring results in a risk. TWP 094i is available to professionals in pack sizes ranging from 0.375 L to 25 L. It is expected that larger pack sizes will be used to fill/re-fill a dipping tank, and that semi-automated or automated transfer will be used for pack sizes of ~ 20 L or greater. Consequently, the semi-automated mixing and loading model has been selected from HEAdhoc Recommendation no. 6. However, in order to determine the risk posed by repeated manual loading of smaller volumes of TWP 094i, exposure associated with manual loading of a volume of TWP 094i equal to that considered in the model for semi-automated or automated transfer (i.e. 100 L) loaded as 5 product pack each of 20 L has also estimated.

Description of Scenario [2.0]: Mixing and loading by professionals prior to manual dipping

Manual mixing and loading

To evaluate exposure on manual dipping tank by a professional, Mixing and loading model 4 was used to estimate exposure to IPBC and Permethrin. The model does not estimate body exposure. Inhalation exposure to aerosol is not considered relevant in the model. As IPBC and Permethrin are non-volatile (the vapour pressure of IPBC (0.0045 Pa at 25°C; PT13 CAR, CA DK, 2013), equivalent to 0.0032 Pa at 20°C, and the vapour pressure of Permethrin (2.2×10^{-6} Pa at 20°C; PT8 CAR, CA IE, 2014) are well below the value of >10 mPa at 20°C used to define a volatile substance HEAdhoc Recommendation no. 10, p. 6), exposure to vapour is not relevant. The model provides an indicative value for hand exposure of 0.5 mL biocidal product per loading, based on loading of 5 product packs each of 20 L. Exposure to IPBC and Permethrin on manual loading of 100 L TWP 094i is calculated as:

Exposure (mL) b.p. per loading * 1000 (conversion factor for mL to mg) * density of b.p. (g/cm^3) * number of loadings * a.s. concentration (%)

Thus exposure to IPBC is:

= 0.5 * 1000 * 1.01 * 5 * (0.75/100) = 18.938 mg

And systemic exposure to IPBC is calculated as:

(Exposure (mg) * dermal absorption (%)) / body weight (kg)

= (18.938 * (29/100) / 60 = 0.0915 mg/kg bw at Tier 1 (no PPE)

equivalent to 0.0092 mg/kg bw at Tier 2 (PPE = gloves, 90% protection)

Likewise, exposure to Permethrin is:

= 0.5 * 1000 * 1.01 * 5 * (0.25/100) = 6.313 mg

And systemic exposure to Permethrin is calculated as:

(Exposure (mg) * dermal absorption (%)) / body weight (kg)

= (6.313 * (50/100) / 60 = 0.0526 mg/kg bw at Tier 1 (no PPE)

equivalent to 0.0053 mg/kg bw at Tier 2 (PPE = gloves, 90% protection)

Semi-automated Mixing and loading

To evaluate exposure on semi-automated pouring/mixing and loading of a manual dipping tank by a professional, the RISKOFDERM *Potential Dermal Exposure Model* calculator was used to estimate exposure to IPBC and Permethrin (process for assessment: Filling, mixing or loading; level of automation: Automated or semi-automated task), and assuming negligible inhalation exposure. The model does not estimate body exposure. No significant amounts of aerosol are foreseen. As IPBC and Permethrin are non-volatile (as noted in the description of the Manual mixing and loading model), exposure to vapour is not relevant. Assuming a daily exposure duration of 10 minutes and a product transfer rate of 10 L/min (giving a daily transfer of 100 L product), a hand exposure of 13.5 mg/min was calculated. Tier 2 considers the use of gloves.

Tier	**Parameter**	**Value**
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Dermal penetration of IPBC	29% (based on read-across to a similar formulation containing 0.75% IPBC)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight of user [2]	60 kg
	Exposure duration [1]	10 min
	Transfer rate of product [1]	10 L/min (as a worst case)
	Dermal exposure, hands (90% percentiles) [1]	13.5 mg/min
	Indicative dermal exposure, body [1]	No exposure foreseen
	Indicative inhalation exposure [1]	Negligible; normal or good ventilation
Tier 2	Gloves [3]	90% protection

[1] Calculated for semi-automated pouring/mixing and loading using the RISKOFDERM Potential Dermal Exposure Model, as recommended in 'Option 2: Semi-automated mixing and loading' of Scenario No. 22 in Table 1 of HEAdhoc Recommendation. no. 6, version 4, May 2020.

[2] HEEG Opinion no. 17 - Default human factor values for use in exposure assessment for biocidal products.

[3] HEEG Opinion 9, Default protection factors for protective clothing and gloves (TM I, 2010).

Calculations for Scenario [2.0]: Mixing and loading by professionals prior to manual dipping

(The calculation sheet is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure from manual Mixing and loading by professionals prior to manual dipping					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Manual mixing and loading					
Scenario [2.0.1]	Tier 1 /	-	0.0915	-	0.0915
Scenario [2.0.1]	Tier 2 / Gloves	-	0.0092	-	0.0092
Semi-automated Mixing and loading					
Scenario [2.0.2]	Tier 1 /	-	0.0049	-	0.0049
Scenario [2.0.2]	Tier 2 / Gloves	-	0.0005	-	0.0005
Permethrin					
Manual mixing and loading					
Scenario [2.0.1]	Tier 1 /	-	0.0526	-	0.0526
Scenario [2.0.1]	Tier 2 / Gloves	-	0.0053	-	0.0053
Semi-automated Mixing and loading					
Scenario [2.0.2]	Tier 1 /	-	0.0028	-	0.0028
Scenario [2.0.2]	Tier 2 / Gloves	-	0.0003	-	0.0003

Scenario [2.1]: Mixing and loading by professional users prior to brushing/rolling

In connection with professional application by brushing and rolling, exposure may occur during decanting or pouring of the product (from larger pack sizes) into a receiving vessel (i.e. painting pot or roller tray) prior to application. This loading exposure has been estimated using Mixing and Loading Model 7 (TNsG 2002, part 2, p. 140) that is suitable for repeated loading.

Description of Scenario [2.1]: Manual Mixing and loading by professionals prior to brushing/rolling
The ready-to-use (RTU) product containing 0.75% w/w IPBC and 0.25% w/w Permethrin is used for wood preservation by loading in a receiving vessel before brush and roller application by a professional (chronic exposure). Model: Mixing and Loading Model 7, TNsG 2002 part 2, p. 140 and HEEG Opinion 1 M&L Model 7, Liquid manual loading/pouring. This model estimates dermal and inhalation exposure according to HEEG Opinion 1 (2008). The Excel spreadsheet embedded in the Biocides Human

Health Exposure Methodology document, version 1 (2015), p. 52, gives a task duration of 10 minutes/day for a professional mixing and loading a RTU product prior to brush and roller application.		
Tier	**Parameters**	**Value**
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Dermal penetration of IPBC	29% (based on read-across to a similar formulation containing 0.75% IPBC)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight of user [1]	60 kg
	Exposure duration [2]	10 minutes
	Indicative exposure values from model [3]	Hands (without gloves): 101 mg/min Inhalation: 0.94 mg/ m^3
Tier 2	Indicative exposure values from model (Hand exposure with gloves) [3]	1.01 mg/min

[1] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[2] Biocides Human Health Exposure Methodology, version 1, 2015.

[3] TNsG 2002 part 2, p. 140 and HEEG Opinion 1 M&L Model 7, Liquid manual loading/pouring.

Calculations for Scenario [2.1] – Manual Mixing and loading by professionals prior to brushing/rolling

(The calculation sheet is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure from manual Mixing and loading by professionals prior to brushing/rolling					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [2.1]	Tier 1 /	0.00002	0.0366	-	0.0366
Scenario [2.1]	Tier 2 / Gloves	0.00002	0.0004	-	0.0004
Permethrin					
Scenario [2.1]	Tier 1 /	0.00001	0.0210	-	0.0210
Scenario [2.1]	Tier 2 / Gloves	0.00001	0.0002	-	0.0002

Scenario [2.2]: Application – Manual dipping indoors by professionals

Description of Scenario [2.2] – Manual dipping indoors by professionals		
The ready-to-use (RTU) product containing 0.75% w/w IPBC and 0.25% w/w Permethrin is used for wood preservation by manual dipping indoors by a professional (chronic exposure). Model: Dipping model 1, TNsG Part 2, p 167 (professional operators during manual dipping in open tanks (wooden articles), includes application and post application exposures). The model considers professionals carrying out a range of dipping activities (including mixing/diluting formulations, handling wet articles, machine minding and loading/unloading) involving a variety of articles. The model reflects conditions where operatives may contact treatment fluids and wet objects and the exposures are expressed as mg/min in-use product. Hand exposure is actual exposure inside gloves. Professionals performing manual dipping are expected to wear impermeable footwear. The model assumes negligible inhalation exposure (< 1 mg/m^3).		
Tier	**Parameters**	**Value**
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Dermal penetration of IPBC	29% (based on read-across to a similar formulation containing 0.75% IPBC)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight of user [1]	60 kg
	Exposure duration [2]	30 minutes daily
	Indicative dermal exposure values [3]	Hands (inside gloves): 25.7 mg/min Body: 178 mg/min Inhalation: < 1 mg/m^3
Tier 2	Clothing penetration factor (coated coverall) [4]	10%

[1] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[2] HEEG Opinion 8, Defaults and appropriate models to assess human exposure for dipping processes (PT 8), 2009, and HEAdhoc Recommendation no. 6, Methods and models to assess exposure to biocidal products in different product types, version 4, 2020.

[3] Dipping model 1, TNsG 2002, part 2, p. 167, and HEAdhoc Recommendation no. 6, Methods and models to assess exposure to biocidal products in different product types, version 4, 2020.

[4] HEEG Opinion 9, Default protection factors for protective clothing and gloves (TM I, 2010).

Calculations for Scenario [2.2]: Manual dipping indoors by professionals

(The calculations sheets are provided in Annex 3.2.1.)

Summary table: estimated systemic exposure from manual dipping indoors by professionals					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [2.2]	Tier 1 / Gloves*	-	0.2215	-	0.2215
Scenario [2.2]	Tier 2 / Gloves, coated coverall	-	0.0473	-	0.0473
Permethrin					
Scenario [2.2]	Tier 1 / Gloves*	-	0.1273	-	0.1273
Scenario [2.2]	Tier 2 / Gloves, coated coverall	-	0.0272	-	0.0272

* The model considered provides an indicative value for hands is 'inside gloves', thus use of gloves is considered at Tier 1.

Scenario [2.3]: Application – Brushing and rolling by professionals

Description of Scenario [2.3]: Application – Brushing and rolling by professionals

The ready-to-use (RTU) product containing 0.75% w/w IPBC and 0.25% w/w Permethrin is used for wood preservation by brushing and rolling outdoors and indoors by a professional (chronic exposure). Application indoors relates to wooden objects painted in a workshop or the like prior to installation compliant with Use class 2 or 3.

Model: 'Professional brush treatment' for liquid PT8 product in the Biocides Human Health Exposure Methodology (BHHEM), version 1, October 2015, p. 120, and in HEAdhoc Recommendation no. 6, version 4, May 2020. The following assumptions are considered in the model: application area: 31.6 m², exposure duration: 240 min. Application area is calculated using a median work rate of 7.6 min/m² (according to TNsG 2002 'Consumer product painting Model 3'; parameters for non-professional paint application, p. 78) and the exposure duration of 240 min; calculation of application area: 1/7.6 min/m² x 240 min = 31.6 m².

The indicative values for dermal and inhalation exposure are normalized to 1% active substance and are referring to the exposure when brushing an area of 1 m² (according to *Summary Report – Human Exposure to Wood Preservatives*, Lingk et al., 2006).

The vapour pressure of IPBC is 0.0045 Pa at 25°C (PT13 CAR, CA DK, 2013), equivalent to 0.0032 Pa at 20°C (calculated according to the Guidance on BPR: Vol IV Environment Parts B+C (2017), pp. 32-33), which is well below the value of > 10 mPa at 20°C used to define a volatile substance in HEAdhoc Recommendation no. 10, p. 6. Likewise, the vapour pressure of Permethrin (0.0000022 Pa at 20°C (PT8 CAR, CA IE, 2014)) is well below the threshold used to define a volatile substance. Consequently, the indicative value for inhalation exposure for a non-volatile compound as given for the model in the BHHEM is appropriate, and the model's requirement to also consider exposure to vapour is not applicable. As exposure to IPBC and Permethrin vapour is not relevant, the model is considered applicable to application of a PT8 product indoors. (See also the corresponding information regarding non-professional application indoors by brushing/rolling in Scenario [3.2].)

The indicative values identified in the 'Professional brush treatment' model in the BHHEM

(2015) are based on the aforementioned study of Lingk et al. (2006), which was recently used in HEAdhoc Recommendation no. 10 'The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling' (May 2020) to derive the indicative values for dermal exposure to water-based paint or solvent-based paint on non-professional application by brushing and rolling. Thus while the recommendation is stated to apply to non-professional application it could be argued that it is also applicable to professional application by brushing and rolling. As the duration of professional brushing/rolling is set to 240 minutes, the Tier 1 exposure for a professional applying TWP 094i by brushing and rolling can be obtained by adjusting the value for the non-professional (calculated in Scenario [3.2]) to account for the shorter duration (155 minutes) in the non-professional model, i.e.:

(Systemic exposure for non-professional (mg/kg bw/d) / 155) * 240

= (0.0334 / 155) * 240 = 0.0517 mg/kg bw/d

This value is ~ 57% (0.0517 vs. 0.0900 mg/kg bw/d) of that generated by the 'Professional brush treatment' model in the BHHEM (2015), thus the BHHEM model is a worse case.

As IPBC and Permethrin are both skin sensitisers, it is expected that professionals will use appropriate gloves and a coated coverall and to mitigate dermal exposure; use of such PPE is included as Tier 2.

Tier	**Parameters**	**Value**
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Dermal penetration of IPBC	29% (based on read-across to a similar formulation containing 0.75% IPBC)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight of user [1]	60 kg
	Exposure duration [2]	240 min
	Application area [2]	31.6 m^2
	Indicative values (normalised to 1% a.s.) [2]	Hands: 0.5417 mg/m^2 Body: 0.2382 mg/m^2 Inhalation (non-volatile compounds): 0.0016 mg/m^2
Tier 2	Gloves [3]	90% protection
	Clothing penetration factor (coated coverall) [3]	10%

[1] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[2] HEAdhoc Recommendation no. 6, Methods and models to assess exposure to biocidal products in different product types, version 4, 2020.

[3] HEEG Opinion 9, Default protection factors for protective clothing and gloves (TM I, 2010).

Calculations for Scenario [2.3]: Application – Brushing and rolling by professionals

(The calculation sheet is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure to IPBC from brushing and rolling by professionals					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [2.3]	Tier 1 / None	0.0006	0.0893	-	0.0900
Scenario [2.3]	Tier 2 / Gloves, coated coverall	0.0006	0.0089	-	0.0096
Permethrin					
Scenario [2.3]	Tier 1 / None	0.0002	0.0513	-	0.0516
Scenario [2.3]	Tier 2 / Gloves, coated coverall	0.0002	0.0051	-	0.0053

A post-application task which may lead to some degree of exposure is cleaning the brush or roller used to apply the product. A water-based formulation might be removed by washing the brush under a stream of tap water, a process that can be expected to result in negligible dermal exposure. Thus, as discussed at WG-III-2017, inclusion of a brush washing scenario may not be warranted for water-based products. The scenario has not been included for TWP 094i.

Scenario [2.4]: Post-application – Drainage and reloading of the manual dipping tank by professionals

As noted in the description of Scenario [2.0], Manual Dipping Model 1 (TNsG part 2, p. 167; Biocides Human Health Exposure Methodology document, version 1 (2015), p. 199), which is used to model exposure on professional manual dipping, is not considered to cover drainage and refilling of the dipping tank. According to HEAdhoc Recommendation no. 6, version 4, May 2020, the same models used to estimate exposure on filling and topping-up of the manual dipping tank can be used to model drainage and refilling of the dipping tank. In Scenario [2.0] only dermal exposure to TWP 094i was considered relevant. Consequently, exposure on drainage and reloading of the dipping tank, which assumes reloading with a volume of 200 L wood preservative, is double the exposure estimate on filling and topping-up with 100 L of TWP 094i calculated for 'Manual mixing and loading' and for 'Semi-automated Mixing and loading' in Scenario [2.0]. According to HEAdhoc Rec. no. 6, drainage and reloading of the manual dipping tank may be expected to occur at monthly intervals, and is thus considered an acute exposure.

Calculations for Scenario [2.4]: Post application – Drainage and reloading of the manual dipping tank by professionals

In the following, the results of the calculations for Scenario [2.0] have been multiplied by a factor of 2.

Summary table: estimated systemic exposure from drainage and reloading of the manual dipping tank by professionals					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Manual drainage and reloading					
Scenario [2.4.1]	Tier 1 / No PPE	-	0.1831	-	0.1831
Scenario [2.4.1]	Tier 2 / Gloves	-	0.0183	-	0.0183
Semi-automated drainage and reloading					
Scenario [2.4.2]	Tier 1 / No PPE	-	0.0098	-	0.0098
Scenario [2.4.2]	Tier 2 / Gloves	-	0.0010	-	0.0010
Permethrin					
Manual drainage and reloading					
Scenario [2.4.1]	Tier 1 / No PPE	-	0.1052	-	0.1052
Scenario [2.4.1]	Tier 2 / Gloves	-	0.0105	-	0.0105
Semi-automated drainage and reloading					
Scenario [2.4.2]	Tier 1 / No PPE	-	0.0056	-	0.0056
Scenario [2.4.2]	Tier 2 / Gloves	-	0.0006	-	0.0006

Secondary exposure of professionals

According to the *Technical Agreements for Biocides – Human Health (TOX)* v.2.0 (of 09.11.2018), Point 'TOX 36' for PT8, "*secondary exposure of professionals handling treated dried wood does not need to be assessed as it is covered by the exposure during the handling of wet wood after the application of the biocidal product. However, other types of secondary exposure to professionals (e.g. sanding treated wood) should still be assessed*".

Scenario [4.1]: Post-application - Cutting and sanding treated wood by professionals

Description of Scenario [4.1]: Cutting and sanding treated wood by professionals

This scenario is considered a chronic exposure scenario.

The model is the cutting and sanding scenario for non-professionals (scenario [4.2]) extrapolated to a scenario for professional (chronic exposure) by increasing the exposure time from 1 to 6 hours per day. As dermal exposure in the model is independent of exposure duration, the increase in exposure duration affects inhalation exposure only. Professionals may be instructed to wear a respiratory protection mask (RPE) when sanding treated wood, though as a worst-case scenario, inhalation exposure without RPE – resulting in an inhalation exposure 6-times higher than the 1-hour exposure set in scenario [4.2] – is assumed. It is assumed that professionals wear gloves when sanding for longer periods; use of such PPE is considered at Tier 2.

Please refer to 'Description of Scenario [4.2]: Cutting and sanding treated wood by non-professionals' for further information on the model.

Tier	Parameters	Value
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Application rate (maximum) of product	70.6 kg/m^3 (~ 140 mL/m^2)
	Density of product	1.01 g/mL
	Concentration of IPBC in the outer 1 cm layer of wood (Calculated for scenario [4.2])	0.141 mg/cm^3
	Concentration of Permethrin in the outer 1 cm layer of wood (Calculated for scenario [4.2])	0.047 mg/cm^3
	Dermal penetration of IPBC	29% (based on read-across to a similar formulation containing 0.75% IPBC)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight (adult) of user [1]	60 kg
	Duration (worker) of exposure [2]	6 h
	Hand area (palms of both hands) (adult) [1]	410 cm^2
	Assuming 40% of the area of both palms (410 cm^2) will be contaminated (adult) [5]	164 cm^2
	Dislodgeable fraction [3]	3%
	Generated dust/m³ of sanded treated wood [2]	5 mg/m^3 (8-hour time weighted average)
	Inhalation rate [1]	1.25 m^3/h
	Density of wood [4]	0.4 g/cm^3
Tier 2	Gloves [6]	90% protection

[1] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[2] TNsG User Guidance, version 1, 2002. p 52.

[3] For 'painted wood (MDF)' from 'Table: transfer coefficients – dislodgeable residues', p. 171, Biocides Human Health Exposure Methodology, version 1, 2015.

[4] Technical Agreements for Biocides (TAB) -TOX v.2.0 (November 2018).

[5] HEAdhoc Recommendation no. 5, Non-professional use of antifouling paints: exposure assessment for a toddler (2015).

[6] HEEG Opinion 9, Default protection factors for protective clothing and gloves (TM I, 2010).

Calculations for Scenario [4.1]: Cutting and sanding treated wood by professionals

(The calculation sheet is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure due to cutting and sanding of treated wood by professionals					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [4.1]	Tier 1 / no PPE	0.0002	0.0034	-	0.0036
	Tier 2 / Gloves	0.0002	0.0002	-	0.0004
Permethrin					
Scenario [4.1]	Tier 1 / no PPE	0.00001	0.0019	-	0.0020
	Tier 2 / Gloves	0.00001	0.0001	-	0.0002

Secondary exposure of a professional user to TWP 094i may also occur due to laundering of contaminated work clothes at home (Scenario [9]), and inhalation of volatilised residues at home (Scenario [8]). These scenarios are presented and calculated under the heading 'Exposure of the general public'.

Combined scenarios

In the following, the results of the combined exposure (application and post-application) of professionals to TWP 094i (RTU product) are provided. As a worst case for combined exposure, the exposures for Scenarios [2.0.2, 2.1, 2.2, 2.3, and 8] are summed, meaning that a professional loads a manual dipping tank (semi-automated Mixing and loading) and loads a painting pot prior to performing these tasks, applies the wood preservative by manual dipping and by brushing and rolling (all on the same work day), and inhales volatilised residues at home (i.e. lives in a building where the indoor surfaces of external window frames and of external door/doorframes have been treated with TWP 094i). It is not considered realistic to also include Scenario [4.1] Cutting and sanding treated wood in the worst-case combined scenario as this task alone has a duration of 6 hours. According to the *Technical Agreements for Biocides – Human Health (TOX)* v.2.0 (09.11.2018), Point 'TOX 37', "*exposure during the application and post application tasks should be assessed but not combined in those cases where the post-application scenario is not a long-term exposure scenario.*" Two post-application tasks the professional user may perform on a long-term basis, but which do not result in daily, long-term exposure are: a) maintenance (drainage and reloading) of the manual dipping tank (Scenario [2.4]), which according to HEAdhoc Recommendation no. 6, version 4, May 2020, is assumed to be performed monthly, and b) laundering work clothes, which in Scenario [9] was assumed to be performed once weekly. To evaluate the risk associated with these two, intermittent activities, the exposure to IPBC when performing

them is considered in relation to the worst-case chronic exposure in Section 2.2.6.3 Risk characterisation.

Summary table: estimated combined systemic exposure[1] from professional uses				
Scenarios combined	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC				
Scenarios [2.0.2, 2.1, 2.2, 2.3, 8]: Mixing & loading, application (manual dipping, brushing/rolling), and post-application (inhalation of volatised residues at home) (chronic exposures)	Tier 1 / No PPE*	0.0008	0.3524	0.3532
	Tier 2 / Gloves, during semi-automated mixing and loading prior to manual dipping [2.0.2] and mixing and loading prior to brushing/ rolling [2.1]; gloves, coated coverall during application by manual dipping and brushing/ rolling [2.2, 2.3]	0.0008	0.0571	0.0579
Permethrin				
As stated for IPBC	Tier 1 / No PPE*	0.0002	0.2025	0.2027
	As stated for IPBC	0.0002	0.0328	0.0330

[1] No oral exposure expected in any of the scenarios.

* No PPE unless included as a standard assumption in the recommended model (i.e. suitable protective gloves worn by professionals when performing manual dipping.

Non-professional exposure

Scenario [3.1]: Mixing/loading by non-professionals

Mixing and loading is not relevant, since TWP 094i is ready-to-use (RTU) for non-professional use and the model for application assumes that the product is used direct from the can.

Scenario [3.2]: Application – Brushing and rolling by non-professionals

Description of Scenario [3.2]: Application – Brushing and rolling by non-professionals
The ready-to-use (RTU) product containing 0.75% w/w IPBC and 0.25% w/w Permethrin is used, direct from the can, for wood preservation by brushing and rolling outdoors and indoors by a non-professional (acute exposure). Application indoors relates to wooden objects painted in a workshop or the like prior to installation compliant with Use class 2 or 3.

Model: Biocides Human Health Exposure Methodology (BHHEM), version 1, October 2015, p. 216, identifies 'Consumer product painting model 3' in TNsG (2002) Part 2, p. 202, (equivalent to TNsG 2007 '2. Brushing sheds and fences, outdoor (direct from can)') as the appropriate model for non-professional application by brushing/rolling. HEAdhoc Recommendation no. 10, 'The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling' (May 2020), has subsequently provided indicative values for dermal exposure to water-based paint or solvent-based paint, and notes that the indicative value for inhalation exposure in Consumer product painting model 3 is applicable to exposure to aerosol of the product during painting, and that exposure to vapour should be calculated for volatile substances. HEAdhoc Recommendation no. 10 does not distinguish between indoor and outdoor painting.

TWP 094i is a water-based product, and the corresponding indicative values for dermal exposure from HEAdhoc Recommendation no. 10 are used. The vapour pressure of IPBC is 0.0045 Pa at 25°C (PT13 CAR, CA DK, 2013), equivalent to 0.0032 Pa at 20°C (calculated according to the Guidance on BPR: Vol IV Environment Parts B+C (2017), pp. 32-33), which is well below the value of > 10 mPa at 20°C used to define a volatile substance HEAdhoc Recommendation no. 10, p. 6. Likewise, the vapour pressure of Permethrin (0.0000022 Pa at 20°C (PT8 CAR, CA IE, 2014)) is well below the threshold used to define a volatile substance. Consequently, the indicative value for inhalation exposure to a low-volatile substance has been selected, and exposure to IPBC and Permethrin vapour does not need be considered according HEAdhoc Recommendation no. 6.

Consumer Product painting model 3 assumes no clothing/100% clothing penetration in Tier 1. The model includes a few minutes stirring of the product in-can.

Exposure duration: 155 min for non-professionals (according to the Human Exposure to Biocidal Products (TNsG User Guidance, version 1, 2002, p. 48)).

Tier	Parameters	Value
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Dermal penetration of IPBC	29% (based on read-across to a similar formulation containing 0.75% IPBC)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight of user [1]	60 kg
	Exposure duration [2]	155 min
	Inhalation rate [1]	1.25 m³/h (0.021 m³/min)
	Indicative values (water-based paint, low volatility active substance) [3]	Hands: 4.07 µL/min Body: 1.7 µL/min Inhalation: 1.63 mg/m³
	No clothing/clothing penetration	100%

[1] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[2] TNsG User Guidance, version 1, 2002, p. 48.

[3] HEAdhoc Recommendation no. 10, The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling, May 2016.

Calculations for Scenario [3.2] - Brushing and rolling by non-professionals

(The calculation sheets is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure from brushing and rolling by non-professionals					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [3.2]	Tier 1 / No PPE	0.0007	0.0327	-	0.0334
Permethrin					
Scenario [3.2]	Tier 1 / No PPE	0.0002	0.0188	-	0.0190

A post-application task which may lead to some degree of exposure is cleaning the brush or roller used to apply the product. A water-based formulation might be removed by washing the brush under a stream of tap water, a process that can be expected to result in negligible dermal exposure. Thus, as discussed at WG-III-2017, inclusion of a brush washing scenario may not be warranted for water-based products. The scenario has not been included for TWP 094i.

Secondary exposure of non-professionals

Scenario [4.2]: Post-application - Cutting and sanding treated wood by non-professionals

Description of Scenario [4.2]: Cutting and sanding treated wood by non-professional

This scenario is considered an acute exposure scenario.

Model: This secondary exposure scenario is based on TNsG 2002 User Guidance – Version 1, pp. 51 - 52, and TNsG 2002, part III, p. 50. A person is sanding (power sander) the surface of penetratively treated wood (posts: 4 cm x 4 cm x 2.5 m, surface area 4032 cm², volume 4000 cm^3) for 1 h. Dermal- and inhalation exposure are considered. The model exposure data used in these calculations are derived from exposure studies on non-professionals where no gloves were worn.

TWP 094i is applied at a maximum rate of ~ 140 mL/m² (at a relative product density of 1.01 g/mL this is equivalent to 141.4 g/m²). The active substance is fixed in the outer 1 cm layer of the treated posts.

The concentration of the active substance (a.s) in the treated wood is calculated as follows:

Application rate product (g/m^2) x a.s. conc. in product (%) x retention in wood (%) x layer thickness (cm)

The amount of active substances present in the treated wood will then be:
Volume wooden post (cm^3) x conc. a.s. in wood (mg/cm^3) / treated volume of wooden post (cm^3)

IPBC:

Conc. IPBC in wood
141.4 g/m² x 0.75% a.s. x 100 % x 1 cm = 10.61 g/m² = 0.1061 mg/cm³

Conc. IPBC in treated outer 1 cm
4000 cm³ x 0.1061 mg a.s./cm³ / 3008 cm³ = 0.141 mg/cm³

Permethrin:

Conc. Permethrin in wood
141.4 g/m² x 0.25% a.s. x 100 % x 1 cm = 3.54 g/m² = 0.0354 mg/cm³

Conc. Permethrin in treated outer 1 cm
4000 cm³ x 0.0354 mg a.s./cm³ / 3008 cm³ = 0.047 mg/cm³

Inhalation route:
It is not possible to predict how much wood dust will be inhaled while sanding wood treated with a wood preservative. As a surrogate parameter, it is assumed that the wood dust concentration does not exceed the applicable Occupational Exposure Limit (OEL) of the EU for respirable hardwood dust, i.e. 5 mg/m³ (Directive 2004/37/EC); the same value is used in TNsG 2002. Exposure towards dust containing IPBC is considered a systemic exposure.

Dermal route:
40% (164 cm²) of the surface area of both palms (410 cm²) is assumed to be contaminated at 100% of the concentration of the active substance in the treated wood (as calculate above) (HEAdhoc Recommendation no. 5, 2015). Transfer efficiency is set at 3%, the value for 'painted wood (MDF)' from (*Biocides Human Health Exposure Methodology*, 2015, p. 171). Dermal exposure is independent of exposure duration.

(Note: Revision of this scenario to increase the duration of exposure from 1 h (as an acute exposure) to 6 hours (as a chronic exposure) is used to assess sanding of treated wood by professionals (Scenario [4.1]).)

Tier	**Parameters**	**Value**
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Application rate (maximum) of product	70.6 kg/m³ (~ 140 mL/m²)
	Density of product	1.01 g/mL
	Concentration of IPBC in the outer 1 cm layer of wood	0.141 mg/cm³
	Concentration of Permethrin in the outer 1 cm layer of wood	0.047 mg/cm³
	Dermal penetration of IPBC	29% (based on read-across to a similar formulation containing 0.75% IPBC)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight (adult) of worker [1]	60 kg
	Duration (worker) of exposure [2]	1 h
	Hand area (palms of both hands) (adult) [1]	410 cm²

	Assuming 40% of the area of both palms (410 cm^2) will be contaminated (adult) [5]	164 cm^2
	Dislodgeable fraction [3]	3%
	Generated dust/m^3 of sanded treated wood [2]	5 mg/m^3 (8-hour time weighted average, TWA)
	Inhalation rate [1]	1.25 m^3/h
	Density of wood [4]	0.4 g/cm^3

[1] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[2] TNsG User Guidance, version 1, 2002, p. 52.

[3] For 'painted wood (MDF)' from 'Table: transfer coefficients – dislodgeable residues', p. 171, Biocides Human Health Exposure Methodology, version 1, 2015.

[4] Technical Agreements for Biocides (TAB) -TOX v.2.0 (November 2018).

[5] HEAdhoc Recommendation no. 5, Non-professional use of antifouling paints: exposure assessment for a toddler (2015).

Calculations for Scenario [4.2]: Cutting and sanding treated wood by non-professionals

(The calculation sheet is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure due to cutting and sanding treated wood by non-professionals					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [4.2]	Tier 1 / no PPE	0.00004	0.0034	-	0.0034
Permethrin					
Scenario [4.2]	- Tier 1 / no PPE	0.00001	0.0019	-	0.0020

Scenario [4.3]: Post-application – Handling treated wood by non-professionals

Description of Scenario [4.3]. Handling treated wood by non-professionals
This scenario is considered an acute exposure scenario for the non-professional. A non-professional is likely to handle dry treated wood, either by mounting the wood to form a structure or moving the treated wood to the intended place. The wood-preservative is assumed completely dry at the time of handling. Exposure via inhalation is considered negligible. The maximum theoretical concentration of the active substances (a.s) on the surface of treated is calculated as follows:

Application rate product (mL/m^2) x density x a.s. conc. (%) expressed as mg/cm^2 IPBC = 140 x 1.01 x 0.75% x 0.1* = 0.1061 mg/cm^2 Permethrin = 140 x 1.01 x 0.25% x 0.1* = 0.0354 mg/cm^2 (* factor combing conversion of mL/m^2 to mL/cm^2 and m/cm^2 to mg/cm^2)		
Tier	**Parameters**	**Value**
Tier 1	IPBC exposure concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Application rate (maximum) of product	140 mL/m^2
	Density of product	1.01 g/mL
	Concentration of IPBC on the surface	0.1061 mg/cm^2
	Concentration of Permethrin on the surface	0.0354 mg/cm^2
	Adult hand surface (palms) [1]	410 cm^2
	Area of hand contaminated	100%
	Dislodgeable fraction [2]	3%
	Dermal penetration of IPBC	29% (based on read-across to a similar formulation containing 0.75% IPBC)
	Dermal penetration of Permethrin	50% (default value for a water-based dilution (i.e. active substance concentration ≤ 5%) in 'Guidance on dermal absorption' (EFSA, 2017)
	Body weight (adult) of worker [1]	60 kg

[1] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[2] For 'painted wood (MDF)' from 'Table: transfer coefficients – dislodgeable residues', p. 171, Biocides Human Health Exposure Methodology, version 1, 2015.

Calculations for Scenario [4.3]: Handling of treated wood by non-professionals

(Calculation sheet is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure due to handling treated wood by non-professionals					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [4.3]	Tier 1 / no PPE	-	0.0063	-	0.0063
Permethrin					
Scenario [4.3]	Tier 1 / no PPE	-	0.0036	-	0.0036

Secondary exposure of a non-professional user to TWP 094i may also occur due to inhalation of volatilised residues at home (Scenario [8]). This scenarios is presented and calculated under the heading 'Exposure of the general public'.

Combined scenarios

In the following, the results of the combined exposure (application and post-application) of non-professionals to TWP 094i (RTU product) are provided. As a worst case for combined exposure, the exposures for Scenarios [3.2, 4.2 and 4.3] are summed, meaning that a non-professional applies the wood preservative by brushing and rolling, cuts and sands treated wood, and handles treated wood on the same work day. The non-professional may also inhale volatilised residues at home (i.e. live in a building where the indoor surfaces of external window frames and of external door/door frames have been treated with TWP 094i). As inhalation of volatile residues is a chronic (secondary) exposure whereas the other non-professional exposures are acute, the inhalation scenario is not included in the calculation for the combined scenario for non-professional use. However, the potential contribution of inhalation of volatile residues is considered in the risk assessment of non-professional use in Section 2.2.6.3 Risk characterisation.

Summary table: estimated combined systemic exposure[1] from non-professional uses				
Scenarios combined	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC				
Scenarios [3.2, 4.2, 4.3] (Brushing and rolling, cutting and sanding treated wood, handling treated wood)	Tier 1 / None	0.0007	0.0424	0.0431
Permethrin				
As for IPBC	Tier 1 / None	0.0002	0.0244	0.0246

[1] No oral exposure expected in any of the scenarios.

Exposure of the general public

The general public may potentially be exposed to TWP 094i. A number of scenarios can be used to model the most likely situations, namely an infant chewing a wood off-cut, an infant playing on a playground structure and mouthing, a toddler touching wet treated wood and mouthing, inhalation of volatilised residues indoors, and an adult laundering work clothes at home.

Scenario [5]: Chewing wood off-cut by infant

Description of Scenario [5]: Chewing wood off-cut by infant		
This scenario is considered an acute exposure scenario. The exposure is expected to be an incidental event where an infant or toddler playing near a person (non-professional) sawing wood treated with TWP 094i finds and chews on an off-cut (wood chip). The infant is considered the worst case. According to TNsG 2002 the scenario is unrealistic for children as they are unlikely to chew treated wood to any significant extent. Model: This secondary exposure scenario is based on TNsG User Guidance, version 1, 2002, p. 51 and TNsG 2002, Part 3, p. 50. The model involves an infant, and is considered to represent the worst case for secondary oral exposure. The model uses an infant body weight of 10 kg, though this has been reduced to 8 kg in accordance with HEAdhoc Recommendation no. 14 (2017). It is assumed that the active substance applied to the treated timber (via the double vacuum process) is located in the outer 1 cm layer, that the infant chews a 4 cm × 4 cm × 1 cm = 16 cm³ chip, that they extract 10% of the active substance from this wood chip via chewing, and that oral absorption of the extracted IPBC and Permethrin is 100%. Inhalation exposure is considered to be negligible.		
Tier	**Parameters**	**Value**
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Application rate (maximum) of product	70.6 kg/m^3 (~ 140 mL/m^2)
	Density of product	1.01 g/mL
	Volume of the piece of wood [1, 2]	16 cm^3 (4 cm x 4 cm x 1 cm)
	Concentration of IPBC in the outer 1 cm layer of wood (Calculated in scenario [4.2])	0.1422 mg/cm^3
	Concentration of Permethrin in the outer 1 cm layer of wood (Calculated in scenario [4.2])	0.0474 mg/cm^3
	Body weight (infant) of the exposed [3]	8 kg
	Efficiency of extraction of the active substance from the wood [1, 2]	10%
	Oral absorption of IPBC (PT13 CAR (DK CA, 2015) and considering current guidance)	100%
	Oral absorption of Permethrin (PT8 CAR (IE CA, 2014) and considering current guidance)	100%

[1] TNsG User Guidance, version 1, 2002.

[2] TNsG 2002, part 3, p. 50.

[3] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

Calculations for Scenario [5]: Chewing wood off-cut by infant

(The calculation sheet is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure due to chewing wood off-cut by infant					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [5]	Tier 1 / no PPE	-	-	0.0284	0.0284
Permethrin					
Scenario [5]	Tier 1 / no PPE	-	-	0.0095	0.0095

Scenario [6]: Playing on playground structure outdoors and mouthing by infant

Description of Scenario [6]: Playing on playground structure outdoors and mouthing by infant		
This scenario is considered a chronic exposure scenario. Model: This secondary exposure scenario is based on two related models in TNsG 2002 User guidance – Version 1 and TNsG 2002, Part 3, pp. 50-51, with refinement based on Recommendation no. 5 of the BPC Ad hoc Working Group on Human Exposure (HEAdhoc) – 'Non-professional use of antifouling paints: exposure assessment for a toddler' (2015). In both models, during playing on a timber structure (weather structure* for an infant, playground structure for a chid) treated superficially with a biocidal product, dermal exposure is considered with oral (hand-to-mouth transfer) exposure also considered in the model for the infant (* considered synonymous with an outdoor playground structure). As the 2 models have the same parameters for dermal exposure, the infant can be considered the worst case (due to oral exposure and, in relation to dermal exposure, their greater surface-area-to-volume ratio). Calculations for a child playing on playground structures have thus not been included. The infant model uses a body weight of 10 kg, though this has been reduced to 8 kg in accordance with HEAdhoc Recommendation no. 14 (2017). The model assumes 20% hand (palms and back of hands) contamination, equivalent to 40% of the palms. The dislodgeable fraction of paint (from wood to hands) is 3%, and the transfer coefficient of dried paint from hands to mouth is 50% (the value for an infant in HEAdhoc Recommendation no. 5 (2015), though considered applicable to an infant. Oral absorption of the IPBC and Permethrin ingested is set at 100%. Inhalation exposure is considered to be negligible.		
Tier	**Parameters**	**Value**
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Application rate (maximum) of product	140 mL/m^2
	Density of product	1.01 g/mL
	Concentration of IPBC on the wood surface (Calculated for scenario [4.3])	0.1061 mg/cm^2
	Concentration of Permethrin on the wood surface (Calculated for scenario [4.3])	0.0354 mg/cm^2

	Dermal penetration of IPBC (based on read-across to an *in vitro* dermal absorption study with a related formulation)	29%
	Dermal penetration of Permethrin (default value for a water-based product in EFSA (2017) *Guidance on dermal absorption*)	50%
	Body weight (infant) of the exposed [1]	8 kg
	Area of hands – both palms and backs of both hands (infant) [1]	196.8 cm²
	Hand area contaminated (infant) [2]	20% (40% of both palms)
	Dislodgeable fraction (transfer coefficient of paint from treated surface to hands) [3]	3%
	Transfer coefficient for hand-to-mouth transfer of dried paint (value for toddler considered applicable to infant) [4]	50%
	Oral absorption of IPBC (PT13 CAR (DK CA, 2015) and considering current guidance)	100%
	Oral absorption of Permethrin (PT8 CAR (IE CA, 2014) and considering current guidance)	100%

[1] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[2] TNsG User Guidance, version 1, 2002 and TNsG 2002, Part 3, pp 50-51.

[3] Biocides Human Health Exposure Methodology, version 1, 2015, p. 171.

[4] HEAdhoc Recommendation no. 5, Non-professional use of antifouling paints: exposure assessment for a toddler (2015).

Calculations for Scenario [6]: Playing on playground structure outdoors and mouthing by infant

(The calculation sheet is provided in Annex 3.2.1.)

Summary table: estimated systemic exposure due to playing on playground structure and mouthing by infant					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [6]	Tier 1 / no PPE	-	0.0045	0.0078	0.0124
Permethrin					
Scenario [6]	Tier 1 / no PPE	-	0.0026	0.0026	0.0052

Scenario [7]: Contact with freshly treated wood by toddler

Calculations for Scenario [7]: Contact with freshly treated wood by toddler		
This scenario is considered an acute exposure scenario. The exposure is incidental. Toddlers play nearby a person (non-professional) treating wood using TWP 094i. Contact with freshly treated (wet) surfaces is assumed to be of short duration, as parents will remove the product from the toddler's hands as soon as the incident is observed. The scenario is based of Recommendation no. 5 of the BPC Ad hoc Working Group on Human Exposure (HEAdhoc) – 'Non-professional use of antifouling paints: exposure assessment for a toddler' (2015) and HEAdhoc Recommendation no. 14 – 'Default human factors values for use in exposure assessment for biocidal products', and considers both dermal and oral (hand-to-mouth transfer) exposure. For calculation of dermal exposure (restricted to the hands) 100% of the area of both palms is assumed to contact the wet paint, with 50% transfer of paint to the palms (a value of 50% is considered worst-case for a penetrative product such as TWP 094i). For the oral exposure, 10% of the paint on the palms is assumed to be ingested due to mouthing of fingers. Oral absorption of the IPBC and Permethrin ingested is set at 100%. Inhalation exposure is considered to be negligible.		
Tier	**Parameters**	**Value**
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Application rate (maximum) of product	140 mL/m^2
	Density of product	1.01 g/mL
	Concentration of IPBC on the wood surface (Calculated for scenario [4.3])	0.1061 mg/cm^2
	Concentration of Permethrin on the wood surface (Calculated for scenario [4.3])	0.0354 mg/cm^2
	Area of palms of both hand areas [1]	115.2 cm^2
	Portion of palms of the hand in contact (contaminated) with wet wood preservative [2]	100%
	Transfer coefficient of wet paint from treated surface to hand [2]	50%
	Transferable fraction of wet paint from hands to mouth [2]	10%
	Dermal penetration of IPBC (based on read-across to an *in vitro* dermal absorption study with a related formulation)	29%
	Dermal penetration of Permethrin (default value for a water-based product in EFSA (2017) *Guidance on dermal absorption*)	50%
	Body weight (toddler) of the exposed [1]	10 kg
	Oral absorption of IPBC (CAR, PT13; DK CA, 2015)	100%
	Oral absorption of Permethrin (PT8 CAR (IE CA, 2014) and considering current guidance)	100%

[1] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[2] HEAdhoc Recommendation no. 5, Non-professional use of antifouling paints: exposure assessment for a toddler (2015).

Calculations for Scenario [7]: Contact with freshly treated wood by toddler

(The calculation sheet is provided in Annex 3.2.1).

Summary table: estimated systemic exposure due to contact with freshly treated wood by toddler					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [7]	Tier 1 / No PPE	-	0.1771	0.0611	0.2382
Permethrin					
Scenario [7]	Tier 1 / No PPE	-	0.1018	0.0204	0.1222

Scenario [8]: Inhalation of volatilised residues indoors from treated wood

Description of Scenario [8]: Inhalation of volatilised residues indoors from treated wood

This scenario is considered a chronic exposure scenario.

Although TWP 094i is intended for outdoor use (Use classes 2 and 3), exposure (adult, child, toddler and infant) may occur due to inhalation of volatilised residues arising from the interior surfaces of external window frames and external door/door frames treated with TWP 094i.

Tier 1 screening tool

Long-term exposure to volatilised residues can be neglected if the Tier 1 screening tool from HEEG Opinion 13 'Assessment of inhalation exposure of volatilised biocide active substance' (2013) yields a value ≤ 1 for the toddler (the worst case, as their inhalation rate:body weight ratio is greater than that of the infant, child, and adult). The screening tool calculations are shown below:

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

IPBC: (0.328 X 281.1 x 0.0045)/0.2 = 2.07

Permethrin: (0.328 X 391.3 x 0.0000022)/0.05 = 0.006

As the value yielded for IPBC is > 1, further assessment of long-term inhalation exposure to volatilised residues is evaluated.

Tier 1

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

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

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

Systemic inhalatory exposure is calculated considering the concentration in air of the substance, daily respiratory rate of the exposed individual, and their body weight.

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

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

The calculation is highly conservative and is designed as a screening tool for identifying a risk. Preserved window frames or joists are required to be coated and hence the wood preservative is sealed and cannot evaporate. Furthermore the vapour pressure of IPBC is in general considered to be low (< 0.5 kPa).

Tier 2

Tier 2 exposure calculations were performed in ConsExpo based on default input values obtained from ConsExpo factsheets as well as information on the composition of the product (see parameters in table below).

Tier	**Parameters**		**Value**
Tier 1	Saturated vapour concentration (SVC) of a.s. used as screening tool		
	IPBC concentration		0.75% (w/w)
	Permethrin concentration		0.25% (w/w)
	Vapour pressure of IPBC [1]		0.0045 Pa (at 25°C)
	Molecular weight of IPBC [1]		281.1 g/mol
	Vapour pressure of Permethrin [1]		0.0000022 Pa (at 20°C)
	Molecular weight of Permethrin [1]		391.3 g/mol
	Henry's law constant (H) [2]		6.45 x 10^{-3} Pa*m^3/mol
	Ideal gas constant (R) [2]		8.315 J/mol.K
	Indoor temperature (T) [2]		298 K (25°C)
	Adult	Inhalation rate [3]	16 m^3/day
		Body weight [3]	60 kg
	Child	Inhalation rate [3]	12 m^3/day
		Body weight [3]	23.9 kg
	Toddler	Inhalation rate [3]	8 m^3/day
		Body weight [3]	10 kg
	Infant	Inhalation rate [3]	5.4 m^3/day
		Body weight [3]	8 kg
Tier 2	ConsExpo use to estimate exposure		
	Model [4]		Exposure to vapour -evaporation
	Room size [5]		20 m^3
	Ventilation rate (room) [5]		0.6/h
	Molecular weight matrix [6]		45 g/mol
	Exposure duration [4]		Set to 1 day
	Emission duration [4]		Set to 1 day
	Mass transfer [4]		Langmuir
	Release area [7]		4 m^2
	Product amount (g) [8]		566 g

[1] IPBC: CAR, PT13 (CA DK, 2013); Permethrin: PT8 CAR (CA IE, 2014).

[2] HEEG Opinion 13, Assessment of inhalation exposure of volatilised biocide active substance (2013).

[3] HEAdhoc Recommendation no. 14, Default human factor values for use in exposure assessments for biocidal products (2017).

[4] 'Exposure duration' and 'Emission duration' set to '1 day' (i.e. constant exposure over 24 hours as a worst case; see ConsExpo model documentation https://www.rivm.nl/bibliotheek/rapporten/2017-0197.pdf#page=35

[5] ConsExpo General Fact sheets, https://www.rivm.nl/bibliotheek/rapporten/090013003.pdf

[6] Default value for a waterborne paint in which the substance of interest is not the main solvent; see p. 22 of ConsExpo Paint Product Fact Sheets, https://www.rivm.nl/bibliotheek/rapporten/320104008.pdf

[7] 'Release area' is a worst-case estimation of the total area of interior wooden surfaces to which the product is applied following the intended uses. TWP 094i is intended for outdoor use (Use classes 2 and 3) only, thus 'release area' is the sum of application to the interior surface of external door/door frames and exterior window frames for a room of 20 m^3.

[8] 'Product amount' is the sum of release area (application area in m^2) multiplied by maximum application rate (in mg; i.e. 140 mL x density of the product (1.01 g/cm^3) = 141.5 g/m^2), i.e. 4 m^2 x 141.5 g/m^2 = 566 g.

Calculations for Scenario [8]: Inhalation of volatilised residues indoors from treated wood

(The calculation sheet is provided in Annex 3.2.1.)

Summary table: systemic exposure due to inhalation of volatilised residues indoors by adult, child, toddler and infant					
Exposure scenario	**Tier / PPE***	**Estimated inhalation uptake** (mg/kg bw/d)	**Estimated dermal uptake** (mg/kg bw/d)	**Estimated oral uptake** (mg/kg bw/d)	**Estimated total uptake** (mg/kg bw/d)
IPBC					
Scenario [8], adult	Tier 1 / no PPE	0.1362	-	-	0.1362
	Tier 2 / no PPE	0.0002	-	-	0.0002
Scenario [8], child	Tier 1 / no PPE	0.2565	-	-	0.2565
	Tier 2 / no PPE	0.0003	-	-	0.0003
Scenario [8], toddler	Tier 1 / no PPE	0.4086	-	-	0.4086
	Tier 2 / no PPE	0.0005	-	-	0.0005
Scenario [8], infant	Tier 1 / no PPE	0.3448	-	-	0.3448
	Tier 2 / no PPE	0.0004	-	-	0.0004
Permethrin					
Scenario [8], adult	Tier 1 / no PPE	0.0001	-	-	0.0001
	Tier 2 / no PPE	0.000001	-	-	0.000001
Scenario [8], child	Tier 1 / no PPE	0.0001	-	-	0.0001
	Tier 2 / no PPE	0.000001	-	-	0.000001
Scenario [8], toddler	Tier 1 / no PPE	0.0002	-	-	0.0002
	Tier 2 / no PPE	0.000002	-	-	0.000002
Scenario [8], infant	Tier 1 / no PPE	0.0002	-	-	0.0002
	Tier 2 / no PPE	0.000001	-	-	0.000001

* Saturated vapour concentration (SVC) was used as the Tier 1 exposure screening tool, while ConsExpo use to estimate exposure at Tier 2.

Scenario [9]: Laundering work clothes at home

Description of Scenario [9] Laundering of work clothes at home		
This scenario is considered an intermittent (acute intermediate) exposure scenario. An activity with the potential for exposure to TWP 094i is laundering of contaminated work clothing. Persons at risk are adults (professionals and the general public; non-professionals are not considered as: a) Tier 1 in the scenario (Scenario [3.2]) for their primary exposure (which results in acceptable exposure) assumes no protective clothing/100% penetration of eventual clothing (i.e. no clothing to wash/no retention of retention of the biocidal product), and b) it is unlikely that they both apply the product and launder the clothes of a professional who was applied the product. Laundering itself is assumed to occur mechanically without any exposure risk to humans. Contact with effluent is unlikely to occur. The only likely exposure is during handling the contaminated clothing while preparing it for laundry. The exposure route is restricted to the hands (dermal) and is dependent on the area and concentration of dislodgeable residues on the surface of the clothing and the transfer coefficient to the human skin. It is assumed, that the clothing to be washed is a coated coverall worn by a professional, that the coverall is washed after one working week (corresponding to 5 working days), and that the total residue accumulated during this time is equivalent to 5-times the daily contamination associated with application of the product by manual dipping (scenario [2.2]), the worst-case exposure scenario for professionals. The transfer area is determined by estimating how many times the coated coverall is touched with the hands while preparing it for laundering. Assuming that this happens three times, twice with the palms of both hands (2 x 410 cm^2) and once with the total surface area of both hand (820 cm^2), the transfer area is 1640 cm^2 (hand surface areas from HEAdhoc Recommendation no. 14). It is assumed that 20% of the residues in the touched area are transferred to the skin (transfer coefficient).		
Tier	**Parameters**	**Value**
Tier 1	IPBC concentration	0.75% (w/w)
	Permethrin concentration	0.25% (w/w)
	Dermal penetration of IPBC (based on read-across to an *in vitro* dermal absorption study with a related formulation)	29%
	Dermal penetration of Permethrin (default value for a water-based product in EFSA (2017) *Guidance on dermal absorption*)	50%
	Clothing contamination, IPBC [1]	36.05 mg/day
	Clothing contamination, Permethrin [1]	12.02 mg/day
	Days before washing	5 days
	Percentage dislodgeable (transfer coefficient) [2]	20%
	Surface of medium coated coverall [3]	22700 cm^2
	Transfer area [4]	1640 cm^2

[1] Clothing contamination equals the 'potential dermal deposit' (body exposure) value from scenario [2.2] minus the amount that penetrates through the clothing (10%), and is expressed as mg a.s./day.

[2] Transfer coefficient (with dry hands) for residue of dried fluid from cotton, knitwear, plastic, and wood from the table 'Transfer coefficients – Dislodgeable residues', p. 171, Biocides Human Health Exposure Methodology, version 1, (2015).

[3] See the CAR for Propiconazole (FI CA, 2007).

[4] Based on a surface area of both palms of 410 cm^2 and total surface of both hands of 820 cm^2; see HEAdhoc Recommendation no. 14 Default human factors values for use in exposure assessment for biocidal products (2017).

Calculations for Scenario [9]: Laundering work clothes at home

(Calculation sheet is provided in Annex 3.2.1)

Summary table: estimated systemic exposure due to laundering work clothes at home					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenario [9]	Tier 1 / no PPE	-	0.0126	-	0.0126
Permethrin					
Scenario [9]	Tier 1 / no PPE	-	0.0072	-	0.0072

Combined scenarios

Only one combined scenarios for the general public is considered directly relevant: Scenarios [6 + 8] for infants (playing on a playground structure and mouthing, and inhalation of volatilised residues indoors, respectively). A combined scenario for adult general public that directly considers their two exposures is not possible as they are of different frequencies (chronic inhalation of volatilised residues indoors vs. intermittent (acute, intermediate) laundering work clothes at home). However in the table below, the two exposures have been combined so that in the risk assessment they can be compared to the long-term AEL for IPBC as a worst case. As the remaining general public scenarios (chewing wood off-cut by infant (Scenario [5]), and contact to freshly treated (wet) wood by toddler (Scenario [7]) are incidental exposures, they are not included in a combined scenario.

Summary table: combined systemic exposure for general public					
Scenarios combined	**Tier / PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
IPBC					
Scenarios, infant [6, 8] (playing on a playground structure and mouthing, inhalation of volatilised residues indoors)	Tier 1 and 2, respect-ively / None*	0.0004	0.0045	0.0078	0.0128

Scenarios, adult [8, 9] (inhalation of volatilised residues indoors, laundering work clothes at home)	*Tier 1 and 2, respect-ively / None**	*0.0002*	*0.0126*	*-*	*0.0127*
Permethrin					
As for IPBC	Tier 1 and 2, respect-ively / None*	0.000001	0.0026	0.0026	0.0052
As for IPBC	*Tier 1 and 2, respect-ively / None**	*0.000001*	*0.0072*	*-*	*0.0072*

* No PPE at Tier 2 in Scenario [8].

Monitoring data

No monitoring data are available.

Dietary exposure

- Exposure of food/feed, drinking water/beverages or livestock can be excluded when the product is applied according to the authorised uses. Additionally, three RMMs are applied to help minimise the risk of dietary exposure:
- Do not use near domestic animals or livestock. (Use 1 and 2)
- Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock, particularly cats. (Use 1 and 2)
- Do not use on wood which may come in direct contact with food, feed and livestock.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal uses)			
	Sector of use	**Intended use**	**Reference value(s)**
IPBC			
1.	Cosmetics and personal care products; perfumes and fragrances	Preservative	The maximum level (depending on product type) is between 0.0075% and 0.02% (Reg. (EC) 1223/2009) Daily recommended dose in Europe is 150 µg/d (with an upper short-term limit of 1000 µg/d)[1]

Permethrin			
1.	Veterinary use		Fat (Bovine, Porcine, Chicken): 500 µg/kg[2] Other tissues: 50 µg/kg (muscle, liver, kidney)[2] Milk: 50 µg/kg[2]
2.	Plant Protection Products		MRL range of different crops and products of animal origin: 0.05 – 0.5 mg/kg[3]

[1] SCCNFP/0826/04 Opinion on Iodopropynyl Butylcarbamate (1 July 2004)

[2] Permethrin, Summary Report (3), Committee for Veterinary Medicinal Products, Sept. 2002; http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits - Report/2009/11/WC500015600.pdf

[3] Products to which MRLs apply (Part A of Annex I to Reg. 396/2005); Permethrin. http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0623&from=EN

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Exposure of livestock can be excluded when the product is applied according to the authorised uses. Additionally, three RMMs are applied to help minimise the risk of livestock exposure:

- Do not use near domestic animals or livestock. (Use 1 and 2)
- Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets, particularly cats. (Use 1 and 2)
- Do not use on wood which may come in direct contact with food, feed and livestock.

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

Exposure of food (and drinking water/beverages) can be excluded when the product is applied according to the authorised uses. Additionally, three RMMs are applied to help minimise the risk of dietary exposure:

- Do not use near domestic animals or livestock. (Use 1 and 2)
- Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets, particularly cats. (Use 1 and 2)
- Do not use on wood which may come in direct contact with food, feed and livestock.

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

Exposure of food (and drinking water/beverages) can be excluded when the product is applied according to the authorised uses. Additionally, two RMMs are applied to help minimise the risk of dietary exposure:

- Do not use near domestic animals or livestock. (Use 1 and 2)
- Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets, particularly cats. (Use 1 and 2)
- Do not use on wood which may come in direct contact with food, feed and livestock.

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

Exposure during production of a biocidal product should be addressed under other European Union (EU) legislation (e.g. REACH) and not repeated under Regulation (EU) 528/2012 (BPR). The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance (a.s.) was not required unless it was totally new to the EU market and manufactured in the EU. This is not the case for IPBC and Permethrin, which are existing biocidal active substances within the EU.

Aggregated exposure

An aggregate exposure assessment is not relevant, since it is not expected that significant, concomitant exposure to IPBC or Permethrin from other sources – including other biocide product types[17] for which IPBC and Permethrin are authorised – will occur at the same time as exposure to IPBC and Permethrin via use of TWP 094i.

Summary of exposure assessment

Scenarios and values to be used in risk assessment - IPBC			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier / PPE**	**Estimated total uptake** (mg/kg bw/day)
1.1	Industrial: Mixing/loading	Not applicable	Not applicable
1.2	Industrial: Application – Fully-automated dipping	Tier 1 / New gloves*	0.3302
		Tier 2a / New gloves, coated coverall	0.0506
		Tier 2b / Used gloves, impermeable coverall	0.0547
1.3	Industrial: Application – Automated flow-coating/deluging or automated spraying	Tier 1 / Gloves*	0.4432
		Tier 2a / Gloves, coated coverall	0.0948
		Tier 2b / Gloves, impermeable coverall	0.0754

[17] Currently PT6 and PT13 for IPBC and PT18 for Permethrin.

Scenarios and values to be used in risk assessment - IPBC			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier / PPE**	**Estimated total uptake** (mg/kg bw/day)
1.4	Industrial: Application – Double vacuum/low pressure process	Tier 1 / Gloves*	0.3622
		Tier 2 / Gloves, coated coverall	0.0729
1.5	Industrial: Post-application – Handling of treated articles	Not applicable	Not applicable
1.6	Industrial: Post-application – maintenance/cleaning of the application system (dipping tank)	Tier 1 / New gloves, coated coverall	0.0506
2.0.1	Professionals: Manual mixing and loading prior to manual dipping	Tier 1/ no PPE	0.0915
		Tier 2 / Gloves	0.0092
2.0.2	Professionals: Semi-automated Mixing and loading prior to manual dipping	Tier 1/ no PPE	0.0049
		Tier 2 / Gloves	0.0005
2.1	Professionals: Manual Mixing/loading prior to brushing and rolling	Tier 1/ no PPE	0.0366
		Tier 2 / Gloves	0.0004
2.2	Professionals: Application – manual dipping	Tier 1 / Gloves*	0.2215
		Tier 2 / Gloves, coated coverall	0.0473
2.3	Professionals: Application – Brushing and rolling	Tier 1 / Gloves	0.0900
		Tier 2 / Gloves, coated coverall	0.0096
2.4.1	Professionals: Manual drainage and reloading of the manual dipping tank	Tier 1 / no PPE	0.1831
		Tier 2 / Gloves	0.0183
2.4.2	Professionals: Semi-automated drainage and reloading of the manual dipping tank	Tier 1 / no PPE	0.0098
		Tier 2 / Gloves	0.0010
3.1	Non-professionals: Mixing/loading	Not applicable	Not applicable
3.2	Non-professionals: Application – Brushing and rolling	Tier 1 / no PPE	0.0334
4.1	Professional worker: Cutting and sanding treated wood	Tier 1 / no PPE	0.0036
		Tier 2 / Gloves	0.0004
4.2	General public (adult): Cutting and sanding treated wood	Tier 1 / no PPE	0.0034
4.3	General public (adult): Handling treated wood	Tier 1 / no PPE	0.0063
5	General public (infant): Chewing wood off-cut	Tier 1 / no PPE	0.0284
6	General public (infant): Playing on playground structure outdoors and mouthing	Tier 1 / no PPE	0.0124

Scenarios and values to be used in risk assessment - IPBC				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**		**Tier / PPE**	**Estimated total uptake** (mg/kg bw/day)
7	General public (toddler): accidental dermal contact to freshly treated wood and hand to mouth transfer		Tier 1 / no PPE	0.2382
8	General public inhales volatilised residues from treated wood installed indoors	Adult	Tier 1 / no PPE**	0.1362
			Tier 2 / no PPE***	0.0002
		Child	Tier 1 / no PPE**	0.2565
			Tier 2 / no PPE***	0.0003
		Toddler	Tier 1 / no PPE**	0.4086
			Tier 2 / no PPE***	0.0005
		Infant	Tier 1 / no PPE**	0.3448
			Tier 2 / no PPE***	0.0004
9	Professional and general public: laundering work clothes at home		Tier 1 / no PPE	0.0126

* The model considered provides an indicative value for hands is 'inside gloves', thus use of gloves is considered at Tier 1.

** Saturated vapour concentration of a.s. used as screening tool (Tier 1).

*** ConsExpo used to estimate exposure (Tier 2).

Scenarios and values to be used in risk assessment - Permethrin			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier / PPE**	**Estimated total uptake** (mg/kg bw/day)
1.1	Industrial: Mixing/loading	Not applicable	Not applicable
1.2	Industrial: Application – Fully-automated dipping	Tier 1 / New gloves*	0.1898
		Tier 2a / New gloves, coated coverall	0.0291
		Tier 2b / Used gloves, impermeable coverall	0.0314
1.3	Industrial: Application – Automated flow-coating/deluging or automated spraying	Tier 1 / Gloves*	0.2547
		Tier 2a / Gloves, coated coverall	0.0544
		Tier 2b / Gloves, impermeable coverall	0.0433
1.4	Industrial: Application – Double vacuum/low pressure process	Tier 1 / Gloves*	0.1207
		Tier 2 / Gloves, coated coverall	0.0243
1.5	Industrial: Post-application – Handling of treated articles	Not applicable	Not applicable

Scenarios and values to be used in risk assessment - Permethrin				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**		**Tier / PPE**	**Estimated total uptake** (mg/kg bw/day)
1.6	Industrial: Post-application – maintenance/cleaning of the application system (dipping tank)		Tier 1 / New gloves, coated coverall	0.0291
2.0.1	Professionals: Manual mixing and loading prior to manual dipping		Tier 1/ no PPE	0.0526
			Tier 2 / Gloves	0.0053
2.0.2	Professionals: Semi-automated Mixing and loading prior to manual dipping		Tier 1/ no PPE	0.0028
			Tier 2 / Gloves	0.0003
2.1	Professionals: Manual Mixing/loading prior to brushing and rolling		Tier 1/ no PPE	0.0210
			Tier 2 / Gloves	0.0002
2.2	Professionals: Application – manual dipping indoors		Tier 1 / Gloves*	0.1273
			Tier 2 / Gloves, coated coverall	0.0272
2.3	Professionals: Application – Brushing and rolling		Tier 1 / Gloves	0.0516
			Tier 2 / Gloves, coated coverall	0.0053
2.4.1	Professionals: Manual drainage and reloading of the manual dipping tank		Tier 1 / no PPE	0.1052
			Tier 2 / Gloves	0.0105
2.4.2	Professionals: Semi-automated drainage and reloading of the manual dipping tank		Tier 1 / no PPE	0.0056
			Tier 2 / Gloves	0.0006
3.1	Non-professionals: Mixing/loading		Not applicable	Not applicable
3.2	Non-professionals: Application – Brushing and rolling		Tier 1 / no PPE	0.0190
4.1	Professional worker: Cutting and sanding treated wood		Tier 1 / no PPE	0.0020
			Tier 2 / Gloves	0.0002
4.2	General public (adult): Cutting and sanding treated wood		Tier 1 / no PPE	0.0019
4.3	General public (adult): Handling treated wood		Tier 1 / no PPE	0.0036
5	General public (infant): Chewing wood off-cut		Tier 1 / no PPE	0.0095
6	General public (infant): Playing on playground structure outdoors and mouthing		Tier 1 / no PPE	0.0052
7	General public (toddler): accidental dermal contact to freshly treated wood and hand to mouth transfer		Tier 1 / no PPE	0.1222
8		Adult	Tier 1 / no PPE**	0.0001
			Tier 2 / no PPE***	0.000001
		Child	Tier 1 / no PPE**	0.0001
			Tier 2 / no PPE***	0.000001

Scenarios and values to be used in risk assessment - Permethrin				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**		**Tier / PPE**	**Estimated total uptake** (mg/kg bw/day)
	General public inhales volatilised residues from treated wood installed indoors	Toddler	Tier 1 / no PPE**	0.0002
			Tier 2 / no PPE***	0.000002
		Infant	Tier 1 / no PPE**	0.0002
			Tier 2 / no PPE***	0.000001
9	Professional and general public: laundering work clothes at home		Tier 1 / no PPE	0.0072

* The model considered provides an indicative value for hands is 'inside gloves', thus use of gloves is considered at Tier 1.

** Saturated vapour concentration of a.s. used as screening tool (Tier 1).

*** ConsExpo used to estimate exposure (Tier 2).

2.2.6.3 Risk characterisation for human health

The rationale for setting the AELs of the active substances IPBC and Permethrin can be found in the respective Competent Authority Report (CAR). The reference doses, and the relevant NOAEL values from which they are derived, are summarised in the following tables.

Reference values for IPBC* to be used in Risk Characterisation

Reference	Study	NOAEL (mg/kg bw/d)	AF[1]	Correction for oral absorption	Value (mg/kg bw/d)
$AEL_{short\text{-}term}$	90-day gavage rat study	35	100	No[2]	0.35
$AEL_{medium\text{-}term}$	90-day gavage rat study	35	100	No[2]	0.35
$AEL_{long\text{-}term}$	2-years rat study	20	100	No[2]	0.2
ARfD	n.r.	n.r.	-	-	n.r.
ADI	n.r.	n.r.	-	-	n.r.

n.r. = not relevant

* Values deduced from the list of endpoints of the PT6 IPBC Assessment Report (September 2013), the most recently approved CAR for IPBC.

[1] Compensating for inter/intra species variation: a 10-fold factor in each case.

[2] > 90% oral absorption. According to current guidance when the oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels.

[3] The NOAEC for effects on the larynx concerns solid IPBC. The relevance of this value has to be considered for the specific products (LoEP, CAR, IPBC PT8, CA DK 2008).

Reference values for Permethrin* to be used in Risk Characterisation

Reference	Study	NOAEL (mg/kg bw/d)	AF[1]	Correction for oral absorption	Value (mg/kg bw/d)
$AEL_{short\text{-}term}$	Rat 2-year oral study (acute effect)	59.4	100	No[2]	0.5
$AEL_{medium\text{-}term}$	12-month dog study	5	100	No[2]	0.05
$AEL_{long\text{-}term}$	12-month dog study	5	100	No[2]	0.05
ARfD	n.r.	n.r.	-	-	n.r.
ADI	n.r.	n.r.	-	-	n.r.

n.r. = not relevant

* Values deduced from the list of endpoints of the PT8 Permethrin Assessment Report (April 2014), the most recently approved CAR for IPBC.

[1] Compensating for inter/intra species variation: a 10-fold factor in each case.

[2] Extensive and rapid. According to current guidance when the oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels.

For risk characterisation, the long-term AEL and short-term AEL were applied in the following manner:

Long-term:
Industrial fully-automated dipping [Scenario 1.2]
Industrial automated flow-coating/deluging and automated spraying [Scenario 1.3]
Industrial double vacuum/low pressure process [Scenario 1.4]
Mixing and loading prior to manual dipping by professionals [Scenario 2.0]
Mixing and loading prior to brush/roller application by professionals [Scenario 2.1]
Manual dipping by professionals [Scenario 2.2]
Brushing and rolling by professionals [Scenario 2.3]
Cutting and sanding treated wood by professionals [Scenario 4.1]
Playing on playground structure outdoors and mouthing by infant [Scenario 6]
Inhalation of volatised residues indoors by adult, child, toddler, and infant [Scenario 8]

Short-term:
Maintenance/cleaning of the application system by industrial workers [Scenario 1.6]
Drainage and reloading of the manual dipping tank by professionals [Scenario 2.4]
Brushing and rolling by non-professionals [Scenario 3.2]
Cutting and sanding treated wood by non-professionals [Scenario 4.2]
Handling treated wood by non-professionals [Scenario 4.3]
Chewing wood off-cut by infant [Scenario 5]
Contact to wet wood by toddler [Scenario 7]
Laundering work clothes at home by professional [Scenario 9

Risk for industrial users

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/day)	**AEL** (mg/kg bw/day)	**Estimated uptake** (mg/kg bw/day)	**Estimated uptake/ AEL** (%)	**Accept-able**
IPBC						
Industrial Mixing and loading / Scenario [1.1]	Negligible					
Industrial application – Fully-automated dipping / Scenario [1.2]	1	20	0.2	0.3302	165	**No**
	2a	20	0.2	0.0506	25.3	Yes
	2b	20	0.2	0.0547	27.3	Yes
Industrial application - Automated flow-coating/deluging or automated spraying / Scenario [1.3]	1	20	0.2	0.4432	222	**No**
	2a	20	0.2	0.0948	47.4	Yes
	2b	20	0.2	0.0754	37.7	Yes
Industrial application – Double vacuum/low pressure process / Scenario [1.4]	1	20	0.2	0.3622	181	**No**
	2	20	0.2	0.0729	36.5	Yes

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/day)	AEL (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	Estimated uptake/ AEL (%)	Accept-able
Post-application – Handling of treated articles / Scenario [1.5]	Covered by calculations for Scenario 1.2.					
Post-application – Maintenance/cleaning of the application system (dipping tank) / Scenario [1.6]	1*	35	0.35**	0.0506	14.5	Yes
Permethrin						
Industrial Mixing and loading / Scenario [1.1]	Negligible					
Industrial application – Fully-automated dipping / Scenario [1.2]	1	5	0.05	0.1898	380	**No**
	2a	5	0.05	0.0291	58.2	Yes
	2b	5	0.05	0.0314	62.9	Yes
Industrial application – Automated flow-coating/deluging or automated spraying / Scenario [1.3]	1	5	0.05	0.2547	509	**No**
	2a	5	0.05	0.0544	109	**No**
	2b	5	0.05	0.0433	86.6	Yes
Industrial application – Double vacuum/low pressure process / Scenario [1.4]	1	5	0.05	0.1207	241	**No**
	2	5	0.05	0.0243	48.6	Yes
Post-application – Handling of treated articles / Scenario [1.5]	Covered by calculations for Scenario 1.2.					
Post-application – Maintenance/cleaning of the application system (dipping tank) / Scenario [1.6]	1*	59	0.5**	0.0291	8.3	Yes

* Tier 1 for this scenario is equivalent to Tier 2a for Scenario [1.2].

** The $AEL_{short\text{-}term}$ was used for this scenario as it is performed infrequently (twice a year at most).

Combined scenarios

Calculation of combined chronic exposure for industrial uses is not warranted as exposure during tasks associated with each application method are considered to be covered by the application scenarios, and the industrial user is only expected to use one application method each work day. Calculation of a combined acute exposure for industrial uses is not warranted, as occasional (~ once-yearly) cleaning of the dipping tank is the only relevant acute exposure identified. Calculation of the risk of combined exposure if fully-automated dipping (a chronic exposure) and cleaning of the dipping tank (an acute exposure) are performed by the same worker on the same day (using Tier 2a of Scenario [1.2] and Tier 1 of Scenario [1.6]) results in and exposure that is 29.0% of the short-term AEL for IPBC (i.e. ((0.0506 + 0.0506)/0.35) x 100 = 29.0%) and 16.6% of the short-term AEL for Permethrin (i.e. ((0.0291 + 0.0.291)/0.5) x 100 = 16.6%), and is thus acceptable. Calculation of a worst-case scenario for industrial users

is not considered warranted based on the limited extent of exposure to IPBC and Permethrin outside of the industrial workplace (refer to information under the heading *Industrial exposures* in Section 2.2.6.2 Exposure assessment.)

Local effects

Risk characterisation (RC) for local effects is triggered if a biocidal product is classified for local effects[18]. As TWP 094i is not classified for local effect end-points (irritation/ corrosion or sensitisation) risk assessment for local effects is not required.

Conclusion for industrial users

TWP 094i has acceptable risk when used by industrial users for wood preservation by fully-automated dipping, automated flow-coating/deluging or automated spraying, and the double vacuum/low pressure process (for the latter process only, the product is used as a ~ 10% in-use dilution) when task-appropriated PPE is worn and relevant RMMs (and general instructions for use) are followed.

Chronic primary exposure considering PPE (new gloves and coated coverall or used gloves and impermeable coverall) for fully-automated dipping results in exposure that is 25.35 or 27.3% of the long-term AEL for IPBC, and 58.2% or 62.9% of the long-term AEL for Permethrin. These values indicate acceptable risk for the individual active substances and their combination; the Hazard Index (HI) for the combination is 0.84 with new gloves and coated coverall and 0.90 with used gloves and impermeable coverall (i.e. < 1, and thus acceptable; see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product' for details). The safe use identified for the automated dipping process is base on it being fully automated (mechanised). In order to comply with this organisational measure, the following RMM, as identified in HEEG Opinion 18[19], is required in order for users to know the requirements for safe use: '*TW0 094i must only be used in fully-automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry*.'

Chronic primary exposure considering PPE (gloves and impermeable coverall) during automated flow-coating/deluging or automated spraying results in exposure that is 37.7% of the long-term AEL for IPBC, and 86.6% of the long-term AEL for Permethrin. These values indicate acceptable risk for the individual active substances but not their combination, as the lowest Hazard Index (HI) that could be calculated for the combination, namely the 'Adjusted HI_{to}', which is derived from organ-specific AELs for

18 Section 4.3.2 Local effects (irritation/corrosion, sensitisation) – Qualitative and semi-quantitative risk characterisation of Guidance on the BPR, Volume III, Parts B+C, Version 4.0, December 2017.

19 HEEG Opinion 18, For exposure assessment for professional operators undertaking industrial treatment of wood by fully-automated dipping (2013).

the individual active substances, is 1.09 (i.e. > 1, and thus unacceptable; see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product' for details). As no additional PPE that would permit safe use was identified, a RMM to reduce potential exposure during the processes is proposed: "*The product shall only be used with flow coating/deluging and spray tunnels equipped with a device for automated transport of the freshly treated wood to automated stacking or to a drying plant, so that manual contact with the freshly treated wood is avoided.*"

Chronic primary exposure considering PPE (gloves and coated coverall) for the double vacuum/low pressure process results in exposure that is 36.5% of the long-term AEL for IPBC and 48.6% of the long-term AEL for Permethrin, giving acceptable risk to the individual active substances and their combination; the Hazard Index (HI) for the combination is 0.90 (i.e. < 1, and thus acceptable; see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product' for details).

In summary, when used as approved and instructed, TWP 094i does not pose an unacceptable health risk for industrial users.

Risk for professional users

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/day)	**AEL** (mg/kg bw/day)	**Estimated uptake** (mg/kg bw/day)	**Estimated uptake / AEL** (%)	**Acceptable**
IPBC						
Manual mixing and loading prior to manual dipping / Scenario [2.0.1]	1	20	0.2	0.0915	45.8	Yes
	2	20	0.2	0.0092	4.6	Yes
Semi-automated Mixing and loading prior to manual dipping / Scenario [2.0.2]	1	20	0.2	0.0049	2.45	Yes
	2	20	0.2	0.0005	0.24	Yes
Manual Mixing and loading prior to brushing/rolling / Scenario [2.1]	1	20	0.2	0.0366	18.3	Yes
	2	20	0.2	0.0004	0.20	Yes
Application – manual dipping indoors / Scenario [2.2]	1	20	0.2	0.2215	111	**No**
	2	20	0.2	0.0473	23.7	Yes
Application – Brushing/rolling / Scenario [2.3]	1	20	0.2	0.0900	45	Yes
	2	20	0.2	0.0096	4.8	Yes
Manual drainage and reloading of the	1	35	0.35*	0.1831	52.3	Yes

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/day)	**AEL** (mg/kg bw/day)	**Estimated uptake** (mg/kg bw/day)	**Estimated uptake / AEL** (%)	**Acceptable**
manual dipping tank / Scenario [2.4.1]	2	35	0.35*	0.0183	5.2	Yes
Semi-automated drainage and reloading of the manual dipping tank / Scenario [2.4.2]	1	35	0.35*	0.0098	2.80	Yes
	2	35	0.35*	0.0010	0.28	Yes
Cutting and sanding treated wood / Scenario [4.1]	1	20	0.2	0.0036	1.79	Yes
	2	20	0.2	0.0004	0.19	Yes
Permethrin						
Manual mixing and loading prior to manual dipping / Scenario [2.0.1]	1	5	0.05	0.0526	105	**No**
	2	5	0.05	0.0053	10.5	Yes
Semi-automated Mixing and loading prior to manual dipping / Scenario [2.0.2]	1	5	0.05	0.0028	5.63	Yes
	2	5	0.05	0.0003	0.56	Yes
Manual Mixing and loading prior to brushing/rolling / Scenario [2.1]	1	5	0.05	0.0210	42.1	Yes
	2	5	0.05	0.0002	0.44	Yes
Application – manual dipping indoors / Scenario [2.2]	1	5	0.05	0.1273	255	**No**
	2	5	0.05	0.0272	54.4	Yes
Application – Brushing/rolling / Scenario [2.3]	1	5	0.05	0.0516	103	**No**
	2	5	0.05	0.0053	10.7	Yes
Manual drainage and reloading of the manual dipping tank / Scenario [2.4.1]	1	59	0.5*	0.1052	21.0	Yes
	2	59	0.5*	0.0105	2.10	Yes
Semi-automated drainage and reloading of the manual dipping tank / Scenario [2.4.2]	1	59	0.5*	0.0056	1.13	Yes
	2	59	0.5*	0.0006	0.11	Yes
Cutting and sanding treated wood / Scenario [4.1]	1	5	0.05	0.0020	4.00	Yes
	2	5	0.05	0.0002	0.34	Yes

* The $AEL_{short\text{-}term}$ was used for this scenario as it is performed infrequently (monthly).

Combined scenarios

The worst-case combined scenario for professionals presented below combines exposure to IPBC and Permethrin from primary- and secondary chronic exposures (including eventual non-occupational exposure) to TWP 094i.

Task/ Scenario	Tier / PPE	Systemic NOAEL (mg/kg bw/day)	AEL (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	Estimated uptake / AEL (%)	Accept-able
IPBC						
Scenarios [2.0.2, 2.1, 2.2, 2.3, 8]: Mixing & loading, application (manual dipping, brushing/rolling), and post-application (inhalation of volatised residues at home) (chronic exposures)	Tier 1 / No PPE*	20	0.2	0.3532	177	**No**
	Tier 2 / Gloves, during semi-automated mixing and loading prior to manual dipping [2.0.2] and mixing and loading prior to brushing/ rolling [2.1]; gloves, coated coverall during application by manual dipping and brushing/ rolling [2.2, 2.3]	20	0.2	0.0579	29.0	Yes
Permethrin						
As for IPBC	Tier 1 / No PPE*	5	0.05	0.2027	405	**No**
	As for IPBC	5	0.05	0.0330	66.1	Yes

* No PPE unless included as a standard assumption in the recommended model (i.e. suitable protective gloves worn by professionals when performing manual dipping.

Local effects

As TWP 094i is not classified for local effect endpoints (including sensitisation) risk assessment for local effects is not required (see the corresponding section for Industrial users for further information).

The List of Endpoints in the CAR (PT13, DK CA, 2015) for IPBC lists a NOAEC of 1.16 mg/m^3 for degradation of the larynx due to inhalation of IPBC, noting that the NOAEC is only relevant for solid IPBC and that its relevance for biocidal products containing IPBC should be evaluated on a case-by-case basis. TWP 094i is not the same as IPBC nor a simple dilution of the active substance. Furthermore, exposure to solid IPBC by users (restricted to professionals and non-professionals cutting and sanding treated wood) will be in the form of IPBC incorporated into wood dust/fibres, i.e. not 'free IPBC'. Consequently, a semi-quantitative local risk assessment of exposure of the larynx is not warranted.

Conclusion for professional users

TWP 094i has acceptable risk when used by professionals for wood preservation by manual dipping or brushing/rolling. Professionals are expected to follow a minimum of instructions, and it is assumed that they wear a coverall and gloves on a daily basis, and impermeable footwear when performing manual dipping.

Chronic primary exposure to TWP 094i during manual dipping (including semi-automated mixing and loading, i.e. Scenarios [2.0.2 + 2.2]) with use of PPE (gloves during loading; gloves and coated coverall during application) results in exposure that is 23.9% (0.24% + 23.7%) of the long-term AEL for IPBC and 55.0% (0.56% + 54.4%) of the long-term AEL for Permethrin, giving acceptable risk for the individual active substances and their combination (see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product').

Chronic primary exposure during brushing/rolling (including mixing and loading, i.e. Scenarios [2.1 + 2.3]) with use of PPE (gloves during loading; gloves and coated coverall during application) results in exposure that is 5.0% (0.2% + 4.8%) of the long-term AEL for IPBC and 11.1% (0.44 + 10.7%) of the long-term AEL for Permethrin, giving acceptable risk for the individual active substances and their combination (see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product').

Chronic secondary exposure during cutting and sanding treated wood (Scenario [4.1]) without use of PPE did not result in unacceptable exposure to the individual active substances nor their combination (see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product').

The worst-case combined scenario for professionals, which realistically combines primary- and secondary chronic exposures (Scenarios [2.0.2, 2.1, 2.2, 2.3, 8]), does not yield an unacceptable risk for the individual active substances (29.0% of the long-term AEL for IPBC, 66.1% of the long-term AEL Permethrin) when appropriate PPE is used, nor for their combination (see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product').

The additional exposure for the intermittent (acute, intermediate) tasks of draining and reloading the dipping tank (0.28% and 5.2%, respectively, of the short-term AEL for IPBC, and 0.11% and 2.1%, respectively, of the short-term AEL for Permethrin, at Tier 2 when performed by a semi-automated process or manually), and a professional periodically laundering their work clothes (3.6% and 1.45%, respectively of the short-term AEL for IPBC and Permethrin; see 'Risk for the general public' below), are not considered to alter the acceptability of the worst-case combined exposure for the professional user.

In summary, when used as approved and instructed, TWP 094i does not pose an unacceptable health risk for professional users.

Risk for non-professional users

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/day)	**AEL** (mg/kg bw/day)	**Estimated uptake** (mg/kg bw/day)	**Estimated uptake / AEL** (%)	**Accept able**
IPBC						
Mixing and loading / Scenario [3.1]	No exposure foreseen					
Application – Brushing and rolling / Scenario [3.2]	1	35	0.35	0.0334	9.54	Yes

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/day)	**AEL** (mg/kg bw/day)	**Estimated uptake** (mg/kg bw/day)	**Estimated uptake / AEL** (%)	**Accept able**
Cutting and sanding treated wood / Scenario [4.2]	1	35	0.35	0.0034	0.97	Yes
Handling treated wood / Scenario [4.3]	1	35	0.35	0.0063	1.80	Yes
Permethrin						
Mixing and loading / Scenario [3.1]	No exposure foreseen					
Application – Brushing and rolling / Scenario [3.2]	1	59	0.5	0.0190	3.81	Yes
Cutting and sanding treated wood / Scenario [4.2]	1	59	0.5	0.0020	0.39	Yes
Handling treated wood / Scenario [4.3]	1	59	0.5	0.0036	0.72	Yes

Combined scenarios

The worst-case combined scenario for non-professional users combines exposure to IPBC from acute primary- and secondary exposure to TWP 094i.

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/day)	**AEL** (mg/kg bw/day)	**Estimated uptake** (mg/kg bw/day)	**Estimated uptake / AEL** (%)	**Accept able**
IPBC						
Scenarios [3.2, 4.2, 4.3] (Brushing and rolling, cutting and sanding treated wood, handling treated wood)	1	35	0.35	0.0431	12.3	Yes
Permethrin						
As for IPBC	1	59	0.5	0.0246	4.9	Yes

Local effects

As TWP 094i is not classified for local effect endpoints (including sensitisation) risk assessment for local effects is not required (see the corresponding section for Industrial users for further information).

Conclusion for non-professional users

TWP 094i is used by non-professionals for wood preservation by brushing and rolling. Non-professionals are expected to follow a minimum of instructions, including avoid contact with skin and eyes.

Acute primary exposure during application by brushing/rolling (Scenario [3.2]) without use of PPE results in exposure that is 9.54% of the short-term AEL for IPBC and 3.81% of the short-term AEL for Permethrin, giving acceptable risk for the individual active substances and their combination (see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product').

Acute secondary exposure during cutting and sanding treated wood (Scenario [4.2]) and handling treated wood (Scenario [4.3]) without use of PPE did not result in unacceptable exposure to the individual active substances nor their combination (see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product').

The worst-case combined scenario for non-professional users, which combines acute primary- and secondary exposures (Scenarios [3.2, 4.2, 4.3]), does not identify an unacceptable risk for the individual active substances (12.3% of the short-term AEL for IPBC and 4.9% of the short-term AEL for Permethrin) nor for their combination (see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product'). The very minor additional potential exposure via chronic inhalation of volatised residues of TWP 094i by an adult (0.08% of the long-term AEL for IPBC, equivalent to 0.05% of the short-term AEL, and 0.001% of the long-term AEL for Permethrin, equivalent to 0.02% of the short-term AEL; see 'Risks for the general public' below) does not alter the acceptability of non-professional use.

In summary, when used as approved instructed, TWP 094i does not pose an unacceptable health risk for non-professional users.

Risk for the general public

Systemic effects

Task/ Scenario		**Tier**	**Systemic NOAEL** (mg/kg bw/day)	**AEL** (mg/kg bw/day)	**Estimated uptake** (mg/kg bw/day)	**Estimated uptake / AEL** (%)	**Acceptable**
IPBC							
Chewing wood off-cut by infant / Scenario [5]		1	35	0.35	0.0284	8.12	Yes
Playing on playground structure outdoors and mouthing by infant / Scenario [6]		1	20	0.2	0.0124	6.18	Yes
Contact to freshly treated wood by toddler / Scenario [7]		1	35	0.35	0.2382	68.1	Yes
Inhalation of volatilized residues indoors / Scenario [8]	Adult	1*	20	0.20	0.1362	68.1	Yes
		2**	20	0.20	0.0002	0.08	Yes
	Child	1*	20	0.20	0.2565	128	**No**
		2**	20	0.20	0.0003	0.15	Yes
	Toddler	1*	20	0.20	0.4086	204	**No**

Task/ Scenario		Tier	Systemic NOAEL (mg/kg bw/day)	AEL (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	Estimated uptake / AEL (%)	Acceptable
		2**	20	0.20	0.0005	0.24	Yes
	Infant	1*	20	0.20	0.3448	172	**No**
		2**	20	0.20	0.0004	0.21	Yes
Laundering work clothes at home by adult / Scenario [9]		1	35	0.35	0.0126	3.60	Yes
Permethrin							
Chewing wood off-off by infant / Scenario [5]		1	59	0.5	0.0095	1.90	Yes
Playing on playground structure outdoors and mouthing by infant / Scenario [6]		1	5	0.05	0.0052	10.4	Yes
Contact to freshly treated wood by toddler / Scenario [7]		1	59	0.5	0.1222	24.4	Yes
Inhalation of volatilized residues indoors / Scenario [8]	Adult	1*	5	0.05	0.0001	0.15	Yes
		2**	5	0.05	0.000001	0.001	Yes
	Child	1*	5	0.05	0.0001	0.28	Yes
		2**	5	0.05	0.000001	0.002	Yes
	Toddler	1*	5	0.05	0.0002	0.45	Yes
		2**	5	0.05	0.000002	0.004	Yes
	Infant	1*	5	0.05	0.0002	0.38	Yes
		2**	5	0.05	0.000001	0.003	Yes
Laundering work clothes at home by adult / Scenario [9]		1	59	0.5	0.0072	1.45	Yes

* Saturated vapour concentration of a.s. used as screening tool.

** ConsExpo used to estimate exposure.

Combined scenarios

The worst-case combined scenario for non-adult general public (infants) combines their secondary chronic exposures to TWP 094i.

A combined scenario for adult general public that directly considers their two exposures is not possible as they are of different frequencies (chronic inhalation of volatilised residues indoors vs. intermittent (acute, intermediate) laundering work clothes at home). However, comparing both exposures against the long-term AEL results in a worst-case exposure that is 6.4% of the long-term AEL for IPBC and 14.5% of the long-term AEL for Permethrin.

Task/ Scenario	**Tier / PPE**	**Systemic NOAEL** (mg/kg bw/day)	**AEL** (mg/kg bw/day)	**Estimated uptake** (mg/kg bw/day)	**Estimated uptake/ AEL** %	**Accep-table**
IPBC						
Scenarios, infant [6, 8] (playing on a playground structure and mouthing, inhalation of volatilised residues indoors)	Tier 1 and 2, respect-ively / No PPE*	20	0.20	0.0128	6.4	Yes
Scenarios, adult [8, 9] (inhalation of volatilised residues indoors, laundering work clothes at home)	*Tier 2 and 1, respect-ively / No PPE**	*20*	*0.20*[1]	*0.0127*	*6.4*	*Yes*
Permethrin						
As for IPBC	Tier 1 and 2, respect-ively / No PPE*	5	0.05	0.0052	10.4	Yes
As for IPBC	*Tier 2 and 1, respect-ively / No PPE**	*5*	*0.05*[1]	*0.0072*	*14.5*	*Yes*

[1] See the introductory comment regarding applying the long-term AEL to an acute to short-term exposure.

* No PPE at Tier 2 in Scenario [8].

Local effects

As TWP 094i is not classified local effect endpoints (including sensitisation) risk assessment for local effects is not required (see the corresponding section for Industrial users for further information).

Conclusion for the general public

Use of TWP 094i leads to secondary exposure of the general public via the oral, dermal and inhalation routes.

The acute secondary exposure scenario of an infant chewing on an off-cut of wood treated with TWP 094i (Scenario [5]) results in exposure that is 8.12% of the short-term AEL for IPBC, and 1.90% of the short-term AEL for Permethrin. The acute secondary exposure scenario of a toddler touching wood freshly treated with TWP 094i and mouthing (Scenario [7]) results in exposure 68.1% of the short-term AEL for IPBC, and 24.4% of the short-term AEL for Permethrin. Thus, neither of the incidental exposure scenarios identified for the non-adult general public result in unacceptable risk for the individual active substances, nor for their combination (see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product').

The chronic secondary exposure scenarios identified for infants, toddlers and children (with the infant taken as the worst-case) result in exposure for infant playing on an outdoor playground structure (Scenario [6]) that is 6.18% of the long-term AEL for IPBC, and 10.4% of the long-term AEL for Permethrin, while inhalation of volatilised residues indoors by a toddler (Scenario [8]) results in exposure that is 0.24% of the long-term AEL for IPBC, and 0.004% of the long-term AEL for Permethrin. Combining the chronic secondary exposures of infants does not identify an unacceptable risk for the individual active substances (6.39% of the long-term AEL for IPBC and 10.4% of the long-term AEL for Permethrin) nor for their combination (see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product').

Chronic secondary exposure of adults via inhalation of volatilised residues indoors results in exposure to IPBC that is 0.08% of the long-term AEL for IPBC and 0.001% of the long-term AEL for Permethrin. Acute, intermediate exposure of adults via home-laundering of the work clothes of professional users of TWP 094i results in exposure to IPBC that is 3.6% of the short-term AEL for IPBC and 1.45% of the long-term AEL for Permethrin. Combining the exposures and comparing the sum against the long-term AEL infants does not identify an unacceptable risk for the individual active substances (6.4% of long-term AEL for IPBC and 14.5% of the long-term AEL for Permethrin) nor for their combination (see the 'Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product').

In summary, normal use of TWP 094i does not pose an unacceptable health risk to the general public.

Risk for consumers via residues in food

No risk of human exposure to TWP 094i via residues in food (or drinking water) is expected when the product is applied according to the recommended uses.

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

The Guidance on the BPR: Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0, December 2017, describes a tiered approach for the risk assessment for products containing multiple active substances and/or substances of concern (SoC). In Tier 1, the risk assessment is performed for each active substance and/or SoC separately for each exposure scenario and for relevant combined scenarios (as done for TWP 094i above).

The %AEL values calculated for each active substance and/or SoC for each exposure scenario are re-expressed as a Hazard Quotient (HQ), where HQ = internal (systemic) exposure/AEL. If the HQ < 1, the risk for an active substance or SoC is considered acceptable for the scenario in question. If the HQ < 1 for each active substance and/or SoC in the product, the risk characterisation can proceed to Tier 2. If the HQ > 1 for an active substance and/or SoC, the risk is not considered acceptable and refinement of hazard and/or exposure assessment needs to be performed to obtain (if possible) a HQ < 1. If no synergistic effects between the active substances and/or substances of

concern (SoC) are identified, the toxicological effects of the combined substances are, by default, considered to be concentration- or dose-additive in Tier 2 (i.e. they are summed and not multiplied in any way).

In Tier 2, the HQ values for the individual active substances/SoCs are combined for each exposure scenario, yielding a Hazard Index (HI) for the scenario, i.e.:

HI = ∑ HQa.s. ('a.s.' = active substance and/or SoC)

If the HI ≤ 1, the risk related to use of the product for the scenario in question is considered acceptable. If the HI > 1, the risk is considered unacceptable and refinement (considering RMMs and/or Tier 3) is needed. Tier 1 and Tier 2 calculations for the individual exposure scenarios, and relevant combined exposure scenarios, for TWP 094i are provided below.

Hazard Quotients and Hazard Index for individual- and combined exposure scenarios

Scenarios	IPBC	Permethrin	Conclusion
Scenario [1.2] Industrial application by fully-automated dipping			
Without PPE (Tier 1)			
Tier 1 %AEL	165	380	**Not acceptable**
Tier 1 HQ	1.65	3.80	
With new gloves and coated coverall (Tier 2a)			
Tier 1 %AEL	25.3	58.2	Acceptable
Tier 1 HQ	0.25	0.58	
Tier 2 HI	0.84		Acceptable
With used gloves and impermeable coverall (Tier 2b)			
Tier 1 %AEL	27.3	62.9	Acceptable
Tier 1 HQ	0.27	0.63	
Tier 2 HI	0.90		Acceptable
Scenario [1.3] Industrial application by automated flow-coating/deluging or automated spraying			
Without PPE (Tier 1)			
Tier 1 %AEL	222	509	**Not acceptable**
Tier 1 HQ	2.22	5.09	
With gloves and coated coverall (Tier 2a)			
Tier 1 %AEL	47.4	109	**Not acceptable**
Tier 1 HQ	0.47	1.09	
With gloves and impermeable coverall (Tier 2b)			
Tier 1 %AEL	37.7	86.6	Acceptable
Tier 1 HQ	0.38	0.87	
Tier 2 HI	1.24		**Not acceptable**
Scenario [1.4] Industrial application by double vacuum/low pressure process			
Without PPE (Scenario considers use of gloves at Tier 1) (Tier 1)			
Tier 1 %AEL	181	241	**Not acceptable**
Tier 1 HQ	1.81	2.41	

With coated coverall (and gloves) (Tier 2)			
Tier 1 %AEL	36.5	48.6	Acceptable
Tier 1 HQ	0.37	0.49	
Tier 2 HI	0.85		Acceptable
Scenario [2.0.1] Professional manual mixing and loading prior to manual dipping			
Without PPE (Tier 1)			
Tier 1 %AEL	45.8	105	**Not acceptable**
Tier 1 HQ	0.46	1.05	
With gloves (Tier 2)			
Tier 1 %AEL	4.58	10.5	Acceptable
Tier 1 HQ	0.05	0.11	
Tier 2 HI	0.15		Acceptable
Scenario [2.0.2] Professional semi-automated mixing and loading prior to manual dipping			
Without PPE (Tier 1)			
Tier 1 %AEL	2.45	5.63	Acceptable
Tier 1 HQ	0.03	0.06	
Tier 2 HI	0.08		Acceptable
With gloves (calculated for use in combined scenarios for professionals) (Tier 2)			
Tier 1 %AEL	0.24	0.56	Acceptable
Tier 1 HQ	0.002	0.006	
Tier 2 HI	0.008		Acceptable
Scenario [2.1] Professional mixing and loading prior to brushing/rolling			
Without PPE (Tier 1)			
Tier 1 %AEL	18.3	42.1	Acceptable
Tier 1 HQ	0.18	0.42	
Tier 2 HI	0.60		Acceptable
With gloves (calculated for use in combined scenarios for professionals) (Tier 2)			
Tier 1 %AEL	0.20	0.44	Acceptable
Tier 1 HQ	0.002	0.004	
Tier 2 HI	0.006		Acceptable
Scenario [2.2] Professional manual dipping			
Without PPE (Scenario considers use of gloves at Tier 1) (Tier 1)			
Tier 1 %AEL	111	255	**Not acceptable**
Tier 1 HQ	1.11	2.55	
With coated coverall (and gloves) (Tier 2)			
Tier 1 %AEL	23.7	54.4	Acceptable
Tier 1 HQ	0.24	0.54	
Tier 2 HI	0.78		Acceptable
Scenario [2.3] Professional brushing and rolling			
Without PPE (Tier 1)			
Tier 1 %AEL	45.0	103	**Not acceptable**
Tier 1 HQ	0.45	1.03	
With gloves and coated coverall (Tier 2)			

Tier 1 %AEL	4.78	10.7	Acceptable
Tier 1 HQ	0.05	0.12	
Tier 2 HI	0.16		Acceptable
Scenario [2.4.1] Professional manual drainage and re-loading of manual dipping tank			
Without PPE (Tier 1)			
Tier 1 %AEL	52.3	21.0	Acceptable
Tier 1 HQ	0.52	0.21	
Tier 2 HI	0.73		Acceptable
Scenario [2.4.2] Professional semi-automated drainage and re-loading of manual dipping tank			
Without PPE (Tier 1)			
Tier 1 %AEL	2.80	1.13	Acceptable
Tier 1 HQ	0.03	0.01	
Tier 2 HI	0.04		Acceptable
Combined scenarios [2.0.2 + 2.1 + 2.2. + 2.3 + 8] for professional			
Without PPE (Tier 1)			
Tier 1 %AEL	177	405	**Not acceptable**
Tier 1 HQ	1.77	4.05	
With gloves and coated coverall (all scenarios) (Tier 2)			
Tier 1 %AEL	29.0	66.1	Acceptable
Tier 1 HQ	0.29	0.66	
Tier 2 HI	0.95		Acceptable
Scenario [3.2] Non-professional brushing and rolling			
Without PPE			
Tier 1 %AEL	9.54	3.81	Acceptable
Tier 1 HQ	0.1	0.04	
Tier 2 HI	0.13		Acceptable
Scenario [4.1] Professional cutting and sanding treated wood			
Without PPE			
Tier 1 %AEL	1.80	4.03	Acceptable
Tier 1 HQ	0.02	0.04	
Tier 2 HI	0.06		Acceptable
Scenario [4.2] Non-professional cutting and sanding treated wood			
Without PPE			
Tier 1 %AEL	0.98	0.39	Acceptable
Tier 1 HQ	0.01	0.004	
Tier 2 HI	0.01		Acceptable
Scenario [4.3] Non-professional handling dry treated wood			
Without PPE			
Tier 1 %AEL	1.80	0.72	Acceptable
Tier 1 HQ	0.02	0.007	
Tier 2 HI	0.03		Acceptable
Combined scenarios [3.2 + 4.2 + 4.3] for non-professional			
Tier 1 %AEL	12.3	4.9	Acceptable

Tier 1 HQ	0.12	0.05	
Tier 2 HI	0.17		Acceptable
Scenario [5] Infant chewing on wood off-cut			
Tier 1 %AEL	8.12	1.90	Acceptable
Tier 1 HQ	0.08	0.02	
Tier 2 HI	0.10		Acceptable
Scenario [6] Infant playing on wooden playground structure outdoors			
Tier 1 %AEL	6.18	10.4	Acceptable
Tier 1 HQ	0.06	0.10	
Tier 2 HI	0.17		Acceptable
Scenario [7] Toddler contact with freshly treated wood			
Tier 1 %AEL	68.1	24.4	Acceptable
Tier 1 HQ	0.68	0.24	
Tier 2 HI	0.93		Acceptable
Scenario [8] Inhalation of volatile residues indoors			
Adult (ConsExpo estimations)			
Tier 1 %AEL	0.081	0.001	Acceptable
Tier 1 HQ	0.0008	0.00001	
Tier 2 HI	0.0008		Acceptable
Infant (ConsExpo estimations)			
Tier 1 %AEL	0.206	0.003	Acceptable
Tier 1 HQ	0.0021	0.0003	
Tier 2 HI	0.002		Acceptable
Scenario [9] Laundering work clothes at home by professional and general public (adult)			
Tier 1 %AEL	3.6	1.45	Acceptable
Tier 1 HQ	0.04	0.015	
Tier 2 HI	0.05		Acceptable
Combined scenarios [8 + 9] for general public (adult)			
Tier 1 %AEL	6.37	14.5	Acceptable
Tier 1 HQ	0.06	0.14	
Tier 2 HI	0.21		Acceptable
Combined scenarios [6 + 8] for general public (infant)			
Tier 1 %AEL	6.39	10.4	Acceptable
Tier 1 HQ	0.06	0.10	
Tier 2 HI	0.17		Acceptable

In the above table, a HI > 1, indicating an unacceptable risk from mixture toxicity, is was calculated for Scenario 1.3). When the HI > 1, both risk refinement considering RMMs and Tier 3 can be performed in parallel.

Tier 3 describes: a) Combined exposure assessment by grouping the substances with common target organ/mode of action (Tier 3A), b) Combined exposure assessment with specific AEL by target organ/mode of action (Tier 3B), and c) Combined exposure assessment by considering mechanism of action, if known (Tier 3C). If there is no target organ or mode of action in common, concentration (dose) addition is not confirmed and the effects of the active substances are considered dissimilar. Consequently,

independent action is the rule and the risks are, in this case, covered by Tier 1 of this approach, i.e. assessment made substance by substance.

The following section gives an overview of the of the target organ/mode of action data for IPBC and Permethrin by summarising their effects as described in the respective Competent Authority Reports (CARs) on the active substances.

IPBC (PT13 CAR: DK CA, 2015)

Mode of action: disturbs cell membrane permeability and fatty acids metabolism.

The IPBC toxicity profile does not indicate a clear primary target organ. Irritancy effects were seen at the local sites of treatment, in the lungs when inhaled, dermally affected skin, or affected stomach in case of diet or gavage studies. At doses ≥ 30 to 40 mg/kg bw/day increased absolute and relative liver weights were observed in rats, sometimes accompanied by hepatocellular changes (hepatocyte hypertrophy). Increased absolute and relative kidney weight (females only) was observed at the same dose range. In a two-year feeding study with rats, an increased incidence in foamy macrophages aggregates was noted in the lungs in males at 40 and 80 mg/kg bw/day.

Permethrin (PT8 CAR: IE CA, 2014)

Mode of action: prevents 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.

Central nervous system neurotoxicity was characterised, in the rat by clinical signs, tremors, staggered gait, and effects on the hind limb. Neuropathological examination of nervous tissue revealed no treatment-related lesions. Histopathological changes in the adrenals of male and female dogs (the most sensitive species) were observed. Reduced bodyweight gain in females and increased liver weight (accompanied by 'hepatic cellular swelling' (slight to moderate enlargement of hepatocytes, sometimes resulting in sinusoidal obliteration)) was observed in both sexes. Increased absolute and relative liver weight (accompanied by hepatocyte hypertrophy), yielding a NOAEL of 7.9 mg/kg bw/d) was also observed in the rat.

The acute AEL and/or chronic AEL values for IPBC and Permethrin (i.e. the non-organ-specific values used in Tier 1 of the risk assessment) are used Tier 3A, while the AEL values available for specific target organs / modes of action of the two active substances are used in Tier 3B; the latter values are presented in the table below.

Target organ/mode of action, and their organ-specific AELs, for IPBC and Permethrin

Target organ/mode of action	**IPBC** NOAEL (& AEL)	**Permethrin** NOAEL (& AEL)
Liver (chronic)	35 mg/kg bw/d (0.35 mg/kg bw/d)	5 mg/kg bw/d (0.05 mg/kg bw/d)
Kidney (chronic)	35 mg/kg bw/d (0.35 mg/kg bw/d)	N.A.
Stomach (chronic)	20 mg/kg bw/d (0.2 mg/kg bw/d)	N.A.
Salivary glands (chronic)	20 mg/kg bw/d (0.2 mg/kg bw/d)	N.A.

Adrenal glands (chronic)	N.A.	5 mg/kg bw/d (0.05 mg/kg bw/d)
Blood iron concentration (acute)	35 mg/kg bw/d (0.35 mg/kg bw/d)	N.A.
Neurotoxicity, tremor (acute)	N.A.	59 mg/kg bw/d (0.5 mg/kg bw/d)
Nasal irritation (acute)	N.A.	59 mg/kg bw/d (0.5 mg/kg bw/d)

IPBC and Permethrin show a different spectrum of target organs/modes of action, however there is an overlap in the case of chronic liver effects (increased weight with underlying hepatocyte hypertrophy) which makes it reasonable to combine the risk values for this target organ (HQ_{to}) for the two active substances for in order to obtain an HI_{to} value for the liver.

In Tier 3A, an approximate HI_{to} value for the liver is calculated for the relevant scenarios (i.e. Scenario 1.3) by combining HQ_{to} values for each active substance derived using the 'non-refined' (i.e. non-organ specific) AEL (calculation: Approx. $HI_{to} = \Sigma HQ_{to}$). This has been done in the table below for those individual- and combined exposure scenarios in which a HI > 1 was derived in the Tier 2 calculations.

Tier 3A calculations

Scenario	**IPBC**	**Permethrin**	**Approx. HI_{to}**	**Conclusion**
Scenario [1.3] (Tier 2b)				
Systemic exposure (mg/kg bw/d)	0.0754	0.0433	–	–
HQ_{to}, Liver (chronic)	0.38	0.87	1.24	**Not Acceptable**

As risk to the liver is not acceptable (i.e. Approx. $HI_{to} > 1$), the assessment should proceed to Tier 3B in which the 'refined' (i.e. organ-specific AELs) are used to derive $HQ_{a.s.\text{-}to}$ values (calculation: Adjusted $HI_{to} = \Sigma HQ_{a.s.\text{-}to}$; 'a.s.' = active substance and/or SoC).

Tier 3B calculations

Scenario	**IPBC**	**Permethrin**	**Adjusted HI_{to}**	**Conclusion**
Scenario [1.3] (Tier 2b)				
Systemic exposure (mg/kg bw/d)	0.0754	0.0433	–	–
$HQ_{a.s.\text{-}to}$, Liver (chronic)	0.22	0.87	1.09	**Not Acceptable**

Use of the organ-specific chronic AELs for the liver for each active substances results in $HQ_{a.s.\text{-}to}$ values < 1 (i.e. acceptable risk) for each active substances in Scenarios [1.3] (Tier 2b), however, the Adjusted HI_{to} value for the combination of active substances is > 1 (i.e. unacceptable risk). If exposure remains unacceptable in Tier 3B, additional PPE

can be proposed. In the case of Scenario [1.3], no additional PPE[20] can be applied that would result in acceptable risk. Consequently, an RMM to reduce potential exposure during the processes is proposed: "*The product shall only be used with flow coating/deluging and spray tunnels equipped with a device for automated transport of the freshly treated wood to automated stacking or to a drying plant, so that manual contact with the freshly treated wood is avoided.*" Considering that the Adjusted HI_{to} value is only marginally (~ 10%) greater than 1, this RMM is considered adequate to give acceptable exposure of industrial workers during flow coating/deluging and automated spraying tasks.

2.2.7 Risk assessment for animal health

Exposure of animals (pets/companion animals and livestock) directly, or via their food or drinking water, is not expected when TWP 094i is applied according to the authorised uses. However, it cannot be excluded that such exposure might occur. As methodology for assessment of exposure of companion animals is lacking, assessment of human exposure can be used as a surrogate. As companion animals may be exposed by the dermal and/or oral routes, and to wet and/or dried product, scenarios evaluating dermal and/or oral exposure of infants/ toddlers, who may be exposed to dried paint dermally and orally (via mouthing of residues), and exposed to wet paints dermally and orally (via mouthing), are the most relevant human exposures. The following scenarios were evaluated in Section 2.2.6. Risk assessment for human health: Chewing wood off-cut by infant (Scenario [5], acute exposure), Playing on playground structure outdoors and mouthing by infant (Scenario [6], chronic exposure), and Contact with freshly treated wood by toddler (Scenario [7], acute exposure). All three scenarios consider dermal and oral exposure. For IPBC, Scenarios [5], [6], and [7] estimated an exposure of 8.1%, 6.2%, and 68% of the applicable AEL. For Permethrin, Scenarios [5], [6], and [7] estimated exposures of 1.9%, 10.4%, and 24% of the applicable AEL. The *Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product* does not indicate a risk for Scenarios [5], [6], and [7] due to combined exposure to the two active substances (Tier 2 Hazard Index (HI) values are < 1 for each scenario. On this basis, safe use on human exposure to TWP 094i is considered to cover incidental exposure of animals in general to the product during application and their exposure (unintended) to treated wood once dry. However, as cats are particularly sensitive to permethrin, they are addressed in a specific General instruction for use[21].

The product should be labelled with the following RMMs:

- Do not use near domestic animals or livestock. (Use 1 and 2)
- Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets, particularly cats. (Use 1 and 2)

20 RPE has not been applied as due to the very low inhation exposure it woud have a negligible degree of mitigation.

21 As proposed for PT8 products in CA-March23-Doc.4.10 – Warning sentence and RMM for cats.

- Keep uninvolved persons, children and pets (particularly cats) away from treated surfaces/areas until dried. (Use 1 and 2)
- Do not use on wood which may come in direct contact with food, feed and livestock.

The product label should include the following General instruction for use:

- Due to the particular sensitivity of cats to permethrin, the product shall only be applied on wood which is applied in areas where contact of cats to treated wood can be excluded.

2.2.8 Risk assessment for the environment

The product TWP 094i is a water-based wood preservative designed to be used in Use class 2 and 3 by non-professionals, professionals and industrial users. It contains the active substances IPBC at 0.75 % w/w and Permethrin at 0.25 % w/w. The product TWP 094i is applied with the following application rates and techniques:

- Professional and non-professional use (brushing, rolling): 100 - 140 mL TWP 094i/m² wood surface
- Professional use (manual dipping): 100 - 140 mL TWP 094i/m² wood surface
- Industrial use (fully-automated dipping, automated flow-coating/deluging, automated spraying): 100 - 140 mL TWP 094i/m² wood surface
- Industrial use (double vacuum/low pressure process): 65.8 – 70.6 kg TWP 094i/m³ wood

With superficial and penetrative treatment, application of a topcoat is required after drying of the surface. The topcoat should be maintained.

The environmental risk assessment focusses on the Use in class 3 as relevant emissions to environmental compartments might occur when *in-situ* treated wooden structures are exposed to frequent wetting outdoors, or outdoor in-situ treatment leads to losses to soil and/or surface water during the application. During application emissions from industrial preventive processes leads to emissions to STP, and surface water and soil subsequently.

The ESD for PT8 does not provide any emission scenario for professional dipping. Therefore, no risk assessment is performed for this use. In addition, the professional manual dipping process is considered covered by the risk assessment for industrial dipping. To mitigate any potential risk following this specific use, the following RMMs are applied:

- During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.
- Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal.

2.2.8.1 **Effects assessment on the environment**

The assessment is based on the active substances IPBC and Permethrin, including the relevant metabolites.

There has not been submitted any new data regarding the active substances. The PNEC values for IPBC/PBC and permethrin have been derived from the Assessment Report (AR) for the active substances when used for PT8 purposes. A new PNECsoil value for permethrin was on the 22nd Coordination Group meeting (CG-22) in order to protect non-target beneficial soil invertebrates. This new value has been used in the present assessment.

Summary table on calculated PNEC values for active ingredients		
Compartment	**PNEC**	
	IPBC	**Permethrin**
STP	0.44 mg/L	0.00495 mg/L
Surface water	0.50 µg/L	0.00047 µg/L
Sediment	Covered by surface water*	0.000217 mg/kg wwt
Soil	0.0043 mg/kg wwt	0.175 mg/kg wwt
Oral bird	Not relevant, as log Kow (IPBC) <3	16.7 mg/kg food
Small mammal	Not relevant, as log Kow (IPBC) <3	120 mg/kg food

**No PNEC for sediment was derived, as both PEC and PNEC are determined by the same method, namely the Equilibrium Partioning Method. The risk for sediment is therefore the same as the risk for surface water.*

Summary table on PNEC values for metabolites				
Compartment	**PNEC**			
	PBC	**Iodine/Iodate/Iodide**	**DCVA**	**PBA**
STP	The one for IPBC is used as a worst case	2900 / - / - (µg iodine/L)	Not relevant, permethrin is not degraded in the STP.	Not relevant, as permethrin is not degraded in the STP.
Surface water	41.3 µg/L	0.59 / 58.5 / 0.83 (µg iodine/L)	0.015 mg/L	0.010 mg/L
Sediment	Covered by surface water	Covered by surface water	0.055 mg/kg dwt (0.012 mg/kg wwt)	0.042 mg/kg dwt (0.009 mg/kg wwt)
Soil	0.149 mg/kg wwt	0.0118 / 0.304 / 0.0043 (mg iodine/kg wwt)	4.6 mg/kg wwt	1.44 mg/kg wwt

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

Background concentration of iodine in the environment	
Compartment	**Background level (as iodine)**
Soil	Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg Global mean value of 5 mg/kg
Groundwater	Mean concentration: 1 µg/l Range: < 1-70 µg/l with extremes up to 400 µg/l
Freshwater (river and lake)	0.5 - 20 µg/l

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

IPBC (Cas. Nr. 55406-53-6) have a harmonised classification of H400 (m-factor = 10) and H410 (m-factor = 1) according to the newest assessment report for IPBC (PT13) (DK CA, 2015) and Permethrin (Cas. Nr. 52645-53-1) have a classification of H400 (m-factor = 100) and H410 (m-factor = 10000) according to the Assessment report for permethrin (PT8) (IE, 2014).
The content of 0.75 % (w/w) IPBC and 0.25 % (w/w) Permehtrin are enough to classify TWP 094i as H400 and H410 alone.

Four substances besides the active substances in TWP 094i have environmental an classifcations, however are the content of these substances does not classify the product for any environmental classification.

Substance of concern:

TWP 094i does not contain any substances of concern for the environment according to Article 3(f) of Regulation (EU) No. 528/2012, and Annex A of the Guidance on the BPR: Volume IV Environment – Assessment & Evaluation, Parts B+C (Version 2.0, October 2017). See Section 3.7.4.2 of the Confidential annex for an elaborated assessment.

A co-formulant is considered a SoC if it has known or possible endocrine-distrupting properties. The product does not have endocrine disruption indications based on current scientific knowledge, including available toxicological- and ecotoxicological information. Thus TWP 094i is not considered to having endocrine-disrupting properties (see Section 3.7.4 of the Confidential annex for a full evaluation).

Further Ecotoxicological studies

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

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

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

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

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

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

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

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

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are

relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

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

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

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

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

Leaching behaviour (ADS)

Two leaching tests ([redacted]) were performed for TWP 094i with topcoat application for surface treatment. Emission rates for IPBC and Permethrin from wood in UC 3 were investigated based on the NT Build 509 Leaching of active components from preservative treated timber – semi-field testing (Approved 2005-03). A summary of the test reports is included in the IUCLID dossier under Point 10.3. A study period of 732 days with a total rainfall amount of 1183 mm within this period was assessed.

Retention of TWP 094i was approx. 180 g/m² and 140 g/m². Application rate of 180 ml/m² showed higher leaching rates in % of active substance leached. Cumulative emissions were calculated for an application rate of 140 ml/m². As a worst case approach the calculations are based on the % of active leached for the application rate of 180 ml/m².

The calculated cumulative leaching rates and flux rates based on the leaching test with topcoat and the higher application rate are summarised in the table below. The results are presented for the times which are relevant for risk assessment (Time 1 = 30 days, Time 3 = 1825, Time 4 = 5475, Time 5 = 7300). The discussion on an additional Time of 365 days is still discussed on EU level. In this dossier this time (Time 2 = 365 days) is already included and assessed only for completeness according to the Follow-up of the 2nd EU Leaching Workshop on wood preservatives (*CA-Sept14-Doc_5_8_-_Follow_up_2nd_EU_Leaching_Workshop_PT8*). No additional assessment factors were added since the studies are semi field studies and no laboratory test, however assessment factors were added do to the use of topcoat in the studies. An assessment factor of 2 was added for assessment period of 5 years (time 3) and an assessment factor of 5 was added for assessment period of 15 and 20 years (time 4 and 5).

For the calculation the accumulated rain amounts were re-calculated to a theoretical standardized rain amount of 700 mm/year. For IBPC these were compared to the total quantity per substance leached out of 1 m² of wood area within the specific time interval based on a logarithmic regression (Step 2 – *The 2nd EU leaching Workshop)*. Based on these data leaching rates for an application rate of 140 ml/m² were calculated based on the % of active leached out.

The trend lines with the corresponding regression equations and coefficients of variation can be found in Annex 3.3.1.

For Permethrin the mean leaching rate were calculated using the cumulative quantity leached during the first test period for Time 1 (after about 30 normalized days) and during the whole test for time 2 (Step 3 - *The 2nd EU leaching Workshop)*.

Results of the leaching tests for product TWP 094i with topcoat

Application Type	Time period	Cumulative emission	Flux Rate
		mg/m²	mg/m²/day
IPBC			
Brushing/Rolling	Time 1: 30 days	**2.29**	9.74E-02
	Time 2: 365 days	**21.02**	5.76E-02
	Time 3: 1825 days (AF=2)	**65.34**	3.58E-02
	Time 4: 5475 days (AF=5)	**203.12**	3.71E-02
	Time 5: 7300 days* (AF=5)	**213.54**	2.93E-02
Permethrin			
Brushing/Rolling	Time 1: 30 days	**3.81E-04**	1.27E-05
	Time 2: 365 days	**4.06E-03**	1.11E-05
	Time 3: 1825 days(AF=2)	**4.06E-02**	2.23E-05
	Time 4: 5475 days (AF=5)	**3.05E-01**	5.57E-05
	Time 5: 7300 days* (AF=5)	**4.06E-01**	5.57E-05

It is assumed that leaching from brushing and rolling represents a worst case compared to pressure treated wood. Therefore, all leaching data are based on application by brushing and rolling.

Testing for distribution and dissipation in soil (ADS)

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

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

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

Testing for distribution and dissipation in air (ADS)

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

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

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

Measured aquatic bioconcentration

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

Estimated aquatic bioconcentration

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

No new data on the active substances and on the product TWP 094i are available. All data regarding the environmental behaviour and ecotoxicty of the active substance, which are relevant for the Environmental Risk Assessment (ERA) of the product, are deduced from the active substance data as provided in the list of endpoints of the AR.

2.2.8.2 **Exposure assessment**

General information

Assessed PT	PT 8
Assessed scenarios	**Scenario1: In-situ treatments (brushing/rolling) application by professionals/amateurs** • Bridge over pond • Timber cladded house **Scenario 2: Industrial preventive processes / industrial application** • Automated spraying • Dipping and Immersion • Double vacuum/low pressure process **Scenario 3: In-service leaching from treated wood (brushing by amateurs and professionals and industrial processes)** • Bridge over pond • Timber cladded house • Noise barrier
ESD(s) used	Emission Scenario Document for Product Type 8: - Emission Scenario Document for Wood Preservative (OECD, 2013)
Approach	Consumption based approach
Distribution in the environment	Calculations are based on ECHA-Guidance (2017 Version 2.0) BPR, Vol. IV, ENV – Part B+C.
Groundwater simulation	For IPBC leaching to groundwater simulation using the FOCUS PEARL 4.4.4 model was performed. The applicants full FOCUS PEARL report is provided in Iuclid Dossier section 13.
Confidential Annexes	
Life cycle steps assessed	All Scenarios: Production: No – closed system considered for production where exposure to environment can be excluded Formulation: No - TWP 094i is supplied as a ready-to-use formulation. Therefore, there is no mixing and loading process for the application. Use: yes Service life: Yes
Remarks	No

Fate and distribution in the environment

For a general assessment of the environmental fate and behaviour of the active substances refer to the chapter on "Fate and Distribution in the Environment" in the respective Document II-A of the active substance dossier. In the following, only a short summary is provided.

IPBC

IPBC is moderately soluble in water having water solubility of 168 mg/L at pH 7 at 20 °C and very slightly volatile having vapor pressure around 0.0045 Pa at 25 °C. IPBC is primary biodegradable according to a Zahn-Wellens test.

The degradation rates in soil were studied at 22°C and a half-life of 2.1 hours was found for IPBC. By extrapolation to 12 °C according to TGD for Risk Assessment (2003), part II a DT_{50} of 4.7 hours is obtained. For the major metabolite PBC a half-life of 4.3 days was found at 22°C corresponding to 9.5 days at 12°C.
For the degradation in water a DT_{50} of 1.4 hours at 22°C corresponding to 3.1 hours at 12°C was found for IPBC for surface water. A DT_{50} of 14.2 days at 22°C corresponding to 31.2 days at 12°C was found for PBC for surface water.

For the degradation in sediment a DT_{50} of 2.2 hours at 22°C corresponding to 4.9 hours at 12°C was found for IPBC for sediment. A DT_{50} of 14.3 days at 22°C corresponding to 31.4 days at 12°C was found for PBC for sediment.

IPBC has moderate K_{OC} values ranging from 61 to 309 with a geometric mean of 113.25 (log 2.1), which is used in the risk assessment.

PBC was identified as a relevant metabolite of IPBC in water, sediment and soil, because it was found in degradation studies at above the limit value of 10%. Due to a relative short half-life of PBC it can be regarded as a transient metabolite.

Another transformation product formed is iodine.

Molecular iodine is a chemically unstable element with oxidizing properties and it is assumed that when iodine reaches the water stream it will dissociated into iodate and iodide.

At TM II, 2012 a discussion paper was presented by DK (TMII2012-ENV-item3f evaluation of iodine released from IPBC). At the meeting it was agreed that 100% iodate (IO_3^-) and 100% iodide (I-) should be evaluated for wood protection products.

Calculations will be based on input data from open literature. These data are in line with the data provided for iodide and iodate in Appendix 3 of the final draft PT6 IPBC CAR which were deduced from the iodine dossier. The data for iodide and iodate cited in Appendix 3 of the final draft of the PT6 IPBC CAR are mostly based on literature data. It is stated in Appendix 3 that ”a lot of research has been made on the fate and distribution of iodine in the environment and all information presented in the dossier for this section is based on open literature, except for the adsorption to soil, for which a study has been conducted.” For the endpoint “adsorption to soil” for iodide and iodate, Kpsoil values have been deduced from the publication by Vidal (2009).

In the First Draft CAR for iodine it is stated “a significant part of the iodine in the aquatic compartment appears to be present as dissolved organic iodine (DOI), indicating that the risk characterisation for the aquatic compartment based only on inorganic iodine species is of quite low relevance” indicating that the risk assessment considering 100% iodide and iodate is very conservative it can be expected that much less than 100% of the different iodine species will be present.

For the soil compartment it was agreed at TMII 2012 that the total iodine concentration in soil is transformed into 100% iodate but only 14% into iodide. However, this distribution refers to the water soluble iodine fraction. It is well known from literature data that large proportions of the iodine in soil occur in an insoluble bound form (e.g. YUITA, 1992). The iodide and iodate content will therefore most likely be considerably lower.

As already done in the draft CARs IPBC PT6 and 13 for the environmental exposure and risk assessment for iodide and iodate, PEC values are calculated on basis of the IPBC PEC values for the corresponding environmental compartments and the risk assessment is mainly based on the background concentration of iodine in the environment. Iodine and

the iodine species iodide and iodate are naturally occurring substances, ubiquitously distributed and there is a natural cycle of iodine species in the environment.

The exposure assessment and risk characterisation for the iodine species are presented in Annex 3.3.3

Permethrin

Permethrin was observed to be hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50°C respectively. Only at pH 9.0/9.6 was permethrin observed to hydrolyse, with DT_{50} values for cis- and trans-permethrin estimated at 35 days and 42 days, respectively (at pH 9.6 and 25°C).

Permethrin is not readily biodegradable according to OECD 301B (CO2 evolution method)/US EPA OPPTS 835.3110 and OECD 301 F (oxygen consumption). Permethrin (25:75 cis:trans) exhibited inherent primary biodegradability, since its biodegradation was found to be above 20% in a validly conducted test (OECD302 C, BOD test). The results cannot be regarded as evidence of inherent ultimate biodegradability, since biodegradation was not above 70%. An effects study on microorganisms in sewage sludge was provided as a STP simulation test of permethrin degradation (40:60 cis:trans). From the data no clear evidence for degradation is observed. Whilst permethrin as a percentage of radioactivity was observed to decline it is likely that permethrin adsorbed to the sewage sludge (~80% AR) due to the strong adsorption characteristics of the parent compound. The remainder of the parent compound was observed in the supernatant. Permethrin is strongly adsorbed to soil (Mean Kf oc 73,442 L/kg (n= 10)). The two metabolites are more mobile. DCVA exhibited Kfocs ranging from 13.95 L/kg to 356.15 L/kg. Corresponding values for PBA ranged from 70.5 L/kg to 157.3 L/kg.

Permethrin (46:54 and 53:47 cis:trans) was observed to degrade in aerobic water/sediments systems. Whole-system first order degradation DT_{50} values for permethrin incubated aerobically in watersediment systems in the dark for 120 days at 20 ± 2 °C were 14.3 days to 24.6 days (equivalent to a corresponding range at 12 °C of 27.1 days to 46.7 days).

Maximum observed levels of DCVA (3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate), PBA (3-phenoxybenzylalcohol to 3-phenoxybenzoic acid) and PB alcohol (3-phenoxybenzyl alcohol) in the water compartment were 62.6 %AR, 28.8%AR and 38.2 %AR respectively. DCVA and PBA were also major metabolites in the sediment compartment (21.7 % and 16.4 % respectively). The whole-system first order degradation DT_{50} values for PB alcohol was measured at 2.7 days for the pond system (5.1 days at 12°C). Whole-system first order degradation DT_{50} values for PBA were measured at 31.8 days for the creek system (60.3 days at 12°C) and 33.4 days for the pond system (63.3 days at 12°C).

Whilst no reliable DT_{50} value could be obtained for DCVA in the water/sediment system, the metabolite is common to other pyrethroid chemistry (e.g. cypermethrin) and reliable DT_{50} values have been reported that provide indicative DT_{50} values in water/sediment (whole system) from 80-145 days for trans-DCVA and 62 to 188 days for cis-DCVA.

A field aquatic dissipation study on a formulated product containing 10.1% w/w permethrin (cis:trans ratio not specified) indicated rapid dissipation from the water phase to sediment for both cis- and trans-permethrin, with DT_{50} values for the water phase calculated in the range 1.3 days to 3.1 days. Cis- and trans-permethrin appeared to be rather immobile in the sediment, remaining in the upper portion (0-5 cm). DT_{50} values determined for the cis- and trans-permethrin isomers in the sediment phase ranged from 118 to 256 days and 18 to 62 days, respectively. Metabolites were only detected in the water compartment and had disappeared by 90 days after the last application in the North Carolina test site and 120 days after the last application in the California test site. Based on the above

results, biodegradation of Permethrin in freshwater occurred under both aerobic and anaerobic conditions.

Direct photolysis of permethrin (49:51 cis:trans) indicated slow degradation of the test material resulting in a DT_{50} value of 118 days with 12 hr sunlight per day under outdoor conditions at latitude of 50°N and the fall season. Control experiments revealed that permethrin was stable in water for a period of 32 days under exclusion of light. Slow degradation of permethrin under aqueous photolysis was also confirmed using the ABIWAS computer program. Overall, it is concluded that significant photolysis of permethrin will not occur under environmentally relevant pH and temperature conditions (12°C).

Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155×10^{-6} Pa at 20°C, 25:75 *cis:trans*) and Henry constant (4.6 x 10-3 - > 4.5×10^{-2} Pa m^3 mol^{-1}).

Degradation of permethrin was investigated under aerobic conditions in several soils. The range of reliable SFO DT_{50}s ranged from 77 d to ~141 d at 12°C. The corresponding geomean DT_{50} was 106 d. The *cis* isomer degraded more slowly than the *trans* isomer based on the *cis:trans* ratio at the time of application changing from 40:60 to 50:50 by day 30 and 78:22 by day 365. The geomean DT_{50} is derived from permethrin samples containing 50-78% of the *trans*- isomer. It can be expected that a DT_{50} value of 106 days is conservative enough to represent the degradation in soil at 12°C of Permethrin samples containing a *cis:trans* ratio of 25:75. Results from another submitted set of studies (giving DT50 values at 12 °C ranging from 11.0 - 21.2 days) are not considered representative of the behaviour of permethrin in soil since the route of degradation was not identified in these latter studies but was shown not to proceed via formation of DCVA and PBA.

The route of degradation of permethrin in soil appears to be dominated by a two-step process. Permethrin breaks down to form DCVA (max 11.3 %AR, SFO DT_{50} 12°C 33.1-~175 d) and PBA (max 15.0 %AR, 1.7-2.5 d at 12°C), and ultimately converts to CO2. Laboratory test data indicated that NER amounts do not exceed 70% AR after 100 days nor do mineralisation rates fall below 5% AR after 100 days for permethrin. Permethrin was observed to be relatively stable when exposed to photolysing conditions in soil. A DT_{50} of 200 d (Florida autumn sunlight) was estimated. However, confidence in the accuracy of this value was low since it was beyond the duration of the test (33 d & 3 hr of Florida autumn sunlight). No transformation product greater than 10 %AR was observed. Permethrin is strongly adsorbed to soil (Mean Kfoc 73,441 L/kg, Koc 26,930 n = 9). Therefore, leaching is not expected to occur. The two major soil metabolites (DCVA & PBA) are expected to be more mobile. The mean Kfoc for DCVA was 93.2 L/kg (n = 5). For PBA the Kfoc was 141.2 L/kg.

Emission estimation

Active substances IPBC and Permethrin

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Application rate of biocidal product	0.140	L/m²	S
Application rate of biocidal product	70.6	Kg/m³	Only Scenario 2c: double vacuum process
Application rate of biocidal product	5.6	Kg/m³	Only Scenario 2b: dipping and immersion
Density of the product	1.01	g/mL	S

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Duration of the initial assessment period [TIME 1]	30	d	OECD ESD PT8 (2013)
Duration of the long-term assessment period [TIME 2]	365	d	Follow-up 2nd EU Leaching workshop for wood preservatives (2013)
Duration of the long-term assessment period [TIME 3/4/5]	1825/5475/ 7300	d	OECD ESD PT8 (2013)
House scenario			
Leachable wood area (standard house)	125	m^2	OECD ESD PT8 (2013)
Fraction lost to soil during application ($F_{soil,brush}$)	0.03 (prof.) 0.05 (amat.)	-	OECD ESD PT8 (2013)
Soil volume (wet) [V_{soil}]	13	m^3	OECD ESD PT8 (2013)
Bridge over pond scenario			
Leachable wood area [$AREA_{bridge}$]	10	m^2	OECD ESD PT8 (2013)
Fraction lost to soil during application ($F_{soil,brush}$)	0.03 (prof.) 0.05 (amat.)	-	OECD ESD PT8 (2013)
Water volume under the bridge	1000	m^3	OECD ESD PT8 (2013)
Noise barrier scenario			
Leachable area of noise barrier	3000	m^2	OECD ESD PT8 (2013)
Volume of receiving soil [V_{soil}]	250	m^3	OECD ESD PT8 (2013)
Fraction released to soil [F_{soil}]	0.3	-	OECD ESD PT8 (2013)
Fraction released to STP [F_{STP}]	0.7	-	OECD ESD PT8 (2013)
IPBC			
Concentration of active substance in the product	0.75	% [w/w]	S
Cumulative quantity of substance leached out of $1m^2$ of treated wood over the initial assessment period (Time 1) [$Q^*_{leach, time1}$]	2.92	mg/m^2	Calculated based on study by [redacted] (2019)
Cumulative quantity of substance leached out of $1m^2$ of treated wood over the initial assessment period (Time 2 / 1 years) [$Q^*_{leach, time2}$]	421.02	mg/m^2	
Cumulative quantity of substance leached out of $1m^2$ of treated wood over the initial assessment period (Time 3 / 5 years) [$Q^*_{leach, time2}$]	65.34	mg/m^2	
Cumulative quantity of substance leached out of $1m^2$ of treated wood over the initial assessment period (Time 4 / 15 years) [$Q^*_{leach, time2}$]	203.12	mg/m^2	
Cumulative quantity of substance leached out of $1m^2$ of treated wood over the initial assessment period (Time 5 / 20 years) [$Q^*_{leach, time3}$]	213.54	mg/m^2	
Permethrin			

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Concentration of active substance in the product	0.25	% [w/w]	S
Cumulative quantity of substance leached out of 1m^2 of treated wood over the initial assessment period (Time 1) [$Q^*_{leach, time1}$]	3.81E-04	mg/m^2	Calculated based on study by [redacted] (2019)
Cumulative quantity of substance leached out of 1m^2 of treated wood over the initial assessment period (Time 2 / 1 years) [$Q^*_{leach, time2}$]	4.06E-03	mg/m^2	
Cumulative quantity of substance leached out of 1m^2 of treated wood over the initial assessment period (Time 3 / 5 years) [$Q^*_{leach, time2}$]	4.06E-02	mg/m^2	
Cumulative quantity of substance leached out of 1m^2 of treated wood over the initial assessment period (Time 4 / 15 years) [$Q^*_{leach, time2}$]	3.05E-01	mg/m^2	
Cumulative quantity of substance leached out of 1m^2 of treated wood over the initial assessment period (Time 5 / 20 years) [$Q^*_{leach, time3}$]	4.06E-01	mg/m^2	

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway								
Scenario		Fresh-water	Freshwater sediment	STP	Air	Soil	Ground-water	Biota[1]
Scenario 1: In-situ treatment	Bridge over pond	Y	Y	N	(Y)	N	N	Y
	House	N	N	N	(Y)	Y	Y	Y
Scenario 2: Industrial application	automated spraying	Y	(Y)	Y	(Y)	(Y)	(Y)	Y
	double vacuum process	Y	(Y)	Y	(Y)	(Y)	(Y)	Y
	dipping and immersion	Y	(Y)	Y	(Y)	(Y)	(Y)	Y
Scenario 3: Service life (for each compartment seevice life of 30 days, 5, 15 and 20 years will be assessed)	Bridge over pond	Y	Y	N	(Y)	N	N	Y
	House	N	N	N	(Y)	Y	Y	Y
	Noise barrier	Y	Y	Y	(Y)	Y	Y	Y

The compartments marked with 'Y' are those of concern for which predicted emissions and local concentrations have been determined for the active substances as well as the metabolites. The compartments marked with '(Y)' are those that might in principle be relevant, but not in the case of the present active substance and the relevant metabolites because of their substance-specific properties or applied risk mitigation measure. The compartments marked with 'N' are not relevant.

1: For Permethrin an assessment for secondary poisioning has been made, for all other compounds this is not relevant.

In the tables below the relevant parameters from the active substance dossiers of IPBC and Permethrin and relevant metabolites (PBC and Iodine species as well as PBA and DCVA) are presented.

IPBC

Input parameters (only set values) for calculating the fate and distribution in the environment		
Input	**Unit**	**IPBC**
Molecular weight	g/mol	281.1
Vapor pressure	Pa	2.36-4.5E-03 (25°C)
Water solubility	mg/l	168 (pH 7, 20°C)
Log Octanol/water partition coefficient	Log 10	2.81 (25°C)
Organic carbon/water partition coefficient (Koc)	L/kg	113.25
Henry's Law Constant	$Pa/m^3/mol$	3.38-6.45E-03 (25°C)
Biodegradability		Not readily
Inherently biodegradable		primary biodegradable
DT_{50} for biodegradation in surface water	d (12ºC)	0.129
DT_{50} for hydrolysis in surface water	d (12ºC)	not relevant under environmental conditions
DT_{50} for photolysis in surface water	D	Stable
DT_{50} for degradation in soil	d (12ºC)	0.196
DT_{50} for degradation in air	Hr	15 (24-h day)
Distribution in STP		IPBC is completely degraded into PBC in the STP PBC**: 0.935% air 96.7% water 2.41 sludge
BCF fish	L/kg	-

** Results taken from the CAR for PT6 (document IIB, p. 111)

Relevant degradation products

Degradation of IPBC yields the primary degradate propargyl butyl carbamate (PBC) as well as iodine. PEC values have been calculated for PBC when relevant. Regarding iodine, IPBC emissions into the environmental compartments STP, surface water and soil, respectively, have been converted to iodine (applying a molecular weight correction) and concentrations have been calculated when relevant. The resulting iodine concentrations have been compared to background concentrations found in the environment. Please refer to annex 3.3.3 for details.

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

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

Permethrin

Input parameters (only set values) for calculating the fate and distribution in the environment		
Input	**Unit**	**Permethrin**
Molecular weight	g/mol	391.29
Vapor pressure	Pa	2.155E-06 (20°C)
Water solubility	mg/l	< 0.00495 (20°C)
Log Octanol/water partition coefficient	Log 10	4.67 (25°C)
Organic carbon/water partition coefficient (Koc)	L/kg	26930
Henry's Law Constant	$Pa/m^3/mol$	> 4.5E-02
Biodegradability		Not readily
Inherently biodegradable		primary biodegradable

DT_{50} for biodegradation in surface water	d (12ºC)	46.7
DT_{50} for hydrolysis in surface water	d (12ºC)	stable
DT_{50} for photolysis in surface water	D	stable
DT_{50} for degradation in soil	d (12ºC)	106
DT_{50} for degradation in air	d	0.701
Distribution in STP		27.6 % water; 72.4 % sludge
BCF fish	L/kg	500-570

Relevant degradation products

For permethrin, the major degradation pathway in water, sediment and soil consists in the cleavage of permethrin into a 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA) and a 3-phenoxybenzoic acid (PBA) moiety. DCVA accounts for up to 62.6% of the applied dose in water, 21.7% in sediment and 11.3% in soil, while PBA accounts for up to 28.8% of the applied dose in water, 16.4% in sediment and up to 15% in soil. In the assessment report for permethrin it is considered that DCVA and PBA are far less toxic than the parent compound and not ecotoxicologically relevant. Nonetheless, as the metabolites are considerably more mobile in soil and DCVA is considerably more persistent than permethrin (in all compartments), risk to the surface water, sediment, soil and groundwater (porewater) compartments has been considered for these metabolites. Please refer to annex 3.3.4 for details.

Input parameters (only set values) for calculating the fate and distribution in the environment – DCVA and PBA				
Input	**DCVA**	**PBA**	**Unit**	**Remarks**
Molecular weight	209.07	214.22	g/mol	
Vapour pressure (at 20°C)	2.6E-01	4.21E-04	Pa	
Water solubility (at 20°C)	127.6	16.91	mg/L	
Organic carbon/water partition coefficient (Koc)	188.53	37.55	L/kg	
DT_{50} for degradation in water	94.4	63.3	d (at 12ºC)	
DT_{50} for degradation in water (incl. dissipation)	56.5	14	d (at 12ºC)	
DT_{50} for degradation in soil	175	2.5	d (at 12ºC)	
Maximum formation rate in soil	11.3	15	%	
Maximum formation rate in water	62.6	28.8	%	
Maximum formation rate in sediment	21.7	16.4	%	
The ratio between the molar masses of DCVA and permethrin is 0.534. The ratio between the molar masses of PBA and permethrin is 0.547.				

Calculated PEC values

IPBC and major metabolites

The Predicted Environmental Concentration (PEC) calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); ECHA-Guidance (2017 Version 2.0) BPR, Vol. IV, ENV – Part B+C.
The PECs for IPBC, Permethrin and degradation products in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 8, taking into account degradation processes and/or dilution (where applicable). Although the iodine-species (IPBC metabolites) and and DCVA and PBA (permethrin metabolites) are considered far less toxic than the parent compound, these metabolites could pose an environmental risk. Therefore, PECs for these metabolites were calculated as well.

The PEC values presented in the following tables are rounded values from EXCEL spread sheets. The calculations for the different PECs within EXCEL are always carried out with unrounded values.

PEC values for IPBC

Summary table on calculated PEC values				
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{gw}**
	[mg/l]**	[mg/l]	[mg/kg wwt]	[µg/l]
Scenario 1: In-situ treatments				
House (prof. - day 0)			1.80E-01	8.50E+01
House (amateur - day 0)			3.00E-01	1.42E+02
Bridge over pond (prof. - day 0)		3.18E-04		
Bridge over pond (amatuer - day 0)		5.30E-04		
Scenario 2: Industrial application**				
automated spraying	3.18E-01	*	RMM	RMM
double vacuum process	1.20E-01	*	RMM	RMM
dipping and immersion	6.36E-02	*	RMM	RMM
Scenario 3: In-service				
Noise Barrier (30 days)	1.02E-04	Covered by Bridge over pond scenario	Covered by House scenario	Covered by House scenario
Noise Barrier (1 years)	6.05E-05			
Noise Barrier (15 years)	3.90E-05			

Noise Barrier (20 years)	3.07E-05			
House (30 days)			1.56E-04	7.36E-02
House (1 years)			9.20E-05	4.35E-02
House (5 years)			5.72E-05	2.70E-02
House (15 years)			5.93E-05	2.80E-02
House (20 years)			4.67E-05	2.21E-02
Bridge over pond (30 days)		1.79E-07		
Bridge over pond (1 years)		1.06E-07		
Bridge over pond (5 years)		6.60E-08		
Bridge over pond (15 years)		6.84E-08		
Bridge over pond (20 years)		5.39E-08		

Blue colored cells: Degradation is included.
*: Refer to PEC values for PBC (IPBC is completely degraded to PBC in the STP)
**: PECstp concentrations refer to the STP influent concentration of IPBC.
RMM: Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal

PEC values for PBC

Summary table on calculated PEC values				
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]*	[mg/l]	[mg/kg wwt]	[µg/l]
Scenario 2: Industrial application				
automated spraying	1.70E-01	1.70E-02	RMM	RMM
double vacuum process	6.42E-02	6.42E-03	RMM	RMM
dipping and immersion	3.40E-02	3.40E-03	RMM	RMM
Scenario 3: In-service				
Noise Barrier (30 days)	5.46E-05	5.46E-06	Covered by House scenario	Covered by House scenario
Noise Barrier (1 years)	3.23E-05	3.23E-06		
Noise Barrier (15 years)	2.08E-05	2.08E-06		
Noise Barrier (20 years)	1.64E-05	1.64E-06		
House (30 days)			3.70E-03	1.02E+00
House (1 years)			2.46E-03	6.82E-01
House (5 years)			1.53E-03	4.24E-01
House (15 years)			1.59E-03	4.39E-01
House (20 years)			1.25E-03	3.46E-01
Bridge over pond (30 days)		1.16E-05		
Bridge over pond (1 years)		1.41E-05		
Bridge over pond (5 years)		8.74E-06		
Bridge over pond (15 years)		9.06E-06		
Bridge over pond (20 years)		7.14E-06		

Blue coloured cells: Degradation is included.
RMM: Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal

PEC values Iodine, Iodate, Iodide

Please refer to annex 3.3.3 for the detailed assessment and calculations.

PEC values Permethrin

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{sed}**	**PEC_{gw}**
	[mg/l]	[mg/l]	[mg/kg wwt]	[mg/kg wwt]	[µg/l]
Scenario 1: In-situ treatments					
House (prof. - day 0)	-	-	6.00E-02	-	1.26E-01
House (amateur - day 0)	-	-	1.00E-01	-	2.10E-01
Bridge over pond (prof. - day 0)	-	1.06E-04	-	6.22E-05	-
Bridge over pond (amatuer - day 0)	-	1.77E-04	-	1.04E-04	-
Scenario 2: Industrial application					
automated spraying	2.93E-02	2.81E-03	RMM	1.65E-03	RMM
double vacuum process	1.11E-02	1.06E-03	RMM	6.24E-04	RMM
dipping and immersion	5.85E-03	5.63E-04	RMM	3.30E-04	RMM
Scenario 3: In-service					
Noise Barrier (30 days)	3.68E-09	Covered by Bridge over pond scenario	Covered by House scenario	Covered by Bridge over pond scenario	Covered by House scenario
Noise Barrier (1 year)	3.23E-09				
Noise Barrier (15 years)	1.61E-08				
Noise Barrier (20 years)	1.61E-08				
House (30 days)	-	-	1.96E-06	-	4.11E-06
House (1 year)	-	-	8.74E-06	-	1.84E-05
House (5 years)	-	-	1.93E-05	-	4.05E-05
House (15 years)	-	-	4.81E-05	-	1.01E-04
House (20 years)	-	-	4.81E-05	-	1.01E-04
Bridge over pond (30 days)	-	2.79E-09	-	1.64E-09	
Bridge over pond (1 year)	-	2.45E-09	-	1.44E-09	
Bridge over pond (5 years)	-	4.90E-09	-	2.87E-09	
Bridge over pond (15 years)	-	1.22E-08	-	7.18E-09	
Bridge over pond (20 years)	-	1.22E-08	-	7.18E-09	

RMM (Risk Mitigation Measures): Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal

Blue coloured cells: Degradation is included.

PEC values DCVA and PBA

Please refer to annex 3.3.4 for the detailed assessment and calculations.

PEC for atmosphere

IPBC

IPBC has a low vapour pressure of 2.36 – 4.5 x 10^{-3} Pa at 25°C and a Henry's Law constant of 3.38 – 6.45 x 10^{-3} Pa×m³/mol. This indicates a very low risk of volatilisation. With regard to the fact that IPBC half-life in air is only about 15 hours, the substance is not considered persistent in air (as stated in the Assessment Report). Thus no assessment for a possible risk of the atmosphere (PEC_{air}) is conducted.

Permethrin

Any predicted environmental concentrations in air are likely to be negligible due to the low vapour pressure of Permethrin (2.155E-06 (20°C)). Therefore, likely concentrations of permethrin in air are not of significant concern and will not be considered further.

PEC groundwater

IPBC, PBC, Iodide and Iodate

IPBC concentrations in groundwater was calculated according to BPR Guidance Vol IV Env. B+C. Pore water concentrations was equalled $PEC_{groundwater}$ to estimate the risk to ground water.

The worst case PEC_{gw} for IPBC was from the House Scenario (15 years) being 0,0280 µg/l.

Concentrations in groundwater for IPBC metabolites (PBC, Iodide, Iodate) were first assessed using the same method as for IPBC. However as the PEC_{GW} for PBC, Iodide and Iodate all exceeded the 0.1 µg/l permissible concentration in groundwater, and the two iodine species also exceeded the background levels of iodine (See "PEC for PBC" and Annex 3.3.3), a FOCUS PEARL 4.4.4 refinement was performed. The assessment was based on an assessment by the applicant ([redacted] 2018). In accordance with the OECD ESD PT8 (2013), Fweatherside=0.5 was used in all calculations.
Scenario 3 (service life / house scenario) with a service life of 15 years showed the highest leaching per year. Therefore, this scenario was chosen as a worst case to calculate PEC_{gw} values.

The calculated worst case PEC_{GW} concentration for PBC, Iodide and Iodate is shown in the table below.
The relevant input values and the result of the FOCUS PEARL can be found in Annex 3.3.3.

Metabolites of IPBC PEC_{GW} – FOCUS PEARL refined	
PEC_{GW}	[µg/l]
PBC	< 0.000001
Iodide	0.074841
Iodate	1.041193

Permethrin and major metabolites

$PEC_{groundwater}$ for permethrin was calculated according to BPR Guidance Vol IV Env. B+C. Pore water concentrations was equalled $PEC_{groundwater}$ to estimate the risk to ground water. For the two major permethrin metabolites DCVA and PBA, concentrations in porewater has been calculated as well. For detailed calculations, please refer to annex 3.3.4.

Neither permethrin or its metabolites exceeded the 0.1 µg/l permissible concentration in groundwater.

The worstcase PEC_{gw} for permethrin and its metabolites is shown in the table:

PEC_{GW} – Permethrin and metabolites	
PEC_{GW}	[µg/l]
Permethrin	0.00010
DCVA	0.00422
PBA	0.00179

Primary and secondary poisoning

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

Secondary poisoning

IPBC

According to Guidance on BPR Vol. IV Environment (ECHA, 2015) the first step in the assessment strategy for secondary poisoning is to consider whether there are indications for bioaccumulation potential. Subsequently, it is necessary to consider whether the substance has a potential to cause toxic effects if accumulated in higher organisms.
Nor IPBC neither PBC are bio-accumulate.
The Log Kow values show that bio-accumulation of IPBC (Log Kow = 2.81) and PBC (Log Kow = 1.64 estimated) is not expected. Moreover, IPBC degrades rapidly in the environment to PBC which has a half-life of 9.5 days and therefore no persistent breakdown products are to be expected.

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

Permethrin

Permethrin is characterized by log Kow value of 4.67 which indicates a high potential for bioaccumulation. However, the results of an experimental BCF test in Bluegill sunfish confirm the low potential for bioaccumulation by a BCF of 570 L/Kgwwt. BCF in earthworm was estimated to be 15108 L/kg wwt.

The Log Kow and some of the estimated BCF values would indicate permethrin has a strong potential to bioconcentrate following uptake via water/porewater (e.g. in worms) and subsequently bioaccumulate through the food chain, resulting in toxic concentrations in predatory birds or mammals ingesting biota containing the chemical.
As a consequence, bioaccumulation of the active substance cannot be completely excluded.

Detailed calculations of PECoral,predator can be found in 3.3.2.

Summary of the PEC values for secondary poisoning (Permethrin)		
	Value	Unit
$PEC_{oral\_predator}$ (Aquatic)	1.35E-05	mg/kg wet fish
$PEC_{oral\_predator}$ (Terrestial)	6.90E-04	mg/kg wet earthworm

2.2.8.3 **Risk characterisation**

Risk Characterisation Ratios (PEC/PNEC) are derived for the use of the wood preservative for all three scenarios. The calculated PEC/PNEC ratios are provided for the STP, the aquatic and terrestrial compartment in the following. As stated in section 2.2.8.2, air is not regarded as compartment of concern for this product with the proposed use patterns. If the PEC/PNEC ratio is below 1, this is interpreted as an acceptable risk to the environment.
Calculated PEC/PNEC values are summarised below, values above 1 are marked with red colour.

PEC/PNECs for IPBC

Summary table on calculated PEC/PNEC values			
	STP	**Water**	**Soil**
Scenario 1: In-situ treatments			
House (prof. - day 0)			4.18E+01
House (amateur - day 0)			6.97E+01
Bridge over pond (prof. - day 0)		6.36E-01	
Bridge over pond (amatuer - day 0)		1.06E+00	
Scenario 2: Industrial application			
automated spraying	7.23E-01		
double vacuum process	2.73E-01		
dipping and immersion	1.45E-01		
Scenario 3: In-service			
Noise Barrier (30 days)	2.32E-04	Covered by Bridge over pond scenario	Covered by House scenario
Noise Barrier (1 years)	1.37E-04		
Noise Barrier (15 years)	8.85E-05		
Noise Barrier (20 years)	6.98E-05		
House (30 days)			3.62E-02
House (1 years)			2.14E-02
House (5 years)			1.33E-02
House (15 years)			1.38E-02
House (20 years)			1.09E-02
Bridge over pond (30 days)		3.59E-04	
Bridge over pond (1 years)		2.12E-04	
Bridge over pond (5 years)		1.32E-04	
Bridge over pond (15 years)		1.37E-04	

Summary table on calculated PEC/PNEC values			
	STP	**Water**	**Soil**
Bridge over pond (20 years)		1.08E-04	

PEC/PNECs for metabolite PBC

Summary table on calculated PEC/PNEC values			
	STP	**Water**	**Soil**
Scenario 2: Industrial application			
automated spraying	*	4.11E-01	
double vacuum process	*	1.55E-01	
dipping and immersion	*	8.22E-02	
Scenario 3: In-service			
Noise Barrier (30 days)	*	1.32E-04	9.30E-03
Noise Barrier (1 years)	*	7.81E-05	6.19E-03
Noise Barrier (15 years)	*	5.03E-05	3.99E-03
Noise Barrier (20 years)	*	3.97E-05	3.15E-03
House (30 days)			2.48E-02
House (1 years)			1.65E-02
House (5 years)			1.03E-02
House (15 years)			1.07E-02
House (20 years)			8.40E-03
Bridge over pond (30 days)	-	2.80E-04	-
Bridge over pond (1 years)		3.40E-04	
Bridge over pond (5 years)	-	2.12E-04	-
Bridge over pond (15 years)	-	2.19E-04	-
Bridge over pond (20 years)	-	1.73E-05	-

*Covered by RCR for IPBC

PEC/PNECs for Permethrin

Summary table on calculated PEC/PNEC values

	STP	Water	Soil	Sediment
Scenario 1: In-situ treatments				
House (prof. - day 0)			3.43E-01	
House (amateur - day 0)			5.71E-01	
Bridge over pond (prof. - day 0)		2.26E+02		2.86E-01
Bridge over pond (amatuer - day 0)		3.76E+02		4.77E-01
Scenario 2: Industrial application				
automated spraying	5.91E+00	5.99E+03		7.60E+00
double vacuum process	2.24E+00	2.26E+03		2.87E+00
dipping and immersion	1.18E+00	1.20E+03		1.52E+00
Scenario 3: In-service				
Noise Barrier (30 days)	7.43E-07	Covered by Bridge over pond scenario	Covered by House scenario	Covered by Bridge over pond scenario
Noise Barrier (1 year)	6.52E-07			
Noise Barrier (15 years)	3.26E-06			
Noise Barrier (20 years)	3.26E-06			
House (30 days)			1.12E-05	
House (1 year)			5.00E-05	
House (5 years)			1.10E-04	
House (15 years)			2.75E-04	
House (20 years)			2.75E-04	
Bridge over pond (30 days)		5.94E-03		7.54E-06
Bridge over pond (1 year)		5.21E-03		6.61E-06
Bridge over pond (5 years)		1.04E-02		1.32E-05
Bridge over pond (15 years)		2.60E-02		3.31E-05
Bridge over pond (20 years)		2.60E-02		3.31E-05

Blue coloured cells: Degradation is included.

Mixture toxicity

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

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

Mixture toxicity is assessed according to the following equation:

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

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

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

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

Summary table on calculated Σ PEC/PNEC values for TWP 094i				
	STP	**Water**	**Soil**	**Sediment**
Scenario 1: In-situ treatments				
House (prof. - day 0)			4.22E+01	
House (amateur - day 0)			7.03E+01	
Bridge over pond (prof. - day 0)		2.26E+02		2.86E-01
Bridge over pond (amatuer - day 0)		3.77E+02		4.77E-01
Scenario 2: Industrial application				
automated spraying	6.64E+00	5.99E+03*		7.60E+00
double vacuum process	2.51E+00	2.26E+03*		2.87E+00
dipping and immersion	1.33E+00	1.20E+03*		1.52E+00
Scenario 3: In-service				
Noise Barrier (30 days)	2.33E-04	Covered by Bridge over pond scenario	Covered by House scenario	Covered by Bridge over pond scenario
Noise Barrier (1 year)	1.38E-04			
Noise Barrier (15 years)	9.18E-05			
Noise Barrier (20 years)	7.31E-05			
House (30 days)			3.62E-02	
House (1 year)			2.14E-02	
House (5 years)			1.34E-02	
House (15 years)			1.41E-02	
House (20 years)			1.11E-02	
Bridge over pond (30 days)		6.30E-03		7.54E-06
Bridge over pond (1 year)		5.42E-03		6.61E-06
Bridge over pond (5 years)		1.06E-02		1.32E-05
Bridge over pond (15 years)		2.62E-02		3.31E-05
Bridge over pond (20 years)		2.62E-02		3.31E-05

*PBC PEC/PNEC values are used.

Atmosphere

Any predicted environmental concentrations in air are likely to be negligible due to the low vapour pressure of IPBC (0.0045 Pa at 25°C) and Permethrin (2.155E-06 (20°C). Therefore, likely concentrations of the actives in air are not of significant concern and are not considered further.

Sewage treatment plant (STP)

The combined active substance PEC/PNEC ratio for "Scenario 2: industrial applications" are above the trigger value of one. However, all waste water or residues from industrial applications containing traces of the biocidal product will be collected and disposed as hazardous waste. The risk mitigation measure: "Any losses should be collected for re-use or disposal." have been applied. Therefore emissions from industrial processes to the environment are not relevant.

PEC/PNEC ratio for "Scenario 3: in-service" are below the trigger value of one.

Conclusion: The results of the risk characterisation show that there is no relevant unacceptable risk for the STP from the use of the product TWP 094i.

Aquatic compartment

A risk was identified for the "Scenario 1: in-situ treatments" bridge over pond scenario (brushing/rolling) application by professionals/amateurs in the water compartment. The risk mitigation measure "Do not apply near bodies of surface water." is applied to the use.

PEC/PNEC ratios following emission to surface water and sediment via STP in "Scenario 2: industrial applications" are above the trigger value of one for all assessed scenarios. However, all waste water or residues from industrial applications containing traces of the biocidal product will be collected and disposed as hazardous waste. The risk mitigation measure: "Any losses should be collected for re-use or disposal." have been applied. Therefore emissions from industrial processes to the environment are not relevant.

The PEC/PNEC ratio for "Scenario 3: in-service" in surface water and sediment are below the trigger value of one.

Regarding the iodine risk assessment for surface water all predicted environmental concentrations are below or within the background concentration (Please refer to Annex 3.3.3).

Conclusion: The results of the risk characterisation show that there is no relevant unacceptable risk for the aquatic compartment from the use of the product TWP 094i.

Terrestrial compartment

A risk was identified for the Scenario 1 (In-situ brushing/rolling application by professionals/amateurs). The risk mitigation measure "During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way." is applied for the use.

The PEC/PNEC ratio for "Scenario 3: in-service" are below the trigger value of one for all assessed scenarios.
Regarding iodine risk assessment for soil all predicted environmental concentrations are below the background concentration (Please refer to Annex 3.3.3).

Conclusion: The results of the risk characterisation show that there is no relevant unacceptable risk for soil from the use of the product TWP 094i.

Groundwater

For "Scenario 1: in-situ treatments" an exceedance of the groundwater limit value of 0.1 0.1 µg/L was identified. To avoid exceedance of the limit value, the following risk mitigation measure is considered sufficient: "During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.".

For "Scenario 2: Industrial application", the following risk mitigation measure is considered sufficient to avoid risk of leaching to groundwater: "Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal.".

For "Scenario 3: in-service", the calculated PEC_{GW} values for IPBC and the metabolite PBC are all below the limit values of 0.1 µg/L as laid down for pesticides in the Drinking Water Directive 98/83/EC.
The calculated PEC_{GW} values for Iodine species, Iodide and Iodate, are below the background concentration in groundwater (Please refer to Annex 3.3.3).

The calculated PEC_{GW} values for Permethrin are all below the limit values of 0.1 µg/L as laid down for pesticides in the Drinking Water Directive 98/83/EC.
The calculated PEC_{GW} values for the metabolites DCVA and PBA are below the groundwater limit (Please refer to Annex 3.3.4).

Conclusion: No relevant unacceptable risk for the groundwater compartment is found.

Primary and secondary poisoning

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

Secondary poisoning

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

Permethrin
Since bioaccumulation of the active substance **Permethrin** in the food chain cannot be completely excluded due to the high log Kow of 4.67 the risk for fish and worm-eating birds and mammals is assessed for the aquatic and terrestrial food chain.

The PNEC values for birds and mammals were derived from the CAR of Permethrin (2014). All values and risk quotients are summarized in the Table below. Risk characterization is based on the max. calculated PEC values for soil and groundwater.

Summary table on secondary poisoning			
Scenario	**$PEC_{oral\ predator}$**	**$PEC/PNEC_{birds}$**	**$PEC/PNEC_{mammals}$**
Scenario 1 – Aquatic food chain			
1	3.49E-06 [mg/kg wet fish]	8.06E-07	1.12E-07
Scenario 1 – Terrestrial food chain			
1	6.90E-04 [mg/kg wet earthworm]	4.13E-05	5.75E-06

Conclusion:
According to the calculated risk quotients above, the risk of permethrin for birds and mammals via secondary poisoning is acceptable.

Aggregated exposure (combined for relevant emission sources)

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

Permethrin is not approved for use in plant protection products. Under the BPR, it is authorised for use in PT8 and PT18 products. Although it is possible that these two uses could overlap in time, it is unlikely that they would overlap in space, as PT18 products are used mainly indoors, with STP as the major receiving compartment, whereas emissions for PT8 products are only considered for outdoor use, with soil and surface water representing the major receiving compartments.

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

Overall conclusion on the risk assessment for the environment of the product

Considering exposure to environmental compartments no risk could be determined for the use of TWP 094i if the following risk mitigation measures are considered:

For amateur and professional use (brushing and rolling):

- Do not apply near bodies of surface water.
- During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

For professional use (manual dipping):

- Do not apply near bodies of surface water.
- During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

- Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water.
- Any losses should be collected for re-use or disposal.

For industrial use:

- Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water.
- Any losses should be collected for re-use or disposal.

All relevant PEC/PNEC ratios are below the trigger value of 1 for "Scenario 3: in-service".

The risk assessment demonstrates a safe use of the product TWP 094i for all relevant environmental compartments exposed and secondary poisoning.

2.2.9 Measures to protect man, animals and the environment

Please refer to Section 2.1 Summary of the product assessment, Section 2.2.6 Risk assessment for human health, Section 2.2.7 Risk assessment for animal health, and Section 2.2.8 Risk assessment for the environment, and to Sections 4 and 5 of the SPC.

2.2.10 Assessment of a combination of biocidal products

TWP 094i is not intended to be used in combination with other biocidal products.

2.2.11 Comparative assessment

A Comparative assessment of TWP 094i is not required at this time; refer to Section 2.1.2.2.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/ No)	Owner
2.2.2/1 2.2.2/2 2.2.2/3 2.2.2/4 2.2.2/6	[redacted]	2018a	TWP 094i: Accelerated Storage Stability (Report no. MG09NQ)	Yes	Troy Chemical Company B.V.
2.2.2/5 2.2.2/21 2.2.2/22 2.2.2/30 2.2.2/31 2.2.3/1 2.2.3/6 2.2.3/13 2.2.3/17	[redacted]	2018b	TWP 094i: Physicochemical Properties (Report no. GS55VM)	Yes	Troy Chemical Company B.V.
2.2.2/6 2.2.2/8 2.2.2/9 2.2.4/1	[redacted]	2018c	TWP 094i: Method Validation	Yes	Troy Chemical Company B.V.
2.2.2/8	[redacted]	2020a	TWP094i: Long term storage at ambient temperature	Yes	Troy Chemical Company B.V.
2.2.2/7 2.2.2/13 2.2.2/14	[redacted]	2021	TWP094i: Accelerated storage (Report no. TROY2021-01-9801)	Yes	Troy Chemical Company B.V.
2.2.2/21	[redacted]	2022	TWP094i: Persistent foaming (Report no. TROY2022-06-9815)	Yes	Troy Chemical Company B.V.
2.2.2/29	[redacted]	2022	TWP094i: Degree of dissolution and dilution stability (Report no. TROY2022-06-9816)	Yes	Troy Chemical Company B.V.
2.2.2/9	[redacted]	2021a	TWP 094: Long term storage at ambient temperature (Report no.8465684)	Yes	Troy Chemical Company B.V.
2.2.3/16	[redacted]	2021b	TWP 094i: Corrosive to metals	Yes	Troy Chemical Company B.V.
2.2.2/9 2.2.2/10	[redacted]	2022	TWP094i: Long term storage at ambient temperature (Report no.8465684)	Yes	Troy Chemical Company B.V.
2.2.5/1	[redacted]	2018a	Laboratory method for determining the protective effectiveness of preservative treatment against blue stain according to EN 152 (2011) after 6 months of field testing, MPA Eberswalde, Test report no:32/17/10057/14, Unpublished	Yes	Troy Chemical Company B.V.
2.2.5/2	[redacted]	2017a	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with leaching procedure according to EN 84 (1997), MPA Eberswalde, Test	Yes	Troy Chemical Company B.V.

			report no: 32/17/10057/19, Unpublished		
2.2.5/3	[redacted]	2018b	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with evaporative aging procedure according to EN 73 (2014), MPA Eberswalde, Test report no: 32/17/10057/20, Unpublished	Yes	Troy Chemical Company B.V.
2.2.5/4	[redacted]	2017b	Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2016) after leaching procedure according to EN 84 (1997), MPA Eberswalde, Test report no: 32/17/10057/21, Unpublished	Yes	Troy Chemical Company B.V.
2.2.5/5	[redacted]	2017c	Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2016) after evaporative aging procedure according to EN 73 (2014), MPA Eberswalde, Test report no: 32/17/10057/26 Unpublished	Yes	Troy Chemical Company B.V.
2.2.5/6	[redacted]	2017d	Determination of the preventive action against Reticulitermes santonensis de Feytaud according to EN 118 (1997) in combination with leaching procedure according to EN 84 (1997), MPA Eberswalde, Test report no: 32/17/10057/31, Unpublished	Yes	Troy Chemical Company B.V.
2.2.5/7	[redacted]	2017e	Determination of the preventive action against Reticulitermes santonensis de Feytaud according to EN 118 (1997) in combination with evaporative aging procedure according to EN 73 (2014), MPA Eberswalde, Test report no: 32/17/10057/36 Unpublished	Yes	Troy Chemical Company B.V.
2.2.8.1	[redacted]	2018a	NT BUILD 509 "Leaching of active ingredients from preservative-treated timber _ Semi field testing"/ 31/17/3149/01A	Yes	Troy Chemical Company B.V.
73.2	[redacted]	2018b	NT BUILD 509 "Leaching of active ingredients from preservative-treated timber _ Semi field testing"/ 31/17/3149/02A	Yes	Troy Chemical Company B.V.
73.2	[redacted]	2018c	31/17/3149/03 Determination of active substance in test product TWP 094i	Yes	Troy Chemical Company B.V.
73.2	[redacted]	2018	Calculation of Predicted Environmental Concentrations of IPBC, PBC, Iodide and Iodate in Groundwater (PECGW) after direct release to soil	Yes	Troy Chemical Company B.V.

			(Calculated with FOCUS PEARL 4.4.4)		

3.2 Output tables from exposure assessment tools

3.2.1 Output tables from exposure assessment tools – human health exposure assessment

Scenario [1.1]: Mixing and loading by industrial users

Exposure calculations not required – refer to the description of Scenario [1.1].

Scenario [1.2]: Application – Fully-automated dipping

Scenario [1.2]: Industrial application by fully automated dipping (chronic, primary exposure)

Modelled using Handling model 1, TNsG Part 2, 2002, p. 160 for Industrial wood preservation - intermittent manual handling of water-wet or solvent-damp wood and associated equipment, and HEEG Opinion No. 18.

	Units	IPBC Tier 1	IPBC Tier 2a	IPBC Tier 2b	Permethrin Tier 1	Permethrin Tier 2a	Permethrin Tier 2b
Active substance	% w/w	0,75	0,75	0,75	0,25	0,25	0,25
Body weight	kg	60	60	60	60	60	60
Dermal penetration rate	%	29	29	29	50	50	50
Potential dermal exposure							
Potential hand exposure (inside gloves)							
Indicative value*	mg/cycle	540,0	540,0	1080,0	540,0	540,0	1080,0
Dipping cycles**	#	1	1	1	1	1	1
Potential hand deposit	mg product	540,0	540,0	1080,0	540,0	540,0	1080,0
Potential body exposure							
Indicative value*	mg/cycle	8570	8570	8570	8570	8570	8570
Dipping cycles**	#	1	1	1	1	1	1
Potential dermal deposit	mg product	8570,0	8570,0	8570,0	8570,0	8570,0	8570,0
Clothing type		None	Coated coverall	Impermeable coverall	None	Coated coverall	Impermeable coverall
Clothing penetration	%	100	10	5	100	10	5
Actual dermal deposit	mg	9110,00	1397,00	1508,50	9110,00	1397,00	1508,50
Total dermal exposure							
Total dermal deposit [a.s.]	mg a.s.	68,33	10,48	11,31	22,78	3,49	3,77
Penetration through skin [a.s.]	mg a.s.	19,81	3,04	3,28	11,39	1,75	1,89
Systemic exposure via dermal route	mg/kg bw/day	0,3302	0,0506	0,0547	0,1898	0,0291	0,0314
$AEL_{long\text{-}term}$	mg/kg bw/day	0,2	0,2	0,2	0,05	0,05	0,05
% $AEL_{long\text{-}term}$	**%**	**165,12**	**25,32**	**27,34**	**379,58**	**58,21**	**62,85**
Total systemic exposure	mg/kg bw/day	0,3302	0,0506	0,0547	0,1898	0,0291	0,0314
$AEL_{long\text{-}term}$	mg/kg bw/day	0,20	0,20	0,20	0,05	0,05	0,05
% $AEL_{long\text{-}term}$	**%**	**165,12**	**25,32**	**27,34**	**379,58**	**58,21**	**62,85**

*: 1080 mg/cycle for hands inside used gloves; 540 mg/cycle for hands inside new gloves; from TNsG Handling model 1 (TNsG Part 2, 2002, p. 160, and HEAdhoc Recommendation no. 6 (May 2020), Table 1, Scenario 20)

**: HEEG Opinion 8 "Defaults and appropriate models to assess human exposure for dipping processes (PT8)" (2009), corrected by a factor of 4 (to account for exposure during only 1 of 4 dipping cycles if fully automated) according to HEEG Opinion no. 18.

Scenario [1.3]: Application – Automated flow-coating/deluging and automated spraying

Scenario [1.3]: Industrial application by automated flow coating/deluging and automated spraying (chronic, primary exposure)

Modelled using indicative exposure values from Dipping Model 1 of HEAdhoc Recommendation no. 6 'Methods and models to assess exposure to biocidal products in different product types' (May 2020).

	IPBC Tier 1	IPBC Tier 2a	IPBC Tier 2b	Permethrin Tier 1	Permethrin Tier 2a	Permethrin Tier 2b
Active substance % (w/w)	0,75%	0,75%	0,75%	0,25%	0,25%	0,25%
Potential body exposure						
Indicative value mg/min	178	178	178	178	178	178
Duration min	60	60	60	60	60	60
Potential dermal deposit mg	10680	10680	10680	10680	10680	10680
Clothing type	None	Coated coverall	Impermeable coverall	None	Coated coverall	Impermeable coverall
Clothing penetration %	100%	10%	5%	100%	10%	5%
Actual dermal deposit [product] mg	10680	1068	534	10680	1068	534
Hand exposure						
Indicative value mg/min (in gloves, actual)	25,7	25,7	25,7	25,7	25,7	25,7
Duration min	60	60	60	60	60	60
Hand deposit mg	1542	1542	1542	1542	1542	1542
Mitigation by gloves	Not applicable (see 'indicative value')	Not applicable (see 'indicative value')	Not applicable (see 'indicative value')	Not applicable (see 'indicative value')	Not applicable (see 'indicative value')	Not applicable (see 'indicative value')
Actual hand deposit [product] mg	1542	1542	1542	1542	1542	1542
Total dermal exposure						
Total dermal deposit [product] mg	12222	2610	2076	12222	2610	2076
Active substance mg	91,67	19,58	15,57	30,56	6,53	5,19
Dermal absorption %	29%	29%	29%	50%	50%	50%
Systemic exposure via dermal route mg	26,5829	5,6768	4,5153	15,2775	3,2625	2,5950
Systemic exposure mg kg^{-1} day^{-1}	0,4430	0,0946	0,0753	0,2546	0,0544	0,0433
Exposure by inhalation						
Indicative value mg/m^3	1	1	1	1	1	1
Duration	60	60	60	60	60	60
Inhalation rate m^3/h	1,25	1,25	1,25	1,25	1,25	1,25
Mitigation by RPE (PF)	1	1	1	1	1	1
Inhaled [product] mg	1,25	1,25	1,25	1,25	1,25	1,25
Systemic exposure via inhalation route mg	0,0094	0,0094	0,0094	0,0031	0,0031	0,0031
Systemic exposure mg kg^{-1} day^{-1}	0,00016	0,00016	0,00016	0,00005	0,00005	0,00005
Systemic exposure						
Total systemic exposure a.s. mg	26,5922	5,6861	4,5247	15,2806	3,2656	2,5981
Body weight kg	60	60	60	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	0,4432	0,0948	0,0754	0,2547	0,0544	0,0433
$AEL_{long\text{-}term}$ mg kg^{-1} day^{-1}	0,2	0,2	0,2	0,05	0,05	0,05
% $AEL_{long\text{-}term}$	**221,6%**	**47,4%**	**37,7%**	**509,4%**	**108,9%**	**86,6%**

Scenario [1.4]: Application: Double vacuum/low pressure process

Modelled using indicative exposure values from Handling Model 1 (TNsG (2002) Part 2, p. 160), as recommended in HEAdhoc Recommendation no. 6 'Methods and models to assess exposure to biocidal products in different product types' (May 2020).

	IPBC Tier 1	IPBC Tier 2	Permethrin Tier 1	Permethrin Tier 2
Active substance in product % (w/w)	0,75%	0,75%	0,25%	0,25%
In-use concentration of a.s. % (w/w)	0,075%	0,075%	0,025%	0,025%
Potential body exposure				
Indicative value mg/cycle	8570	8570	8570	8570
Duration cycles	6	6	6	6
Potential dermal deposit mg	51420	51420	51420	51420
Clothing type	None	Coated coverall	None	Coated coverall
Clothing penetration %	100%	10%	100%	10%
Actual dermal deposit [product] mg	51420	5142	51420	5142
Hand exposure				
Indicative value mg/cycle (in gloves, actual); (HEAdhoc Recommendation No. 6, pp. 19-20)	1080	1080	1080	1080
Duration cycles	6	6	6	6
Hand deposit mg	6480	6480	6480	6480
Mitigation by gloves	Not applicable	Not applicable	Not applicable	Not applicable
Actual hand deposit [product] mg	6480	6480	6480	6480
Total dermal exposure				
Total dermal deposit [product] mg	57900	11622	57900	11622
Active substance mg	43,43	8,72	14,48	2,91
Dermal absorption %	50%	50%	50%	50%
Systemic exposure via dermal route mg	21,7125	4,3583	7,2375	1,4528
Systemic exposure mg/kg/day	0,3619	0,0726	0,1206	0,0242
Exposure by inhalation				
Indicative value mg/m³	1,9	1,9	1,9	1,9
Duration (min) = 60 minutes (set for 6 cycles in Handling Model 1 (HEAdhoc Recommendation No. 6, pp. 19-20))	60	60	60	60
Inhalation rate m^3/h	1,25	1,25	1,25	1,25
Mitigation by RPE (PF)	1	1	1	1
Inhaled [product] mg	2,38	2,38	2,38	2,38
Systemic exposure via inhalation route mg	0,018	0,018	0,006	0,006
systemic exposure mg/kg/day	0,00030	0,00030	0,00010	0,00010
Systemic exposure				
Total systemic exposure a.s. mg	21,7303	4,3761	7,2434	1,4587
Body weight kg	60	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	0,3622	0,0729	0,1207	0,0243
$AEL_{long\text{-}term}$ mg kg^{-1} day^{-1}	0,2	0,2	0,05	0,05
% $AEL_{long\text{-}term}$	**181%**	**36,5%**	**241%**	**48,6%**

Scenario [1.5]: Post-application – Handling of treated articles

Not specifically calculated – refer to the description of Scenario [1.5].

Scenario [1.6]: Post-application – maintenance/cleaning of the system

Not specifically calculated – refer to the description of Scenario [1.6].

Combined exposure for industrial users

Relevant combined exposure scenarios for the individual active substance have not been identified for industrial uses.

No oral exposure.

IPBC

Scenarios	Dermal Exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	$AEL_{long\text{-}term}$ (mg/kg bw/day)	% of AEL
Tier 1					
1.2	0,34981	0,00000	0,34981	0,2	175
1.3	0,44305	0,00016	0,44320	0,2	222
1.4	0,36188	0,00030	0,36217	0,2	181
Tier 2					
1.2	0,07022	0,00000	0,07022	0,2	35,1
1.3	0,09461	0,00016	0,09477	0,2	47,4
1.4	0,07264	0,00030	0,07293	0,2	36,5
Tier 3					
1.2	0,05468	0,00000	0,05468	0,2	27,3
1.3	0,07526	0,00016	0,07541	0,2	37,7

Permethrin

Scenarios	Dermal Exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	$AEL_{long\text{-}term}$ (mg/kg bw/day)	% of AEL
Tier 1					
1.2	0,20104	0,00000	0,20104	0,05	402
1.3	0,25463	0,00005	0,25468	0,05	509
1.4	0,12063	0,00010	0,12072	0,05	241
Tier 2					
1.2	0,04035	0,00000	0,04035	0,05	80,7
1.3	0,05438	0,00005	0,05443	0,05	109
1.4	0,02421	0,00010	0,02431	0,05	48,6
Tier 3					
1.2	0,03143	0,00000	0,03143	0,05	62,9
1.3	0,03435	0,00005	0,03440	0,05	68,8

IPBC & Permethrin

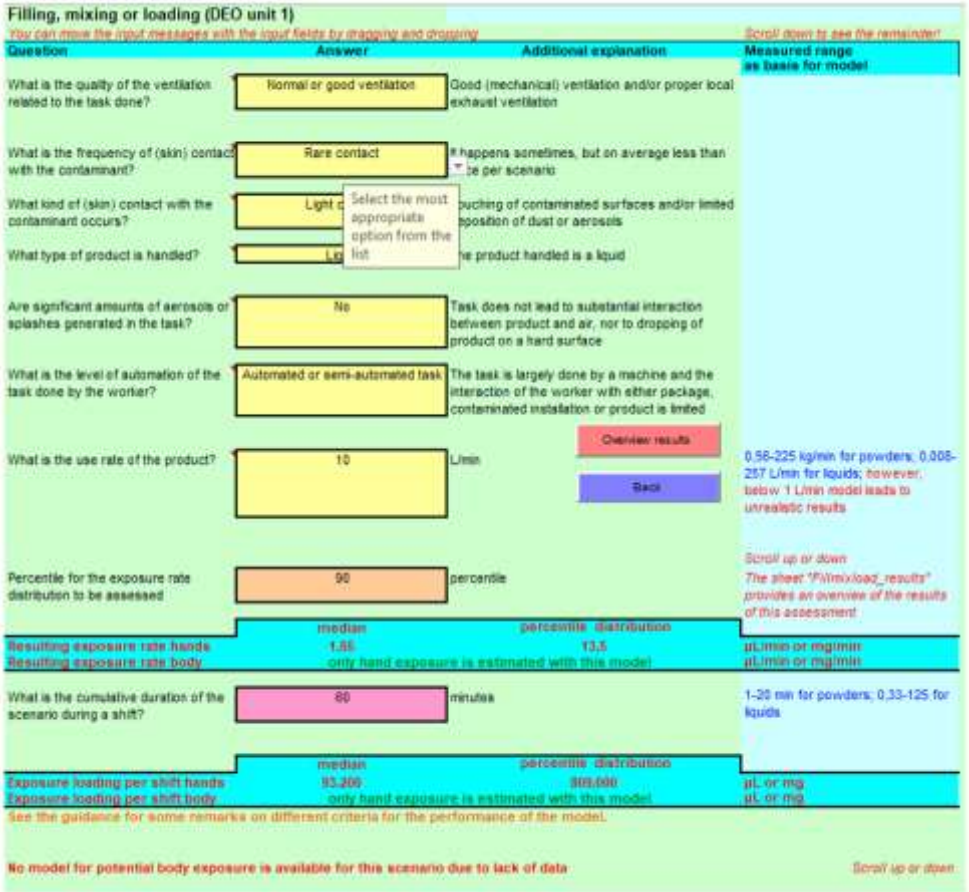
Scenarios	IPBC Hazard Quotient (HQ) (%AEL/100)	IPBC HQ acceptable	Permethrin Hazard Quotient (HQ) (%AEL/100)	Permethrin HQ acceptable	Hazard Index (HI) (Σ HQ for IPBC + Permethrin)	HI acceptable (≤ 1)
Tier 1						
1.2	1,75	No	4,02	No	5,77	No
1.3	2,22	No	5,09	No	7,31	No
1.4	1,81	No	2,41	No	4,23	No
Tier 2						
1.2	0,35	Yes	0,81	Yes	1,16	No
1.3	0,47	Yes	1,09	No	1,56	No
1.4	0,36	Yes	0,49	Yes	0,85	Yes
Tier 3						
1.2	0,27	Yes	0,63	Yes	0,90	Yes
1.3	0,38	Yes	0,69	Yes	1,07	No

Scenario [2.0]: Mixing and loading by professional users prior to manual dipping

Scenario [2.0.2]: Semi-automated Mixing and loading

Calculation based on a dermal loading derived using RISKOFDERM Dermal Model Loading liquid, automated or semi-automated

	IPBC Tier 1	IPBC Tier 2	Permethrin Tier 1	Permethrin Tier 2
Active substance concentration (%w/w)	0,75%	0,75%	0,25%	0,25%
Duration of activity (min)	10	10	10	10
Dermal exposure				
Hands, rate (90% percentile) (mg/min); calculated for process 'Filling, mixing or loading' using RISKOFDERM Dermal Model Loading liquid, automated or semi-automated	13,5	13,5	13,5	13,5
Hands, loading (90% percentile) (mg)	135	135	135	135
Penetration through gloves (%)	100%	10%	100%	10%
Hand dermal deposit as a.s. (mg)	1,0125	0,1013	0,3375	0,0338
Systemic exposure				
Dermal absorption (%)	29%	29%	50%	50%
Body weight, adult (kg)	60	60	60	60
Total systemic exposure (mg/kg bw)	0,0049	0,0005	0,0028	0,0003
$AEL_{long-term}$ (mg/kg bw/d)	0,20	0,20	0,05	0,05
% $AEL_{long-term}$	**2,45%**	**0,24%**	**5,63%**	**0,56%**



Scenario [2.0.1]: Manual mixing and loading

Calculation based on Mixing and loading model 4 of HEAdhoc Recommendation no. 6, version 4, May 2020

	IPBC Tier 1	IPBC Tier 2	Permethrin Tier 1	Permethrin Tier 2
Active substance concentration (%w/w)	0,75%	0,75%	0,25%	0,25%
Dermal exposure				
0.5 ml b.p./loading (75th percentile); based on 20 L container volume)	0,5	0,5	0,5	0,5
Number of loadings	5	5	5	5
Hand deposit as b.p. (ml)	2,5000	2,5000	2,5000	2,5000
Hand deposit as b.p. (mg)	2525	2525	2525	2525
Penetration through gloves (%)	100%	10%	100%	10%
Hand dermal deposit as b.p. (mg)	2525,0	252,5	2525,0	252,5
Hand dermal deposit as a.s. (mg)	18,9375	1,8938	6,3125	0,6313
Systemic exposure				
Dermal absorption **(%)**	29%	29%	50%	50%
Body weight, adult (kg)	60	60	60	60
Total systemic exposure (mg/kg bw)	0,0915	0,0092	0,0526	0,0053
$AEL_{long\text{-}term}$ (mg/kg bw/d)	0,20	0,20	0,05	0,05
% $AEL_{long\text{-}term}$	**45,8%**	**4,58%**	**105,2%**	**10,52%**

Scenario [2.1]: Mixing and loading by professional users prior to brushing/rolling

Mixing and loading Model 7 for pouring and pumping liquids; HEEG Opinion 1, 2008 page 5

	Units	IPBC Tier 1	IPBC Tier 2	Permethrin Tier 1	Permethrin Tier 2
Product					
Concentration [active substance]	%w/w	0,75	0,75	0,25	0,25
Body weight	kg	60	60	60	60
Dermal penetration rate	%	29	29	50	50
Inhalation rate	m^3/min	0,021	0,021	0,021	0,021
Dermal exposure					
Hand exposure					
Indicative value	mg/min	101	1,01	101	1,01
Duration	min	10	10	10	10
Potential external dermal exposure [product]	mg	1010	10,1	1010	10,1
Penetration through PPE (gloves)	%	100	100	100	100
Actual external dermal exposure [product]	mg	1010	10,1	1010	10,1
Actual external dermal exposure [active substance]	mg	7,6	0,1	2,5	0,0
Actual internal dermal exposure [active substance]	mg	2,2	0,022	1,3	0,013
Systemic exposure via dermal route	mg/kg bw/day	0,0366	0,0004	0,0210	0,0002
Inhalation exposure					
Aerosol					
Indicative value	mg/m^3	0,94	0,94	0,94	0,94
Duration	min	10	10	10	10
Inhaled volume	m^3	0,2083	0,2083	0,2083	0,2083
Potential inhalation exposure [product]	mg	0,1958	0,1958	0,1958	0,1958
Penetration through RPE	%	100	100	100	100
Actual inhalation exposure [product]	mg	0,1958	0,1958	0,1958	0,1958
Actual inhalation exposure [active substance]	mg	0,0015	0,0015	0,0005	0,0005
Systemic exposure via inhalation route	mg/kg bw/day	0,00002	0,00002	0,00001	0,00001
Total systemic exposure (dermal and inhalation)	mg/kg bw/day	0,0366	0,0004	0,0210	0,0002
$AEL_{long\text{-}term}$	mg/kg bw/day	0,20	0,20	0,05	0,05
% $AEL_{long\text{-}term}$	%	**18,3**	**0,20**	**42,1**	**0,44**

Scenario [2.2]: Application – Manual dipping indoors by professionals

Dipping model 1 TNsG part 2, p 167 for manual dipping in open tanks (wooden articles).

Product	Units	IPBC Tier 1	IPBC Tier 2	Permethrin Tier 1	Permethrin Tier 2
Active substance	% w/w	0,75	0,75	0,25	0,25
Body weight	kg	60	60	60	60
Dermal penetration rate	%	29	29	50	50
Potential dermal exposure					
Potential hand exposure (inside gloves)					
Indicative value*	mg b.p./min	25,7	25,7	25,7	25,7
Exposure duration**	min	30	30	30	30
Potential hand deposit	mg product	771,0	771,0	771,0	771,0
Potential body exposure					
Indicative value*	mg b.p./min	178	178	178	178
Exposure duration**	min	30	30	30	30
Potential dermal deposit	mg product	5340,0	5340,0	5340,0	5340,0
Clothing penetration	%	100	10	100	10
Actual dermal deposit	mg	5340,00	534,00	5340,00	534,00
Total dermal exposure					
Total dermal deposit [a.s.]	mg a.s.	45,83	9,79	15,28	3,26
Penetration through skin *[a.s.]*	mg a.s.	13,29	2,84	7,64	1,63
Systemic exposure via dermal route	mg/kg bw/day	0,2215	0,0473	0,1273	0,0272
$AEL_{long\text{-}term}$	mg/kg bw/day	0,2	0,2	0,05	0,05
% $AEL_{long\text{-}term}$	%	110,76	23,65	254,63	54,38
Total systemic exposure	mg/kg bw/day	0,2215	0,0473	0,1273	0,0272
$AEL_{long\text{-}term}$	mg/kg bw/day	0,2	0,2	0,05	0,05
% $AEL_{long\text{-}term}$	**%**	**110,8**	**23,65**	**254,6**	**54,38**

*: TNsG Dipping model 1 TNsG part 2, p 167

**: HEEG opinion "Defaults and appropriate models to assess human exposure for dipping processes (PT8)", 2009

*** Short-term inhalation exposure rate for adults according to the recommendation no. 14 of the BPC Ad hoc working Group on human exposure. Version 2, 2017

Scenario [2.3]: Application – Brushing and rolling by professionals

TNsG, 2007: "in-situ application of wood preservatives / brushing sheds and fences, outdoor" (page 62), HEAdhoc 6: "Methods and models to assess exposure to biocidal products in different product types, version 3" (page 20).

	Units	IPBC Tier 1	IPBC Tier 2	Permethrin Tier 1	Permethrin Tier 2
Active substance	% w/w	0,75	0,75	0,25	0,25
Body weight	kg	60	60	60	60
Dermal penetration rate	%	29	29	50	50
Potential dermal exposure					
Potential hand exposure					
Indicative value (1%)	mg/m²	0,5417	0,5417	0,5417	0,5417
Indicative value, corrected	mg/m²	0,4063	0,4063	0,1354	0,1354
Application area	m²	31,6	31,6	31,6	31,6
Potential hand deposit	mg	12,8	12,8	4,3	4,3
Penetration through gloves*	%	100	10	100	10
Actual hand deposit	mg	12,8	1,3	4,3	0,4
Potential body exposure					
Indicative value (1%)	mg/m²	0,2382	0,2382	0,2382	0,2382
Indicative value, corrected	mg/m²	0,1787	0,1787	0,0596	0,0596
Application area	m²	31,6	31,6	31,6	31,6
Potential dermal deposit	mg	5,65	5,65	1,88	1,88
Clothing penetration*	%	100	10	100	10
Actual body deposit	mg	5,65	0,56	1,88	0,19
Total dermal exposure					
Total dermal deposit [a.s.]	mg	18,4836	1,8484	6,1612	0,6161
Penetration through skin *[a.s.]*	mg	5,36	0,54	3,08	0,31
Systemic exposure via dermal route	mg/kg bw/day	0,0893	0,0089	0,0513	0,0051
$AEL_{long\text{-}term}$	mg/kg bw/day	0,200	0,200	0,200	0,200
% $AEL_{long\text{-}term}$	%	44,669	4,467	25,672	2,567
Exposure by inhalation					
Indicative value (1%)	mg/m²	0,0016	0,0016	0,0016	0,0016
Indicative value, corrected	mg/m²	0,0012	0,0012	0,0004	0,0004
Application area	m²	31,6	31,6	31,6	31,6
Inhaled a.s.	mg	0,04	0,04	0,01	0,01
Systemic exposure via inhalation route	mg/kg bw/day	0,0006	0,0006	0,0002	0,0002
$AEL_{long\text{-}term}$	mg/kg bw/day	0,2	0,2	0,05	0,05
% $AEL_{long\text{-}term}$	%	0,32	0,32	0,42	0,42
Total systemic exposure	mg/kg bw/day	0,0900	0,0096	0,0516	0,0053
$AEL_{long\text{-}term}$	mg/kg bw/day	0,2	0,2	0,05	0,05
% $AEL_{long\text{-}term}$	%	**45,0**	**4,78**	**103,1**	**10,69**

* TNsG 2002, Part 2, p. 36

Scenario [2.4]: Post-application – Drainage and reloading of the manual dipping tank by professionals

Scenario [2.4.2]: Semi-automated drainage and reloading

Calculation based on a dermal loading derived using RISKOFDERM Dermal Model Loading liquid, automated or semi-automated

	IPBC Tier 1	IPBC Tier 2	Permethrin Tier 1	Permethrin Tier 2
Active substance concentration (%w/w)	0,75%	0,75%	0,25%	0,25%
Duration of activity (min)	20	20	20	20
Dermal exposure				
Hands, rate (90% percentile) (mg/min); calculated for process 'Filling, mixing or loading' using RISKOFDERM Dermal Model Loading liquid, automated or semi-automated	13,5	13,5	13,5	13,5
Hands, loading (90% percentile) (mg)	270	270	270	270
Penetration through gloves (%)	100%	10%	100%	10%
Hand dermal deposit as a.s. (mg)	2,025	0,2025	0,675	0,0675
Systemic exposure				
Dermal absorption **(%)**	29%	29%	50%	50%
Body weight, adult (kg)	60	60	60	60
Total systemic exposure (mg/kg bw)	0,0098	0,0010	0,0056	0,0006
$AEL_{short\text{-}term}$ (mg/kg bw/d)	0,35	0,35	0,5	0,5
% $AEL_{short\text{-}term}$	**2,80%**	**0,28%**	**1,13%**	**0,11%**

Scenario [2.4.1]: Manual drainage and reloading

Calculation based on Mixing and loading model 4 of HEAdhoc Recommendation no. 6, version 4, May 2020

	IPBC Tier 1	IPBC Tier 2	Permethrin Tier 1	Permethrin Tier 2
Active substance concentration (%w/w)	0,75%	0,75%	0,25%	0,25%
Dermal exposure				
0.5 ml b.p./loading (75th percentile); based on 20 L container volume)	0,5	0,5	0,5	0,5
Number of loadings	10	10	10	10
Hand deposit as b.p. (ml)	5,0000	5,0000	5,0000	5,0000
Hand deposit as b.p. (mg)	5050	5050	5050	5050
Penetration through gloves (%)	100%	10%	100%	10%
Hand dermal deposit as b.p. (mg)	5050,0	505,0	5050,0	505,0
Hand dermal deposit as a.s. (mg)	37,8750	3,7875	12,6250	1,2625
Systemic exposure				
Dermal absorption **(%)**	29%	29%	50%	50%
Body weight, adult (kg)	60	60	60	60
Total systemic exposure (mg/kg bw)	0,1831	0,0183	0,1052	0,0105
$AEL_{short\text{-}term}$ (mg/kg bw/d)	0,35	0,35	0,5	0,5
% $AEL_{short\text{-}term}$	**52,3%**	**5,23%**	**21,0%**	**2,10%**

Scenario [4.1]: Post-application - Cutting and sanding treated wood by professionals

Parameter	IPBC Tier 1	IPBC Tier 2	Permethrin Tier 1	Permethrin Tier 2	Units
Application rate of product	140	140	140	140	ml/m²
Density of product	1,01	1,01	1,01	1,01	g/cm³
Concentration of a.s. in product	0,75	0,75	0,25	0,25	%
Amount of a.s. on treated wood	0,1410	0,1410	0,0470	0,0470	mg/cm³
Dermal exposure					
Hand area (palms of both hands) (adult)	410	410	410	410	cm²
Assuming that 40% of both palms will be contaminated (adult)	164	164	164	164	cm²
Amount of a.s. on hands (adult)	23,1279	23,1279	7,7093	7,7093	mg/d
Dislodgeable fraction	3	3	3	3	%
Dermal penetration	29	29	50	50	%
Penetration through gloves*	100	5	100	5	%
Dermal exposure (adult) towards IPBC	0,20	0,01	0,12	0,01	mg/d
Considering a body weight of 60 kg (adult)	0,0034	0,0002	0,0019	0,0001	mg/kg bw/d
$AEL_{long\text{-}term}$	0,2	0,2	0,05	0,05	mg/kg bw/d
Utilization of $AEL_{long\text{-}term}$	1,68	0,08	3,85	0,19	%
Inhalation exposure					
Generated dust/m³ of sanded treated wood (8-hour time-weighted average)	5	5	5	5	mg/m³
Duration	6	6	6	6	h
Inhalation rate	1,25	1,25	1,25	1,25	m³/h
Generated dust /8 h	37,5	37,5	37,5	37,5	mg
Density of wood (0.4 g/cm³)	400	400	400	400	mg/cm³
Volume of the dust (8 h)	0,09	0,09	0,09	0,09	cm³
Amount of a.s. in the volume of the outer 1 cm layer	0,1410	0,1410	0,0470	0,0470	mg/cm³
Total amount of a.s. in dust (8 h)	0,0132	0,0132	0,0044	0,0044	mg/d
Considering a body weight of 60 kg	0,00022	0,00022	0,00007	0,00007	mg/kg bw/d
$AEL_{long\text{-}term}$	0,2	0,2	0,05	0,05	mg/kg bw/d
Utilization of $AEL_{long\text{-}term}$	0,11	0,11	0,15	0,15	%
Combined dermal and inhalation exposure	0,0036	0,0004	0,0020	0,0002	mg/kg bw/d
Utilization of $AEL_{long\text{-}term}$	**1,79**	**0,19**	**4,00**	**0,34**	**%**

* Protection from solids from HEEG Opinion 9 (2010)

Combined exposure for professionals (Scenarios [2.0.2 + 2.1 + 2.2 + 2.3 + 8])

No oral exposure.

IPBC

Scenarios	Dermal Exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	$AEL_{long\text{-}term}$ (mg/kg bw/day)	% of AEL
Tier 1					
1.2	0,33024	0,00000	0,33024	0,2	165
1.3	0,44305	0,00016	0,44320	0,2	222
1.4	0,36188	0,00030	0,36217	0,2	181
Tier 2 or 2a					
1.2	0,05064	0,00000	0,05064	0,2	25,3
1.3	0,09461	0,00016	0,09477	0,2	47,4
1.4	0,07264	0,00030	0,07293	0,2	36,5
Tier 2b					
1.2	0,05468	0,00000	0,05468	0,2	27,3
1.3	0,07526	0,00016	0,07541	0,2	37,7

Permethrin

Scenarios	Dermal Exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	$AEL_{long\text{-}term}$ (mg/kg bw/day)	% of AEL
Tier 1					
1.2	0,18979	0,00000	0,18979	0,05	380
1.3	0,25463	0,00005	0,25468	0,05	509
1.4	0,12063	0,00010	0,12072	0,05	241
Tier 2 or 2a					
1.2	0,02910	0,00000	0,02910	0,05	58,2
1.3	0,05438	0,00005	0,05443	0,05	109
1.4	0,02421	0,00010	0,02431	0,05	48,6
Tier 2b					
1.2	0,03143	0,00000	0,03143	0,05	62,9
1.3	0,04325	0,00005	0,04330	0,05	86,6

IPBC & Permethrin

Scenarios	IPBC Hazard Quotient (HQ) (%AEL/100)	IPBC HQ acceptable	Permethrin Hazard Quotient (HQ) (%AEL/100)	Permethrin HQ acceptable	Hazard Index (HI) (Σ HQ for IPBC + Permethrin)	HI acceptable (≤ 1)
Tier 1						
1.2	1,65	No	3,80	No	5,45	No
1.3	2,22	No	5,09	No	7,31	No
1.4	1,81	No	2,41	No	4,23	No
Tier 2 or 2a						
1.2	0,25	Yes	0,58	Yes	0,84	Yes
1.3	0,47	Yes	1,09	No	1,56	No
1.4	0,36	Yes	0,49	Yes	0,85	Yes
Tier 2b						
1.2	0,27	Yes	0,63	Yes	0,90	Yes
1.3	0,38	Yes	0,87	Yes	1,24	No

Scenario [3.1]: Mixing/loading by non-professionals

Exposure calculations not required – refer to the description of Scenario [3.1].

Scenario [3.2]: Application – Brushing and rolling by non-professionals

Calculation based on HEAdhoc Recommendation no. 10 (2016)

	IPBC	Permethrin
Concentration (w/w) of a.s. (IPBC) in TWP 094i	0,75%	0,25%
Body weight of exposed adult (kg)	60	60
Potential body exposure		
Indicative value (µl/min) (for a water-based paint acc. to HEAdhoc Recommendation no. 10 (2016))	1,7	1,7
Density of TWP 094i (g/cm^3)	1,01	1,01
Duration of exposure (minutes)	155	155
Potential dermal deposit (mg)	266,14	266,14
Hand exposure		
Indicative value (µl/min) (for a water-based paint acc. to HEAdhoc Recommendation no. 10 (2016))	4,07	4,07
Density of TWP 094i (g/cm^3)	1,01	1,01
Duration of exposure (min)	155	155
Hand deposit (mg)	637,16	637,16
Total dermal exposure		
To TWP 094i (mg)	903,29	903,29
To the a.s. (mg)	6,77	2,26
Dermal absorption (%)	29%	50%
Systemic exposure to the a.s. via dermal route (mg)	1,965	1,129
Systemic exposure via dermal route (mg/kg bw/d)	**0,0327**	**0,0188**
Exposure by inhalation		
Indicative value (mg/m³) (for a non-volatile substance acc. to HEAdhoc Recommendation no. 10 (2016))	1,63	1,63
Duration of exposure (min)	155	155
Inhalation rate (m^3/h)	1,25	1,25
Inhaled TWP 094i (mg)	5,26	5,26
Systemic exposure to the a.s. via inhalation route (mg)	0,039	0,013
Systemic exposure via inhalation route (mg/kg bw/d)	**0,00066**	**0,00022**
Systemic exposure		
Total systemic exposure to a.s. (mg)	2,0041	1,1423
Total systemic exposure (mg/kg bw/d)	**0,0334**	**0,0190**
$AEL_{short\text{-}term}$ (mg/kg bw/d)	0,35	0,5
% $AEL_{short\text{-}term}$	**9,54%**	**3,81%**

Scenario [4.2]: Post-application - Cutting and sanding treated wood by non-professionals

Parameter	IPBC	Permethrin	Units
Application rate of product	140	140	ml/m²
Density of product	1,01	1,01	g/cm^3
Concentration of a.s. in product	0,75	0,25	%
Amount of a.s. on treated wood	0,1410	0,0470	mg/cm^3
Dermal exposure			
Hand area (palms of both hands) (adult)	410	410	cm²
Assuming that 40% of both palms will be contaminated (adult)	164	164	cm²
Amount of a.s. on hands (adult)	23,1279	7,7093	mg/d
Dislodgeable fraction	3	3	%
Dermal penetration	29	50	%
Dermal exposure (adult) towards IPBC	0,20	0,12	mg/d
Considering a body weight of 60 kg (adult)	0,0034	0,0019	mg/kg bw/d
$AEL_{short-term}$	0,35	0,5	mg/kg bw/d
Utilization of $AEL_{short-term}$	0,96	0,39	%
Inhalation exposure			
Generated dust/m³ of sanded treated wood (8-hour time-weighted average)	5	5	mg/m³
Duration	1	1	h
Inhalation rate	1,25	1,25	m³/h
Generated dust /h	6,25	6,25	mg
Density of wood (0.4 g/cm³)	400	400	mg/cm³
Volume of the dust (1 h)	0,02	0,02	cm³
Amount of a.s. in the volume of the outer 1 cm layer	0,1410	0,0470	mg/cm³
Total amount of a.s. in dust (1 h)	0,0022	0,0007	mg/d
Considering a body weight of 60 kg	0,00004	0,00001	mg/kg bw/d
$AEL_{short-term}$	0,35	0,5	mg/kg bw/d
Utilization of $AEL_{short-term}$	0,010	0,002	%
Combined dermal and inhalation exposure	0,0034	0,0019	mg/kg bw/d
Utilization of $AEL_{short-term}$	**0,97**	**0,39**	**%**

Scenario [4.3]: Post-application – Handling treated wood by non-professionals

Parameter	IPBC	Permethrin	Units
Application rate of product	140	140	ml/m²
Density of product	1,01	1,01	g/cm^3
Concentration of a.s. in product	0,75	0,25	%
Amount of a.s. on treated wood (conservative assumption that the entire a.s. is present on the surface)	0,1061	0,0354	mg/cm²
Dermal exposure			
Area of hands - both palms (adult) (acc. to HEEG Opinion 14, 2017)	410	410	cm²
Assuming that 100% of hand area will be contaminated	410	410	cm²
Amount of a.s. on hands (non-professionals)	43,48	14,49	mg/day
Dislodgeable fraction (Biocides Human Health Exposure Methodology 2015 p.171)	3	3	%
Dermal penetration	29	50	%
Dermal exposure (non-professionals)	0,3783	0,2174	mg/day
Considering a body weight of 60 kg (acc. to HEEG Opinion 14, 2017) (non-professionals)	0,0063	0,0036	mg/kg bw/day
$AEL_{short-term}$	0,35	0,5	mg/kg bw/d
Utilization of $AEL_{short-term}$	**1,80**	**0,72**	**%**

Combined exposure for non-professionals (Scenarios [3.2 + 4.2 + 4.3])

No oral exposure.

IPBC

Scenario	Dermal Exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	$AEL_{short-term}$ (mg/kg bw/day)	% of AEL
3.2	0,0327	0,0007	0,0334	0,35	9,54
4.2	0,0034	0,0000	0,0034	0,35	0,97
4.3	0,0063	0,0000	0,0063	0,35	1,80
Combined	0,0424	0,0007	0,0431	0,35	12,3

Permethrin

Scenario	Dermal Exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	$AEL_{short-term}$ (mg/kg bw/day)	% of AEL
3.2	0,0188	0,0002	0,0190	0,5	3,81
4.2	0,0019	0,0000	0,0019	0,5	0,39
4.3	0,0036	0,0000	0,0036	0,5	0,72
Combined	0,0244	0,0002	0,0246	0,5	4,9

IPBC & Permethrin

Scenarios	IPBC Hazard Quotient (HQ) (%AEL/100)	IPBC HQ acceptable	Permethrin Hazard Quotient (HQ) (%AEL/100)	Permethrin HQ acceptable	Hazard Index (HI) (Σ HQ for IPBC + Permethrin)	HI acceptable (≤ 1)
3.2	0,10	Yes	0,04	Yes	0,13	Yes
4.2	0,01	Yes	0,00	Yes	0,01	Yes
4.3	0,02	Yes	0,01	Yes	0,03	Yes
Combined	0,12	Yes	0,05	Yes	0,17	Yes

Scenario [5]: Chewing wood off-cut by infant

Parameter	IPBC	Permethrin	Units
Volume of the piece of wood (4 cm x 4 cm x 1 cm)	16	16	cm^3
Amount of a.s. in the volume of the outer 1 cm layer	0,1410	0,0470	mg/cm^3
Amount of a.s. in 1 cm outer layer	2,2564	0,7521	mg/d
Oral extraction of a.s. from the wood (acc. to User Guidance (2002))	10	10	%
Oral absoprtion of extracted a.s.	100	100	5
Oral exposure towards a.s.	0,2256	0,0752	mg/d
Oral exposure towards a.s. considering a body weight of 8 kg	0,0282	0,0094	mg/kg bw/d
$AEL_{short-term}$	0,35	0,5	mg/kg bw/d
Utilization of $AEL_{short-term}$	**8,06**	**1,88**	**%**

Scenario [6]: Playing on playground structure outdoors and mouthing by infant

Parameter	IPBC	Permethrin	Units
Application rate of product	140	140	ml/m²
Density of product	1,01	1,01	g/ml
Concentration of IPBC in product	0,75	0,25	%
Amount of IPBC on treated wood (conservative assumption that the entire a.s. is present on the surface)	0,1061	0,0354	mg/cm²
Dermal exposure			
Area of hands - both palms and backs of both hands (infant) (acc. to HEAdhoc Recommendation no. 14 (2017))	196,8	196,8	cm²
Assuming that 20% of hand area (40% of both palms) will be contaminated (toddler) (acc. to TNsG 2002, Part 3, pp 50-51)	39,36	39,36	cm²
Amount of IPBC hands exposed to (infant)	4,17	1,39	mg/day
Dislodgeable fraction (acc. to Biocides Human Health Exposure Methodology, version 1, 2015, p. 171.)	3	3	%
Dermal penetration	29	50	%
Dermal exposure of infant	0,0363	0,0209	mg/day
Consideration of a body weight of 8 kg (infant) (acc. to HEAdhoc Recommendation no. 14 (2017))	0,0045	0,0026	mg/kg bw/day
$AEL_{long\text{-}term}$	0,20	0,05	mg/kg bw/day
Utilization of **$AEL_{long\text{-}term}$** (infant)	2,27	5,22	%
Oral exposure			
Oral (hand-to-mouth) transfer on licking of hands (infant) (acc. to HEAdhoc Recommendation no. 5 (2015)) with 100% of the transferred a.s. absorbed (acc. to the PT13 CAR for IPBC, DK CA, 2015)	50	50	%
Oral exposure of infant	0,0626	0,0209	mg/kg bw/day
Consideration of a body weight of 8 kg (infant) (acc. to HEAdhoc Recommendation no. 14 (2017))	0,0078	0,0026	mg/kg bw/day
$AEL_{long\text{-}term}$	0,20	0,05	mg/kg bw/day
Utilization of $AEL_{long\text{-}term}$ (infant)	3,91	5,22	%
Combined oral and dermal exposure (infant)	0,0124	0,0052	mg/kg bw/day
Utilization of $AEL_{long\text{-}term}$ (infant)	**6,18**	**10,4**	**%**

Scenario [7]: Contact with freshly treated wood by toddler

Dermal and oral exposure through hand-to-mouth transfer. Based on HEAdhoc Recommendation No. 5 (Toddler scenario PT 21; BPC Ad hoc Working group on Human Exposure, 2015)

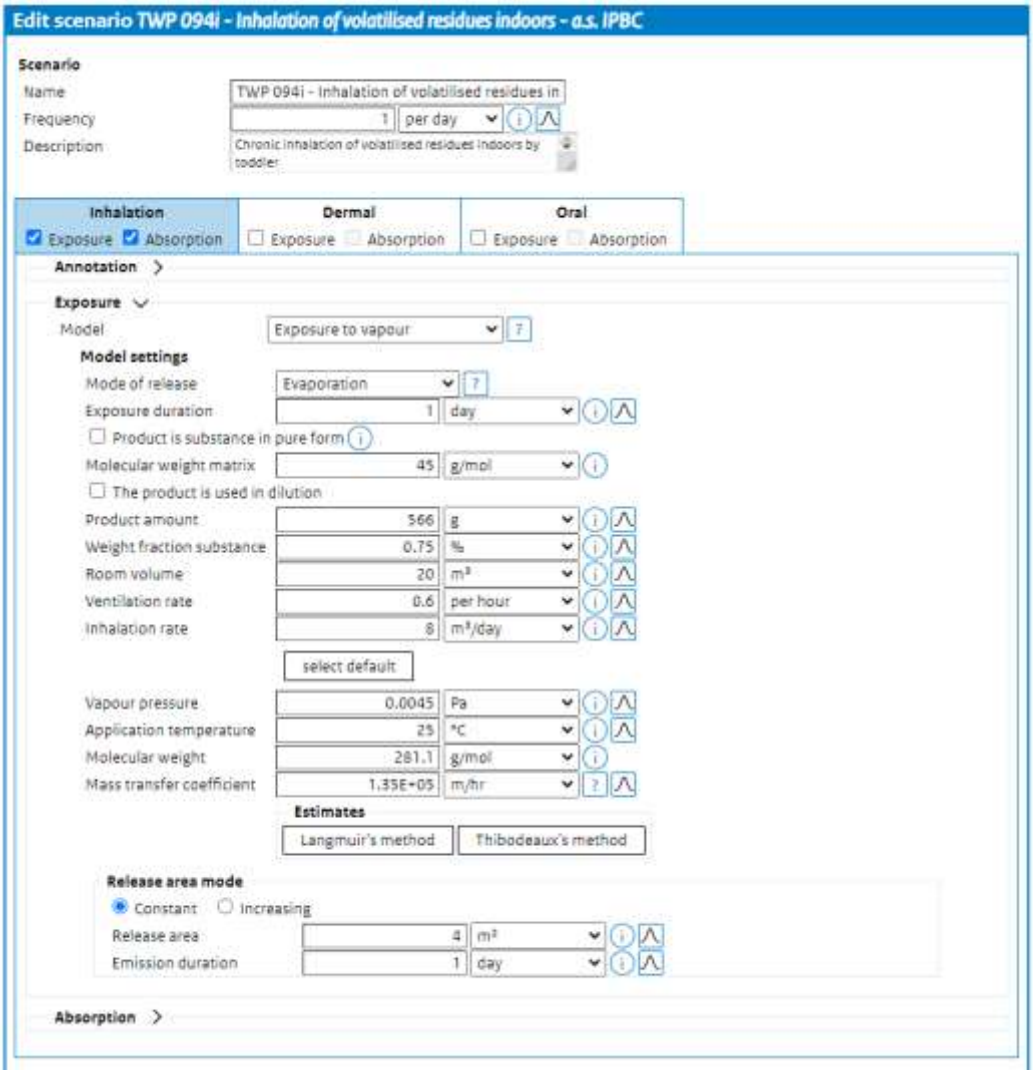
Parameter	**IPBC**	**Permethrin**	**Units**
Application rate of product	140	140	ml/m²
Density of product	1,01	1,01	g/ml
Concentration of a.s. in product	0,75	0,25	%
Amount of a.s. on treated wood (conservative assumption that the entire a.s. is present on the surface)	0,1061	0,0354	mg/cm²
Dermal exposure			
Area of hands - both palms of both hands (toddler) (acc. to HEAdhoc Recommendation no. 14 (2017))	115,2	115,2	cm²
Assuming that 100% of hand area will be contaminated (toddler).	115,2	115,2	cm²
Transfer coefficient (acc. to HEAdhoc Recommendation no. 5 (2015))	50	50	%
Amount of a.s. on hands (toddler)	6,11	2,04	mg/day
Dermal penetration	29	50	%
Dermal exposure (toddler)	1,7715	1,0181	mg/day
Considering a body weight of 10 kg (toddler) (acc. to HEAdhoc Recommendation no. 14 (2017))	0,1771	0,1018	mg/kg bw/day
$AEL_{short\text{-}term}$	0,35	0,5	mg/kg bw/day
Utilization of **$AEL_{short\text{-}term}$** (toddler)	50,61	20,36	%
Oral exposure			
Transferable fraction of paint from hand to mouth (for wet paint) (acc. to HEAdhoc Recommendation no. 5 (2015))	10	10	%
Oral exposure of toddlers	0,6108	0,2036	mg/day
Considering a body weight of 10 kg (toddler) (acc. to HEAdhoc Recommendation no. 14 (2017))	0,0611	0,0204	mg/kg bw/day
$AEL_{short\text{-}term}$	0,35	0,5	mg/kg bw/day
Utilization of **$AEL_{short\text{-}term}$** (toddler)	17,45	4,07	%
Combined oral and dermal exposure (toddler)	0,2382	0,1222	mg/kg bw/day
Utilization of $AEL_{short\text{-}term}$ (toddler)	**68,1**	**24,4**	**%**

Scenario [8]: Inhalation of volatilised residues indoors from treated wood

Tier 1: Inhalation of volatilised residues at 100% of the SVC for the a.s.		
	IPBC	**Permethrin**
Concentration a.s. % (w/w)	0,75%	0,25%
Saturated vapour pressure		
Vapour pressure (Pa)	4,50E-03	2,20E-06
Molecular weight (g/mol)	281,1	319,3
Gas constant	8,31	8,31
Temperature (K)	298	298
Saturated vapour concentration (SVC) (mg/m^3)	5,11E-01	2,84E-04
Adult exposure by inhalation		
Inhalation rate (m^3/d)	16	16
Systemic exposure via inhalation route (mg)	8,17	0,00
Body weight (kg)	60	60
Systemic exposure (mg/kg bw/d)	0,13621	0,00008
AEL long-term (mg/kg bw/d)	0,2	0,05
% AEL$_{long-term}$	**68,1%**	**0,15%**
Child exposure by inhalation		
Inhalation rate (m^3/d)	12	12
Systemic exposure via inhalation route (mg)	6,13	0,00
Body weight (kg)	23,9	23,9
Systemic exposure (mg/kg bw/d)	0,25647	0,00014
AEL long-term (mg/kg bw/d)	0,2	0,05
% AEL$_{long-term}$	**128,2%**	**0,28%**
Toddler exposure by inhalation		
Inhalation rate (m^3/d)	8	8
Systemic exposure via inhalation route (mg)	4,09	0,00
Body weight (kg)	10	10
Systemic exposure (mg/kg bw/d)	0,40864	0,00023
AEL long-term (mg/kg bw/d)	0,2	0,05
% AEL$_{long-term}$	**204,3%**	**0,45%**
Infant exposure by inhalation		
Inhalation rate (m^3/d)	5,4	5,4
Systemic exposure via inhalation route (mg)	2,76	0,00
Body weight (kg)	8	8
Systemic exposure (mg/kg bw/d)	0,34479	0,00019
AEL long-term (mg/kg bw/d)	0,2	0,05
% AEL$_{long-term}$	**172,4%**	**0,38%**

Tier 2: ConsExpo estimation of inhalation of volatilised residues		
Active substance	**IPBC**	**Permethrin**
Vapour pressure (Pa)	4,50E-03	2,20E-06
Molecular weight (g/mol)	281,1	319,3
Mean event concentration (mg/m^3) *	6,10E-04	9,90E-08
Adult exposure by inhalation		
Inhalation rate (m^3/d)	16	16
Systemic exposure via inhalation route (mg)	0,0098	0,0000
Body weight (kg)	60	60
Systemic exposure (mg/kg bw/d)	0,0002	0,0000000
AEL long-term (mg/kg bw/d)	0,2	0,05
% $AEL_{long-term}$	**0,081%**	**0,000%**
Child exposure by inhalation		
Inhalation rate (m^3/d)	12	12
Systemic exposure via inhalation route (mg)	0,01	0,00
Body weight (kg)	23,9	23,9
Systemic exposure (mg/kg bw/d)	0,0003	0,000000
AEL long-term (mg/kg bw/d)	0,2	0,05
% $AEL_{long-term}$	**0,153%**	**0,000%**
Toddler exposure by inhalation		
Inhalation rate (m^3/d)	8	8
Systemic exposure via inhalation route (mg)	0,0049	0,0000
Body weight (kg)	10	10
Systemic exposure (mg/kg bw/d)	0,0005	0,000000
AEL long-term (mg/kg bw/d)	0,2	0,05
% $AEL_{long-term}$	**0,244%**	**0,000%**
Infant exposure by inhalation		
Inhalation rate (m^3/d)	5,4	5,4
Systemic exposure via inhalation route (mg)	0,0033	0,0000
Body weight (kg)	8	8
Systemic exposure (mg/kg bw/d)	0,00041	0,000000
AEL long-term (mg/kg bw/d)	0,2	0,05
% $AEL_{long-term}$	**0,206%**	**0,000%**

* Mean event concentration (mg/m^3) dervied via ConsExpo.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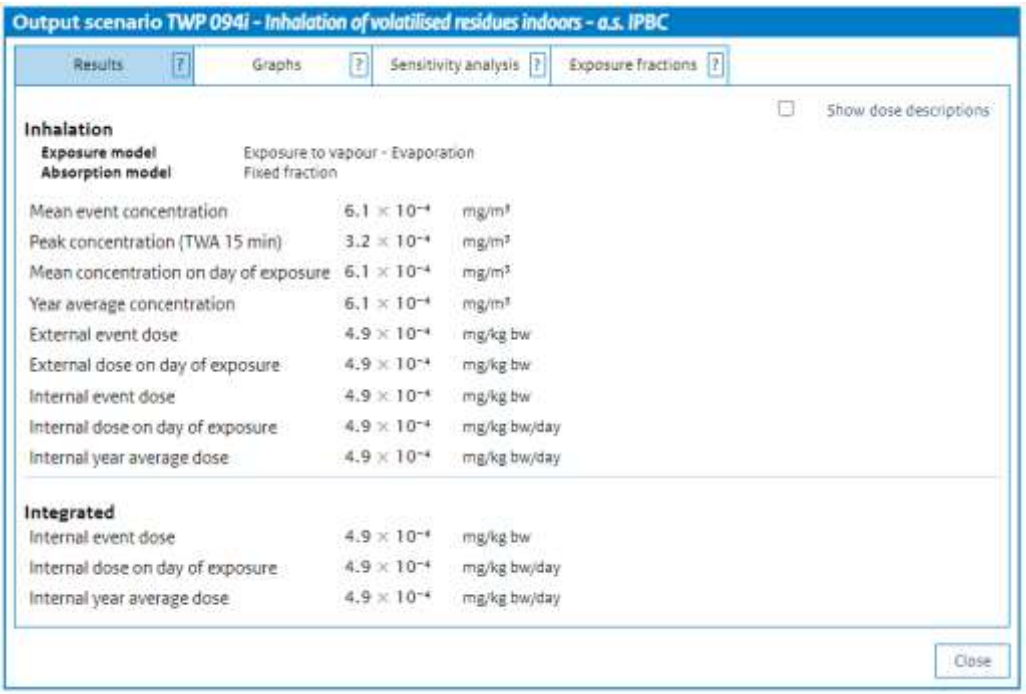
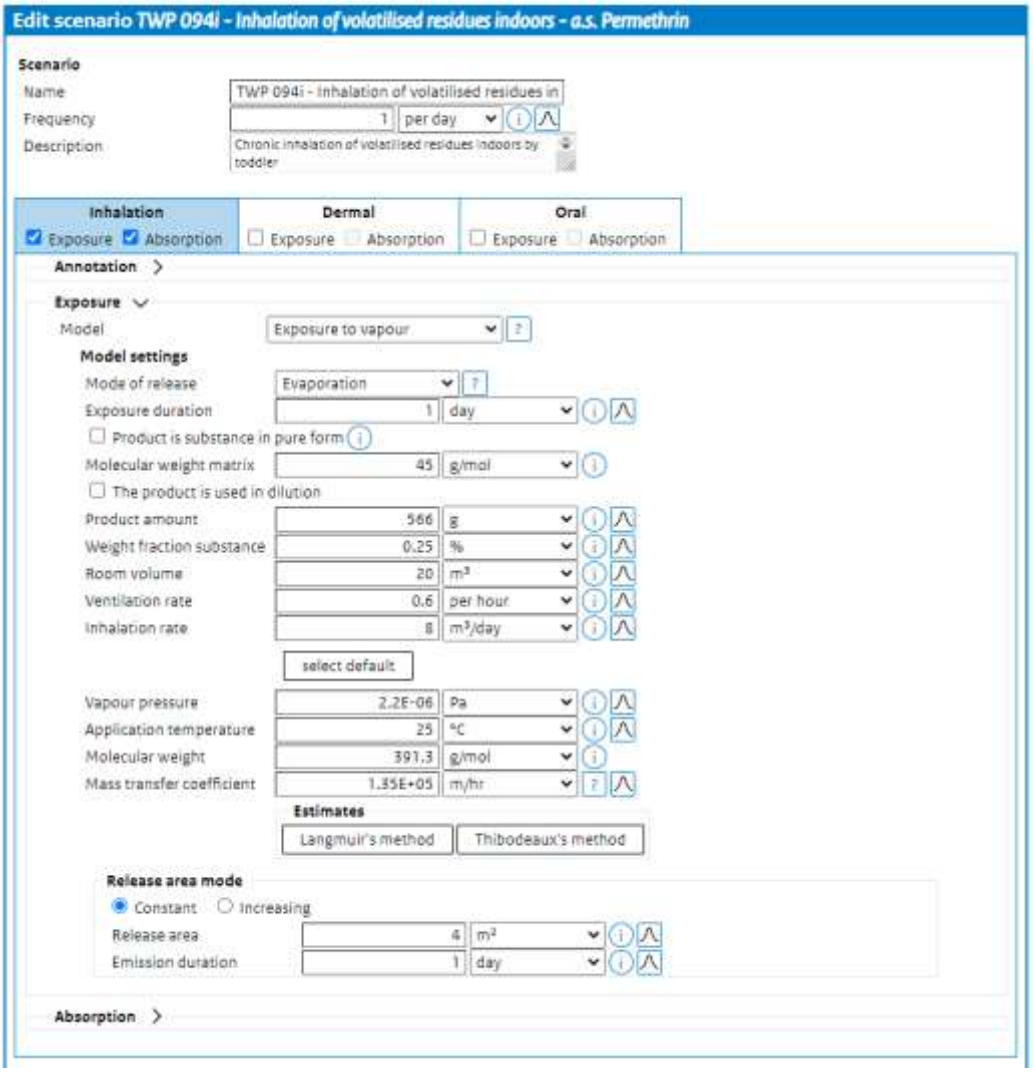
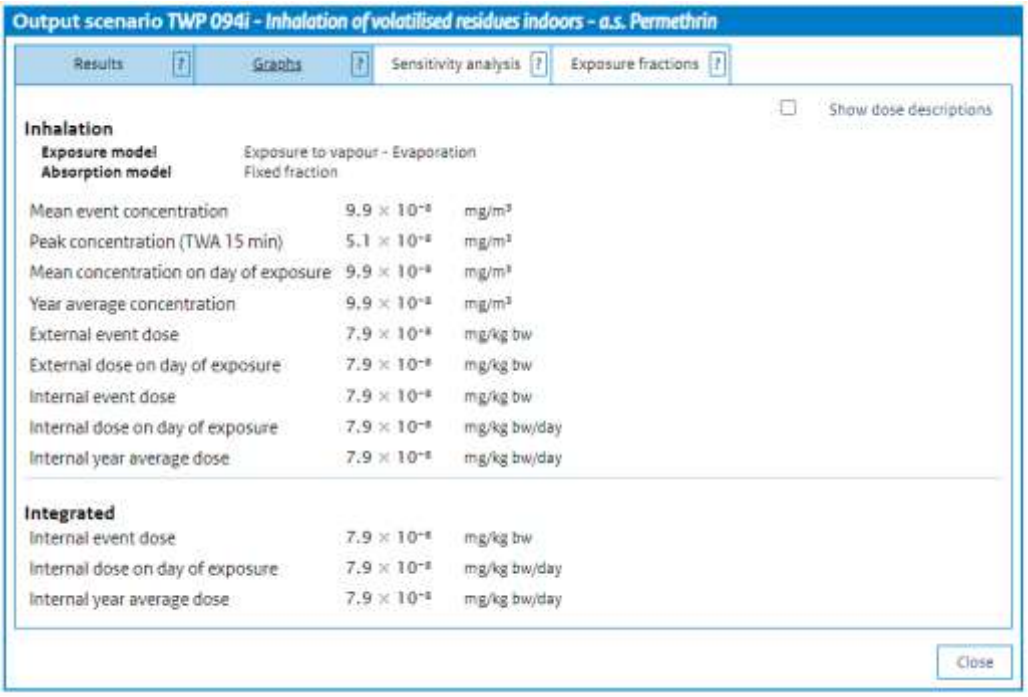
Scenario
Name
TWP 094i - Inhalation of volatilised residues in
Frequency
1
per day
Description
Chronic inhalation of volatilised residues indoors by toddler
Inhalation
Exposure
Absorption
Dermal
Exposure
Absorption
Oral
Exposure
Absorption
Annotation
Exposure
Model
Exposure to vapour
Model settings
Mode of release
Evaporation
Exposure duration
1
day
Product is substance in pure form
Molecular weight matrix
45
g/mol
The product is used in dilution
Product amount
566
g
Weight fraction substance
0.75
%
Room volume
20
m³
Ventilation rate
0.6
per hour
Inhalation rate
8
m³/day
select default
Vapour pressure
0.0045
Pa
Application temperature
25
°C
Molecular weight
281.1
g/mol
Mass transfer coefficient
1.35E+05
m/hr
Estimates
Langmuir's method
Thibodeaux's method
Release area mode
Constant
Increasing
Release area
4
m²
Emission duration
1
day
Absorption


Output scenario TWP 094i - Inhalation of volatilised residues indoors - a.s. IPBC
Results
Graphs
Sensitivity analysis
Exposure fractions
Show dose descriptions
Inhalation
Exposure model
Exposure to vapour - Evaporation
Absorption model
Fixed fraction
Mean event concentration 6.1 × 10⁻⁴ mg/m³
Peak concentration (TWA 15 min) 3.2 × 10⁻⁴ mg/m³
Mean concentration on day of exposure 6.1 × 10⁻⁴ mg/m³
Year average concentration 6.1 × 10⁻⁴ mg/m³
External event dose 4.9 × 10⁻⁴ mg/kg bw
External dose on day of exposure 4.9 × 10⁻⁴ mg/kg bw
Internal event dose 4.9 × 10⁻⁴ mg/kg bw
Internal dose on day of exposure 4.9 × 10⁻⁴ mg/kg bw/day
Internal year average dose 4.9 × 10⁻⁴ mg/kg bw/day
Integrated
Internal event dose 4.9 × 10⁻⁴ mg/kg bw
Internal dose on day of exposure 4.9 × 10⁻⁴ mg/kg bw/day
Internal year average dose 4.9 × 10⁻⁴ mg/kg bw/day
Close


Edit scenario TWP 094i - Inhalation of volatilised residues indoors - a.s. Permethrin
Scenario
Name
TWP 094i - Inhalation of volatilised residues in
Frequency
1
per day
Description
Chronic inhalation of volatilised residues indoors by toddler
Inhalation
Exposure
Absorption
Dermal
Exposure
Absorption
Oral
Exposure
Absorption
Annotation
Exposure
Model
Exposure to vapour
Model settings
Mode of release
Evaporation
Exposure duration
1
day
Product is substance in pure form
Molecular weight matrix
45
g/mol
The product is used in dilution
Product amount
566
g
Weight fraction substance
0.25
%
Room volume
20
m³
Ventilation rate
0.6
per hour
Inhalation rate
8
m³/day
select default
Vapour pressure
2.2E-06
Pa
Application temperature
25
°C
Molecular weight
391.3
g/mol
Mass transfer coefficient
1.35E+05
m/hr
Estimates
Langmuir's method
Thibodeaux's method
Release area mode
Constant
Increasing
Release area
4
m²
Emission duration
1
day
Absorption


Output scenario TWP 094i - Inhalation of volatilised residues indoors - a.s. Permethrin
Results
Graphs
Sensitivity analysis
Exposure fractions
Show dose descriptions
Inhalation
Exposure model
Exposure to vapour - Evaporation
Absorption model
Fixed fraction
Mean event concentration 9.9 × 10⁻⁸ mg/m³
Peak concentration (TWA 15 min) 5.1 × 10⁻⁸ mg/m³
Mean concentration on day of exposure 9.9 × 10⁻⁸ mg/m³
Year average concentration 9.9 × 10⁻⁸ mg/m³
External event dose 7.9 × 10⁻⁸ mg/kg bw
External dose on day of exposure 7.9 × 10⁻⁸ mg/kg bw
Internal event dose 7.9 × 10⁻⁸ mg/kg bw
Internal dose on day of exposure 7.9 × 10⁻⁸ mg/kg bw/day
Internal year average dose 7.9 × 10⁻⁸ mg/kg bw/day
Integrated
Internal event dose 7.9 × 10⁻⁸ mg/kg bw
Internal dose on day of exposure 7.9 × 10⁻⁸ mg/kg bw/day
Internal year average dose 7.9 × 10⁻⁸ mg/kg bw/day
Close

Scenario [9]: Laundering work clothes at home

Parameter	IPBC	Permethrin	Units
Concentration of a.s. in product	0,75	0,25	%
Potential body (clothing) exposure (from Scenario [2.2] - Manual dipping)	5340	5340	mg product
Amount that penetrates through clothing (10%)	534	534	mg product
Total body (clothing) exposure	4806	4806	mg product
Dermal exposure			
Clothing contamination [a.s.]	36,045	12,015	mg a.s./day
Surface area of medium coated coverall	22700	22700	cm^2
Total amount on coverall after day 1	0,0016	0,0005	$mg/cm^2/day$
Total amount on coverall after day 5	0,0079	0,0026	mg/cm^2
Area of hands - total surface (adult) (acc. to HEEG Opinion 14, 2017)	820	820	cm^2
Transfer area (touching 3 times with the hands)	1640	1640	cm2
Percentage dislodgeable	20	20	%
Potential dermal exposure	2,6041	0,8680	mg/day
Dermal penetration	29	50	%
Body weight	60	60	kg bw
Total systemic exposure	0,0126	0,0072	mg/kg bw/d
$AEL_{short-term}$	0,35	0,5	mg/kg bw/d
Utilization of $AEL_{short-term}$	**3,60**	**1,45**	**%**

Combined exposure for general public (adult) (Scenarios [8 + 9])

No oral exposure.

IPBC

Scenario	Dermal Exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	$AEL_{long\text{-}term}$ (mg/kg bw/day)	% of AEL
8	0,0000	0,0002	0,0002	0,2	0,08
9	0,0126	0,0000	0,0126	0,2	6,29
Combined	0,0126	0,0002	0,0127	0,2	6,37

Permethrin

Scenario	Dermal Exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	$AEL_{long\text{-}term}$ (mg/kg bw/day)	% of AEL
8	0,0000	0,0000	0,0000	0,05	0,00
9	0,0072	0,0000	0,0072	0,05	14,5
Combined	0,0072	0,000000	0,0072	0,05	14,5

IPBC & Permethrin

Scenarios	IPBC Hazard Quotient (HQ) (%AEL/100)	IPBC HQ acceptable	Permethrin Hazard Quotient (HQ) (%AEL/100)	Permethrin HQ acceptable	Hazard Index (HI) (Σ HQ for IPBC + Permethrin)	HI acceptable (≤ 1)
8	0,00	Yes	0,00	Yes	0,00	Yes
9	0,06	Yes	0,14	Yes	0,21	Yes
Combined	0,06	Yes	0,14	Yes	0,21	Yes

Combined exposure for general public (infant) (Scenarios [6 + 8])

IPBC

Scenario	Dermal Exposure (mg/kg bw/day)	Oral exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	$AEL_{long\text{-}term}$ (mg/kg bw/day)	% of AEL
6	0,0045	0,0078	0,0000	0,0124	0,2	6,18
8	0,0000	0,0000	0,0004	0,0004	0,2	0,21
Combined	0,0045	0,0078	0,0004	0,0128	0,2	6,39

Permethrin

Scenario	Dermal Exposure (mg/kg bw/day)	Oral exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	$AEL_{long\text{-}term}$ (mg/kg bw/day)	% of AEL
6	0,0026	0,0026	0,0000	0,0052	0,05	10,44
8	0,0000	0,0000	0,0000	0,0000	0,05	0,00
Combined	0,0026	0,0026	0,000000	0,0052	0,05	10,4

IPBC & Permethrin

Scenarios	IPBC Hazard Quotient (HQ) (%AEL/100)	IPBC HQ acceptable	Permethrin Hazard Quotient (HQ) (%AEL/100)	Permethrin HQ acceptable	Hazard Index (HI) (Σ HQ for IPBC + Permethrin)	HI acceptable (≤ 1)
6	0,06	Yes	0,10	Yes	0,17	Yes
8	0,00	Yes	0,00	Yes	0,00	Yes
Combined	0,06	Yes	0,10	Yes	0,17	Yes

3.3 Output tables for environmental risk assessment

3.3.1 Leaching calculations

Two leaching tests ([redacted]) were performed for TWP 094i with topcoat application for surface treatment. Emission rates for IPBC and Permethrin from wood in UC 3 were investigated based on the NT Build 509 Leaching of active components from preservative treated timber – semi-field testing (Approved 2005-03). A summary of the test reports is included in the IUCLID dossier under Point 10.3. A study period of 732 days with a total rainfall amount of 1183 mm within this period was assessed.
Retention of TWP 094i was approx. 180 g/m² and 140 g/m². Application rate of 180 ml/m² showed higher leaching rates in % of active substance leached. Cumulative emissions were calculated for an application rate of 140 ml/m². As a worst case approach the calculations are based on the % of active leached for the application rate of 180 ml/m².

Summary of the results for the application rate of 180 ml/m² can be found below:

Test duration [days]	Cumulated precipitation [m]	Cumulated loss of a.s.			
		IPBC*		Permethrin	
		[mg/m^2]	[%]	[mg/m^2]	[%]
26	50	2,69	0,20	0,00043	0,0001
39	108	6,95	0,51	0,00109	0,0002
81	194	13,37	0,98	0,00226	0,0005
211	398	27,81	2,04	0,00267	0,0006
288	569	28,23	2,07	0,00277	0,0006
365	618	28,24	2,07	0,00277	0,0006
511	798	28,31	2,08	0,00479	0,0011
617	1005	28,38	2,08	0,00718	0,0016
732	1183	28,43	2,09	0,00892	0,0020

*includes PBC

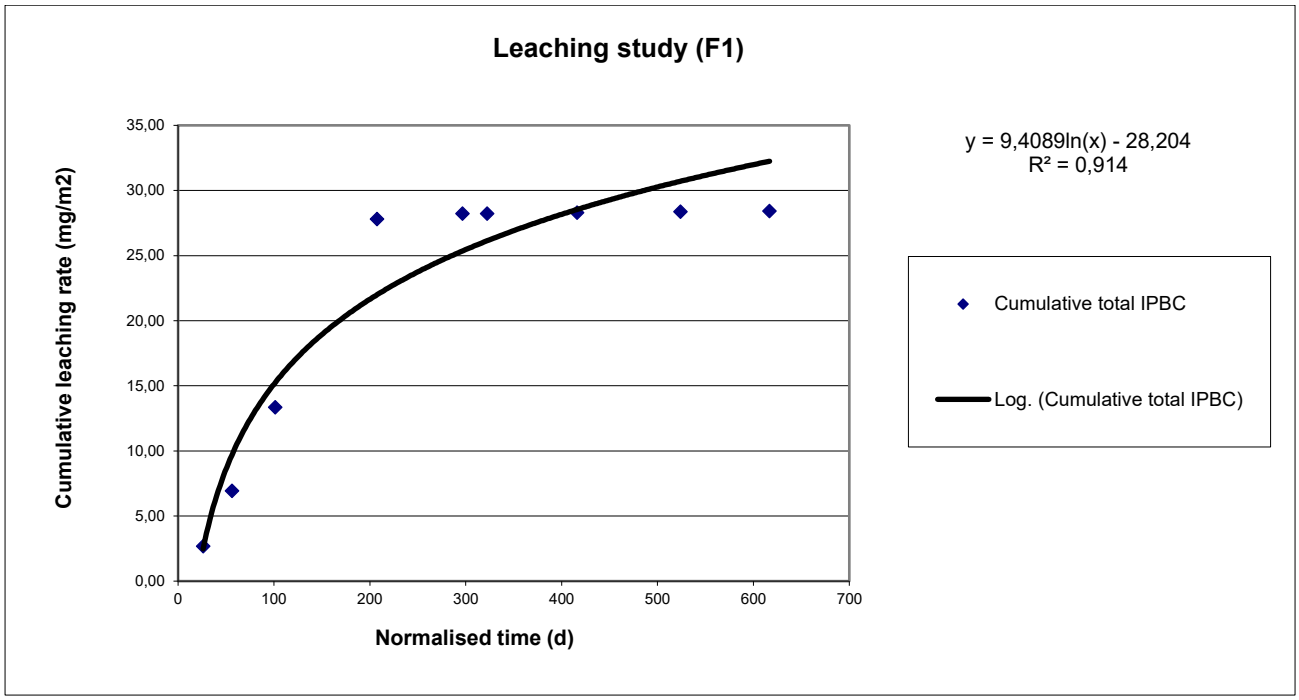
The calculated cumulative leaching rates and flux rates based on the leaching test with topcoat and the higher application rate are summarised in the table below. The results are presented for the times which are relevant for risk assessment (Time 1 = 30 days, Time 3 = 1825, Time 4 = 5475, Time 5 = 7300). The discussion on an additional Time of 365 days is still discussed on EU level. In this dossier this time (Time 2 = 365 days) is already included and assessed only for completeness according to the Follow-up of the 2nd EU Leaching Workshop on wood preservatives (*CA-Sept14-Doc_5_8_-_Follow_up_2nd_EU_Leaching_Workshop_PT8*). No additional assessment factors were added since the studies are semi field studies and no laboratory test, however assessment factors were added do to the use of topcoat in the studies. An assessment factor of 2 was added for assessment period of 5 years (time 3) and an assessment factor of 5 was added for assessment period of 15 and 20 years (time 4 and 5).

For the calculation the accumulated rain amounts were re-calculated to a theoretical standardized rain amount of 700 mm/year. For IBPC these were compared to the total quantity per substance leached out of 1 m^2 of wood area within the specific time interval based on a logarithmic regression (Step 2 – *The 2nd EU leaching Workshop)*. Based on these data leaching rates for an application rate of 140 ml/m² were calculated based on the % of active leached out.

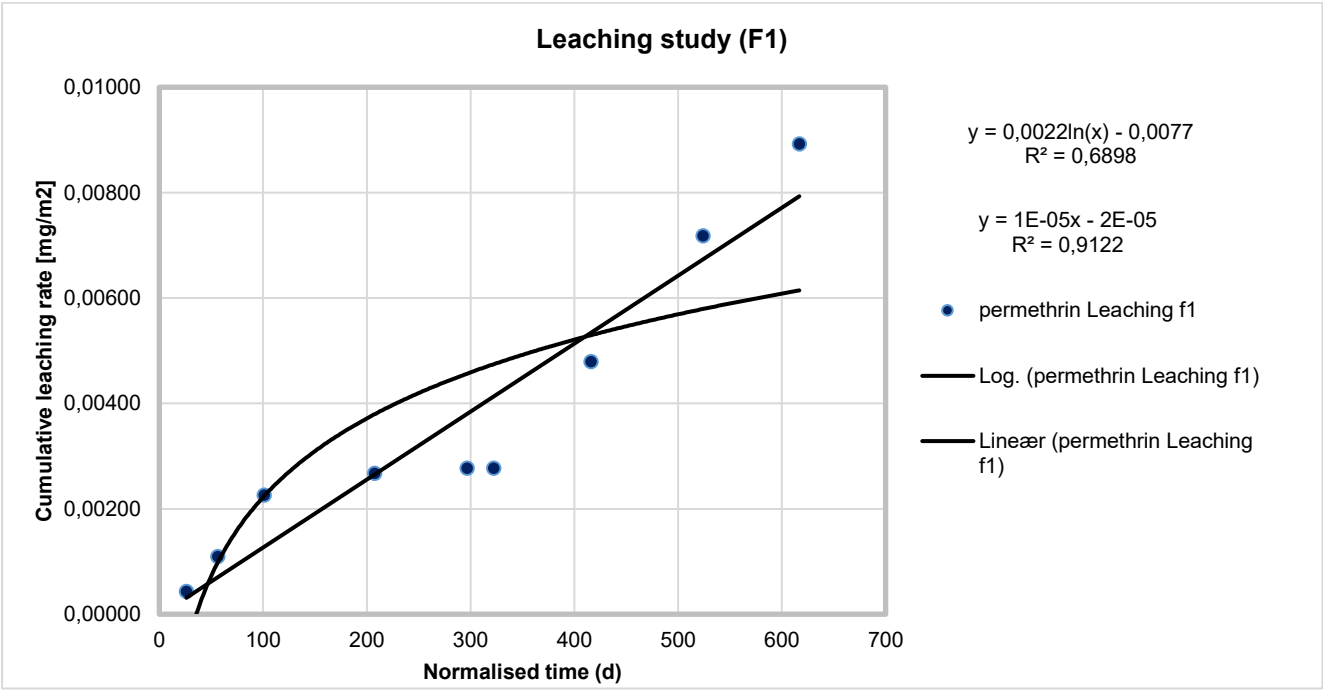
The trend lines with the corresponding regression equations and coefficients of variation can be found in Annex 3.3.1.

For Permethrin the mean leaching rate were calculated using the cumulative quantity leached during the first test period for Time 1 (after about 30 normalized days) and during the whole test for time 2 (Step 3 - *The 2nd EU leaching Workshop)*.

IPBC trend lines with the corresponding regression equations and coefficients of variation:



Permethrin trend lines with the corresponding regression equations and coefficients of variation:



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

Assessment of secondary poisoning via the aquatic food chain

Since a measured BCF fish of 570 L/kg wwt is available this value will be used for calculation of $PEC_{oral,\ predator}$.

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

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

Explanation of symbols

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

Table 22

For assessment via the aquatic food chain, the PEC_{water} value from "scenario 3: in-service: Bridge over pond, 20 years including degradation" has been used (4.25E-08 mg/L), because this was the largest relevant concentration. Concentrations from Scenario 1 "In situ treatments" are not used, as this scenarios are presented for completeness reasons only. According to table 23[22] a BMF of 1 was chosen, and as in ECHA Guidance (2017 Version 2.0) BPR, Vol. IV, ENV – PART B+C it was assumed that 50 % of the diet of predators will come from local sources while the other 50 % will come for regional sources.

Assuming a BCF fish of 570, a PEC_{water} of 4.72E-08 mg/L and a BMF of 1, the max. **PEC oral,predator for fish eating birds and mammals results in a concentration of 1.35E-05 mg/kg wet fish**.

Assessment of secondary poisoning via the terrestrial food chain

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

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

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

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

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

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

Since a measured BCF earthworm of 15108 L/kg earthworm is available this value will be used.
$C_{earthworm}$ was calculated according to the following equation:

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

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

Symbol	Value	Unit	Reference
C_{soil} (max)	4.81E-05	mg*kgwwt^{-1}	Input from ECHA Spreadsheet house scenario
$C_{porewater}$ (max)	1.01E-07	mg*L^{-1}	Input from ECHA Spreadsheet house scenario
$W_{earthworms}$	1	kg_{wwt} tissue	Default (BPR, Vol. IV, ENV – Part B+C.)
Fgut	0.1	kg_{dwt}*kg_{wwt}^{-1}	Default (BPR, Vol. IV, ENV – Part B+C.)
Fsolid	0.6	m^3*m^{-3}	Default (BPR, Vol. IV, ENV – Part B+C.)
$RHO_{earthworm}$	1.0	kgwwt.L-1	Default (BPR, Vol. IV, ENV – Part B+C.)
RHOsoil (wet)	1700	kg/m^3	Default (BPR, Vol. IV, ENV – Part B+C.)
RHOsolid	2500	kg*m^{-3}	Default (BPR, Vol. IV, ENV – Part B+C.)
$BCF_{earthworm}$	15108	L*$kg_{wet\ earthworm}^{-1}$	Permethrin AR (2014)
CONVsoil	1.133E+00		Output (BPR, Vol. IV, ENV – Part B+C equation 102b)
$C_{earthworm}$ / $PEC_{oral\ preadator}$	**6.90E-04**	**mg*$kg_{wet\ earthworm}^{-1}$**	Output (BPR, Vol. IV, ENV – Part B+C equation 103c))

Based on the parameter above, the **max. PEC oral,predator for worm- eating birds and mammals results in a concentration of 6.90E-04 mg/kg wet earthworm**

3.3.3 Environmental risk assessment for iodine (transformation product from IPBC)

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

BACKGROUND VALUES

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

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

The PNEC values used for the environmental risk characterisation are from the CAR for Iodine.

PNEC Values for iodine species			
	Iodine (I_2)	**Iodide (I^-)**	**Iodate (IO_3^-)**
Soil (mg iodine/kg wwt)	0.0118	0.0043	0.304
STP (µg iodine/L)	2900	-	-
Water (µg iodine/L)	0.59	0.83	58.5
Sediment (mg/kg wwt)	Covered by surface water		

PEC CALCULATIONS AND RISK CHARACTERISATION

The PEC calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Vol IV, Part B). For the iodine risk assessment only the worst case scenarios (highest IPBC output values) for each relevant compartment has been taken into consideration.

In the evaluation of iodine released from IPBC, it is chosen to consider 100% formation of both iodide and iodate. This proposed assessment is however worst case as it is expected that much less than 100% of the different iodine species will be present. However, for calculation of soil concentrations it is assumed that the total iodine concentration in soil is transformed into 14% iodide and 100% iodate (CAR for IPBC, PT6 (2013) and agreed to use for PT 8 products at TM II, 2012).
If 100 % transformation of IPBC is assumed, the molar fraction of PBC produced is 0.552 and for iodine (I_2) it is 0.451 (2 moles of IPBC to form one mole of I_2). Further it is assumed that all iodine is transformed either to iodide or iodate. As one mole of iodine (I_2) forms two moles of iodide (I^-) the molar fraction between iodine and iodide is 1, whereas for iodate (IO_3^-) the molar fraction is 1.38.

The calculated PECs are presented below.

Summary table on calculated PEC values IPBC <u>without degradation</u>				**PEC values Iodide**				**PEC values Iodate**			
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{STP}**	**PEC_{water}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{STP}**	**PEC_{water}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg wwt]	[mg/l]	[mg/l]	[mg/kg wwt]	[µg/l]	[mg/l]	[mg/l]	[mg/kg wwt]	[µg/l]
Scenario 2: Industrial application											
automated spraying	3.18E-01	3.18E-02		1.15E-01	1.43E-02			1.58E-01	1.98E-02		
double vacuum process	1.20E-01	1.20E-02		4.34E-02	5.43E-03			5.99E-02	7.49E-03		
dipping and immersion	6.36E-02	6.36E-03		2.30E-02	2.87E-03			3.17E-02	3.96E-03		
Scenario 3: In-service											
Noise Barrier (30 days)	1.02E-04	1.02E-05	6.19E-03	3.69E-05	4.61E-06	3.91E-04	7.46E-02	6.37E-05	6.36E-06	3.85E-03	7.36E-01
Noise Barrier (1 years)	6.05E-05	6.04E-06	4.45E-02	2.18E-05	2.73E-06	2.81E-03	5.37E-01	3.76E-05	3.76E-06	2.77E-02	5.29E+01
Noise Barrier (15 years)	3.90E-05	3.89E-06	4.30E-01	1.41E-05	1.76E-06	2.72E-02	5.19E+00	2.42E-05	2.42E-06	2.68E-01	5.11E+01
Noise Barrier (20 years)	3.07E-05	3.07E-06	4.52E-01	1.11E-05	1.38E-06	2.86E-02	5.45E+00	1.91E-05	1.91E-06	2.81E-01	5.37E+01
House (30 days)	-	-	1.65E-02			1.04E-03	1.99E-01			1.03E-02	1.96E+00
House (1 years)			1.19E-01			7.51E-03	1.43E+00			7.40E-02	1.41E+01
House (5 years)	-	-	3.70E-01			2.33E-02	4.46E+00			2.30E-01	4.39E+01
House (15 years)	-	-	1.15E+00			7.25E-02	1.39E+01			7.15E-01	1.37E+02
House (20 years)	-	-	1.21E+00			7.63E-02	1.46E+01			7.52E-01	1.44E+02
Bridge over pond (30 days)	-	2.92E-05	-		1.32E-05				1.82E-05		
Bridge over pond (1 years)		2.10E-04			9.48E-05				1.31E-04		
Bridge over pond (5 years)	-	6.53E-04	-		2.95E-04				4.07E-04		
Bridge over pond (15 years)	-	2.03E-03	-		9.16E-04				1.26E-03		

Bridge over pond (20 years)	-	2.14E-03	-		9.63E-04			1.33E-03		

Grey cells are used for risk characterisation.

PEC FOR SEWAGE TREATMENT PLANT

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

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

For the worst case ($PEC_{STP,IPBC}$ 0.102 µg/L) for the in-service scenario "noise barrier, 30 days" this results in a $PEC_{STP,iodine}$ of 0.0369 µg/L. In the Assessment Report of Iodine a $PNEC_{STP}$ of 2900 µg/L is reported. The calculated PEC STP is below the PNEC and therefore, no unacceptable risk is concluded.

PEC SURFACE WATER

For the iodine risk assessment, the "bridge over pond" scenario has been chosen as a worst case since it represents an intake into a static water body. Iodine as an inorganic compound is not biodegradable so it was assumed, that the whole IPBC emissions might accumulate during the service life.
For a 20 years' service life period this results in an concentration of 0.963 µg/L iodine (2.14 µg/L IPBC). This value is within the background concentration of iodine of 0.5 – 20 µg/L. No unacceptable risk is concluded.

PEC SEDIMENT

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

PEC SOIL

With reference to the iodine risk assessment for soil, the same procedure as for surface water has been followed, taking the house scenario and a service life of 20 years. IPBC emissions are assumed to accumulate over 20 years, and this yields to 0.545 mg/kg iodine, 0.076 mg/kg iodide and 0.752 mg/kg iodate wwt soil (1.21 mg IPBC /kg wwt).

The PEC/PNEC ratios for iodine, iodide and iodate in soil are above 1 for the house scenario, which is indicative of unacceptable risk. However, the calculated iodine concentration 0.545 mg/kg wwt (0.618 mg/kg dwt) is within the reported background level for iodine in soil (0.5-20 mg/kg dwt).

Taking into account the reported background level for iodine, the risk to soil from the use of the product TWP094i is considered to be acceptable.

PEC FOR AIR

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

PEC FOR GROUNDWATER

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

Parameters	**Unit**		**PBC**	**Iodide**	**Iodate**	**Remark**
Physio-chemical properties						
Molecular weight	g/mol		155.2	126.904	174.903	
Water solubility	mg/l		2860	1E+05	1E+05	
Reference temp.	°C		25	25	25	
Vapour pressure	Pa		18.8	1E-06	1E-06	
Reference temp.	°C		25	25	25	
Degradation parameters						
DT50	d		9.5	1000	1000	
Reference temp.	°C		12	20	20	
Sorption parameters						
Koc	ml/g		198.1	290	290	
Kom	ml/g		114.85	168.2	168.2	
Exponent of Freunlich isotherm	-		0.9	0.9	0.9	
Management related substance parameters						
Crops	-		Grass			
Dosages	kg/ha		0.0007477	0.0000856	0.0008426	
Incorporation depth	cm		0	0	0	

For the simulation leaching from a painted house was considered. The scenario with a service life of 15 years showed the highest leaching per year, and was therefore chosen as a worst case. The dosages were calculated for the metabolites from the molarratios between them and IPBC, and it was further assumed in the modeling, that IPBC is transformed to 100 % PBC and Iodine in the soil compartment, and Iodine is transformed to 100 % Iodate and 14 % Iodide.

Calculation of the application rate [kg.ha-1] of IPBC for the PEARL simulation

Parameter	IPBC	Unit	Remarks
Inputs			
Cumulative leaching of AS TIME 4	203,12	mg/m2	derived from leaching test
Service life TIME 4	15	years	according to ESD for PT8
Number of house pr ha	16	ha	
Area of house	125	m2	

Fweatherside	0,5		
Number of events pr year	10		
Output			
Leaching per year	1,35E-05	kg/m2/year	cumulative leaching*1E-06/Time4
Total amount leached per year per ha	2,71E-02	kg/ha/year	leaching per year * nr. of houses * Area of house
Total amout leached pr year pr ha * Fweatherside	1,35E-02	kg/ha/year	
10-jan	0,0013542	kg/ha	total amout leached out pr year and hectare, considering Fweatherside, and the number of events pr year
15-feb	0,0013542		
24-mar	0,0013542		
29-apr	0,0013542		
05-jun	0,0013542		
11-jul	0,0013542		
17-aug	0,0013542		
22-sep	0,0013542		
29-okt	0,0013542		
01-dec	0,0013542		

Summary table on calculated PEC_{GW} values using FOCUS PEARL 4.4.4

Scenario	PEC_{PBC}	PEC_{iodide}	PEC_{iodate}
	[µg/L]	[µg/L]	[µg/L]
Châteaudun	< 0.000001	0.061193	0.896099
Hamburg	< 0.000001	0.064403	0.994872
Jokioinen	< 0.000001	0.001969	0.188947
Kremsmünster	< 0.000001	0.050377	0.750220
Okehampton	< 0.000001	0.066308	0.853637
Piacenza	< 0.000001	0.074841	0.996285
Porto	< 0.000001	0.042660	0.525049
Sevilla	< 0.000001	0.043846	0.686912
Thiva	< 0.000001	0.071946	1.041193

The estimated PEC_{GW} for iodide and iodate were in the range of 0.001969 - 0.074841 µg/l and 0.188947 – 1.041193 µg/l, respectively. The permissible concentration as laid down by the Drinking Water Directive 2006/118/EC is applied to organic substances. Furthermore, the FOCUS-modelling was developed for organic substances and transport processes for inorganic substances are not covered by this model. However, in compliance with the approach provided in the PT6 IPBC CAR, a groundwater assessment for iodide and iodate is performed by considering the natural background concentration

of the inorganic degradation products. The background concentration for iodine in groundwater is 1 – 70 µg/l with extremes up to 400 µg/l. This corresponds to a background concentration of 1.38 – 96.6 µg/l with extremes up to 552 µg/l for iodate by considering the molecular weight correction factor of 1.38. The background concentration for iodide is identical to the iodine background concentrations since the molecular weight correction factor between iodine and iodide is 1.

PBC PEC_{GW} values were all <0.00001 µg/l.

Conclusion:
The PEC_{GW} for both Iodate and Iodide are within the background concentrations, and PBC is below the 0.1 µg/l permissible concentration. The PEC_{GW} values for all three metabolites are considered acceptable.

Overall conclusion for metabolites:
Taking into account the reported background level for iodine, the risk to STP, surface water, soil and groundwater from the use of the product TWP 094i is considered to be acceptable.

3.3.4 Environmental risk assessment for DCVA and PBA (transformation product from Permethrin)

PEC calculations

For the loading of the aquatic compartment (surface water and sediment) via the STP (Scenario: Noise Barrier), the two permethrin metabolites DCVA and PBA has been assessed using amethod, in accordance with the CAR for Permethrin (PT8):

It is assumed that 100% of the emitted Permethrin enters the STP. It separates to sludge and aqueous phases as dictated by the Koc value of Permethrin. The aqueous phase is released and partitions between surface water and sediment as per Koc Permethrin. The concentration is then multiplied by the ratio of the molecular weight of the metabolite to that of Permethrin. This method clearly overestimates loading of the metabolites to the sediment compartment and thus gives a very conservative PEC values for the sediment compartment.

The indirect emission of metabolites to soil should be calculated according to the AHEE-2 document (ENV TAB entry 10, July 2021), however as emission to soil via the indirect route is not worst case, this was not done to keep the calculations simple.

For scenarios where passage through a sewage treatment plant is not relevant (Scenarios: House and Bridge over Pond), concentrations of the permethrin metabolites have been calculated by multiplying the concentration of permethrin in a compartment by the metabolite's formation fraction (according to the "harmonised LoEP for pyrethroid metabolites – BPC-35, AP 09.01). This value is then multiplied by the ratio of the molecular weight of the metabolite to that of permethrin.

Parameters for calculation of PEC metabolites

	DCVA	**PBA**
Molecular weight [g/mol]	209.07	214.22
Molecular correction factor	0.534	0.548
$K_{soil\text{-}water}$ (m^3/m^3)	1.17	3.75
Formation fraction	1	1
DT50 soil (12 °C - days)	175	2.5

From the PEC_{soil} of the metabolites, the PEC_{gw} for the expected groundwater concentrations were calculated according to the Guidance BPR Vol. IV Env Part B+C (2017) (eq. 70) using $K_{soil\text{-}water}$ coefficients calculated for each metabolite.

Results of the PEC calculations for DCVA:

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{sed}**	**PEC_{gw}**
	[mg/l]	[mg/l]	[mg/kg wwt]	[mg/kg wwt]	[µg/l]
Scenario 3: In-service					
Noise Barrier (30 days)		1.89E-10	3.91E-07	1.11E-10	5.68E-04
Noise Barrier (1 year)		1.66E-10	1.75E-06	9.71E-10	2.54E-03
Noise Barrier (15 years)		8.28E-10	9.62E-06	4.85E-10	1.40E-02

Noise Barrier (20 years)		8.28E-10	9.62E-06	4.85E-10	1.40E-02
House (30 days)			1.04E-06		1.52E-03
House (1 year)			4.67E-06		6.78E-03
House (5 years)			1.03E-05		1.49E-02
House (15 years)			2.57E-05		3.73E-02
House (20 years)			2.57E-05		3.73E-02
Bridge over pond (30 days)		1.49E-09		8.74E-10	
Bridge over pond (1 year)		1.31E-09		7.66E-10	
Bridge over pond (5 years)		2.61E-09		1.53E-09	
Bridge over pond (15 years)		6.54E-09		3.83E-09	
Bridge over pond (20 years)		6.54E-09		3.83E-09	

PEC/PNEC-ratios for DCVA:

Summary table on calculated PEC/PNEC values				
	STP	**Water**	**Soil**	**Sediment**
Scenario 3: In-service				
Noise Barrier (30 days)	not relevant	1.26E-08	8.50E-08	9.22E-09
Noise Barrier (1 year)	not relevant	1.10E-08	3.80E-07	8.09E-09
Noise Barrier (15 years)	not relevant	5.52E-08	2.09E-06	4.04E-08
Noise Barrier (20 years)	not relevant	5.52E-08	2.09E-06	4.04E-08
House (30 days)			2.27E-07	
House (1 year)			1.01E-06	
House (5 years)			2.24E-06	
House (15 years)			5.59E-06	
House (20 years)			5.59E-06	
Bridge over pond (30 days)		9.94E-08		7.28E-08
Bridge over pond (1 year)		8.72E-08		6.39E-08
Bridge over pond (5 years)		1.74E-07		1.28E-07
Bridge over pond (15 years)		4.36E-07		3.19E-07

Bridge over pond (20 years)		4.36E-07		3.19E-07	

Blue colored cells include degradation.

Results of the PEC calculations for PBA:

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{sed}**	**PEC_{gw}**
	[mg/l]	[mg/l]	[mg/kg wwt]	[mg/kg wwt]	[µg/l]
Scenario 3: In-service					
Noise Barrier (30 days)		1.94E-10	4.01E-07	1.14E-10	1.82E-04
Noise Barrier (1 year)		1.70E-10	1.79E-06	9.96E-11	8.13E-04
Noise Barrier (15 years)		8.50E-10	9.88E-06	4.98E-10	4.48E-03
Noise Barrier (20 years)		8.50E-10	9.88E-06	4.98E-10	4.48E-03
House (30 days)			1.07E-06		4.86E-04
House (1 year)			4.79E-06		2.17E-03
House (5 years)			1.06E-05		4.78E-03
House (15 years)			2.64E-05		1.20E-02
House (20 years)			2.64E-05		1.20E-02
Bridge over pond (30 days)		1.53E-09		8.97E-10	
Bridge over pond (1 year)		1.34E-09		7.87E-10	
Bridge over pond (5 years)		2.68E-09		1.57E-09	
Bridge over pond (15 years)		6.71E-09		3.93E-09	
Bridge over pond (20 years)		6.71E-09		3.93E-09	

PEC/PNEC-ratios for PBA:

Summary table on calculated PEC/PNEC values				
	STP	**Water**	**Soil**	**Sediment**
Scenario 3: In-service				
Noise Barrier (30 days)	not relevant	1.94E-08	2.79E-07	1.26E-08
Noise Barrier (1 year)	not relevant	1.70E-08	1.25E-06	1.11E-08
Noise Barrier (15 years)	not relevant	8.50E-08	6.86E-06	5.53E-08
Noise Barrier (20 years)	not relevant	8.50E-08	6.86E-06	5.53E-08
House (30 days)			7.44E-07	

House (1 year)			3.33E-06	
House (5 years)			7.33E-06	
House (15 years)			1.83E-05	
House (20 years)			1.83E-05	
Bridge over pond (30 days)		1.53E-07		9.96E-08
Bridge over pond (1 year)		1.34E-07		8.74E-08
Bridge over pond (5 years)		2.68E-07		1.75E-07
Bridge over pond (15 years)		6.71E-07		4.37E-07
Bridge over pond (20 years)		6.71E-07		4.37E-07

Blue colored cells include degradation.

Conclusion
For all relevant compartments, no unacceptable risks was found for the two permethrin metabolites DCVA and PBA.

3.4 New information on the active substance

Not applicable.

3.5 Residue behaviour

Not applicable.

3.6 Summaries of the efficacy studies

Please see the IUCLID dossier.

3.7 Confidential annex

Refer to the Confidential annex for full details on the composition and formulation of TWP 094i, derivation of the dermal absorption value for IPBC, additional information used for classification of TWP 094i, and the assessment of endocrine-disrupting properties.

3.8 **Authority Confidential annex** (for authorities only)

Information on product composition and formulation of co-formulants that is for authority use only.