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

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

(submitted by the evaluating Competent Authority)

IRUXYL FAMILY

Product type 8

Permethrin, Propiconazole, IPBC as included in the Union list of approved active substances

Case Number in R4BP: BC-NR022887-09

Evaluating Competent Authority: Spain

Date: August 2023

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1 CONCLUSION

Physical-chemical properties and Analytical Methods

IRUXIL FAMILY is a biocidal product family (BPF) of AL (Any other liquid) products. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Its technical characteristics are acceptable for an AL formulation. The stability data indicate a shelf life of more than 2 years at ambient temperature.

The biocidal product is not classified from the physico-chemical aspect.

The analytical methods provided are fully validated for the determination of the active substances, IBPC, Propiconazole and Permethrin. Methods for the determination of the residues are available in the CAR of the active substances.

Efficacy

The efficacy studies submitted have demonstrated that the product may be authorised for use class 1 as preventive treatment against wood-boring beetles and in situation of use class 2 against wood boring beetles and bluestain in service. The product is intended for industrial, trained professional, professional and non-professional users, which may use it by different application methods: superficial treatment, brushing/rolling, spraying and dipping treatment for soft woods.

Sufficient efficacy has been proved for preventive treatment against wood boring beetles and blue stain fungus at the application dose of 200 g/m^2.

Human Health

The biocidal product family "IRUXIL FAMILY" contains the active substances propiconazole (0.225%), IPBC (0.225%) and permethrin (0.25%). No substance has been identified as substance of concern.

Taking into consideration the currently legal harmonized classification of the active substance as Repr. 1B; H360D, propiconazole must be considered as a candidate for substitution or exclusion using the criteria in Article 10 (1) and 5 (1) of the Biocides Regulation (EU) No 528/2012 (BPR).

Therefore, in line with Article 23 (1) of the BPR a comparative assessment has been carried out by the ES CA according to the "Technical Guidance Note on comparative assessment of biocidal products" *(TNsG-CA i.e. CA-May15-Doc4.3a-final)*.

Also, the active substance propiconazole is considered to have an endocrine mode of action as it shows endocrine activity by interfering steroidogenesis. Thus, propiconazole is considered to have endocrine disrupting properties according to Section B of Regulation (EU) 2017/2100.

After evaluating the exposure and characterizing the risk to human health of the IRUXIL Family products according to the pattern of use requested by the applicant, the conclusions for each scenario are:

Summary table: scenarios for IRUXIL Family			Users
Scenario number	**Scenario and (e.g. mixing /loading)**	**Conclusion**	
1	Mixing and loading of RTU	A **safe** situation has been identified for industrial mixing and loading of product.	Industrial (Trained professionals)
2	Mixing and loading of RTU	A **safe** situation has been identified for trained professional and non-professional mixing and loading of product	Trained professionals Professionals Non-professionals users
3	Brushing and rolling	A **safe** situation has been identified for industrial (trained professionals) and trained professional brushing application of product when gloves and coverall (PF 90%), are worn. Moreover, a **safe** situation has been identified for non-professional brushing application of product without PPE.	Industrial (Trained professionals), Trained professionals Professionals Non-professionals
4	Spray application	An **unsafe** situation has been identified for trained professional spraying application of product when PPE, gloves, coated coverall (PF 95%) and mask P3, are worn.	Trained Professionals
5	Fully automated spray application	An **safe** situation has been identified for industrial fully automated spraying application of product when when PPE, new gloves for each work shif, coated coverall (PF 95%) and mask P3, are worn.	Industrial (Trained professionals)
6	Manual dipping	An **unsafe** situation has been identified for industrial and trained professional manual-dipping application of product when PPE, gloves, coated coverall (PF 95%) and mask P3, are worn	Industrial (Trained professionals), Trained professionals
7	Fullly automated dipping process	An **safe** situation has been identified for industrial fully automated dipping process of product when when PPE, new gloves for each work shift and, coated coverall (PF 95%), are worn	Industrial (Trained professionals),
8	Cleaning of brush equipment	A **safe** situation has been identified for industrial, trained professional and non-professional cleaning of brush application of product even when no gloves are worn	Industrial (Trained professionals), Trained professional Professionals Non-professionals
9	Cleaning spray-application equipment	A **safe** situation has been identified for trained professional and industrial cleaning spray-application equipment with gloves.	Industrial and trained professionals
10	Sawing and sanding treated wood	A **safe** situation has been identified for trained professional cutting and sanding treated wood.	Trained Professional
11	Sawing and sanding treated wood	A **safe** situation has been identified for non-professional cutting and sanding treated wood.	non-professional
12	Chewing wood off-cut	A **safe** situation has been identified for infant chewing treated wood chips.	General public

Summary table: scenarios for IRUXIL Family			Users
Scenario number	**Scenario and (e.g. mixing /loading)**	**Conclusion**	
13	Playing on playground structure outdoors and mouthing.	A **safe** situation has been identified for toddler playing and mouthing on playground weathered wood structure outdoors preventively treated with the product.	General public
14	Inhalation residues indoors	A **safe** situation has been identified for general public inhaling volatilised residues indoors.	General public
15	Laundering work-cloths at home	A **safe** situation has been identified for general public laundering contaminated work clothing at home derived from brushing application. When residues from automated dipping treatment and default absorption values from EFSA are deemed, unsafe situation is expected.	General public

Explanatory note (only for Spain authorisation):

According to national legislation, in Spain there are three user categories:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (P): professionals that use the biocidal products in the context of their profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
- Non-professional users (NP): users who are not professionals and that apply the biocidal product in the context of their private life.

The conclusions reached in this PAR, which affect the intermediate category of "Professional", will only be applicable at the Spanish level.

Environment

A risk assessment for the environment has been carried out for the intended uses of the biocidal product family IRUXIL FAMILY as a wood preservative in to be used in use classes 1 and 2. Based on the environmental risk assessment, it is unlikely that assessed uses cause any unacceptable risk for the environment if the directions for use and the label instructions are to be followed. Therefore, the approval of IRUXIL FAMILY can be granted from an environmental perspective.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier[1]	**Country (if relevant)**
IRUXIL FAMILY	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Industrias Químicas Irurena, SA
	Address	Ctra. de Tolosa, s/nº Apartado 30 Nº 12, 20730 Azpeitia Spain
Authorisation number	ES/APPF(NA)-2023-08-00887	
Date of the authorisation	09/08/2023	
Expiry date of the authorisation	09/08/2028	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	INDUSTRIAS QUIMICAS IRURENA, S.A.
Address of manufacturer	Ctra. de TOLOSA s/nº, 20730 Azpeitia Spain
Location of manufacturing sites	Ctra. de TOLOSA s/nº, 20730 Azpeitia Spain

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Permethrin
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1, 50569 Köln - Germany
Location of manufacturing sites	Bayer Vapi Private Limited. Plot # 306/3 II Phase, GIDC, Vapi, 396 195 Gujarat India

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

Active substance	Propiconazole
Name of manufacturer	JANSSEN PMP
Address of manufacturer	Turnhoutseweg 30 2340 Beerse, Belgium
Location of manufacturing sites	Jiangsu Sevencontinent Green Chemical Ltd., North Area of Dongsha Chem-Zone Zhangjiagang 215600 Jiangsu China

Active substance*	IPBC
Name of manufacturer (1)	Troy Chemical Company BV
Address of manufacturer (1)	Poortweg 4C 2612 PA Delft, The Netherlands
Location of manufacturing sites	Plant 1: Troy Corporation, One Avenue L, 07105 Newark, New Jersey, United States Plant 2: Troy Rheinland GmbH, Industriepark 23, 56593 Horhausen, Germany
Name of manufacturer (2)	LANXESS Deutschland GmbH
Address of manufacturer (2)	Kennedyplatz 1, 50569 Köln – Germany
Location of manufacturing sites	Shanghai Hui long Chemicals Co., Ltd, Dengta Jiazhu Rd. 201815 District Shanghai China

2.1.2 Product FAMILY composition and formulation

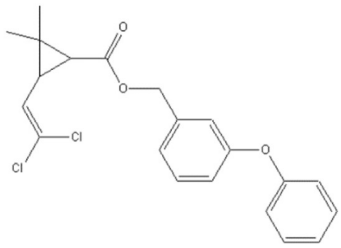
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

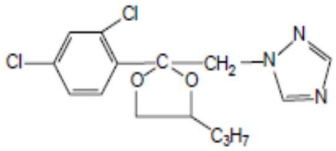
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

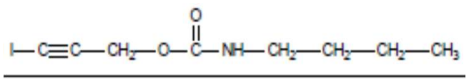
Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituents	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2

Minimum purity / content	≥93% w/w sum of all permethrin isomers The cis:trans ratio is 25:75.
Structural formula	$C_{21}H_{20}Cl_2O_3$ 

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

Main constituents	
ISO name	IPBC
IUPAC or EC name	3-Iodo-2-propynyl butyl carbamate
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	

2.1.2.2 Candidate(s) for substitution

The biocidal product family IRUXIL FAMILY contains the active substance Propiconazole, which meets the criteria for substitution under Article 10 of the Biocidal Products Regulation (EU) No 528/2012. Propiconazole is considered to be very persistent (vP) and toxic for reproduction category 1B, and therefore meets the criteria for being CMR. Therefore, in line with Article 23 (1) of the Biocides Regulation, the Spanish CA has conducted a comparative assessment for the product family IRUXIL FAMILY according to the "Technical Guidance Note on comparative assessment of biocidal products" as agreed upon by the member states on the 55th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 (document: CA-May15-Doc.4.3.a - Final - TNG on comparative assessment.doc).

The Spanish CA concludes that there is not an adequate chemical diversity for products to control wood discolouring fungi, blue-stain fungi and wood booring beetles for Use Class 1 and Use Class 2 by professional users, trained-professional users and general public in the line with Article 23(3)(b) and the technical guidance note on comparative assessment.

The comparative assessment is finalised at this stage. The product family IRUXIL FAMILY is authorised for a period not to exceed 5 years in accordance with Article 23 (6) of BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Permethrin	3-phenoxybenzyl(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.25	0.25
Propiconazole	1-[[2-(2, 4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]- 1 H-1,2,4-triazole	Active substance	60207-90-1	262-104-4	0.225	0.225
IPBC	3-Iodo-2-propynyl butyl carbamate	Active substance	55406-53-6	259-627-5	0.225	0.225

For further information about the composition of the biocidal product family, please refer to the confidential annex.

Safety Data Sheets for propiconazole, permethrin, IPBC, 1,2-benzisothiazol-3(2H)-one and mixture of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2Hisothiazol-3-one (3:1) containing mixtures shall be available for the mixture upon request.

2.1.2.4 Qualitative and quantitative information on the composition of the meta-SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Permethrin	3-phenoxybenzyl(1 RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.25	0.25
Propiconazole	1-[[2-(2, 4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]- 1 H-1,2,4-triazole	Active substance	60207-90-1	262-104-4	0.225	0.225
IPBC	3-Iodo-2-propynyl butyl carbamate	Active substance	55406-53-6	259-627-5	0.225	0.225

For further information about the composition of the biocidal product family, please refer to the confidential annex.

2.1.2.5 Information on technical equivalence

The active substance supplier JANSSEN PMP is the approved supplier of the Propiconazole substance whilst LANXESS is the approved supplier of Permethrin and IPBC. In addition, there is a second approved supplier of IPBC, TROY Chemical Company BV and the decision for the technical equivalence for the locaton of plant 2, is recorded by ECHA under TAP-D-1377728-13-00/F, asset number: EU-0020400-0000, dated May 2019.

2.1.2.6 Information on the substance(s) of concern

No substances of concern (SoCs) are considered in any product of IRUXIL family.

2.1.2.7 Endocrine disrupting properties

According to the CARs and BPC opinons of active substances permethrin and IPBC, neither are considered to have endocrine disrupting properties.

In accordance with the BPC opinion of propiconazole for PT8 (March 2022), propiconazole has endocrine disrupting properties with respect to humans:

"Propiconazole has activity on steroidogenesis as it is an inhibitor of aromatase enzyme (CYP19). Aromatase converts testosterone to estradiol, and its inhibition leads to imbalance in circulating hormone levels. There is a plausible link between endocrine

activity and adverse effects so propiconazole is considered to have endocrine disrupting properties according to Section A of Regulation (EU) 2017/2100.

With regard to endocrine disrupting properties, a risk assessment was presented for peer review, although no agreed methodology on how to assess such risks under the BPR is available. HH WG-IV 2021 (Working Group – Human Health) concluded that it was not possible to agree on the methodology to perform the risk assessment, on the point of departure and on the margin of exposure that would give confidence in a conclusion on safe use. Thus, it is not possible to conclude on the risk derived from the ED properties."

Currently, is not possible to reach a conclusion regarding the level of risks of using propiconazole considering its endocrine disrupting properties, as neither guidance nor a harmonised understanding on the principles of an ED risk assessment is available.

During the screening of ED properties of co-formulants, some alerts were rised. However, a conclusion has not yet been agreed for these substances and they are still identified as potential EDs. Based on this information, ES CA considers that the authorisation of the biocidal product family IRUXIL FAMILY can proceed with a post-authorisation condition to, if necessary, reconsider when the conclusion of the ED status has been agreed. Please, see the confidential PAR for futher details.

2.1.2.8 Type of formulation

Any other liquid (AL)

2.1.3 Hazard and precautionary statements[2]

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

2 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Classification	
Hazard category	Aquatic acute 1, Aquatic Chronic 1
Hazard statement	H400, H410
Labelling	
Signal words	Warning
Hazard pictogram	 GHS09
Hazard statements	H410: Very toxic to aquatic life with long lasting effects
Precautionary statements	P273: Avoid release to the environment. P391: Collect spillage. Industrial (trained professionals) and Trained professionals P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations. Non-professionals and Professionals P501: Dispose of content and / or its container as hazardous waste according to the regulations in force
Note	EUH208: Contains Permethrin, Propiconazole, 3-Iodo-2-propynyl butyl carbamate, 1,2-benzisothiazol-3(2H)-one and reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3-one. May produce an allergic reaction.

2.1.4 Authorised uses for Meta SPC1

IRUXIL Family is formed by two formulations IRUXIL W and IRUXIL W-I. Both formulations have the same active substances, same active substances' concentration, similar composition withing specified variations and similar levels of risk and efficacy. The main difference between both formulations lies in the uses. Both of them are intended to be used in use classes 1 and 2, however whilst IRUXIL W is intended to be used by trained professional, professional and non-professional users, IRUXIL W-I is intended to be used by trained professional, non-professional and industrial (trained professional) users. Taking into account these assumptions both formulations are grouped in the same and unique Meta SPC of IRUXIL family.

In order to clarify the structure of the family, the uses of each formulation are developed below.

SPC1 Formulation Iruxil W

2.1.4.1 Use # 1 - Preventive treatment by brushing/roller application indoor – Trained Professional and professional

Table 1. Use # 1 – Preventive treatment by brushing/roller application indoor – Trained professional and professional

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Fungicide, insecticide.
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus L.* (Larvae) Wood discolouring fungi or Blue stain fungi *Aureobasidium pullulans P268* *Sclerophome pithyophila S231*
Field of use	Indoor Preventive wood preservation in use class 1 against WBB and in situation of use class 2 against WBB and blue stain fungi in service.
Application method(s)	Brushing /rolling
Application rate(s) and frequency	Brushing Method: Painting with a brush or a roller Treatment: Preventive, Dose: 200g/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Trained professional. Professional.
Pack sizes and packaging material	Can of 250 mL and 750 mL.

2.1.4.1.1 Use-specific instructions for use[3]

Use the water-based RTU product undiluted and apply to wood directly out of the original container by using a brush. After the application, clean the equipment with synthetic resin thinners or brush cleaner. The product is for use on timbers not in ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

[3] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.1.2 Use-specific risk mitigation measures

Protective chemical resistant gloves and coverall (PF 90%) for application (gloves and coverall material to be specified by the authorisation holder within the product information).

2.1.4.1.3 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.

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

See general directions for use.

2.1.4.1.5 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.

2.1.4.2 Use #2 - Preventive treatment by brushing/roller application indoor – Non professional (General public)

Table 2. Use # 2 - Preventive treatment by brushing/roller application indoor – Non-professional (General public)

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Fungicide, insecticide.
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus L.* (Larvae) Wood discolouring fungi or Blue stain fungi *Aureobasidium pullulans P268* *Sclerophome pithyophila S231*
Field of use	Indoor Preventive wood preservation in use class 1 against WBB and in situation of use class 2 against WBB and blue stain fungi in service.
Application method(s)	Brushing /rolling

Application rate(s) and frequency	Brushing Method: Painting with a brush or a roller Treatment: Preventive, Dose: 200g/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Non-professional (General public)
Pack sizes and packaging material	Can of 250 mL and 750 mL

2.1.4.2.1 Use-specific instructions for use[4]

Use the water-based RTU product undiluted and apply to wood directly out of the original container by using a brush. After the application, clean the equipment with synthetic resin thinners or brush cleaner. The product is for use on timbers not in ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

2.1.4.2.2 Use-specific risk mitigation measures

See general directions for use.

2.1.4.2.3 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.

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

See general directions for use.

2.1.4.2.5 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.

SPC1 Formulation Iruxil W-I

2.1.4.3 Use #3 – Preventive treatment by brushing/roller application indoor – Industrial (Trained Professional)

- Table 3. Use # 3 – Preventive treatment by brushing/roller application indoor – Industrial (Trained professional)

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Fungicide, insecticide.
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus L.* (Larvae) Wood discolouring fungi or Blue stain fungi *Aureobasidium pullulans P268* *Sclerophome pithyophila S231*
Field of use	Indoor Preventive wood preservation in use class 1 against WBB and in situation of use class 2 against WBB and blue stain fungi in service.
Application method(s)	Brushing/rolling.
Application rate(s) and frequency	Brushing Method: Painting with a brush or a roller Treatment: Preventive, Dose: 200g/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Industrial (Trained professional)
Pack sizes and packaging material	Bucket 4L, 5L and 20L, Drum 200L and IBC 1000L

2.1.4.3.1 Use-specific instructions for use[5]

Use the water-based RTU product undiluted and apply to wood directly out of the original container by using a brush. After the application, clean the equipment with synthetic resin thinners or brush cleaner. The product is for use on timbers not in ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

2.1.4.3.2 Use-specific risk mitigation measures

Protective chemical resistant gloves and coverall (PF 90%) for application (gloves and

coverall material to be specified by the authorisation holder within the product information).

2.1.4.3.3 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.

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

See general directions for use.

2.1.4.3.5 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.

2.1.4.4 Use #4 – Preventive treatment by brushing/roller application indoor – Trained professional and professional

- Table 4. Use # 4 –Preventive treatment by brushing/roller application indoor – Trained professional and professional

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Fungicide, insecticide.
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus L.* (Larvae) Wood discolouring fungi or Blue stain fungi *Aureobasidium pullulans P268* *Sclerophome pithyophila S231*
Field of use	Indoor Preventive wood preservation in use class 1 against WBB and in situation of use class 2 against WBB and blue stain fungi in service.
Application method(s)	Brushing /rolling
Application rate(s) and frequency	Brushing Method: Painting with a brush or a roller Treatment: Preventive, Dose: 200g/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Trained professional

	Professional
Pack sizes and packaging material	Can of 750 mL.

2.1.4.4.1 Use-specific instructions for use[6]

Use the water-based RTU product undiluted and apply to wood directly out of the original container by using a brush. After the application, clean the equipment with synthetic resin thinners or brush cleaner. The product is for use on timbers not in ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

2.1.4.4.2 Use-specific risk mitigation measures

Protective chemical resistant gloves and coverall (PF 90%) for application (gloves and coverall material to be specified by the authorisation holder within the product information).

2.1.4.4.3 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.

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

See general directions for use.

2.1.4.4.5 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.

6 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.5 Use #5 - Preventive treatment by brushing/roller application indoor – Non professional (General public)

- Table 5. Use # 5 – Preventive treatment by brushing/roller application indoor – Non professional (General public)

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Fungicide, insecticide.
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus L.* (Larvae) Wood discolouring fungi or Blue stain fungi *Aureobasidium pullulans P268* *Sclerophome pithyophila S231*
Field of use	Indoor Preventive wood preservation in use class 1 for WBB and in situation of use class 2 for WBB and blue stain fungi in service.
Application method(s)	Brushing/rolling
Application rate(s) and frequency	Brushing Method: Painting with a brush or a roller Treatment: Preventive, Dose: 200g/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Non professional (General public)
Pack sizes and packaging material	Can of 750 mL

2.1.4.5.1 Use-specific instructions for use[7]

Use the water-based RTU product undiluted and apply to wood directly out of the original container by using a brush. After the application, clean the equipment with synthetic resin thinners or brush cleaner. The product is for use on timbers not in ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

[7] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.5.2 Use-specific risk mitigation measures

See general directions for use.

2.1.4.5.3 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.

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

See general directions for use.

2.1.4.5.5 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.

2.1.4.6 Use #6 – Preventive treatment by fully automated spraying application – Industrial (Trained Professional)

- Table 6 Use # 6 – Preventive treatment by fully automated spraying application – Industrial (Trained professional).

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Fungicide, insecticide.
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus L.* (Larvae) Wood discolouring fungi or Blue stain fungi *Aureobasidium pullulans P268* *Sclerophome pithyophila S231*
Field of use	Indoor Preventive wood preservation in use class 1 against WBB and in situation of use class 2 against WBB and blue stain fungi in service.
Application method(s)	Closed system: fully automated spraying.
Application rate(s) and frequency	Spraying Method: Fully automated Treatment: Preventive, Dose: 200g/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Industrial (Trained professional)

Pack sizes and packaging material	Bucket 4L, 5L and 20L, Drum 200L and IBC 1000L

2.1.4.6.1 Use-specific instructions for use[8]

Product IRUXIL FAMILY must only be used in fully automated spraying processes

New wear gloves each work-shift, impermeable coverall and P3 mask.

The water-based RTU product is used undiluted for automated spraying by industrials and trained professionals. Automated spraying is a fully automated process. After the treatment, the wood is lifted out by the fork-lift truck. The wood is then transferred by the fork-lift truck to a storage area where it is placed to dry.

The product is for use on timbers not in ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water. A top-coat is recommended to be applied to treated wood.

2.1.4.6.2 Use-specific risk mitigation measures

Wear protective chemical resistant new gloves each work-shift (glove material to be specified by the authorisation holder within the product information).

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a full face mask with particle filter P3 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

2.1.4.6.3 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.

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

See general directions for use

2.1.4.6.5 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 #7 – Preventive treatment by manual dipping application – Industrial (Trained Professional)

- Table 7. Use # 7 – Preventive treatment by manual dipping application – Industrial (Trained professional)

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Fungicide, insecticide.
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus L.* (Larvae) Wood discolouring fungi or Blue stain fungi *Aureobasidium pullulans P268* *Sclerophome pithyophila S231*
Field of use	Indoor Preventive wood preservation in use class 1 against WBB and in situation of use class 2 against WBB and blue stain fungi in service.
Application method(s)	Manual dipping application.
Application rate(s) and frequency	Dipping Method: manual Treatment: Preventive, Dose: 200g/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Industrial (Trained professional)
Pack sizes and packaging material	Bucket 4L, 5L and 20L, Drum 200L and IBC 1000L

2.1.4.7.1 Use-specific instructions for use[9]

New wear gloves each work-shift, impermeable coverall and P3 mask. The water-based RTU product IRUXIL W-I is used undiluted for manual dipping by industrials and trained professionals. The transfer of the impregnation solutions to the dipping tank for manual dipping is done automated by connecting lines. During manual dipping, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative

in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts manually the wooden article from the dipping tank and stacks the article to dry. The product is for use on timbers not in ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water. A top-coat is recommended to be applied to treated wood.

2.1.4.7.2 Use-specific risk mitigation measures

New gloves each work shift and protective coverall (PF95%) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information). Respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a full face mask with particle filter P3 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

2.1.4.7.3 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.

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

See general directions for use

2.1.4.7.5 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.

2.1.4.8 Use #8 – Preventive treatment by manual dipping application –Trained Professional

- Table 8. Use # 8 – Preventive treatment by manual dipping application –Trained Professional

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Fungicide, insecticide.

Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus L.* (Larvae) Wood discolouring fungi or Blue stain fungi *Aureobasidium pullulans P268* *Sclerophome pithyophila S231*
Field of use	Indoor Preventive wood preservation in use class 1 against WBB and in situation of use class 2 against WBB and blue stain fungi in service.
Application method(s)	Manual dipping application.
Application rate(s) and frequency	Dipping Method: manual Treatment: Preventive, Dose: 200g/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Trained professional
Pack sizes and packaging material	Can 750 ml

2.1.4.8.1 Use-specific instructions for use[10]

New wear gloves each work-shift, impermeable coverall and P3 mask.

The water-based RTU product IRUXIL W-I is used undiluted for manual dipping by industrials and trained professionals. The transfer of the impregnation solutions to the dipping tank for manual dipping is done automated by connecting lines. During manual dipping, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts manually the wooden article from the dipping tank and stacks the article to dry.

The product is for use on timbers not in ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water. A top-coat is recommended to be applied to treated wood.

2.1.4.8.2 Use-specific risk mitigation measures

New gloves each work shift and protective coverall (PF95%) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

Respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a full face mask with particle filter P3 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

2.1.4.8.3 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.

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

See general directions for use.

2.1.4.8.5 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.

2.1.4.9 Use #9 – Preventive treatment by fully automated dipping application – Industrial (Trained Professional)

- Table 9 Use # 0 – Preventive treatment by fully automated dipping application – Industrial (Trained professional).

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Fungicide, insecticide.
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus L.* (Larvae) Wood discolouring fungi or Blue stain fungi *Aureobasidium pullulans P268* *Sclerophome pithyophila S231*
Field of use	Indoor Preventive wood preservation in use class 1 against WBB and in situation of use class 2 against WBB and blue stain fungi in service.
Application method(s)	Closed system: fully automated dipping.
Application rate(s) and frequency	Dipping Method: Fully automated Treatment: Preventive, Dose: 200g/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Industrial (Trained professional)

Pack sizes and packaging material	Bucket 4L, 5L and 20L, Drum 200L and IBC 1000L

2.1.4.9.1 Use-specific instructions for use[11]

Product IRUXIL FAMILY must only be used in fully automated dipping processes

New wear gloves each work-shift, impermeable coverall and P3 mask.

The water-based RTU product is used undiluted for automated dipping by industrials and trained professionals. The transfer of the impregnation solutions to the dipping tank or bathing tray for automated dipping is done automated by connecting lines. For automated dipping, an operator using a fork-lift truck lowers the wood into the dipping tank or transfers the wood to a bathing tray. Automated dipping is a fully automated process. After the treatment, the wood is lifted out by the fork-lift truck. The wood is then transferred by the fork-lift truck to a storage area where it is placed to dry.

The product is for use on timbers not in ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water. A top-coat is recommended to be applied to treated wood.

2.1.4.9.2 Use-specific risk mitigation measures

Wear protective chemical resistant new gloves each work-shift (glove material to be specified by the authorisation holder within the product information).

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).
Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a full face mask with particle filter P3 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

2.1.4.9.3 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.

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

See general directions for use

2.1.4.9.5 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

-Read attached instructions before use. -Comply with instructions of use. -Wash hands thoroughly after handling. -Assure no animals are present during treatment. -Product can be use to treat softwoods, - The users should be inform if the treatment is ineffective and report straightforward to the registration holder. -For wood or wood product that by their nature are not susceptible to brown rot fungi. -This product may not be used together with product against wood destroying fungi to prevent double treatment of fungicides. -For industrial users: the user of the product must have received adequate training within the framework of that industry, in a way that allows him to have the knowledge and skills in handling chemical products and in the correct use of the necessary personal protective equipment for the safe performance of his work.

2.1.5.2 Risk mitigation measures

- Can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product in Spain. Appropriate protective measures must be taken if necessary. - Keep cats away from treated surfaces. Due to their particular sensitivity permethrin, the product can cause severe adverse reactions in cats. When the product is applied by <u>professional and non-professional users</u> the following RMM must be considered to avoid any risk to the environment: - 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 tarpoline) and disposed of in a safe way. - To avoid leakage into the soil, store treated objects or materials until completely dried on impermeable ground and under roof. When the product is applied by <u>industrial (trained professional) users</u> the following RMM must be considered to avoid any risk to the environment:

- 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).

- Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber;

- During the application phase, prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water);

- 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, including any contaminated water/soil must be collected for reuse or disposal in accordance with local/national/international requirements.

- Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

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

First aid instructions

Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: 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.

Product dangerous for the environment, in case of large spills or if the product contaminates lakes, rivers, or sewers, inform the responsible authorities according to local legislation. Prevent the contamination of drains, surface or subterranean waters, and the ground.
Methods and material for containment and cleaning up: Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant. Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Industrial and Trained Professional:

Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.

Code the waste according Decision 2014/955/EU.

Do not release to soil, ground, surface water or any kind of sewer.

Professional and General public:

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.

Do not release into soil, ground, surface water or any kind of sewer.

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.

2.1.5.6 Other information

Definitions:
-Industrial (trained professional): industrial factory workers, having received specific training in management biocidal products according to the national legislation in force.
-Trained professional (TP):pest control operators, having received specific training in management of biocidal products according to the national legislation in force.
-Professional (P): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
-General public (non-professional): users who are not professionals and who apply the product in the context of their private life.

2.1.6 Packaging of the biocidal product

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)
IRUXIL W	Can, jerry can, timplate	250ml	Tinplate with an interior coating	Tinplate with an interior coating	Professional and non-professional	Yes
	Can, jerry can, timplate	750ml	Tinplate with an interior coating	Tinplate with an interior coating	Professional and non-professional	Yes
	bucket	4L, 20 L	Tinplate with an interior coating	Tinplate with an interior coating	Industrial (trained professional)	Yes
	Drum	200L	Steel with an interior coating	Steel with an interior coating	Industrial (trained professional)	Yes
IRUXIL W-I	Can, jerry can, timplate	750 mL	Tinplate with an interior coating	Tinplate with an interior coating	Professional and non-professional	Yes
	bucket	4, 5, 20L	Tinplate with an interior coating	Tinplate with an interior coating	Industrial (trained professional)	Yes
	Drum	200L	Steel with an interior coating	Steel with an interior coating	Industrial (trained professional)	Yes
	Intermediate Bulk Container (IBC)	1000L	Plastic	Plastic	Industrial (trained professional)	Yes

2.1.7 Documentation

2.1.7.1 Data submitted in relation to product application

[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]

2.1.7.2 Access to documentation

The applicant supplies the Letters of Access (LoAs) for three active substances included in biocidal product submitted: LANXESS Deutschland GmbH as owner of data dossiers for Permethrin and IPBC active substances, JANSSEN PMP as owner of data dossier for Propiconazole and Troy Chemical Company BV as owner of data dossier for IPBC.

2.2 Assessment of the biocidal product FAMILY

2.2.1 Intended uses as applied for by the applicant

IRUXIL W Formulation

Table 1. Use #1 – Preventive treatment by brushing/roller application indoor – Professional.

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes bajulus* – House longhorn beetle - larvae
Field of use	Indoor Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Brushing /rolling
Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	Professional
Pack sizes and packaging material	Can of 250 mL and 750 mL

Table 2. Use #2 – Preventive treatment by brushing/roller application indoor - General public

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes bajulus* – House longhorn beetle - larvae
Field of use	Indoor Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Brushing /rolling

Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Can of 250 mL and 750 mL

Table 3. Use #3 – Preventive treatment by spraying surface application indoor - Professional

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes* bajulus – House longhorn beetle - larvae
Field of use	Indoor Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Spraying
Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	Professional (trained and non-trained professionals)
Pack sizes and packaging material	Can of 250 mL and 750 mL

IRUXIL W-I Formulation

Table 4. Use #1 – Preventive treatment by brushing/roller application indoor - Industrial

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes bajulus* – House longhorn beetle - larvae
Field of use	Indoor Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Brushing /rolling
Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	Industrial (trained professionals)

Pack sizes and packaging material	Bucket 4L, 5L and 20L, Drum 200L and IBC 1000L

Table 5. Use #2 – Preventive treatment by brushing/roller application indoor - Professional

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes bajulus* – House longhorn beetle - larvae
Field of use	Indoor Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Brushing /rolling
Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	Professional
Pack sizes and packaging material	Can of 750 mL

Table 6. Use #3 – Preventive treatment by brushing/roller application indoor – General Public

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes bajulus* – House longhorn beetle - larvae
Field of use	Indoor Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Brushing /rolling
Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	General Public
Pack sizes and packaging material	Can of 750 mL

Table 7. Use #4 – Preventive treatment by spraying surface application indoor - Professional

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes* bajulus – House longhorn beetle - larvae
Field of use	Indoor Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Spraying
Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	Professional
Pack sizes and packaging material	Can of 750 mL

Table 8. Use #5 – Preventive treatment by automated spraying surface application indoor - Industrial

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes* bajulus – House longhorn beetle - larvae
Field of use	Indoor Industrial Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Automated spraying in closed system.
Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	Industrial (trained professional)
Pack sizes and packaging material	Bucket 4L, 5L and 20L, Drum 200L and IBC 1000L

Table 9. Use #6 – Preventive treatment by Manual dipping - Industrial

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes* bajulus – House longhorn beetle - larvae
Field of use	Indoor application in industrial sites Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Manual dipping
Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	Industrial (trained professional)
Pack sizes and packaging material	Bucket 4L, 5L and 20L, Drum 200L and IBC 1000L

Table 10. Use #7 – Preventive treatment by Manual dipping - Professional

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes* bajulus – House longhorn beetle - larvae
Field of use	Indoor application in industrial sites Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Manual dipping
Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	Professional
Pack sizes and packaging material	Can of 750 mL

Table 11. Use #8 – Preventive treatment by Automated dipping – Industrial use

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide, insecticide
Target organism (including development stage)	*Ascomycetes* – Wood discolouring fungi - hyphae *Hylotrupes* bajulus – House longhorn beetle - larvae
Field of use	Indoor application in industrial sites Preventive wood preservation in use class 1 and 2 against blue stain fungi.
Application method(s)	Fully automated dipping
Application rate(s) and frequency	Preventive treatment at application rate of 200 g/m^2.
Category(ies) of users	Industrial (trained professional)
Pack sizes and packaging material	Bucket 4L, 5L and 20L, Drum 200L and IBC 1000L

2.2.2 Physical, chemical and technical properties

Formulation 1 – IRUXIL W

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual method	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	Milky liquid	Report No. 095346-2-a (2021)
Colour at 20 °C and 101.3 kPa	Visual method	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	Light beige tone	Report No. 095346-2-a (2021)
Odour at 20 °C and 101.3 kPa	Visual method	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	Mild odour, characteristic.	Report No. 095346-2-a (2021)
Acidity / alkalinity	Internal method	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	pH = 7.5 at 25 ºC (Initial) pH = 7.41 at 25 ºC (After accelerated storage)	Report No. 095346-2-a (2021)
Relative density	UNE-EN ISO 2811-1:2016	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	1.04 g/cm^3 at 20.0 ±0.5 ºC	Report No. 095128-2-a (2021)
Storage stability test – **accelerated storage stability test 6 weeks at 45ºC**	CIPAC MT46.3	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	A phase separation is observed at the bottom of the bottle after ageing at 45°C for 6 weeks. However, upon cooling the contents are easily re-suspended by shaking the bottle. IPBC (% w/w) $[C]_0$ = 0.225 % $[C]_f$ = 0.217 % Δ[C] < 10% Permethrin (% w/w) $[C]_0$ = 0.250 % $[C]_f$ = 0.217 % Δ [C] < 10% Propiconazole (% w/w) $[C]_0$ = 0.225 % $[C]_f$ = 0.254 % Δ [C] < 10%	Report No. 095346-2-a (2021)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			The appearance of the commercial packaging and the weight of the test item did not change significantly. Furthermore, no significant changes are observed in the pH value.	
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 46.3	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	The product Iruxil W after an environmental storage more than 2 years presents the following results: • The chemical stability of the permethrin active ingredients in the Iruxil W complies with a decrease below 10%, meeting the established FAO/WHO criteria for biocidal products. • The initial value complies with the nominal value of 0.250% Permethrin, 0.225% IPBC and 0.225% Propiconazole. No changes are observed in the appearance of the samples before and after environmental storage test. No significant changes are observed in the pH value.	Report No. 095346-1-a (2021)
Storage stability test – **low temperature stability test 7 days at 0ºC**	This study does not need to be conducted as the product must not be stored under conditions of ≤ 0°C.			

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Please refer to the results of long term storage stability test.			Report No. 095346-1-a (2021)
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Stability at elevated and decreased temperatures confirmed by the respective storage stability test. Humidity does not affect the properties of the product as t he product is water based.			Report No. 095346-1-a (2021)
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Please refer to the results of long term storage stability test.			Report No. 095346-1-a (2021)
Wettability	Not applicable for this type of formulation.			
Suspensibility, spontaneity and dispersion stability	Not applicable for this type of formulation.			
Wet sieve analysis and dry sieve test	Not applicable for this type of formulation.			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable for this type of formulation.			
Disintegration time	Not applicable for this type of formulation.			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable for this type of formulation.			
Persistent foaming	Not applicable for this type of formulation.			
Pourability	Not applicable for this type of formulation.			
Burning rate — smoke generators	Not applicable for this type of formulation.			
Burning completeness — smoke generators	Not applicable for this type of formulation.			
Composition of smoke — smoke generators	Not applicable for this type of formulation.			

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Spraying pattern — aerosols	Not applicable for this type of formulation.			
Physical compatibility	This product is not intended to be used with other products, so this study is not necessary			
Chemical compatibility	This product is not intended to be used with other products, so this study is not necessary			
Degree of dissolution and dilution stability	The study does not need to be conducted as both products are not diluted before application			
Surface tension	DIN EN 14370 ASTM D 971	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	30.7 mN/m at 20 ºC	Figueras J. 2021, BYK Aditives & Instruments
Viscosity	ASTM D1200 - 94	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	The flow time of the product IRUXIL W at 20ºC is 90 s	Report No. 095128-2-a (2021)
			The flow time of the product IRUXIL W at 40ºC is 41.7 s.	Report No. 098771-2-a (2022)

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

The IRUXIL W formulation is a AL (Any other liquid) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a light beige milky liquid with mild odour, characteristic. The pH of the product is 7.5.

There is no effect of high temperature on the stability of the formulation, since after 6 weeks at 45 ºC, neither the active ingredient content nor the technical properties were changed.

The stability data indicate a shelf life of more than 2 years at ambient temperature when stored in a metal container. (commercial packaging material). Its technical characteristics are acceptable for an AL formulation.

Formulation 2 – IRUXIL WI

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual method	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	Milky liquid	Report No. 095348-2-a (2021)
Colour at 20 °C and 101.3 kPa	Visual method	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	Light beige tone	Report No. 095348-2-a (2021)
Odour at 20 °C and 101.3 kPa	Visual method	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	Mild odour, characteristic.	Report No. 095348-2-a (2021)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Acidity / alkalinity	Internal method	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	pH = 7.5 at 25 ºC (Initial) pH = 7.61 at 25 ºC (After accelerated storage)	Report No. 095348-2-a (2021)
Relative density	UNE-EN ISO 2811-1:2016	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	1.03 g/cm^3 at 20.0±0.5 ºC	Report No. 095128-1-a (2021)
Storage stability test – **accelerated storage stability test 6 weeks at 45ºC**	CIPAC MT46.3	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	Temperature 45ºC (6 weeks) IPBC (% w/w) $[C]_0$ = 0.225 % $[C]_f$ = 0.208 % Δ[C] < 10% Permethrin (% w/w) $[C]_0$ = 0. 250 % $[C]_f$ = 0.219 % Δ[C] < 10% Propiconazole (% w/w) $[C]_0$ = 0.225 % $[C]_f$ = 0.235 % Δ[C] < 10% The appearance of the commercial packaging and the weight of the test item did not change significantly. Furthermore, no significant changes are observed in the pH value.	Report No. 095348-2-a (2021)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 46.3	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	The product Iruxil W-I after an environmental storage more than 2 years presents the following results: • The chemical stability of the permethrin active ingredients in the Iruxil W-I complies with a decrease below 10%, meeting the established FAO/WHO criteria for biocidal products. • The initial value complies with the nominal value of 0.250% Permethrin, 0.225% IPBC and 0.225% Propiconazole. No changes are observed in the appearance of the samples before and after environmental storage test. No significant changes are observed in the pH value.	Report No. 095348-1-a (2021)
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Please refer to the results of long term storage stability test (Report no. 095348-1).			Report No. 095348-1-a (2021)
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Stability at elevated and decreased temperatures confirmed by the respective storage stability test. Humidity does not affect the properties of the product as t he product is water based.			Report No. 095348-1-a (2021)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Please refer to the results of long term storage stability test (Report no. 095348-1).			Report No. 095348-1-a (2021)
Wettability	Not applicable for this type of formulation.			
Suspensibility, spontaneity and dispersion stability	Not applicable for this type of formulation.			
Wet sieve analysis and dry sieve test	Not applicable for this type of formulation.			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable for this type of formulation.			
Disintegration time	Not applicable for this type of formulation.			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable for this type of formulation.			
Persistent foaming	Not applicable for this type of formulation.			
Pourability	Not applicable for this type of formulation.			
Burning rate — smoke generators	Not applicable for this type of formulation.			
Burning completeness — smoke generators	Not applicable for this type of formulation.			
Composition of smoke — smoke generators	Not applicable for this type of formulation.			
Spraying pattern — aerosols	Not applicable for this type of formulation.			
Physical compatibility	This product is not intended to be used with other products, so this study is not necessary			
Chemical compatibility	This product is not intended to be used with other products, so this study is not necessary			
Degree of dissolution and dilution stability	The study does not need to be conducted as both products are not diluted before application			
Surface tension	DIN EN 14370 ASTM D 971	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	35.4 mN/m at 20 ºC	Figueras J. 2021, BYK Aditives & Instruments

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Viscosity	ASTM D1200 - 94	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	The flow time of the product IRUXIL W-I at 20ºC is 10.8 s	Report No. 095128-1-a (2022)
			The flow time of the product IRUXIL W-I at 40ºC is 10.1 s	Report No. 098771-1-a (2022)

Conclusion on the physical, chemical and technical properties of the product
The IRUXIL W-I formulation is a AL (Any other liquid) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a light beige milky liquid with mild odour, characteristic. The pH of the product is 7.5. There is no effect of high temperature on the stability of the formulation, since after 6 weeks at 45 ºC, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of more than 2 years at ambient temperature when stored in a metal container. (commercial packaging material). Its technical characteristics are acceptable for an AL formulation.

2.2.3 Physical hazards and respective characteristics

Formulation 1 – IRUXIL W

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties.			
Flammable gases	Not applicable to AL formulations.			
Flammable aerosols	Not applicable to AL formulations.			
Oxidising gases	Not applicable to AL formulations.			
Gases under pressure	Not applicable to AL formulations.			
Flammable liquids	Calculation from SDS - EQGEST	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	Flash point = 142ºC	SDS IRUXIL W
Flammable solids	Not applicable to AL formulations.			
Self-reactive substances and mixtures	There are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. Therefore, this study is not necessary.			
Pyrophoric liquids	The experience in manufacture or handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperatures. Therefore, this study is not need to be performed.			
Pyrophoric solids	Not applicable to AL formulations.			
Self-heating substances and mixtures	The product IRUXIL W does not ignite itself at temperature < 350ºC, so it shall not be classified as a self-heating substance or mixture. Therefore, this study is not necessary.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Substances and mixtures which in contact with water emit flammable gases	Waiver: The product is intended to be used diluted in water. So, in contact with water it do not emit flammable gases.			
Oxidising liquids	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with oxidising properties and hence, the classification procedure does not need to be applied.			
Oxidising solids	Not applicable to AL formulations.			
Organic peroxides	The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of test and criteria.			
Corrosive to metals	UN Test C1	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%) Batch: 21121532	No corrosion attack was occurred after 5 days of exposure at the temperature of 55 ºC and the loss mass was lower than 13.5 %.	Report No a370.2-AEGIS (2022)
Auto-ignition temperatures of products (liquids and gases)	Calculation from SDS – EQGEST	IRUXIL W (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	The product was found not to self-ignite below 400°C.	SDS IRUXIL W
Relative self-ignition temperature for solids	Not applicable to AL formulations.			
Dust explosion hazard	Not applicable to AL formulations.			

Conclusion on the physical hazards and respective characteristics of the product
IRUXIL W formulation is has no oxidizing, no organic peroxides and explosive properties. The flash point of the product was >99º·C, therefore the product does not need to be classified as 'flammable liquid'. Hence, the product does not require classification under Regulation (EC) No 1272/2008 for physical hazards.

Formulation 2 – IRUXIL WI

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties.			
Flammable gases	Not applicable to AL formulations.			
Flammable aerosols	Not applicable to AL formulations.			
Oxidising gases	Not applicable to AL formulations.			
Gases under pressure	Not applicable to AL formulations.			
Flammable liquids	Calculation from SDS - EQGEST	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	Flash point = 152ºC	SDS IRUXIL W-I
Flammable solids	Not applicable to AL formulations.			
Self-reactive substances and mixtures	There are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. Therefore, this study is not necessary.			
Pyrophoric liquids	The experience in manufacture or handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperatures. Therefore, this study is not need to be performed.			
Pyrophoric solids	Not applicable to AL formulations.			
Self-heating substances and mixtures	The product IRUXIL W-I does not ignite itself at temperature < 350ºC, so it shall not be classified as a self-heating substance or mixture. Therefore, this study is not necessary.			
Substances and mixtures which in contact with water emit flammable gases	The product is intended to be used diluted in water. So, in contact with water it do not emit flammable gases.			
Oxidising liquids	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with oxidising properties and hence, the classification procedure does not need to be applied.			
Oxidising solids	Not applicable to AL formulations.			
Organic peroxides	The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of test and criteria.			
Corrosive to metals	UN Test C1	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%) Batch: 22010266	No corrosion attack was occurred after 5 days of exposure at the temperature of 55 ºC and the loss mass was lower than 13.5 %.	Report No a370.2-AEGIS (2022)
Auto-ignition temperatures of products (liquids and gases)	Calculation from SDS - EQGEST	IRUXIL W-I (Permethrin 0.250%, IPBC 0.225% and propiconazole 0.225%)	The product was found not to self-ignite below 400°C.	SDS IRUXIL W-I
Relative self-ignition temperature for solids	Not applicable to AL formulations.			
Dust explosion hazard	Not applicable to AL formulations.			

Conclusion on the physical hazards and respective characteristics of IRUXIL W-I
IRUXIL W-I formulation is has no oxidizing, no organic peroxides and explosive properties. The flash point of the product was >99º·C, therefore the product does not need to be classified as 'flammable liquid'. Hence, the product does not require classification under Regulation (EC) No 1272/2008 for physical hazards.

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									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IRUXIL W formulation									
IPBC	HPLC-UV	Range: 0.0887904 mg/ml 5 measurements per test concentration	Range: 0.02 – 0.2 mg/ml Linearity correlation: 1.00000	The method is specific. No interfering substances reported	From 96.62 to 105.42	100.7 %	-	0.02 mg/L.	Report No 098800-1-a (2022)
Propiconazole	HPLC-UV	Range: 0.0907721 mg/ml 5 measurements per test concentration	Range: 0.02 – 0.2 mg/ml Linearity correlation: 1.00000	The method is specific. No interfering substances reported	From 100.15 to 103.12	101.1 %	-	0.02 mg/L.	Report No 098800-1-a (2022)
Permethrin	HPLC-UV	Range: 0.09072625 mg/ml 5 measurements per test concentration	Range: 0.02 – 0.2 mg/ml Linearity correlation: 0.99999	The method is specific. No interfering substances reported.	From 94.79 to 97.31	95.7 %	-	0.02 mg/L.	Report No 098800-1-a (2022)
IRUXIL W-I formulation									

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IPBC	HPLC-UV	5 measurements per test concentration	1	The method is specific. No interfering substances reported.	(95 – 105)	100.7%	2.87 %	0.02 mg/L.	Report No 098800-2-a (2022)
Propiconazole	HPLC-UV	5 measurements per test concentration	1	The method is specific. No interfering substances reported.	(95 – 105)	102.1 %	0.72 %	0.02 mg/L.	Report No 098800-2-a (2022)
Permethrin)	HPLC-UV	5 measurements per test concentration	0.99999	The method is specific. No interfering substances reported.	(95 – 105)	100.0%	1.81 %	0.02 mg/L.	Report No 098800-2-a (2022)
Please refer to the active substances' AR for further methods and information.									

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substances' AR for further methods and information.									

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substances' AR for further information.									

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substances' AR for further information.									

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substances' AR for further information.									

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substances' AR for further information.									

Analytical methods for monitoring of active substances and residues in food and feeding stuff								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substances' AR for further information.									

Conclusion on the methods for detection and identification of the product
According to guideline SANCO/3030/99 the analytical methods provided are fully validated for the determination of the active substances: IPBC, Propiconazole and Permethrin.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

IRUXIL Family formulations are a ready to use water-based wood preservation product based on the active substances permethrin, propiconazole and IPBC.
It is used for preventive treatment of wood against wood rotting and discolouring fungi, house longhorn beetle (*Hylotrupes bajulus*) by superficial application on wood for use in use class 1 and in situation of class 2. The application rate for a preventive treatment is 200 ml/m^2 (fungicidal and insecticidal).
The product always has to be applied with a top-coat on wood that is exposed to weathering.
The product is applied by industrial users, trained professional and professional users and general public.

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

The organisms to be controlled for preventive treatment are wood rotting and wood discolouring fungi and house longhorn beetle (*Hylotrupes bajulus*).
The object to be protected is wood (more specifically wood in use class 1 and wood in situation of use class 2 for preventive use).

2.2.5.3 Effects on target organisms, including unacceptable suffering

IRUXYL family products causes mortality of wood rotting and wood discolouring fungi and house longhorn beetle (*Hylotrupes bajulus*).

2.2.5.4 Mode of action, including time delay

The mode of action of the insecticidal active substance permethrin is a neurotoxic effect mediated through preventing the closure of the voltage-gated sodium channels in the axonal membranes.
Propiconazole is a triazole fungicide which inhibits the demethylation step in the ergosterol biosynthesis of fungi.

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).

2.2.5.5 Efficacy data

The family initially consisted of three products: IRUXIL W, IRUXIL W-L and IRUXIL CR3. The applicant has withdrawn from the family IRUXIL CR3 product, the one with the highest concentration of active substances. Studies carried out with this product will not be taken into account. Even so, we include a separate summary table with these studies. On the other hand, the applicant has submitted several studies that have not been accepted by ES CA. These studies have also been included in a separate table.

KEY STUDIES

Experimental data on the efficacy of the biocidal product against target organisms								
Test product	**Field of use envisaged**	**Test substance**	**Organisms to be protected**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
IRUXIL W-I	Preventive-Insecticide	Permethrine	*Pinus sylvestris*	House longhorn beetle*: Hylotrupes bajulus (L.)*	EN 46-1:2016 (EN73)	•Brushing procedure method •.100 % (w/w) • Exposure: 4 weeks. • Toxic values: 199,60±3.34 ml/m^2	100 % larvae were recovered dead without having made tunnels in the wood. At least 80% of the larvae inserted in all untreated control specimens survive.	*Test report: 092354-2-a*
	Preventive Fungicide	Tebuconazole IPBC	*Pinus sylvestris*	Blue stain *Aureobasidium pullulans P268 Sclerophoma pithyophila S231*	EN 152-1:2011) EN73.	•Brushing procedure. • 100% (w/w) •Varnising of speciments: Type B • 2 coats. •Artificial ageing. •Exposure: 6 weeks. •Retention (toxic values): 201,43 ±1,15 g/m^2.	Visual examination after biological essay is 0. At the end of test no individual rating ≥2. Minimun stain-free zone: 2.16 mm Mean stain-free zone: 5.62 mm. Visual examination of control samples after biological essay is 3. The test is valid since the average grade for the test specimens treated with the reference product is greater than 1.	*Test report: 092354-5-a*
IRUXIL W	Preventive-Insecticide	Permethrine	*Pinus sylvestris*	House longhorn beetle*: Hylotrupes bajulus (L.)*	EN 46-1:2016 (EN73)	•Brushing procedure method •.100 % (w/w) • Exposure: 4 weeks. • Toxic values:	100 % larvae were recovered dead without having made tunnels in the wood. At least 80% of the larvae inserted in all untreated control	*Test report: 092354-1-a* Key study.

						199,73±3.34 ml/m^2	specimens survive.	
	Preventive fungicide	Tebuconazole IPBC	*Pinus sylvestris*	Blue stain *Aureobasidium pullulans P268 Sclerophoma pithyophila S231*	EN 152-1:2011) EN73.	•Brushing procedure. • 100% (w/w) •Varnising of speciments: Type B • 2 coats. •Artificial ageing. •Exposure: 6 weeks. •Retention (toxic values): 201,26 ±1,40 g/m^2.	Visual examination after biological essay is 0 except one specimen which is 1. At the end of test no individual rating ≥2. Minimun stain-free zone: 3.48 mm Mean stain-free zone: 4.73 mm. Visual examination of control samples after biological essay is 3. The test is valid since the average grade for the test specimens treated with the reference product is greater than 1.	*Test report: 092354-4-a* Key study.
IRUXIL W-1	Preventive-Insecticide	Permethrine	*Pinus sylvestris*		Complementary pinewood immersion application method test accordindg to the requirements of the EN46-1:2016 standard.	•Immersion procedure. • 100% (w/w) • 2 immersions. • 3 treated replicates. •Retention: 200 g/m^2 in 5+5 minutes. The immersion process is carried out in both supports (spruce and pine wood). All the test pieces used have all faces sealed with epoxy	The objective of the test is to demonstrate the feasibility of achieving retention of 200 g/m^2 by immersion with IRUXIL W-1 on a Pine and Spruce support. Results: In both woods and with a 5+5 min immersion, the 200 g/m^2 required for preventive efficacy are reached.	*Test report:* Pine wood immersion test.

						varnish, except for the face to be treated, and have the measurements established by standard EN 46-1:2016 (50*25*15 mm).		

IRUXIL W-L and IRUXIL W. Studies not accepted.

Experimental data on the efficacy of the biocidal product against target organisms								
Test product	**Field of use envisaged**	**Test substance**	**Organisms to be protected**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
IRUXIL W-I	Preventive-Insecticide	Permethrine	*Pinus sylvestris*	House longhorn beetle*: Hylotrupes bajulus (L.)*	EN 46:2006 (EN73)	•Dipping application method (60 minutes) •.100 % (w/w) • Exposure: 4 weeks. • Toxic values: 199,58±15,76 g/m^2	100 % larvae were recovered dead without having made tunnels in the wood. At least 80% of the larvae inserted in all untreated control specimens survive. However, there are deviations with the number of larvae on these controls. In addition, the study was carried out with an expire norm.	*Test report: 19623.1* Not accepted.
	Preventive Fungicide	Tebuconazole IPBC	*Pinus sylvestris*	Blue stain *Aureobasidium pullulans P268 Sclerophoma pithyophila S231*	UNE 56419: 1991 (EN 152-1: 1988) EN73.	•Brushing procedure. • 100% (w/w) •Varnising of specimentes :Type A •Artificial ageing. •Exposure: 6 weeks.	Visual examination after biological essay is 0. At the end of test no individual rating ≥2. Minimun stain-free zone: 5 mm Mean stain-free zone: 6.7 mm.	*Test report: 20095(M1)* Not accepted.

						•Retention (toxic values): 199.62 ±7.98 g/m^2.	Visual examination of control samples after biological essay is 3. The test has not provided data of virulence control. In addition, it was carried out with an expire norm.	
HIDROXIL-HX	Preventive-Insecticide	Permethrine	*Pinus sylvestris*	House longhorn beetle*: Hylotrupes bajulus (L.)*	UNE 56402 : 1996 (EN46 : 1988) EN73 and EN84	•Dipping application method.(60 minutes) •.100 % (w/w) •Exposure: 4 weeks. • Toxic values: EN73: 190,66 g/m^2 EN84:187,20 g/m^2	<u>EN73:</u> 75 % larvae were recovered dead without having made tunnels in the wood and 11.6 % having made tunnels. 7 larvae were alive (11.6%) and 1 was not recovered (1.6 %) <u>EN84</u>: 76 % larvae were recovered dead without having made tunnels in the wood and 5% having made tunnels. 8 larvae were alive (13%) and 3 were not recovered (5%). 76% of the larvae inserted in all untreated control specimens survive. The test has not demonstrated efficacy for both aeging process and in adittion, it was carried out with an expire norm.	*Test report: 11749.6* Not accepted.
HIDROXIL R3	Preventive Fungicide	Tebuconazole IPBC	*Pinus sylvestris*	Wood destroying basidiomicetes. *Coniophora puteana*	EN113 :1996	See the information on test report: *15676.3*	Same data on test report: *15676.3*	*Test report: 15676.4* Not accepted.

				Gloeophyllum trabeum *Poria placenta*				
IRUXIL W	Preventive-Insecticide	Permethrine	*Pinus sylvestris*	House longhorn beetle*: Hylotrupes bajulus (L.)*	EN 46:2006	See the information on test report: *14552.4*	Same data on test report: *14552.4*	*Test report: 14552* Not accepted.
PROTEX	Preventive-Insecticide	Permethrine	*Pinus sylvestris*	House longhorn beetle*: Hylotrupes bajulus (L.)*	EN 46:2006	See the information on test report: *14552.4*	Same data on test report: *14552.4*	*Test report: 14552.2* Not accepted.
	Preventive Fungicide	Tebuconazole IPBC	*Pinus sylvestris*	Blue stain *Aureobasidium pullulans P268* *Sclerophoma pithyophila S231*	UNE 56419:1991 (EN 152-1:1988)	See the information on test report: *11749.5*	Same data on test report: *11749.5.*	*Test report: 11749.9* Not accepted.

IRUXIL CR3 studies. Product withdraw.

Experimental data on the efficacy of the biocidal product against target organisms								
Test product	**Field of use envisaged**	**Test substance**	**Organisms to be protected**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
IRUXIL CR3 (HIDROXIL R3)	Preventive Insecticide	Permetrinee	*Pinus sylvestris*	House longhorn beetle*: Hylotrupes bajulus (L.)*	UNE 56402:1996 (EN46:1988) EN73 and EN84	•Dipping application method.(60 minutes). •.100 % (w/w) • Exposure: 4 weeks. • Toxic values: EN73: 197,08 g/m^2 EN84: 197,91 g/m^2	EN73: 100 % larvae were recovered dead without having made tunnels in the wood. EN84: 96% larvae were recovered dead without having made tunnels in the wood. 2 larvae were not recovered. At least 80% of the larvae	*Test report: 14552.4*

							inserted in all untreated control specimens survive. The study was carried out with an expire norm and it has a 4 of reliability.(* see conclusions)	
	Preventive Fungicide	Tebuconazole IPBC	*Pinus sylvestris*	Blue stain *Aureobasidium pullulans P268 Sclerophoma pithyophila S231*	UNE 56419:1991 (EN 152-1:1988)	See the information on test report: *11749.5*	Same data on test report: *11749.5.*	*Test report: 11749.10*
	Preventive-Insecticide	Permethrine	*Pinus sylvestris*	Subterranean termite *Reticulitermes grassei*	EN 118:2007 (EN73 and EN84)	• Superficial treatment (brushing) • EN73:199,37 g/m^2 • EN84:197.31 g/m^2 • Exposure: 8 weeks.	The study seems validated. All the treated blocks are ranked 0 at the end of the study. The study was carried out with an expired norm.	*Test report: 15676.5*
IRUXIL CR3	Preventive Fungicide	Tebuconazole IPBC	*Pinus sylvestris*	Wood destroying basidiomicetes. *Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta*	EN 113:1996 EN73 and EN84	• Vacuum impregnation. • Concentration of the product tested: 11.5-13.5-15.19-18.11-20.4% (w/w) • Exposure period: 16 weeks	**EN73:** Toxic values: *Coniophora puteana* Mid-toxic value=b.r.v.= 119.2785 kg/m^3. Toxic values: *Gloeophyllum trabeums* b.r.v.= 108.192 Kg/m^3 Toxic values: *Poria placenta* b.r.v.: 104.130 Kg/m^3 **Critical value**= highest v.b.r. for	*Test report: 15676.3*

							EN73= **238.55 g/m²** **<u>EN83:</u>** <u>Toxic values</u>: *Coniophora puteana* Mid-toxic value=b.r.v.= 109.857 kg/m^3. <u>Toxic values</u>: *Gloeophyllum trabeums* Mic-toxic value=b.r.v.= 117.977 Kg/m^3 <u>Toxic values</u>: *Poria placenta* Mic-toxic value=b.r.v.= 117.458 Kg/m^3 **Critical value**= highest v.b.r. for EN84= **235.954 g/m²** The test overtakes the maximum application limit of 100 Kg/m^3 according to the norm EN599-1:2014.	
HIDROXIL R3	Preventive Fungicide	Tebuconazole IPBC	*Pinus sylvestris*	Wood destroying basidiomicetes. *Coniophora puteana* *Gloeophyllum trabeum Poria placenta*	EN113:1996	See the information on test report: *15676.3*	Same data on test report: *15676.3*	*Test report: 15676.4*

Conclusion on the efficacy of the product

The applicant has submitted serveral studies to support the efficacy of IRUXIL W and IRUXIL W-I, the two products that comprise the family. The products have demonstrated preventive efficacy against wood boring beetles (*Hylotrupes bajulus*) and blue stain fungi.
The applicant initially provided 17 trials, some were withdrawn. These tests are all included in the efficacy table although some of them will not be taken into account for evaluation.

Wood boring beetles:

Thanks to *Test report: 092354-2*-a (IRUXIL W-I) and *Test report: 092354-1-a* (IRUXIL W) according to EN46-1 (EN73), the family has demonstrated preventive efficacy against *Hylotrupes bajulus*.
According to the TNsG on product evaluation (2008) for general claims against "wood boring beetles"*, it is acknowledged that the majority of applications for authorization are likely to be for treatment against H. bajulus. Therefore, data against this beetle species should be available and will be considered adequate to cover this claim*. Therefore, we accept that the applicant has only provided tests on this insect.
The study has been carried out in softwood and for surface application.
Dose rate: 200ml/m^2 or 208g/m^2.
Use class 1: situation in which the wood or wood based product is inside a contruction, not expose to the weather and wetting.
The application methods indicated in the EN 46-1 standard for the treatment of the samples are by brushing as well as by dipping. The test has been done by brusing, therefore we consider that the application by brushing or spraying is covered in this test.
The application method by immersion has been requested, the applicant has provided a justification to cover this method and has indicated the necessary immersion time and the amount of product used that is needed to achieve a retention of 200g/m^2. Therefore, the immersion method has been accepted.

Blue stain fungi:

Thanks to *Test report*: 092354-5-a (IRUXIL W-I) and *Test report*: 092354-4-a (IRUXIL W) according to EN152-1 (EN73). The degree of blushiness of both the virulence control and the referente product validate the assay.
The toxic value by surface treatment: 200 g/m^2.

According to note 24 of efficacy guideline "Guidance on the Biocidal Products Regulation" Vol II Efficacy, Version 3.0 2018, section 5.5.8.2.2.3, products can only claim protection against blue stain but it has to be clearly indicated in the instructions of use. Therefore these phrases will be included:

- For wood or wood product that by their nature are not susceptible to brown rot fungi.
- This product may not be used together with product against wood destroying fungi to prevent double treatment of fungicides.

Conclusion:

Based on the efficacy evaluation, the product may be authorised for use class 1 as preventive treatment against wood-boring beetles and in situation of

use class 2 against wood boring beetles and bluestain fungi in service by surface treatment brushing/rolling, spraying and dipping for softwood. Dose rate: 200g/m².

2.2.5.6 Occurrence of resistance and resistance management

Accoding to the FRAC, regarding these kind of substances, resistance is known in various fungal species. Several resistance mechanisms are known incl. target site mutations in cyp51 (erg 11) gene, e.g. V136A, Y137F, A379G, I381V; cyp51 promotor; ABC transporters and others.

Generally wise to accept that cross resistance is present between DMI fungicides active against the same fungus. DMI fungicides are Sterol Biosynthesis Inhibitors (SBIs), but show no cross resistance to other SBI classes. Medium risk.

Resistance to DMIs is mostly characterized by a slow, step-wise erosion of efficacy over several years of intensive use rather than by a rapid loss of control.
- Users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance" have, on investigation, been attributed to cutting recommended use rates, or to poorly timed applications.
- If the performance of SBIs declines and sensitivity testing confirms the presence of less sensitive isolates, SBIs should only be used in mixture or in alternation with effective non-cross-resistant partner fungicides..

The active substance IPBC is not specifically on list of fungicide common names as reference substante for any group from FRAC. Anyway, IPBC has a carbamet molecule and we can make an approach to the carbamate group. According to FRAC carbamates has low to medium risk. Resistance management required.

FRAC focuses mainly on fungicide resistance to products intended for agriculture. In the list of pathogenic species, no wood destroying species are included.

Resistance to pyrethroid insecticides such as permethrin has been reported for a number of pests both in agriculture and public health. However, no data has been found in the literature regarding resistance occurrence to cypermethrin among wood-boring beetle and termites.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the following recommendations have to be implemented:

-Always read the label or leaflet before use and follow all the instructions provided.

-The users should inform if the treatment is ineffective and report straightforward to the registration holder.

2.2.5.7 Known limitations

No limitations are known.

2.2.5.8 Evaluation of the label claims

User category	Non professional.	A.10

	Industrial. Trained professional.	A.20 A.30
Wood category	Softwood.	B.10
Wood product	Solid wood.	C.10
Application aim	Preventive.	D.40
Field of use	Use class 1. In situation of use class 2.	E.10 -
Method of application rate	Superficial application. Brush/roller Superficial application. Spray. (manual and automated) Superficial application. Dipping. (manual and automated)	F.10 F.11 F.14
Target organisms	House longhorn beetle (*H. bajulus*) Blue stain in service.	G.31 G.21.2

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

Not applicable.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Meta-SPC 1

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin.
Justification for the value/conclusion	Based on the classification of the active substances and the different co-formulants and their respective content in the Meta-SPC 1. Meta-SPC 1 contains coformulants classified as Skin corrosive and/or Skin irritant 2 (H315). However, the sum of its concentration in the mixture is not enough trigger the classification of the meta_SPC for this risk category. Therefore, the meta-SPC **does not meet the criteria for classification for skin irritation / corrosion** according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification for skin corrosion/irritation required.

Data waiving

Information requirement	Skin corrosion and irritation
Justification	In order to avoid further testing on vertebrates no studies on the skin irritation of the products were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected.

Eye irritation

Meta-SPC 1

Conclusion used in Risk Assessment – Eye irritation / damage	
Value/conclusion	Not irritating to eye
Justification for the value/conclusion	Based on the classification of the active substances and the different co-formulants and their respective content in the Meta-SPC 1. IPBC is classified as Eye damage Category 1, H318. Furthermore, Meta-SPC 1 contains four coformulants classified as Eye Irritant 2 (H319) and one coformulant classified as Eye damage Category 1 (H318). However, the sum of its concentration in the mixture is not enough trigger the classification of the meta-SPC for this risk category. Therefore, the meta-SPC **does not meet the criteria for classification for eye irritation / damage** according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Eye irritation
Justification	In order to avoid further testing on vertebrates no studies on eye irritation of the products family were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected.

Respiratory tract irritation

Meta-SPC 1

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.

Justification for the value/conclusion	Based on the classification of the active substances and the different co-formulants and their respective content in the Meta-SPC 1. Active substance IPBC is classified as STOT RE 1, H372 (larynx), but it is present in a concentration lower than the triggering value for classifying the product. Therefore, the meta-SPC **does not meet the criteria for classification for respiratory tract irritation** according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Respiratory tract irritation
Justification	In order to avoid further testing on vertebrates no studies on respiratory tract irritation of the products were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected.

Skin sensitization

Meta-SPC 1

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	Based on the classification of the active substances and the different co-formulants, and their respective content in the Meta-SPC 1. Propiconazole, IPBC and permethrin have a harmonized classification of Skin Sens. 1 (H317). The concentrations of propiconazole, IPBC and permethrin in Meta-SPC 1 are 0.225%, 0.225% and 0.25%, respectively. In addition, one coformulant is classified as Skin Sens. 1C (H317). According to Table 3.4.5 of the CLP Regulation (EC) No 1272/2008, the generic concentration limit of a component of a mixture classified as skin sensitizer that triggers the classification of the mixture is ≥ 1%. As the concentration of all active substances in the meta-SPC is below the concentration limit of ≥ 1% for skin sensitization, the

	meta-SPC **does not meet the criteria for classification for skin sensitization** according to Regulation (EC) No 1272/2008. However, as Permethrin, IPBC and propiconazole concentrations are below 1% but above 0.1% (threshold limit for elicitation), EUH208 is required on the label. In addition, the biocidal product contains BIT and CMIT/MIT(3:1) also classified for skin sensitisation which are above their threshold limit for elicitation, so EUH208 should also be required. Labelling with **EUH208** (Contains "Permethrin, IPBC, propiconazole, 1,2-benzisothiazol-3(2H)-one and mixture of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2Hisothiazol-3-one (3:1)". May produce an allergic reaction) is required.
Classification of the product according to CLP	No classification required. **EUH208:** Contains "Permethrin, IPBC, propiconazole, 1,2-benzisothiazol-3(2H)-one and mixture of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2Hisothiazol-3-one (3:1)". May produce an allergic reaction.

Data waiving	
Information requirement	Skin sensitization
Justification	In order to avoid further testing on vertebrates no studies on the skin sensitization of the products were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected.

Respiratory sensitization (ADS)

Meta-SPC 1

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing to respiratory tract.
Justification for the value/conclusion	Based on the classification of the active substances and the different co-formulants and their respective content in the Meta-SPC 1. None of the components of the product are classified as respiratory sensitizer, so the **Meta-SPC 1 is not classified as respiratory sensitizer.** Therefore, the meta-SPC **does not meet the criteria for classification for respiratory sensitization** according to Regulation (EC) No 1272/2008.

Classification of the product according to CLP	No classification required.

Data waiving	
Information requirement	Respiratory sensitization
Justification	In order to avoid further testing on vertebrates no studies on the skin sensitization of the products were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected**.**

Acute toxicity

Acute toxicity by oral route

Meta-SPC 1

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route.
Justification for the selected value	For Meta-SPC 1, 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 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 product itself is not required. According to chapter 3.1.3.6 "Classification of mixtures based on ingredients of the mixture (Additivity formula)" of the CLP Regulation, the ATE of the mixture (ATE_{mix}) is determined by calculation from the ATE values for all relevant ingredients according to the following formula and using the LD50/LC50-values as provided for in section 11 ("Toxicological Information") of the SDS of the respective components for Oral, Dermal or Inhalation Toxicity: $\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$ where: C_i = concentration of ingredient i (% w/w or % v/v) i = the individual ingredient from 1 to n n = the number of ingredients ATE_i = Acute Toxicity Estimate of ingredient i. Propiconazole, IPBC and permethrin are classified with Acute Tox. 4; H302 and the LD50 values are 1500 mg/kg (CAR), 300-500 mg/kg bw and 480 mg/kg bw, respectively. The concentrations of propiconazole,

	IPBC and permethrin in Meta-SPC 1 are 0.225%, 0.225% and 0.25%, respectively. According to CLP Regulation, section 3.1.3.3., page 124, "(d) when only range data (or acute toxicity hazard category information) are available for components in a mixture, they may be converted to point estimates in accordance with Table 3.1.2 when calculating the classification of the new mixture using the formulas in sections 3.1.3.6.1 and 3.1.3.6.2.3". In table 3.1.2, the converted acute toxicity point estimated is 500 for the experimentally obtained acute toxicity range values of 300 < LD50 ≤ 2000 mg/kg bw. The potential acute oral toxicity of the product is calculated as follows: ATEmix = 100/[(0.225/1500) + (0.225/500) + (0.25/480)] = 100/(0.00015 + 0.00045 + 0.00052) = 89219.3 mg/kg bw. According to Tab.3.1.2 of the CLP Regulation (EC) No 1272/2008, the calculated ATE of the mixture for acute oral toxicity is > 2000 mg/kg bw. Thus, the meta-SPC **does not meet the criteria for classification for acute toxicity (oral)** according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification required.

Data waiving	
Information requirement	Acute toxicity: oral
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing with vertebrates. Instead of that, we rely on toxicity data from the ingredients present in the formulation. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "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."

Acute toxicity by inhalation

Meta-SPC 1

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.

Justification for the selected value	For Meta-SPC 1, 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 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 product itself is not required. According to chapter 3.1.3.6 "Classification of mixtures based on ingredients of the mixture (Additivity formula)" of the CLP Regulation, the ATE of the mixture (ATE_{mix}) is determined by calculation from the ATE values for all relevant ingredients according to the following formula and using the LD50/LC50-values as provided for in section 11 ("Toxicological Information") of the SDS of the respective components for Oral, Dermal or Inhalation Toxicity: $\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$ where: C_i = concentration of ingredient i (% w/w or % v/v) i = the individual ingredient from 1 to n n = the number of ingredients ATE_i = Acute Toxicity Estimate of ingredient i. IPBC is classified with Acute Tox. 3; H331, while permethrin is classified with Acute Tox. 4; H332. The LC50 values for IPBC and permethrin are for dust/mist 0.67 mg/L and 4.638 mg/L, respectively, according to the CARs. The concentrations of IPBC and permethrin in Meta-SPC 1 are 0.225% and 0.25%, respectively. The potential acute inhalation toxicity of the product is calculated as follows: ATEmix = 100/[(0.225/0.67) + (0.25/4.638)] = 100/(0.336 + 0.054) = 256.48 mg/L According to Tab.3.1.2 of the CLP Regulation (EC) No 1272/2008, the calculated ATE of the mixture for acute inhalation toxicity is > 5 mg/L for dust/mist mg/kg bw. Thus, **Meta-SPC 1 does not need to be classified with respect to acute inhalation toxicity.**
Classification of the product according to CLP	No classification required.

Data waiving	
Information requirement	Acute toxicity: inhalation

Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing with vertebrates. Instead of that, we rely on toxicity data from the ingredients present in the formulation. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "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."

Acute toxicity by dermal route

Meta-SPC 1

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	Based on the classification of the active substances and the different co-formulants and their respective content in the Meta-SPC 1. None of the ingredients of the product is classified as acute toxic for inhalation route, therefore the meta-SPC **does not meet the criteria for classification for acute dermal toxicity** according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification required.

Data waiving	
Information requirement	Acute toxicity: dermal
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing with vertebrates. Instead of that, we rely on toxicity data from the ingredients present in the formulation.

Information on dermal absorption

There is no experimental data available on the dermal absorption of this family formulations since no study has been conducted thus far. The applicant proposed the use of the dermal absorption values as seen in the susbtances CAR for exposure calculations, but the read-across was not accepted. ES CA do not accept the justification of the applicant and, as a result, risk assessment calculations for human exposure have been made according to the EFSA default value for human risk assessment.

According to the Guidance on the BPR (Volume III: Human health Part A: Information Requirements, Ver. 1.2, May 2018), *"before new studies are commenced, it should be checked whether the intended use is safe when the appropriate default value is applied. If no experimental data are available, studies with similar formulations should be looked for or further information used that may give at least a rough estimate……but in this case strict and transparent rules should be followed as to when another formulation or product can be considered similar"*

EFSA Guidance Document on Dermal Absorption (EFSA, 2017) stablishes that dermal absorption data on another (reference) formulation can be used if the formulation for which dermal absorption needs to be determined is closely related. This occurs when all the following conditions are met:

- Content of relevant components in the formulation to be assessed (e.g. other active substance, synergist, safener, wetting agent, surfactant, solvent, emulsifier, preservative, stabiliser, detergent, adhesive, antifreezing substance (= all co-formulants), similar chemical types of co-formulants might be grouped as described below) is within permitted variation ranges of those in the reference formulation. Addition of substances not contained in the reference formulation might be acceptable up to a concentration of ≤ 0.5%, but only if it is shown or scientifically justified that this minor change does not have an impact on physical–chemical or toxicological properties of the formulation. In individual cases, greater variations might be acceptable, for example, replacement of a co-formulant by water or increase of an inert compound
- Co-formulants of both formulations are chemically and physicochemically closely related.
- Additional active substances do not possess properties that may change skin permeability (e.g. irritant and sensitising properties).
- Formulation is of the same or lower skin irritancy based on scores in studies.
- Formulation having the same or no sensitising potential based on classification.
- Active substance concentration is within permitted variations of that in the reference formulation based on the FAO and WHO specifications for pesticides (FAO/WHO, 2016, chapter 4.3.2)

It is considered unlikely that the above criteria will be met when moving from one formulation type to another.

According to the CAR for active substance Permethrin, a dermal absorption value of 3% has been set derived in a human volunteers dermal penetration study. The first two volunteers have been excluded from the derivation as they have a very low recovery and were regarded as outlines compared to the other 4 volunteers. In addition, the values have been normalised to 100% to compensate for the low recovery allowing derivation of a dermal absorption value of 3% as a rounded figure. This value of 3% cannot be accepted since it is not possible to establish a similarity between the formulation tested in the study of volunteers provided in the CAR and the range of compositions included in the BPF IRUXIL family. Furthermore, according to the guidance on Dermal Absorption, scientifically sound human volunteer *in vivo* data, even if ethically performed, cannot be used. Therefore, according to the BPC opinion on the approval of the active substance permethrin in product type 8, further data may be required, in particular regarding dermal absorption of the products and should be provided by applicants at the product authorization stage.

According to the CAR for active substance IPBC, an *in vitro* study with human skin gave dermal absorption values (including skin residues) of 30, 10, and 1.6% for solvent-based formulations containing 0.6, 2.3, and 17.1% IPBC, respectively and 100% default for solutions containing <0.5%-0.6% IPBC. The proposed 10% value cannot be accepted since it is not possible to establish a similarity between the tested formulations provided in the CAR and the range of compositions included in the BPF IRUXIL family. Therefore, according to BPC opinion further data may be required, in particular regarding dermal absorption of the products and should be provided by applicants at the product authorization stage.

According to the CAR for active substance propiconazole dermal absorption values used in the calculations are 1 % for the undiluted water based product (10 % a.s., Wocosen 100 SL), and 2% for the dilution (1% a.s.) and the solvent based product (app. 1.4% a.s., Wocosen 12 OL). The proposed value cannot be accepted since it is not possible to establish a similarity between the tested formulation provided in the CAR (Wocosen 12 OL) and the range of compositions included in the BPF IRUXIL family.

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Propiconazole	IPBC	Permethrin
Values used in the RA	70%	70%	70%
Justification for the selected value(s)	Default value from Guidance on dermal absorption (EFSA, 2017)	Default value from Guidance on dermal absorption (EFSA, 2017)	Default value from Guidance on dermal absorption (EFSA, 2017)

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

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), no substance of concern was identified.

Available toxicological data relating to a mixture

No toxicological studies have been performed with the formulated product. Instead of that, the classification of the product relies on the available toxicity studies for the active substances Permethrin, IPBC and propiconazole.

No further studies on the toxicity of the product are considered necessary as there are valid data available on the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) 1072/2008 (CLP) and synergistic effects between any of the components are not expected and the rest of the coformulants.

2.2.6.2 Exposure assessment

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

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	no	Yes	Yes	n.a.
Dermal	Yes*	Yes	Yes	no	Yes	Yes	n.a.
Oral	no	no	no	no	no	Yes	n.a.

n.a. not applicable

Explanatory note:

The exposure assessments are based on model calculations using models and default values from Biocides Human Health Exposure Methodology (October 2015) and HEEG opinions. Justifications for deviations from Biocides Human Health Exposure Methodology are provided in the respective description of the scenarios.

Taking into account Spanish definition of professionals[12], the decision on this category of users will depend on the necessary PPEs to obtain a non-concern situation from risk characterization of exposure scenarios. See section 2.2.6.3.

As a first step, primary exposure assessments are performed for all individual scenarios (work tasks) which are relevant for wood preservatives – PT8 (see table "list of scenarios" below) considering the concentrations of 0.225% propiconazole, 0.225% IPBC and 0.25% permethrin.

In a second step, the exposure calculated for the individual work tasks are combined (added up) for the following intended uses:

Meta SPC 1 (Iruxil W formulation)

- Use #1 –Preventive treatment by brushing/roller application indoor – Trained professional, Professional and General public.
- Use #2 – Preventive treatment by spraying surface application indoor – Trained professional and Professional.

Meta SPC 1 (Iruxil W-I formulation)

[12] Professional users (NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
Non-professional users (NP): users who are not professionals and that apply the biocidal product is in his private life.

- Use #3 –Preventive treatment by brushing/roller application indoor – Industrial, trained professional, professional and general public.
- Use #4 – Preventive treatment by spraying surface application indoor – Trained Professional and professional.
- Use #5 – Preventive treatment by automated spraying surface application indoor – Industrial.
- Use #6 – Preventive treatment by Manual dipping -Industrial and trained professional, Professional–Indoor
- Use #7 – Preventive treatment by Automated dipping – Industrial use – Indoor.

Secondary (indirect) exposure is defined as the exposure via the environment, which the exposed person may not be aware of (for example handling treated material, consumption of residues in food or drinking water), and which may even be long-term (TNsG on Annex I inclusion p. 20 (EC, 2002b)).

Secondary exposure scenarios involve skin contact and possible exposure by inhalation. Treated wood is not placed on the market until the product is dry. In practice, persons handling large amounts of treated timber (e.g. professional users of treated timber) would be expected to wear gloves to protect their hands from splinters or abrasions.

Secondary exposure of the general public includes dermal contact with contaminated surfaces or handling contaminated objects. Skin contact and oral contact with treated wood objects or hand-to-mouth contact is related to infants, toddlers and children playing on weathered structure. Children and infants are assumed to be a group at risk due to their low body weight and some secondary exposure scenarios are related to them. The exposure of toddler is considered to be covered by those of infants due to the lower body weight of infants.

Secondary exposure can occur soon after the application of the product or as a single event (acute phase), or thereafter during the long term and may be continuous (chronic phase).

Dermal exposure may occur during the mix and loading step through the hands, during spraying application where the hands and the body are exposed, in the cleaning of the application equipment and during disposal of product's aerosol can and cleaning of the treated areas through hands and forearms.

According to the different types of formulation and the application methods, the following scenarios are considered relevant for the assessment of human risk exposure:

2.2.6.2.1 List of scenarios

Summary table: scenarios for IRUXIL Family			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
Primary exposure			
1	Mixing and	Primary exposure by users during preparation	Industrial

Summary table: scenarios for IRUXIL Family			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
	loading of RTU	of the product before application by loading formulation in the container to be used for application. The water-based RTU product is delivered in Intermediate Bulk Container (IBC) or by tanker. Dilution is not required for the RTU product. This task is done by professional where they are exposed during the mixing and loading operations during automated addition by connecting lines.	(Trained professional)
2	Mixing and loading of RTU	Primary exposure by users during preparation of the product before application. The fluid is delivered in a container and is decanted from containers that are manually handled. This task is done by users where they are exposed during the mixing and loading operations during manual addition.	Trained professional, Professional and Non-professionals
3	Application: brushing and rolling	Primary exposure during product application. The activities of the users are stirring the RTU product and applying it to wood using a brush indoors.	Industrial (Trained professional). Trained professional, Professionals and Non-professionals
4	Application: spraying	Primary exposure during product application. Spraying application is performed by the operator on the wood surfaces by a handheld or knapsack sprayer, in absence of general public. Indoor application at premises like parquet, flooring, wood decor (plinths, friezes, baseboards) or carpentry (doors and windows) is considered a worse case for human exposure.	Trained Professional Professional
5	Application: Automated spray	Primary exposure during product application. The spraying process is done by automated machines in hermetic closed tanks at indoor industrial premises without operator presence during the application.	Industrial (Trained professional)
6	Application: manual dipping	Primary exposure during product application. During manual dipping, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts manually the wooden article from the dipping tank and stacks the article to dry. Manual dipping is	Industrial (Trained professional) and trained professional, professional

Summary table: scenarios for IRUXIL Family			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
		undertaken during a very short time during the day.	
7	Application: automated dipping	After loading the product into vessels systems, the product may be applied to the freshly cut wood by two different methods. (1) Automated dipping process. (2) Fully automated dipping process. For automated dipping, an operator using a fork-lift truck lowers the wood into the dipping tank or transfers the wood to a bathing tray. Automated dipping is a fully automated process. After the treatment, the wood is lifted out by the fork-lift truck. The wood is then transferred by the fork-lift truck to a storage area where it is placed to dry. Due to the fully automation exposure from 1 cycle per day is considered. The operator exposure arises from handling the treated wood.	Industrial (Trained professional)
8	Post-application: Cleaning application equipment - brushing	Primary exposure by cleaning of brush by washing out after product application	Industrial, trained professional, professional and non-professional
9	Post-application: Cleaning application equipment - spraying/dipping	Primary exposure by cleaning of spraying /dipping equipment after product application. The post-application phase includes disposal. For maintenance of treatment vessels and dipping tanks, test and clean greasing door seals, collecting fallen timber as well as clearing sludge is considered. For maintenance of flow coating systems, the cleaning of spray nozzles is considered.	Industrial (Trained professional) and trained professionals
Secondary exposure by professionals and general public			
10	Sawing and sanding treated wood	Secondary exposure from cutting and sanding treated wood by professional worker (chronic exposure).	Trained Professional
11	Sawing and sanding treated wood	Secondary exposure from cutting and sanding treated wood by general public (acute exposure).	General public (adult)
12	Chewing wood off-cut	Secondary exposure by infant picks up and chews wood off-cut, which has been treated with wood preservative (acute exposure).	General public (infant)
13	Playing on playground structure outdoors and mouthing	Secondary exposure by infant playing on and mouthing weathered structure (chronic exposure).	General public (infant)

Summary table: scenarios for IRUXIL Family			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
14	Inhalation of volatilized residues	Secondary exposure to wood preservatives may arise via residues volatilised from treated wood indoors (chronic exposure).	General public (infant and child, adult)
15	Laundering work-cloths	Secondary exposure: laundering is undertaken in a domestic, automatic washing machine	General public (adult)

Primary exposure

2.2.6.2.2 Industrial (Trained professionals) exposure

Scenario [1] – Mixing and loading of RTU

Description of Scenario [1] Mixing/loading of RTU
The water-based RTU product is delivered in IBC or by tanker. Dilution is not required for the RTU product. The transfer of the RTU product is done automated by connecting lines. According to HEEG Opinion 17, endorsed at TM III 2013, For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping: "where the wood preservative fluid is delivered by tanker and is transferred from the tanker into the dip tank using connecting hosing then, it could be assumed, providing the operator wears suitable PPE, exposure of the operator's skin is minimal and does not need to be quantified." The inhalation exposure is considered to be less than during the individual applications phases and, thus, to be covered by the application scenarios.

Calculations for Scenario [1] Mixing/loading of RTU

Not required since the exposure can be regarded to be negligible.

Further information and considerations on scenario [1] Mixing/loading of RTU

Not required.

Scenario [3] - Application by brushing/rolling

Description of Scenario [3]. Application by brushing/rolling
At industrial brushing scenario the user applies the product over the wood by using a brush in absence of general public.

This task is developed for preventive treatments. According to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, following values are used in exposure assessment (Consumer painting model 3):		
	Parameters	Value
Tier 1	Hand exposure[1]	0.5417 mg/m^2
	Body exposure[1]	0.2382 mg/m^2
	Inahalation[1]	0.0016 mg/m^2
	Exposure duration[1]	240 min
	Application area[1]	31.6 m^2
	Dermal absorption (all substances)	70%
	Body weight[2]	60 kg
	Inhalation rate[2]	1.25 m^3/h
Tier 2	Coverall permeation[3]	10%
	Gloves Permeation[3]	10%

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure and Biocides Human Health Exposure Methodology Consumer painting model 3

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Coated coveralls.

Calculations for Scenario [3]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**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]**
3Scenario [3] - Brushing /rolling	TIER 1 (without PPE)	Permethrin	2.11E-06	7.19E-04	-	7.21E-04
		IPBC	1.90E-06	6.47E-04	-	6.49E-04
		Propiconazole	1.90E-06	6.47E-04	-	6.49E-04
	TIER 2 (with gloves and coverall)	Permethrin	2.11E-06	7.19E-05	-	7.40E-05
		IPBC	1.90E-06	6.47E-05	-	6.66E-05
		Propiconazole	1.90E-06	6.47E-05	-	6.66E-05

Further information and considerations on scenario [3]

No further information is considered relevant for this scenario.

Relevant calculations are included in Annex 3.2

Scenario [5] - Application by fully automated spraying

Description of Scenario [5]. Application by fully automated spraying
Industrial automated spraying scenario, as requested for the applicant consists in depositing the piece of wood on a belt that automatically transports the piece to the interior of the painting booth (robot with spray guns) where it is painted in a closed atmosphere (it is of interest not only for protection of the operator but also to reduce material loss, overspray is recirculated). The gun robot feeds itself according to consumption. When the piece enters the robot, the spraying is activated by means of detectors, and when the piece leaves the spraying stops. As the pieces pass, the product is applied or stopped by sensors. Optionally, if more coats are to be applied, the pieces are also automatically transported to another closed booth where the next coat would be applied. Once applied, and also automatically, the piece is transported to the drying area, which may include an oven and a drying area at room temperature. Once dry, the pieces are collected. The operator leaves the piece unpainted at one point and picks it up already dry at another point. Therefore, the contact with liquid product and its spray in practice is almost non-existent. Reading across from HEEG opinion 8 – Defaults and appropriate models to assess human exposure for dipping processes, dermal exposure pattern of automated spraying is comparable to that of automated dipping process. Based on this assumption the appropriate model to assess the automated spraying process is Handling model 1. This model is used to assess the professional intermittently handling water-wet or solvent-damp wood and associated equipment after vacuum pressure processes (p. 26 of User Guidance, 2002). For application a default value of 60 minutes was used, by 4 cycles per day. According to the HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4. inhalation exposure resulting from aerosol formation should be negligible.

	Parameters	Value
Tier 1	Hand exposure[1]	1080 mg/cycle (inside gloves)
	Body exposure[1]	8570 mg/cycle
	Inahalation[1]	1.9 mg/m^3
	Exposure duration[2]	4 cycles (dermal exposure) 240 min (inhalation exposure)
	Dermal absorption (all substances)	70%
	Body weight[3]	60 kg
	Inhalation rate[3]	1.25 m^3/h

	Factor reduction exposure (fully automated)	4
Tier 2	Coverall permeation[4]	5%
Tier 3	Mask P3 Permeation[5]	2.5%
Tier 4	Hand exposure new gloves for each work shift[6]	135 mg/cycle (inside new gloves)

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.

[2] HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8)

[3] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products

[4] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

[5] EN 529-2005

[6] HEEG Opinion 9 Default protection factors for protective clothing and gloves.

Calculations for Scenario [5]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [5] Automated spraying	TIER 1 with gloves (including in model)	Permethrin	3.96E-04	2.81E-01	-	2.82E-01
		IPBC	3.56E-04	2.53E-01	-	2.54E-01
		Propiconazole	3.56E-04	2.53E-01	-	2.54E-01
	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	3.96E-04	4.40E-02	-	4.44E-02
		IPBC	3.56E-04	3.96E-02	-	4.00E-02
		Propiconazole	3.56E-04	3.96E-02	-	4.00E-02
	TIER 3 with gloves (including in model)+ coverall 5%+mask P3	Permethrin	9.90E-06	4.40E-02	-	4.40E-02
		IPBC	8.91E-06	3.96E-02	-	3.96E-02
		Propiconazole	8.91E-06	3.96E-02	-	3.96E-02
	TIER 4 new gloves	Permethrin	3.96E-04	1.64E-02	-	2.17E-02

	each cycle (including in model)+ coverall 5%+mask P3	IPBC	3.56E-04	1. 48E-02	-	1. 95E-02
		Propiconazole	3.56E-04	1.48E-02	-	1. 95E-02

Further information and considerations on scenario [5]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2. inhalation exposure result negligible.

Scenario [6] - Application by manual dipping

Description of Scenario [6]. Application by manual dipping

During manual dipping, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts manually the wooden article from the dipping tank and stacks the article to dry. Manual dipping is undertaken during a very short time during the day.
A duration time of 30 min is considered according to Biocides Human Health Exposure Methodology (October 2015) – PT8 "Professional manual dipping of wood articles".

The model used is Dipping model 1 (TNsG 2002 User Guidance – Version 1 and HEEG opinions 8 - 2009) for dermal and inhalation exposure estimation. This model includes the mixing/loading. However, according to BPC Recommendation no.6 (version 4) "*A realistic scenario should include the mixing and loading, application and the post-application phase. In addition, maintenance which is conducted infrequently may also occur on a day of application.*" In view of that, the following options from the model has been used for each sub-task of the main task:

- Pre-application: Option 3: Automated mixing and loading
- Application: Dipping Model 1, TNsG 2002
- Post application: Option 3: Automated draining and reloading

	Parameters		Value
Tier 1	Pre-application	Hand exposure[1]	0.92 mg/min (without gloves)
		Exposure duration[1]	10 min
		Frequency	daily
	Application	Hand exposure[1]	25.70 mg/min (inside used gloves)
		Body exposure[1]	178 mg/min
		Inahalation[1]	1 mg/m^3

		Exposure duration[1]	30 min
		Frequency	daily
	Post-application	Hand exposure[1]	0.92 mg/min (without gloves)
		Exposure duration[1]	10 min
		Frequency	monthly
	Dermal absorption (all substances)		70%
	Body weight[2]		60 kg
	Inhalation rate[2]		1.25 m^3/h
Tier 2	Coverall permeation[3]		5%
Tier 3	Mask P3 Permeation[4]		2.5%
Tier 4	New gloves for each work shift		12.85 mg/min (inside used gloves)

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

[4] EN 529-2005

Calculations for Scenario [6]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [6] (Manual dipping)	TIER 1 with gloves (including in model)	Permethrin	2.60E-05	1.78E-01	-	1.78E-01
		IPBC	2.34E-05	1.60E-01	-	1.60E-01
		Propiconazole	2.34E-05	1.60E-01	-	1.60E-01
	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	2.60E-05	3.03E-02	-	3.03E-02
		IPBC	2.34E-05	2.73E-02	-	2.73E-02
		Propiconazole	2.34E-05	2.73E-02	-	2.73E-02
	TIER 3 with gloves (including in	Permethrin	6.51E-07	3.03E-02	-	3.03E-02
		IPBC	5.86E-07	2.73E-02	-	2.73E-02
		Propiconazole	5.86E-07	2.73E-02	-	2.73E-02

	model)+ coverall 5%+mask P3					
	TIER 4 with new gloves for each work shift + coverall 5%+mask P3	Permethrin	6.51E-07	1.95E-02	-	1.95E-02
		IPBC	5.86E-07	1.76E-02	-	1.76E-02
		Propiconazole	5.86E-07	1.76E-02	-	1.76E-02

Further information and considerations on scenario [6]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [7] - Application by fully automated dipping

Description of Scenario [7]. Application by fully automated dipping
HEEG opinion 8 (2009) is applied for exposure assessment. Automated dipping treatment includes the following operations; an operator using a fork-lift truck lowers the wood into the dipping tank or transfers the wood to a bathing tray. Automated dipping is an automated process. After the treatment, the wood is lifted out by the fork-lift truck. The wood is then transferred by the fork-lift truck to a storage area where it is placed to dry. The operator exposure arises from handling the treated wood. Four cycles (60 min per cycle) per day are considered according to Biocides Human Health Exposure Methodology (October 2015) – PT8 "Professional automated dipping/immersion of wood articles". Use 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 the 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 the treated articles are surface dry. The untreated wood may only be lowered by a separate lifting unit into the dipping tank. According to the HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4 i.e. 1 cycle per day.

The model used is Handling model 1 water-based (TNsG 2002 User Guidance – Version 1 and HEEG opinions 8 and 18 - 2009/2013) for dermal exposure estimation. Inhalation exposure should be negiigible.		
	Parameters	Value
Tier 1	Hand exposure[1]	1080 mg/cycle (inside gloves)
	Body exposure[1]	8570 mg/cycle
	Inahalation[1]	negligible
	Dermal absorption (all substances)	70%
	Body weight[2]	60 kg
	Exposure duration	4 cycle (fully automated)
Tier 2	Coverall[3]	95% protection
Tier 3	Fully automated dipping process factor	4
Tier 4	Hand exposure new gloves (including model)[4] + Fully automated dipping process factor	135 mg/cycle

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. Inhalation exposure negligible (fully automated)

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

[4] TNsG 2002. Handling model 1 (Hand exposure new gloves 50th % value).

Calculations for Scenario [7]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [7] Fully automated dipping	TIER 1 with gloves (including in model)	Permethrin	-	1.13E+00	-	1.13E+00
		IPBC	-	1.01E+00	-	1.01E+00
		Propiconazole	-	1.01E+00	-	1.01E+00
	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	-	1.76E -01	-	1.76E -01
		IPBC	-	1.58E-01	-	1.58E-01
		Propiconazole	-	1.58E-01	-	1.58E-01

	TIER 3 FULLY AUTOMATED 1/4 (with gloves (including in model)+ coverall 5%)	Permethrin	-	4.40E-02	-	4.40E-02
		IPBC	-	3.90E-02	-	3.90E-02
		Propiconazole	-	3.90E-02	-	3.90E-02
	TIER 4 Fully automated 1/4 with NEW gloves for each work shift + coverall 5%	Permethrin	-	1.64E-02	-	1.64E-02
		IPBC	-	1.48E-02	-	1.48E-02
		Propiconazole	-	1.48E-02	-	1.48E-02

Further information and considerations on scenario [7]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [8] – Cleaning brushing equipment

Description of Scenario [8]. Cleaning brushing equipment
A post-application task which may lead to some degree of exposure is cleaning the brush used to apply the product. Brush cleaning by professionals can be expected to last for no more than 15 minutes and might result in some exposure to hands. To calculate the exposure due to washing out brushes, the HEEG opinion 11 and its computerised calculator have been used. Cleaning the brush used for applying paint may be done by repeated dipping and swilling it in a vessel containing an appropriate solvent. A large brush might have a size of 10 x 10 x 2 cm, corresponding to a volume of 200 ml. It is assumed that after painting one eighth (1/8) of the brush volume is paint. Cleaning is assumed to be done in three steps, each time using fresh solvent. The volume at each step should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 ml the volume of the cleaning water-based would be at least 400 ml per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush (i.e. 10 % of the paint originally on the brush remains after one washing). After each step the brush is assumed to be squeezed by the hand to get rid of as much solvent as possible. It is assumed that with this step 50% of the solution in the washed brush is released and may potentially contaminate the hand. However, it is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which absorbs 90% of the released liquid. It is assumed the brush is washed and squeezed for a maximum of 3 times. During brush cleaning, professionals may retain gloves worn during brush application of the product (Tier 2 assessment). No exposure of areas of the body other than the hands is assumed to occur; and exposure via inhalation is considered negligible.

	Parameters	Value
Tier 1	Volume of each washing solution[1]	200 mL
	Remaining residues in brush after each washing step[1]	10%
	Remaining residues in brush after each washing squeezing[1]	50%
	Penetration through cleaning cloth during squeezing[1]	10%
	Dermal absorption (all substances)	70%
	Body weight[2]	60 kg
Tier 2	Gloves	90% protection

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

Calculations for Scenario [8]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [8] - Cleaning brush	Tier 1/ no gloves	Permethrin	-	3.91E-03	-	3.91E-03
		IPBC	-	3.52E-03	-	3.52E-03
		Propiconazole	-	3.52E-03	-	3.52E-03
	Tier 2/ with gloves	Permethrin	-	3.91E-04	-	3.91E-04
		IPBC	-	3.52E-04	-	3.52E-04
		Propiconazole	-	3.52E-04	-	3.52E-04

Further information and considerations on scenario [8]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, mixing and loading, application and cleaning process for industrials were combined for each active substance.

Combined scenarios for dipping treatment are not necessary as exposure model has already takes into account pre- and post-application tasks.

Combined scenarios for fully automated spraying/dipping treatment are not necessary.

Summary table: estimated combined exposure from industrial users						
Combined scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Brushing treatment [3] + [8]	[3] Tier 2 +[8] Tier 2/	Permethrin	2.11E-06	4.63E-04	-	4.65E-04
		IPBC	1.90E-06	4.17E-04	-	4.19E-04
		Propiconazole	1.90E-06	4.17E-04	-	4.19E-04

2.2.6.2.3 Trained professional exposure

Scenario [2] – Mixing and loading of RTU

Description of Scenario [2] Mixing/loading of RTU
The water-based RTU product is delivered in IBC/drum (200 – 1000 L) or in a can/bucket/jerry can (up to 20 L). Dilution is not required for the RTU product. For IBC/drum, the transfer of the RTU product is done automated by connecting lines. According to HEEG opinion 18 (2013), "where the wood preservative fluid is delivered by tanker and is transferred from the tanker into the dip tank using connecting hosing then, it could be assumed, providing the operator wears suitable PPE, exposure of the operator's skin is minimal and does not need to be quantified." For the automated mixing and loading, the inhalation exposure is considered to be less than during the individual applications phases and, thus, to be covered by them. Alternatively, the RTU product is delivered in containers (up to 4 L) and decanted before application into smaller containers which can be handled manually. For the manual mixing and loading task the "Mixing and loading Model 7 – pouring liquids" is used for dermal and inhalation exposure according to HEEG opinion 1 (2008).

	Parameters	Value
Tier 1	Body weight	60 kg
	Exposure duration	10 min
	Hand exposure	101 mg/min
	Inhalation exposure	0.94 mg/m^3
Tier 2	Gloves	Dermal: 1.01 mg/min (under gloves)

Calculations for Scenario [2] Mixing/loading of RTU

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [2] - Mixing & loading	TIER 1 (without PPE)	Permethrin	8,16E-06	2,95E-02	-	2,95E-02
		IPBC	7.34E-06	2,65E-02	-	2,65E-02
		Propiconazole	7.34E-06	2,65E-02	-	2,65E-02
	TIER 2 (with gloves)	Permethrin	8.16E-06	2,95E-04	-	3,03E-04
		IPBC	7.34E-06	2,65E-04	-	2,72E-04
		Propiconazole	7.34E-06	2,65E-04	-	2,72E-04

Further information and considerations on scenario [2] Mixing/loading of RTU

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [3] - Application by brushing/rolling

This scenario has already been assessed for industrial exposure. No differences are considered between industrial and trained professional users at application process so same outputs from industrial exposure assessment are deemed for professional users.

Calculations for Scenario [3]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [3] - Brushing /rolling	TIER 1 (without PPE)	Permethrin	2.11E-06	7.19E-04	-	7.21E-04
		IPBC	1.90E-06	6.47E-04	-	6.49E-04
		Propiconazole	1.90E-06	6.47E-04	-	6.49E-04
	TIER 2 (with	Permethrin	2.11E-06	7.19E-05	-	7.40E-05
		IPBC	1.90E-06	6.47E-05	-	6.66E-05

	gloves and coverall)	Propiconazole	1.90E-06	6.47E-05	-	6.66E-05

Further information and considerations on scenario [3]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [4] - Application by spraying

Description of Scenario [4]. Application by spraying		
Spraying application is performed by the operator on the wood surfaces by a handheld or knapsack sprayer in absence of general public. Indoor application at premises like parquet, flooring, wood decor (plinths, friezes, baseboards) or carpentry (doors and windows) is considered a worse case for human exposure. This task is developed for preventive treatment. Following the Biocides Human Health Exposure Methodology, to evaluate the operator exposure for the application method for trained-professionals, spraying model 2 of TNsG 2002, Part 2, has been chosen as the most similar scenario. This model is evaluated for indoor treatments which is considered worst-case scenario for human risk compared to outdoor use. The model includes the tasks for "mixing and loading" and "spray application" at a pressure from 4 to 7 bar.		
	Parameters	Value
Tier 1	Hand exposure[1]	273 mg/min
	Body exposure[1]	222 mg/min
	Inahalation[1]	76 mg/m^3
	Exposure duration[1]	80 minutes (by two events of 40 minutes) without distinction between the M&L and application phases.
	Dermal absorption (all substances)	70%
	Body weight[2]	60 kg
	Inhalation rate[2]	1.25 m^3/h
Tier 2	Hands exposure[1] (inside gloves)	7.8 mg/min
Tier 3	Coverall permeation[3]	5%
Tier 4	Mask P3 Permeation[4]	2.5%
Tier 5	New gloves per shift work[3]	5%

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.
[4] EN 529-2005

Calculations for Scenario [4]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake** [mg/kg bw/d]	**Estimated dermal uptake** [mg/kg bw/d]	**Estimated oral uptake** [mg/kg bw/d]	1.24E+00 [mg/kg bw/d]
Scenario 4 (spraying)	TIER 1 without gloves	Permethrin	5.28E-03	1,16E+00	-	1,16E+00
		IPBC	4.75E-03	1,04E+00	-	1,04E+00
		Propiconazole	4.75E-03	1,04E+00	-	1,04E+00
	TIER 2 with gloves (including in model)	Permethrin	5.28E-03	5,36E-01	-	5,41E-01
		IPBC	4.75E-03	4,83E-01	-	4,87E-01
		Propiconazole	4.75E-03	4,83E-01	-	4,87E-01
	TIER 3 with gloves (including in model)+ coverall 5%	Permethrin	5.28E-03	4,41E-02	-	4,94E-02
		IPBC	4.75E-03	3,97E-02	-	4,44E-02
		Propiconazole	4.75E-03	3,97E-02	-	4,44E-02
	TIER 4 with gloves (including in model)+ coverall 5%+mask P3	Permethrin	1.32E-04	4,41E-02	-	4,42E-02
		IPBC	1.19E-04	3,97E-02	-	3,98E-02
		Propiconazole	1.19E-04	3,97E-02	-	3,98E-02
	TIER 5 with new gloves + coverall 5%+mask P3	Permethrin	1.32E-04	3,44E-02	-	3,45E-02
		IPBC	1.19E-04	3,18E-02	-	3,19E-02
		Propiconazole	1.19E-04	3,18E-02	-	3,19E-02

Further information and considerations on scenario [4]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [6.] - Application by manual dipping

Description of Scenario [6]. Application by manual dipping			
During manual dipping, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts manually the wooden article from the dipping tank and stacks the article to dry. Manual dipping is undertaken during a very short time during the day. A duration time of 30 min is considered according to Biocides Human Health Exposure Methodology (October 2015) – PT8 "Professional manual dipping of wood articles". The model used is Dipping model 1 (TNsG 2002 User Guidance – Version 1 and HEEG opinions 8 - 2009) for dermal and inhalation exposure estimation. This model includes the mixing/loading. However, according to BPC Recommendation no.6 (version 4) "*A realistic scenario should include the mixing and loading, application and the post-application phase. In addition, maintenance which is conducted infrequently may also occur on a day of application.*" In view of that, the following options from the model has been used for each sub-task of the main task of professional users: • Pre-application: Option 3: Manual mixing and loading • Application: Dipping Model 1, TNsG 2002 • Post application: Option 1: Manual draining and reloading			
	Parameters		Value
Tier 1	Pre-application	Hand exposure[1]	0.5 ml b.p/loading (without gloves)
		Exposure duration[1]	1 loading
		Frequency	daily
	Application	Hand exposure[1]	25.70 mg/min (inside used gloves)
		Body exposure[1]	178 mg/min
		Inahalation[1]	1 mg/m^3
		Exposure duration[1]	30 min
		Frequency	daily
	Post-application	Hand exposure[1]	0.5 ml b.p/loading (without gloves)
		Exposure duration[1]	10 loading
		Frequency	monthly
	Dermal absorption (all substances)		70%
	Body weight[2]		60 kg
	Inhalation rate[2]		1.25 m^3/h
Tier 2	Coverall permeation[3]		5%
Tier 3	Mask P3 Permeation[4]		2.5%

Tier 4	Hand exposure[4] New gloves for each work shift (application)	12.85 mg/min (inside used gloves)

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

[4] EN 529-2005

Calculations for Scenario [6]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [6] (Manual dipping)	TIER 1 with gloves (including in model)	Permethrin	2.60E-05	1.78E-01	-	1.78E-01
		IPBC	2.34E-05	1.60E-01	-	1.60E-01
		Propiconazole	2.34E-05	1.60E-01	-	1.60E-01
	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	2.60E-05	3.03E-02	-	3.03E-02
		IPBC	2.34E-05	2.73E-02	-	2.73E-02
		Propiconazole	2.34E-05	2.73E-02	-	2.73E-02
	TIER 3 with gloves (including in model)+ coverall 5%+mask P3	Permethrin	6.51E-07	3.03E-02	-	3.03E-02
		IPBC	5.86E-07	2.73E-02	-	2.73E-02
		Propiconazole	5.86E-07	2.73E-02	-	2.73E-02
	TIER 4 with new gloves for each work shift + coverall 5%+mask P3	Permethrin	6.51E-07	1.95E-02	-	1.95E-02
		IPBC	5.86E-07	1.76E-02	-	1.76E-02
		Propiconazole	5.86E-07	1.76E-02	-	1.76E-02

Further information and considerations on scenario [6]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [8] – Cleaning brushing equipment

As in the case of scenario [3] brushing application, this scenario has already been assessed for industrial exposure and no differences are considered between industrial and professional users at application process. Hence, same outputs from industrial exposure assessment are deemed for professional users.

[1] HEEG opinion 11 - Exposure model Primary exposure scenario – washing out of a brush which has been used to apply a paint (TM III 2010).

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

Calculations for Scenario [8]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [8] - Cleaning brush	Tier 1/ no gloves	Permethrin	-	3.91E-03	-	3.91E-03
		IPBC	-	3.52E-03	-	3.52E-03
		Propiconazole	-	3.52E-03	-	3.52E-03
	Tier 2/ with gloves	Permethrin	-	3.91E-04	-	3.91E-04
		IPBC	-	3.52E-04	-	3.52E-04
		Propiconazole	-	3.52E-04	-	3.52E-04

Further information and considerations on scenario [8]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [9.] – Cleaning spraying equipment

The same exposure assessment carried out for industrial (trained professional) users is deemed for trained professional users. Hence, same outputs from industrial (trained professional) exposure assessment are deemed for trained professional users.

Calculations for Scenario [9]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [9] Cleaning spray equipment	TIER 1 without PPE	Permethrin	negligible	3.23E-02	-	3.23E-02
		IPBC	negligible	2.91E-02	-	2.91E-02
		Propiconazole	negligible	2.91E-02	-	2.91E-02
	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	negligible	2.66E-03	-	2.66E-03
		IPBC	negligible	2.39E-03	-	2.39E-03
		Propiconazole	negligible	2.39E-03	-	2.39E-03

Due that professional users are trained to use PPE in their work-tasks, Tier 2 is deemed as the most adequate.

Further information and considerations on scenario [9]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, mixing and loading, application and cleaning process for professionals were combined for each active substance.

Combined scenarios for dipping treatment are not necessary as exposure model has already takes into account pre- and post-application tasks.

Summary table: estimated combined exposure from professional users						
Combined scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Combined brushing	[2] Tier 2 (gloves)	Permethrin	1,03E-05	7,57E-04	-	7,68E-04
		IPBC	9,24E-06	6,82E-04	-	6,91E-04

treatment [2]+[3] + [8]	+ [3] Tier 2 (gloves) + [8] Tier 2 (gloves)	Propiconazole	9,24E-06	6,82E-04	-	6,91E-04
Combined spraying treatment [4] + [9]	[4] Tier 2 (gloves) + [9] Tier 2 (gloves and coverall)	Permethrin	5,28E-03	5,39E-01	-	5,44E-01
		IPBC	4,75E-03	4,85E-01	-	4,90E-01
		Propiconazole	4,75E-03	4,85E-01	-	4,90E-01
	[4] Tier 3 (gloves and coverall) +[9] Tier 2 (gloves and coverall)	Permethrin	5,28E-03	4,68E-02	-	5,20E-02
		IPBC	4,75E-03	4,21E-02	-	4,68E-02
		Propiconazole	4,75E-03	4,21E-02	-	4,68E-02
	[4] Tier 5 (new gloves, coverall and mask P3) +[9] Tier 2 (gloves and coverall)	Permethrin	1,32E-04	3,71E-02	-	3,72E-02
		IPBC	1,19E-04	3,42E-02	-	3,43E-02
		Propiconazole	1,19E-04	3,42E-02	-	3,43E-02

2.2.6.2.4 Professional exposure

Due to the particular spanish trained professional and professional users definition:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types.

In the case of product IRUXIL FAMILY the assessment exposure for trained professional users is considered adequated for professionals and no new evaluation is necessary.

2.2.6.2.5 Non-Professional exposure

Scenario [2] – Mixing and loading of RTU

Description of Scenario [2] Mixing/loading of RTU		
According to HEEG opinion 1, for smaller quantities (<1L), Mixing&Loading model 2 (HSL 2001) in TNsG version 1 part 2 p.134 is used as worst case to assess the risk for general public at single event.		
	Parameters	Value
Tier 1	Body weight	60 kg
	Exposure duration	1 single event
	Hand exposure (bare hands)	12.8 mg/event

Calculations for Scenario [2] Mixing/loading of RTU

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [2] - Mixing & loading	TIER 1 (without PPE)	Permethrin	8.16E-06	3.73E-04	-	3.81E-04
		IPBC	7.34E-06	3.36E-04	-	3.43E-04
		Propiconazole	7.34E-06	3.36E-04	-	3.43E-04

Further information and considerations on scenario [2] Mixing/loading of RTU

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [3] - Application by brushing/rolling

Description of Scenario [3]. Application by brushing/rolling
This task is developed for preventive treatments where general public applies the product over the wood by using a brush. As worst case, this scenario has been assessed for general public by taking into account the same indicative values as considered for professional users but without PPE.

	Parameters	Value
Tier 1	Hand exposure[1]	0.5417 mg/m^2
	Body exposure[1]	0.2382 mg/m^2
	Inahalation[1]	0.0016 mg/m^2
	Exposure duration[1]	240 min
	Application area[1]	31.6 m^2
	Dermal absorption (all substances)	70%
	Body weight[2]	60 kg
	Inhalation rate[2]	1.25 m^3/h

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure and Biocides Human Health Exposure Methodology

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

Calculations for Scenario [3]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [3] - Brushing /rolling	TIER 1 (without PPE)	Permethrin	2.11E-06	7.19E-04	-	7.21E-04
		IPBC	1.90E-06	6.47E-04	-	6.49E-04
		Propiconazole	1.90E-06	6.47E-04	-	6.49E-04

Further information and considerations on scenario [3]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [8] – Cleaning brushing equipment

As in the scenario before [3], the same scenario used for professional users is considered for general public without considering the use of gloves as PPE (Tier 1).

Description of Scenario [8]. Cleaning brushing equipment
A post-application task which may lead to some degree of exposure is cleaning the brush used to apply the product. Brush cleaning by professionals can be expected to last for no more than 15 minutes and might result in some exposure to hands.

To calculate the exposure due to washing out brushes, the HEEG opinion 11 and its computerised calculator have been used.

Cleaning the brush used for applying paint may be done by repeated dipping and swilling it in a vessel containing an appropriate solvent. A large brush might have a size of 10 x 10 x 2 cm, corresponding to a volume of 200 ml. It is assumed that after painting one eighth (1/8) of the brush volume is paint. Cleaning is assumed to be done in three steps, each time using fresh solvent. The volume at each step should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 ml the volume of the cleaning water-based would be at least 400 ml per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush (i.e. 10 % of the paint originally on the brush remains after one washing).

After each step the brush is assumed to be squeezed by the hand to get rid of as much solvent as possible. It is assumed that with this step 50% of the solution in the washed brush is released and may potentially contaminate the hand. However, it is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which absorbs 90% of the released liquid. It is assumed the brush is washed and squeezed for a maximum of 3 times.

No exposure of areas of the body other than the hands is assumed to occur; and exposure via inhalation is considered negligible.

	Parameters	Value
Tier 1	Volume of each washing solution[1]	400 mL
	Remaining residues in brush after each washing step[1]	10%
	Remaining residues in brush after each washing squeezing[1]	50%
	Penetration through cleaning cloth during squeezing[1]	10%
	Dermal absorption (all substances)	70%
	Body weight[2]	60 kg

[1] HEEG opinion 11 - Exposure model Primary exposure scenario – washing out of a brush which has been used to apply a paint (TM III 2010).

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

Calculations for Scenario [8]

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**

			[mg/kg bw/d]	[mg/kg bw/d]	[mg/kg bw/d]	[mg/kg bw/d]
Scenario [8] - Cleaning brush	Tier 1/ no gloves	Permethrin	-	3.91E-03	-	3.91E-03
		IPBC	-	3.52E-03	-	3.52E-03
		Propiconazole	-	3.52E-03	-	3.52E-03

Further information and considerations on scenario [8]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, mixing and loading, application and cleaning processes concerned to brushing treatment by non-professionals were combined for each active substance.

Summary table: estimated combined exposure from non-professional users						
Combined scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Brushing treatment [2]+[3]+[8]	[2b] Tier 1 + [3] Tier 1 + [8] Tier 1 / no PPE	Permethrin	1,03E-05	5,01E-03	-	5,02E-03
		IPBC	9,24E-06	4,51E-03	-	4,51E-03
		Propiconazole	9,24E-06	4,51E-03	-	4,51E-03

2.2.6.2.6 Secondary exposure

Exposure of the general public

Secondary exposure may occur in the residential environment following pest-control measures. These exposures include inhalation of volatilized residues and dermal contact of contaminated surfaces. Hand-to-mouth contact might apply to infants and toddlers playing on the floor. Adults may be subject to inhalation exposure only, whereas children may be exposed by inhalation and dermal contact (playing on the floor). Toddlers and infants may be additionally exposed via oral ingestion (hand-to-mouth contact).

In addition, in those cases where work-cloths are washed at home, indirect exposure can occur also.

Reference Scenarios for Preventive Products:	Acute phase reference scenarios: - Adult - cutting and sanding treated wood (non-professional) - Infant - chewing wood off-cut Chronic phase reference scenarios: - Adult - cutting and sanding treated wood (professional) - Adult - inhalation of volatilised residues indoors - Adult - laundering work clothes at home - Child - playing on playground structure outdoors - Infant - playing on weathered structure and mouthing

Scenario [10] – Sawing and sanding treated wood

Description of Scenario [10] - Sawing and sanding treated wood

Cutting and sanding treated wood by professional worker is considered a chronic exposure scenario.

The application rate of 200 mL product/m² of the water-based product (taking into account the concentrations of 0.225% propiconazole, 0.225% IPBC and 0.25% permethrin) is considered the highest-end-retention.

According to TNsG 2002 User Guidance- Version 1, the model exposure data used in these calculations are derived from exposure studies on amateurs where no gloves were worn. Considering professionals would usually wear gloves, the exposure level would be lower in practice. Furthermore, the acute sanding scenario is extrapolated to the chronic situation by assuming that the exposure time is 6 hours per day.

For dermal exposure (hands - no gloves worn), the concentration on the surface of timber is taken into account, with the conservative assumption that the entire retained a.s. is present on the surface. The surface area of both palms of hands is 420 cm² and during prolonged and repeated contact 20% of the hand is contaminated (TNsG 2002, Part 3, p.51 and User Guidance, p.52). The transfer efficiency is 2% for rough-sawn wood (TNsG 2002, Part 2, p.206) and dermal uptake is 10% (TNsG 2002, Part 3, p.50).

During sawing/sanding of treated wood, dermal and inhalation exposure of workers is considered.

This secondary exposure scenario is based on TNsG 2002 User guidance - Version 1 and TNsG 2002, part III.

	Parameters	Value
Tier 1	Application rate	200 g/m²
	Density of the product	1.02 g/ml
	Dermal absorption	70%
	Body weight[1]	60 kg

Inhalation rate[2] (short- and long-term)	1.25 m³/h (0.021 m³/min)
Hand area (palms of both hands) (adult)[2]	410 cm²
Assuming that 20% of hand area will be contaminated (adult).	82 cm²
Transfer coefficient[3]	2%
Exposure duration	6 h
Generated dust / m³ of sanded treated wood. U.K. WEL of 5 mg/m³ wood dust (8-hour time-weighted average)	5 mg/m³
Density of wood[4]	0.4 g/cm³
Volume of wooden post to be sanded	4000 cm³

[1] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products.

[2] HEEG opinion 17. Default human factor values for use in exposure assessments for biocidal products (2013).

[3] TNsG 2007. Human exposure to Biocidal Products (for dried fluids on rough sawn wood).

[4] Manual of Technical Agreements of the Biocides Technical Meeting (MOTA) V.6 (2013), 4.2.5 for PT8 (p 30.).

Calculations for Scenario [10] – Sawing and sanding treated wood

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [10] - Sawing and Sanding treated wood	Tier 1/ no gloves	Permethrin	8.03E-05	1.00E-03	-	1.08E-03
		IPBC	7.23E-05	9.00E-04	-	9.72E-04
		Propiconazole	7.23E-05	9.00E-04	-	9.72E-04

Further information and considerations on scenario [10]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [11] – Sawing and sanding treated wood

Description of Scenario [11] - Sawing and sanding treated wood
Cutting and sanding treated wood by general public (adults) is considered an acute exposure scenario.

The application rate of 200 mL product/m² of the water-based product (taking into account the concentrations of 0.225% propiconazole, 0.225% IPBC and 0.25% permethrin) is considered the highest-end-retention.

For the acute situation, exposure duration of 1 h is assumed. The model exposure data used in these calculations are derived from exposure studies on amateurs where no gloves were worn.

During sawing/sanding of treated wood, dermal and inhalation exposure of adults is considered.

This secondary exposure scenario is based on TNsG 2002 User guidance - Version 1 and TNsG 2002, part III.

	Parameters	Value
Tier 1	Application rate	200 g/m²
	Density of the product	1.02 g/ml
	Dermal absorption	70%
	Body weight[1]	60 kg
	Inhalation rate[2] (short- and long-term)	1.25 m³/h (0.021 m³/min)
	Hand area (palms of both hands) (adult)[2]	410 cm²
	Assuming that 20% of hand area will be contaminated (adult).	82 cm²
	Transfer coefficient[3]	2%
	Exposure duration	1 h
	Generated dust / m³ of sanded treated wood. U.K. WEL of 5 mg/m³ wood dust (8-hour time-weighted average)	5 mg/m³
	Density of wood[4]	0.4 g/cm³
	Volume of wooden post to be sanded	4000 cm³

[1] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products.

[2] HEEG opinion 17. Default human factor values for use in exposure assessments for biocidal products (2013).

[3] TNsG 2007. Human exposure to Biocidal Products (for dried fluids on rough sawn wood).

[4] Manual of Technical Agreements of the Biocides Technical Meeting (MOTA) V.6 (2013), 4.2.5 for PT8 (p 30.).

Calculations for Scenario [11] – Sawing and sanding treated wood

Summary table: estimated exposure from users						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**

			[mg/kg bw/d]	[mg/kg bw/d]	[mg/kg bw/d]	[mg/kg bw/d]
Scenario [11] - Sawing and Sanding treated wood	T3ier 1/ no gloves	Permethrin	1.34E-05	1.00E-03	-	1.01E-03
		IPBC	1.20E-05	9.00E-04	-	9.12E-04
		Propiconazole	1.20E-05	9.00E-04	-	9.12E-04

Further information and considerations on scenario [11]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [12] – Chewing wood off-cut

Description of Scenario [12] - Chewing wood off-cut
Infant picks up and chews wood off-cut, which has been treated with wood preservative. This scenario is considered an acute exposure scenario. The application rate of 200 mL product/m² of the water-based products (taking into account the concentrations of 0.225% propiconazole, 0.225% IPBC and 0.25% permethrin) is considered the highest-end-retention. For infants who are chewing wood it is assumed that the active substances in the treated timber is located in the outer 1 cm layer. It is assumed that the infant is chewing a 4 cm × 4 cm × 1 cm = 16 cm³ chip and in doing so extracts 10% of the active substance. For children this scenario is not relevant according to TNsG 2002. This scenario is regarded as unrealistic for children, as opposed to infants, because children are highly unlikely to chew treated wood in any significant amounts. This secondary exposure scenario is based on TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a). During sawing/sanding of treated wood, dermal and inhalation exposure of adults is considered.

	Parameters	Value
Tier 1	Application rate	200 g/m²
	Extraction by chewing[1]	10%
	Size of wood composites chip[1]	16 cm^3
	Surface of wood composite chip treated[1]	16 cm^2
	Oral absorption	100%
	Dermal absorption	70%
	Body weight[2]	8 kg

[1] TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a).

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products.

Calculations for Scenario [12] – Chewing wood off-cut

Summary table: estimated exposure from infant by chewing wood off-cut						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [12] - Chewing wood off-cut	Tier 1/ no gloves	Permethrin	-	-	1.00E-02	1.00E-02
		IPBC	-	-	9.00E-03	9.00E-03
		Propiconazole	-	-	9.00E-03	9.00E-03

Further information and considerations on scenario [12]

No further information is considered relevant for this scenario.

The calculation sheets are provided in Annex 3.2.

Scenario [13] – Playing on playground structure outdoors and mouthing

Description of Scenario [13] - Playing on playground structure outdoors and mouthing		
Toddler playing on and mouthing weathered structure. These scenarios are considered chronic exposure scenarios. The application rate of 200 mL product/m² of the water-based products (taking into account the concentrations of 0.225% propiconazole, 0.225% IPBC and 0.25% permethrin). In this scenario, during playing on timber structure, dermal as well as oral (through hand-to-mouth transfer) exposure is considered. This secondary exposure scenario is based on TNsG 2002 User guidance - Version 1 and TNsG 2002, part III, and on the HEAdhoc Recommendation no. 5 (2015).		
	Parameters	Value
Tier 1	Application rate	200 g/m²
	Density of the product	1.02 g/ml
	Dermal absorption	70%
	Body weight[1]	10 kg
	Contact surface (hands)[1]	231 cm²
	Hands contaminated area (%)[2]	20%

	Dislodgeable fraction for dried objects on wood (%)[2]	2%
	Wood surface area mouthing [2]	50 cm^2
	Oral absorption	100%

[1] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products.

[2] TNsG on Human Exposure to Biocidal Products Part 3, p51.

Calculations for Scenario [13] – Playing on playground structure outdoors and mouthing

Summary table: estimated exposure from toddler playing on playground structure outdoors and mouthing						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [13] - Playing on playground structure outdoors and mouthing	Tier 1/ no PPE	Permethrin	-	3.24E-03	2.50E-02	2.82E-02
		IPBC	-	2.92E-03	2.25E-02	2.54E-02
		Propiconazole	-	2.92E-03	2.25E-02	2.54E-02

Further information and considerations on scenario [13]

Local exposure and risk assessment is not relevant for playing on playground structure outdoors and mouthing, since the concentrations of the active substances to which dermal contact occurs are reduced by the transfer coefficient of 2 % for dried fluids on rough sawn wood. Hence, no further information is considered relevant for this scenario.

Scenario [14] – Inhalation of volatilized residues

Description of Scenario [14] - Inhalation of volatilized residues
Chronic exposure to wood preservatives may arise via residues volatilised from treated wood indoors. Propiconazole and permethrin have very low vapour pressures of 5.6E-05 Pa and 2.155E-06 Pa, respectively (at 20°C). IPBC has a slightly higher vapour pressure of 1.4E-03 Pa (at 20°C). Although, inhalation from treated dried wood is considered to be very low, exposure by volatilised residues indoors was calculated using the SVC (saturated vapour concentration) approach (according to HEEG opinion 13 on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance, 2011).

As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed for each active substance:

$$0.328 \times \frac{mw \times vp}{AEL_{long-ter}} \leq 1$$

Let mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa).For toddler (based on an inhalation rate of 8 m^3/24 hr and bw of 10 kg) and using an AEL in mg a.s./kg bw/d, if then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is negligible then the inhalation risk for the infant, child and for the adult can also be considered to be negligible.

For the product, there are three active substances:

Active substance	Vapour pressure a.s. (Pa)	Molecular weight a.s.	AEL longterm (mg a.s./kgbw/d)	Cte	Result	Negligible / included
Permethrin	2.16E-06	391.29	0.05	0.328	5.53E-03	negligible
IPBC	4.50E-03	281.1	0.2	0.328	2.07E+00	**included**
Propiconazole	5.60E-05	342.2	0.04	0.328	1.57E-01	negligible

Based on the results table above, the inhalation exposure of IPBC should be included in the risk assessment.

	Parameters		Value
Tier 1	IPBC	Vapour pressure a.s.	4.50E-03 Pa
		Molecular weight a.s.	281.1 g/mol
	Cte of gases[1]		8.31451 J mol^{-1} K^{-1}
	Temperature[1] (K)		298 K
	Body weight[1]		
		Adult	60 kg
		Children	23.9 kg
		Toddler	10 kg
		Infant	8 kg
	Inhalation rate[1]		
		Adult	16 m^3/ 24 h
		Children	12 m^3/ 24h
		Toddler	8 m^3/ 24 h
		Infant	5.4 m^3/ 24h

[1] HEEG opinion 13 on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance).

Calculations for Scenario [14] – Inhalation of volatilized residues

Summary table: estimated exposure inhalation of volatilized residues						
Exposure scenario	**Active substance**	**Human group**	**Estimated inhalation uptake** [mg/kg bw/d]	**Estimated dermal uptake** [mg/kg bw/d]	**Estimated oral uptake** [mg/kg bw/d]	**Estimated total uptake** [mg/kg bw/d]
Scenario [14] - Inhalation of volatilized residues	IPBC	Adult	1.36E-03	-	-	1.36E-03
		Children	2.56E-03	-	-	2.56E-03
		Toddler	4.08E-03	-	-	4.08E-03
		Infant	3.45E-03	-	-	3.45E-03

Further information and considerations on scenario [14]

No further information is considered relevant for this scenario.

The calculation sheets are provided in 3.2.1 Human Health Risk Assessment Appendix.

Scenario [15] – Laundering work clothes

Description of Scenario [15] - Laundering work clothes
Exposure to IRUXIL family products can occur when washing contaminated work clothes. Persons at risk are adults. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. In general, this approach assumes that the washing is carried out in a domestic automatic washing machine, therefore, the exposure will be dermally through the hands, from handling the contaminated clothes before and during the introduction of the clothes in the washing machine. Laundering is considered to be after a five day work week as the worst case, hence the total amount of product on work clothes is assumed to be five times the daily contamination associated with the application method used and it is assumed that the clothing to be washed is a coverall worn by a trained professional. The contamination of the coveralls is based on the worst professional scenario, automated dipping (Scenario [14]) as Tier 1 and on brushing scenario [3] from which the tier that shows safe use as Tier 2. The sum transfer area is determined by estimating how many times the coverall is touched by the hands while preparing it for laundering. As a first tier, it is assumed that this happens three times, twice with the palms of both hands and once with the total hands surface, the sum transfer area is 1640 cm^2. As a worst-case assumption, 50% of the residues in the touched area is transferred to the skin (transfer coefficient). The scenario is modelled after the CAR for Propiconazole in PT8 (FI CA, 2007).

	Parameters	Value
Tier 1	Clothing contamination from automated dipping scenario [14]	32566 mg/day
	Days before washing	5 days

	Percentage dislodgeable (transfer coefficient)[2]	30%
	Surface of medium coated coverall[2]	22700 cm^2
	Sum transfer area[3]	1640 cm^2
	Dermal absorption	70%
	Body weight	60 kg
Tier 2	Clothing contamination from brushing scenario [3]	6.77 mg/day

[1] Clothing contamination equals the highest potential body exposure minus the amount that penetrates through the clothing (10 %), and is expressed as mg a.s./day.

[2] TNsG 2002, part 2, p 204 Cotton, knitwear, plastic, wood Dried fluid 30 % - wet hand.

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

Calculations for Scenario [15] – Laundering work clothes

Summary table: estimated exposure from people laundering work clothes						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [15] Laundering work clothes	TIER 1 From fully automated dipping	Permethrin	-	1.03E-01	-	1.03E-01
		IPBC	-	9.26E-02	-	9.26E-02
		Propiconazole	-	9.26E-02	-	9.26E-02
	TIER 2 From brushing scenario	Permethrin	-	2.14E-05	-	2.14E-05
		IPBC	-	1.93E-05	-	1.93E-05
		Propiconazole	-	1.93E-05	-	1.93E-05

Further information and considerations on scenario [15]

No further information is considered relevant for this scenario.

Combined scenarios

No combined scenarios are considered of concern for general public.

2.2.6.2.7 Monitoring data

No monitoring studies have been developed by the applicant as they are not considered necessary.

2.2.6.2.8 Dietary exposure

Not required since exposure to food, drinking water or livestock can be excluded when the product is applied according to the recommended uses. Additionally, the RMM "Do not apply the product to wood or place treated wood in areas where food/feed, food

utensils or food processing surfaces may come into contact with, or be contaminated by the product or treated wood." is applied to exclude contact with food and feedstuff.

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

Production/formulation of the biocidal product

Exposure resulting from the production and formulation of the active substances and of the biocidal product are not considered. The production/formulation of the biocidal product is done in accordance with local and national occupational health and safety regulations.

During the production and formulation of the biocidal product, human are not exposed to the product residues as the process is automated in a closed system and the operator is segregated from the product source.

Therefore, no risk assessment is needed at this regard. Moreover, all the steps of the manufacturing process at IRURENA manufacturing plants are performed according to the instructions given in the Directive 98/24/EC - risks related to chemical agents at work.

Environmental exposure

In case of spillages, the biocidal product is taken up with inert material (sand, earth, chemical absorbent, etc.) and collected in dedicated properly labelled drums. It is disposed of as chemical waste in accordance with local and national laws and regulations. Consequently, there is no release into the environment and, thus, no environmental exposure assessment is applicable.

Disposal of the biocidal product

The waste disposal has to be done in accordance with Directive 2008/98/EC, covering waste and dangerous waste. For the disposal of the product and packaging, the allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

2.2.6.2.10 Aggregated exposure (combined for relevant emission sources)

Not applicable as this product is not intended to be used under a different biocidal product type.

2.2.6.2.11 Summary of exposure assessment

Scenarios and values to be used in risk assessment					
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d) of permethrin**	**Estimated total uptake (mg/kg bw/d) of IPBC**	**Estimated total uptake (mg/kg bw/d) of propiconazole**
1	industrials	-	negligible		
2	professional	Tier 2 / gloves	3,03E-04	2,72E-04	2,72E-04
2b	Non-professional	Tier 1 / none	3.81E-04	3,43E-04	3.43E-04
3	industrials, professionals and non-professionals	Tier 1/ none	7.21E-04	6.49E-04	6.49E-04
		Tier 2/ Gloves and coverall	7.40E-05	6.66E-05	6.66E-05
4	professionals	Tier 1/ None	1.16	1.04	1.04
		Tier 2/ Gloves	5.41E-01	4.87E-01	4.87E -01
		Tier 3/ Gloves and coverall	4.94E-02	4.44E-02	4.44E-02
		Tier 4/ Gloves, coverall and mask	4.42E-02	3.98E-02	3.98E-02
		Tier 5/ New Gloves, coverall and mask	3.72E-02	3.43E-02	3.43E-02
5	industrials	Tier 1/ Gloves,	2.82E-01	2.54E-01	2.54E-01
		Tier 2/ Gloves impermeable coverall	4,44E-02	4,00E-02	4,00E-02
		Tier 3/ Gloves impermeable coverall and mask P3	4,40E-02	3,96E-02	3,96E-02
		Tier 4/ New gloves each cycle, impermeable coverall and mask P3	2,17E-02	1,95E-02	1,95E-02
6	industrials and professional	Tier 1/ Gloves	1.78E-01	1.60E-01	1.60E-01
		Tier 2/ Gloves and impermeable coverall	3.03E-02	2.73E-02	2.73E-02

Scenarios and values to be used in risk assessment					
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d) of permethrin**	**Estimated total uptake (mg/kg bw/d) of IPBC**	**Estimated total uptake (mg/kg bw/d) of propiconazole**
		Tier 3/ Gloves, impermeable coverall and mask P3	3.03E-02	2.73E-02	2.73E-02
		Tier 4/ New gloves for each work shift, impermeable coverall and mask P3	1.95E-02	1.76E-02	1.76E-02
7	industrials	Tier 1/ Gloves	1.13E+00	1.01E+00	1.01E+00
		Tier 2/ Gloves and impermeable coverall	1.76E-01	1.58E-01	1.58E-01
		Tier 3 (fully automated)/ Gloves and impermeable coverall	4.40E-02	3.90E-02	3.90E-02
		Tier 4 (fully automated)/ New gloves for each work shift and impermeable coverall	1.64E-02	1.48E-02	1.48E-02
8	Industrials, professionals and non-professionals	Tier 1/ none	3.91E-03	3.52E-03	3.52E-03
		Tier 2/ Gloves	3.91E-04	3.52E-04	3.52E-04
9	Industrials and professionals	Tier 1/ none	3.23E-02	2.91E-02	2.91E-02
		Tier 2/ Gloves and impermeable coverall	2.66E-03	2.39E-03	2.39E-03
Combined [3] + [8]	industrials	Tier 2/ Gloves and coverall	4.65E-04	4.19E-04	4.19E-04
Combined [2] + [3] + [8]	professionals	[2] Tier 2 (gloves) + [3] Tier 2 (gloves) + [8] Tier 2 (gloves)	7.68E-04	6.91E-04	6.91E-04
Combined [4] + [9]	Professionals	[4] Tier 2 (gloves) + [9] Tier 2 (gloves and coverall)	5.44E-01	4.90E-01	4.90E-01
		[4] Tier 3 (gloves and coverall) +[9] Tier 2 (gloves and coverall)	5.20E-02	4.68E-02	4.68E-02

Scenarios and values to be used in risk assessment					
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d) of permethrin**	**Estimated total uptake (mg/kg bw/d) of IPBC**	**Estimated total uptake (mg/kg bw/d) of propiconazole**
		[4] Tier 5 (new gloves, coverall and mask P3) +[9] Tier 2 (gloves and coverall)	3.72E-02	3.43E-02	3.43E-02
Combined [2] + [3] + [8]	Non-professionals (general public)	[2] Tier 1 + [3] Tier 1 + [8] Tier 1/ no PPE	5.02E-03	4.51E-03	4.51E-03
10 – secondary chronic exposure	professionals	Tier1/ None	1.08E-03	9.72E-04	9.72E-04
11 – secondary acute exposure	general public –adult	Tier1/ None	1.01E-03	9.12E-04	9.12E-04
12 – secondary acute exposure	general public - infant	Tier1/ None	1.00E-02	9.00E-03	9.00E-03
13 – secondary chronic exposure	general public - infant	Tier1/ None	2.82E-02	2.54E-02	2.54E-02
14– secondary chronic exposure	general public - adult	Tier1/ None	n.r.	1.36E-03	n.r.
	general public - child	Tier1/ None	n.r.	2.56E-03	n.r.
	general public - toddler	Tier1/ None	n.r.	4.08E-03	n.r.
	general public - infant	Tier1/ None	n.r.	3.45E-03	n.r.
15– secondary exposure chronic exposure	general public - adult	Tier1 from fully automated dipping scenario/ None	1.03E-01	9.26E-02	9.26E-02
		Tier2 from brushing scenario/ None	2.14E-05	1.93E-05	1.93E-05

n.r. not relevant.

2.2.6.3 Risk characterisation for human health

The risk characterisation is conducted by comparison of human exposure and the toxicity using the Acceptable Exposure Limit (AEL) approach in which the exposure estimates are compared with the systemic reference values that were determined by dividing the relevant N(L)OAEL (mg/kg/day) by an overall Assessment Factor (AF). Risks are considered acceptable if the systemic exposure/AEL ratio is < 1.

Reference values to be used in Risk Characterisation for <u>Permethrin</u>

The data provided in the following table are according to the AR on permethrin (PT8 – 2014).

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	2 year oral study in rats (acute effects)	59.43 mg/kg bw/d[2]	100	-	0.5 mg/kg bw/d[2]
AELmedium-term	1 year study in dog	5 mg/kg bw/d	100	-	0.05 mg/kg bw/d
AELlong-term	1 year study in dog	5 mg/kg bw/d	100	-	0.05 mg/kg bw/d
ARfD	-	-	-	-	n.r.
ADI	-	-	-	-	n.r.

[1] The default assessment factor of 100 is obtained from [10 (interspecies variation) x 10 (intraspecies variation)] which is considered appropriate by the active substance's AR.

[2]According to AR (PT8 – 2014), "*dividing the NOAEL value 59.43-mg/kg bw/day by an overall assessment factor of 100 derives a reference value of 0.59-mg/kg bw/day. However, this AEL_{acute} from an inhalation study enquires estimate of received dose with all the attendant uncertainties. The oral Ishmael and Litchfield gives a very similar AEL of 0.5 mg/kg bw/day Therefore, ARfD or AEL_{acute} reference value is set at of 0.5 mg/kg bw/day*."

n.r.: not relevant

Reference values to be used in Risk Characterisation for IPBC

The data provided in the following table are according to the AR on IPBC (PT13 – 2015).

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	90 day gavage rat study	35 mg/kg bw/d	100	-	0.35 mg/kg bw/d
AELmedium-term	-	-	-	-	-
AELlong-term	2 years rats study	20 mg/kg bw/d	100	-	0.2 mg/kg bw/d
ARfD	-	-	-	-	n.r.
ADI	-	-	-	-	n.r.

[1] The default assessment factor of 100 is obtained from [10 (interspecies variation) x 10 (intraspecies variation)] which is considered appropriate by the active substance's AR.

n.r.: not relevant

Reference values to be used in Risk Characterisation for <u>Propiconazole</u>

The data provided in the following table are according to the AR on propiconazole (PT8 – 2007, adapted LoEP PT7).

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	Developmental study in rat	NOAEL: 30 mg/kg bw/d	100	-	0.3 mg/kg bw/d
AELmedium-term	-	-	-	-	-
AELlong-term	2-year rat study	NOAEL: 3.6 mg/kg bw/d	100	-	0.08 mg/kg bw/d
ARfD	-	-	-	-	n.r.
ADI	-	-	-	-	n.r.

[1]The default AF of 100 is applied on the basis of a 10-fold factor for inter-species variation and a 10 factor for intra-species variation.

n.r.: not relevant

Maximum residue limits or equivalent

Not relevant

2.2.6.3.1 Risk for industrial users

General remark:

The results reflect industrial applications using the RTU IRUXIL family products containing 0.225% propiconazole, 0.225% IPBC and 0.25% permethrin.

Systemic effects

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Scenario [1] / Mixing and loading of RTU (automated)	TIER 1 (without PPE)	Permethrin	5	0.05	negligible	negligible	yes
		IPBC	20	0.2	negligible	negligible	yes
		Propiconazole	3.6	0.08	negligible	negligible	yes
Scenario [3] - Brushing /Rolling application	TIER 1 (without PPE)	Permethrin	5	0.05	7.21E-04	1.4%	yes
		IPBC	20	0.2	6.495E-04	0.3%	yes
		Propiconazole	3.6	0.08	6.49E-04	0.8%	yes
		Permethrin	5	0.05	7.40E-05	0.1%	yes

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
	TIER 2 (with gloves and coverall)	IPBC	20	0.2	6.66E-05	0.0%	yes
		Propiconazole	3.6	0.08	6.66E-05	0.1%	yes
Scenario [5] Fully-automated spraying	TIER 1 with gloves (including in model)	Permethrin	5	0.05	2.82E-01	**563.7%**	**no**
		IPBC	20	0.2	2.54E-01	**317.1%**	**no**
		Propiconazole	3.6	0.08	2.54E-01	**126.8%**	**no**
	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	5	0.05	4,44E-02	88.8%	yes
		IPBC	20	0.2	4,00E-02	49.9%	yes
		Propiconazole	3.6	0.08	4,00E-02	20.0%	yes
	TIER 3 with gloves (including in model)+ coverall 5%+mask P3	Permethrin	5	0.05	4,40E-02	88.0%	yes
		IPBC	20	0.2	3,96E-02	49.9%	yes
		Propiconazole	3.6	0.08	3,96E-02	19.8%	yes
	TIER 4 new gloves each cycle (including in model)+ coverall 5%+mask P3	Permethrin	5	0.05	2,17E-02	33.7%	yes
		IPBC	20	0.2	1,95E-02	18.9%	yes
		Propiconazole	3.6	0.08	1,95E-02	7.6%	yes
Scenario [7] Fully automated dipping	TIER 1 with gloves (including in model)	Permethrin	5	0.05	1.13E+00	**2251.7%**	**no**
		IPBC	20	0.2	1.01E+00	**1266.6%**	**no**
		Propiconazole	3.6	0.08	1.01E+00	**352.8%**	**no**
	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	5	0.05	1.76E-01	**198.0%**	**no**
		IPBC	20	0.2	1.58E-01	79.2%	yes
		Propiconazole	3.6	0.08	1.58E-01	88.0%	yes
	TIER 3 FULLY AUTOMATED 1/4 (with gloves (including in model)+ coverall 5%)	Permethrin	5	0.05	4.40E-02	49.5%	yes
		IPBC	20	0.2	3.96E-02	19.8%	yes
		Propiconazole	3.6	0.08	3.96E-02	32.7%	yes

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
	TIER 4 Fully automated 1/4 with NEW gloves for each work shift + coverall 5%	Permethrin	5	0.05	1.64E-02	18.4%	yes
		IPBC	20	0.2	1.48E-02	7.4%	yes
		Propiconazole	3.6	0.08	1.13E+00	**2251.7%**	**no**
Scenario [8] - Cleaning brush	Tier 2/ with gloves	Permethrin	5	0.05	3.91E-03	0.8%	yes
		IPBC	20	0.2	3.52E-03	0.2%	yes
		Propiconazole	3.6	0.08	3.91E-03	0.4%	yes
Scenario [9] Cleaning spray equipment	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	5	0.05	2.66E-03	5.3%	yes
		IPBC	20	0.2	2.39E-03	1.2%	yes
		Propiconazole	3.6	0.08	2.39E-03	3.0%	yes

Combined scenarios

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Brushing treatment [3] + [8]	[3] Tier 2 +[8] Tier 2/ with PPE	Permethrin	5	0.05	4,65E-04	0.9%	Yes
		IPBC	20	0.2	4,19E-04	0.2%	Yes
		Propiconazole	3.6	0.08	4,19E-04	0.5%	Yes

COMBINED EXPOSURE TO SEVERAL ACTIVE SUBSTANCES WITHIN THE BIOCIDAL PRODUCT

According to Guidance on the Biocidal Products Regulation Volume III Human Health Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to each active substances in product has been carried out.

Tier 1:

The decision-making criterion for acceptability of risk remains as in the case of quantitative risk characterization unchanged: the estimated level of exposure to each substance must be lower than its AEL in the considered scenario or the HQ. The Hazard Quotient is defined by the ratio of internal exposure and AEL.

HQ= Internal Exposure / AEL

If HQ <1: the risk from the individual components is considered acceptable and the effects of the biocidal product/mixture must be assessed (as outline in Tier 2 below).

If HQ >1: the risk from the individual components is not considered acceptable and before proceeding to Tier 2 refinement of hazard and/or exposure assessment needs to be performed first so that the HQ <1.

Tier 2:

The effects used to establish the AELs for each of the substances in the mixture/biocidal product are considered concentration or dose-additive. This approach is known to be conservative but corresponds to a pragmatically approach avoiding wasted time in a regulated context with many dossiers to assess. Hazard Quotient is defined by the ratio of internal exposure and AEL:

HQ= Internal Exposure / AEL

HQ for each substance will be used to calculate a HI for the mixture/biocidal product according to the following method:

$HI = \Sigma HQ_{a.s.}$

The HI being the sum of the HQs for each substance. The Hazard Quotient is defined as: estimation of internal exposure/AEL.

If HI ≤1 the risk related to use of the mixture will be considered acceptable;

If HI >1 the risk related to use of the mixture will be considered unacceptable and refinement is needed.

Scenario / task	Tier/ PPE	Active substance	AEL (mg/ kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	HQi	HI =Σ Hqi	Acceptable (Yes/No)
Brushing treatment [3] + [8]	[2.a] Tier 2 +[8] Tier 2/ with PPE	Permethrin	0.05	4,65E-04	0.9%	0.01	<1	Yes
		IPBC	0.2	4,19E-04	0.2%	0.00		
		Propiconazole	0.08	4,19E-04	0.5%	0.01		
Fully Automated spraying treatment [5]	[5] Tier 1 Fully automated with gloves (including in model)	Permethrin	0.05	2.82E-01	563.7%	5.64	>1	No
		IPBC	0.2	2.54E-01	317.1%	3.18		
		Propiconazole	0.08	2.54E-01	126.8%	1.26		
	[5] Tier 2 Fully automated with gloves (including in model)+ coverall 5%	Permethrin	0.05	4,44E-02	88.8%	0.88	>1	No
		IPBC	0.2	4,00E-02	49.9%	0.49		
		Propiconazole	0.08	4,00E-02	20.0%	0.20		
	[5] Tier 3 Fully automated with gloves (including in model)+ coverall 5%+mask P3	Permethrin	0.05	4,40E-02	88.0%	0.88	>1	No
		IPBC	0.2	3,96E-02	49.9%	0.50		
		Propiconazole	0.08	3,96E-02	19.8%	0.20		
	[5] Tier 4 Fully automate 1/4 with NEW gloves for each work shift + coverall 5%)	Permethrin	0.05	2,17E-02	33.7%	0.34	<1	Yes
		IPBC	0.2	1,95E-02	18.9%	0.19		
		Propiconazole	0.08	1,95E-02	7.6%	0.07		
Scenario [6] (Manual dipping - Industrial)	TIER 1 with gloves (including in model)	Permethrin	0.05	1.78E-01	**357.0%**	3.57	>1	No
		IPBC	0.2	1.60E-01	80.0%	0.80		
		Propiconazole	0.08	1.60E-01	**201.0%**	2.01		
	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	0.05	3.03E-02	61.0%	0.61	>1	No
		IPBC	0.2	2.73E-02	14.0%	0.14		
		Propiconazole	0.08	2.73E-02	34.0%	0.34		
		Permethrin	0.05	3.03E-02	61.0%	0.61	>1	No

Scenario / task	Tier/ PPE	Active substance	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	HQi	HI =Σ Hqi	Acceptable (Yes/No)
	TIER 3 (with gloves (including in model)+ coverall 5% + mask P3)	IPBC	0.2	2.73E-02	14.0%	0.14		
		Propiconazole	0.08	2.73E-02	34.0%	0.34		
	TIER 4 (with new gloves for each work shift + coverall 5% + mask P3)	Permethrin	0.05	1.95E-02	39.0%	0.39	<1	Yes
		IPBC	0.2	1.76E-02	8.9%	0.09		
		Propiconazole	0.08	1.76E-02	21.9%	0.22		
Scenario [7] Fully automated dipping	TIER 1 with gloves (including in model)	Permethrin	0.05	1.13E+00	**2251.7%**	22.52	>1	No
		IPBC	0.2	1.01E+00	**1266.6%**	12.66		
		Propiconazole	0.08	1.01E+00	**352.8%**	3.52		
	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	0.05	1.76E-01	**198.0%**	1.98	>1	No
		IPBC	0.2	1.58E-01	79.2%	0.79		
		Propiconazole	0.08	1.58E-01	88.0%	0.88		
	TIER 3 FULLY AUTOMATED 1/4 (with gloves (including in model)+ coverall 5%)	Permethrin	0.05	4.40E-02	49.5%	0.49	>1	No
		IPBC	0.2	3.96E-02	19.8%	0.20		
		Propiconazole	0.08	3.96E-02	32.7%	0.33		
	TIER 4 Fully automate 1/4 with NEW gloves for each work shift + coverall 5%)	Permethrin	0.05	1.64E-02	18.4%	0.18	<1	Yes
		IPBC	0.2	1.48E-02	7.4%	0.07		
		Propiconazole	0.08	1.48E-02	20.0%	0.20		

A Tier 3B approach is considered since the 3 active substances have target organs in common.

The liver is a target organ common to permethrin, propiconazole and IPBC. The kidney is a target organ common to permethrin, propiconazole and IPBC. Blood is a target organ common to propiconazole. The adrenal is a target organ common to propiconazole and permethrin. The lung is a target organ common to IPBC.

Specific target organ AELS can be derived for each active substance based on the available data in the CARs.

	Permethrin	**Propiconazole**	**IPBC**
General long term AEL	0.05	0.08	0.2
Specific AEL: liver	0.1 (6 months dog)	0.08 (2 generation rat)	0.2 (90 days rat)
Specific AEL: kidney		0.5 (28 days rat)	0.35 (90 days rat)
Specific AEL: Hemato		0.761 (90 days rat)	
Specific AEL: adrenals	0.05 (12 months dog)	0.04 (24 months rat)	
Specific AEL: lungs			0.2 (24 months rat)

Note: AEL was estimated by using a default assessment factor of 100 [10 (interspecies variation) x 10 (intraspecies variation)] obtained from NOAELs values described in active substance's CARs.

The comparison of the exposure for automated dipping and automated spraying treatments values with the specific AELs leads to the following results:

- Fully Automated spraying treatment [5]:

	Permethrin	**IPBC**	**Propiconazole**		
Combined exposure ([5] Tier 4)	1.68E-02	1.51E-02	1.51E-02		
AEL liver	0,1	0,2	0,08		**HI**
%AEL	17%	8%	19%	43%	0,43
AEL kidney		0,35	0,5		
%AEL		4%	3%	7%	0,07
AEL hematology			0,761		
%AEL			2%	7%	0,07
AEL adrenals	0,05		0,036		
%AEL	34%		42%	76%	0,76
AEL Lung		0,2			
%AEL		8		28%	0,28

- Manual dipping treatment (combined [6]):

	Permethrin	**IPBC**	**Propiconazole**
Combined exposure ([6] Tier 3)	3.03E-02	2.73E-02	2.73E-02

AEL liver	0.1	0.2	0.08		**HI**
%AEL	30%	14%	34%	78%	0.78
AEL kidney		0.35	0.5		
%AEL		8%	5%	13%	0.13
AEL hematology			0.761		
%AEL			4%	4%	0.04
AEL adrenals	0.05		0.036		
%AEL	61%		76%	136%	**1.36**
AEL Lung		0.2			
%AEL		14%		14%	0.14

- Fully automated dipping treatment (combined [7])

	Permethrin	**IPBC**	**Propiconazole**		
Combined exposure ([7] Tier 4)	1,64E-02	1,48E-02	1,48E-02		
AEL liver	0,1	0,2	0,08		**HI**
%AEL	16%	7%	19%	42%	0,42
AEL kidney		0,35	0,5		
%AEL		4%	3%	7%	0,07
AEL hematology			0,761		
%AEL			2%	3%	0,03
AEL adrenals	0,05		0,036		
%AEL	33%		41%	74%	0,74
AEL Lung		0,2			
%AEL		7		13%	0.13

Local effects

No local effects are needed to be considered from the application of IRUXIL family products under label instructions.

CONCLUSION

The water-based RTU products from IRUXIL W-I formulation containing propiconazole, IPBC, permethrin are used undiluted by industrials for wood preservation by brushing, automated spraying, manual dipping and automated dipping.

Workers in industrial premises are trained professionals. Appropriate PPE (gloves, impermeable coverall (95% protection), eye/face protection) should be used for exposure control.

Using the RTU product containing 0.225% propiconazole, 0.225% IPBC, 0.25% permethrin, the following risk characterisation is given:

Brushing/ rolling treatment: the risk is acceptable for the RTU IRUXIL Family products, by considering default protective personal equipment (gloves, coverall) for industrial users.

Automated spraying: the risk is considered unacceptable for the RTU IRUXIL Family products, even considering default protective personal equipment (gloves, impermeable coverall and masks) for industrial users when default values of dermal absorption are deemed. The risk during fully automated spraying with new gloves for each work shift is considered acceptable, by considering PPE (new gloves for each work shift, impermeable coverall and mask P3). The exposure of the adrenal glands and liver is deemed at risk.

Manual dipping: the risk is considered acceptable for the RTU IRUXIL Family products, even considering default protective personal equipment (new gloves for each work shift, impermeable coverall and masks) for industrial users. The exposure of the adrenal glands is deemed at risk.

Automated dipping: the risk is considered unacceptable for the RTU IRUXIL Family products, even considering default protective personal equipment (gloves, impermeable coverall and masks) for industrial users when default values of dermal absorption are deemed. The exposure of the adrenal glands is deemed at risk. The risk during fully automated dipping with new gloves for each work shift is considered acceptable, by considering PPE (new gloves for each work shift, impermeable coverall and mask P3)

2.2.6.3.2 Risk for trained professional users

The exposure assessment for trained professional and non-trained operators is evaluated. Both trained professional and non-trained professional users should wear gloves and coverall as PPE for their protection. The main difference between them is the frequency of applications over a year. Whilst the product application is considered daily for trained professional users, only few treatments are deemed for non-trained professional users who uses the product occasionally or when the infestation appears. In order to difference both users $AEL_{long\text{-}term}$ is considered to establish the risk of trained professional users and $AEL_{med\text{-}term}$ is used for non-trained professional users.

The exposure assessment for trained and non-trained professional operators is evaluated under the comparison with the proposed $AEL_{long\text{-}term}$ and $AEL_{med\text{-}term}$ respectively for permethrin, IPBC and propiconazole as a Risk Characterization Ratio (RCR). If this quotient is above to the trigger value of 100% it will mean an unacceptable risk exposure for human. Due that AELlong-term and AELmed-term values are the same for Permethrin and IPBC, similar outputs are expected to be obtained for both professional users so the current assessment is focused on trained professional as the worst representative case.

Systemic effects

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Scenario [2] / Mixing and loading of RTU	TIER 2 (with gloves)	Permethrin	5	0.05	3.03E-04	0.6%	yes
		IPBC	20	0.2	2.72E-04	0.1%	yes
		Propiconazole	3.6	9.98	2.72E-04	0.3%	yes

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Scenario [3] - Brushing /Rolling application	TIER 1 (without PPE)	Permethrin	5	0.05	7.21E-04	1.4%	yes
		IPBC	20	0.2	6.49E-04	0.3%	yes
		Propiconazole	3.6	0.08	6.49E-04	0.8%	yes
	TIER 2 (with gloves and coverall)	Permethrin	5	0.05	7.40E-05	0.1%	yes
		IPBC	20	0.2	6.66E-05	0.0%	yes
		Propiconazole	3.6	0.08	6.66E-05	0.1%	yes
Scenario [4] spraying	TIER 1 without gloves	Permethrin	5	0.05	1.16E+00	**2320.6%**	**no**
		IPBC	20	0.2	1.04E+00	**522.1%**	**no**
		Propiconazole	3.6	0.08	1.04E+00	**1305.3%**	**no**
	TIER 2 with gloves (including in model)	Permethrin	5	0.05	5.41E-01	**609.2%**	**no**
		IPBC	20	0.2	5.87E-01	**243.7%**	**no**
		Propiconazole	3.6	0.08	5.87E-01	**1304.5%**	**no**
	TIER 3 with gloves (including in model)+ coverall 5%	Permethrin	5	0.05	4.94E-02	98.8%	yes
		IPBC	20	0.2	4.44E-02	22.2%	yes
		Propiconazole	3.6	0.08	4.44E-02	44.4%	yes
	TIER 4 with gloves (including in model)+ coverall 5%+mask P3	Permethrin	5	0.05	4.42E-02	88.5%	yes
		IPBC	20	0.2	3.98E-02	19.9%	yes
		Propiconazole	3.6	0.08	3.98E-02	49.8%	yes
	TIER 5 with new gloves coverall 5%+mask P3	Permethrin	5	0.05	3.72E-02	70.9%	yes
		IPBC	20	0.2	3.43E-02	15.9%	yes
		Propiconazole	3.6	0.08	3.43E-02	39.9%	yes
Scenario [6] Manual dipping	TIER 1 with gloves (including in model)	Permethrin	5	0.05	1.78E-01	**356.6%**	**no**
		IPBC	20	0.2	1.60E-01	80.2%	yes
		Propiconazole	3.6	0.08	1.60E-01	**200.6%**	**no**

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	5	0.05	3.03E-02	60.7%	yes
		IPBC	20	0.2	2.73E-02	13.6%	yes
		Propiconazole	3.6	0.08	2.73E-02	34.1%	yes
	TIER 3 with gloves (including in model)+ coverall 5%+mask P3	Permethrin	5	0.05	3.03E-02	60.7%	yes
		IPBC	20	0.2	2.73E-02	13.6%	yes
		Propiconazole	3.6	0.08	2.73E-02	34.1%	yes
	TIER 4 (with new gloves for each work shift + coverall 5% + mask P3)	Permethrin	0.05	0.05	1.95E-02	39.0%	Yes
		IPBC	0.2	0.2	1.76E-02	8.9%	Yes
		Propiconazole	0.08	0.08	1.76E-02	21.9%	yes
Scenario [8] - Cleaning brush	Tier 2/ with gloves	Permethrin	5	0.05	3.91E-04	0.8%	yes
		IPBC	20	0.2	3.52E-04	0.2%	yes
		Propiconazole	3.6	0.08	3.52E-04	0.4%	yes
Scenario [9] Cleaning spray equipment	TIER 2 with gloves (including in model)+ coverall 5%	Permethrin	5	0.05	2.66E-03	5.3%	yes
		IPBC	20	0.2	2.39E-03	1.2%	yes
		Propiconazole	3.6	0.08	2.39E-03	3.0%	yes
Scenario [10] - Sawing and sanding treated Wood. (Secondary exposure)	Tier 1/ no gloves	Permethrin	5	0.05	1.01E-03	2.0%	yes
		IPBC	20	0.2	9.12E-04	0.5%	yes
		Propiconazole	3.6	0.08	9.12E-04	1.0%	yes

Combined scenarios

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
		Permethrin	5	0.05	7,68E-04	2%	Yes

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Brushing treatment [2] +[3] + [8]	[2] Tier 2 + [3] Tier 2 + [8] Tier 2	IPBC	20	0.2	6,91E-04	0%	Yes
		Propiconazole	3.6	0.08	6,91E-04	1%	Yes
Spraying treatment [4] + [9]	[4] Tier 2 + [9] Tier 2	Permethrin	5	0.05	5.44E-01	**1088%**	**No**
		IPBC	20	0.2	4.90E-01	**245%**	**No**
		Propiconazole	3.6	0.08	4.90E-01	**613%**	**No**
	[4] Tier 3 +[9] Tier 2	Permethrin	5	0.05	5.20E-02	**104%**	**No**
		IPBC	20	0.2	4.68E-02	23%	Yes
		Propiconazole	3.6	0.08	4.68E-02	59%	Yes
	[4] Tier 4 +[9] Tier 2	Permethrin	5	0.05	4.69E-02	94%	Yes
		IPBC	20	0.2	4.22E-02	21%	Yes
		Propiconazole	3.6	0.08	4.22E-02	53%	Yes
	[4] Tier 5 +[9] Tier 2	Permethrin	5	0.05	3.2E-02	74%	Yes
		IPBC	20	0.2	3.43E-02	17%	Yes
		Propiconazole	3.6	0.08	3.43E-02	43%	Yes

COMBINED EXPOSURE TO SEVERAL ACTIVE SUBSTANCES WITHIN THE BIOCIDAL PRODUCT

According to Guidance on the Biocidal Products Regulation Volume III Human Health Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to each active substances in product has been carried out.

Tier 1:

The decision-making criterion for acceptability of risk remains as in the case of quantitative risk characterization unchanged: the estimated level of exposure to each substance must be lower than its AEL in the considered scenario or the HQ. The Hazard Quotient is defined by the ratio of internal exposure and AEL.

HQ= Internal Exposure / AEL

If HQ <1: the risk from the individual components is considered acceptable and the effects of the biocidal product/mixture must be assessed (as outline in Tier 2 below).

If HQ >1: the risk from the individual components is not considered acceptable and before proceeding to Tier 2 refinement of hazard and/or exposure assessment needs to be performed first so that the HQ <1.

Tier 2:

The effects used to establish the AELs for each of the substances in the mixture/biocidal product are considered concentration or dose-additive. This approach is known to be conservative but corresponds to a pragmatically approach avoiding wasted time in a

regulated context with many dossiers to assess. Hazard Quotient is defined by the ratio of internal exposure and AEL:

HQ= Internal Exposure / AEL

HQ for each substance will be used to calculate a HI for the mixture/biocidal product according to the following method:

$HI = \Sigma HQ_{a.s.}$

The HI being the sum of the HQs for each substance. The Hazard Quotient is defined as: estimation of internal exposure/AEL.

If HI ≤1 the risk related to use of the mixture will be considered acceptable;

If HI >1 the risk related to use of the mixture will be considered unacceptable and refinement is needed.

Scenario / task	Tier/ PPE	Active substance	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	HQi	HI =Σ Hqi	Acceptable (Yes/No)
Brushing treatment [2] +[3] + [8]	[2] Tier 2 + [3] Tier 2 + [8] Tier 2	Permethrin	0.05	7,68E-04	2%	0.02	<1	Yes
		IPBC	0.2	6,91E-04	0%	0.00		
		Propiconazole	0.08	6,91E-04	1%	0.01		
Spraying treatment [4] + [9]	[4] Tier 2 + [9] Tier 2	Permethrin	0.05	5.44E-01	**1088%**	10.68	>1	No
		IPBC	0.2	4.90E-01	**245%**	2.45		
		Propiconazole	0.08	4.90E-01	**613%**	6.13		
	[4] Tier 3 +[9] Tier 2	Permethrin	0.05	5.20E-02	**104%**	1.04	>1	No
		IPBC	0.2	4.68E-02	23%	0.23		
		Propiconazole	0.08	4.68E-02	59%	0.59		
	[4] Tier 4 +[9] Tier 2	Permethrin	0.05	4.69E-02	94%	0.94	>1	No
		IPBC	0.2	4.22E-02	21%	0.21		
		Propiconazole	0.08	4.22E-02	53%	0.53		
	[4] Tier 5 +[9] Tier 2	Permethrin	0.05	3.2E-02	74%	0.74	>1	No
		IPBC	0.2	3.43E-02	17%	0.17		
		Propiconazole	0.08	3.43E-02	43%	0.43		
Scenario [6] (Manual dipping - Professional)	TIER 1 with gloves	Permethrin	0.05	1.78E-01	**356.6%**	3.56	>1	No
		IPBC	0.2	1.60E-01	80.2%	0.80		
		Propiconazole	0.08	1.60E-01	**200.6%**	2.01		
	TIER 2 with gloves + coverall 5%	Permethrin	0.05	3.03E-02	60.7%	0.61	>1	No
		IPBC	0.2	2.73E-02	13.6%	0.14		
		Propiconazole	0.08	2.73E-02	34.1%	0.34		
	TIER 3 (with gloves + coverall 5% + mask P3)	Permethrin	0.05	3.03E-02	60.7%	0.61	>1	No
		IPBC	0.2	2.73E-02	13.6%	0.14		
		Propiconazole	0.08	2.73E-02	34.1%	0.34		
	TIER 4 (with new gloves for each work shift + coverall 5% + mask P3)	Permethrin	0.05	1.95E-02	39.0%	0.39	<1	Yes
		IPBC	0.2	1.76E-02	8.9%	0.09		
		Propiconazole	0.08	1.76E-02	21.9%	0.22		
Scenario [10] - Sawing and sanding treated Wood. (Secondary exposure)	Tier 1 (no gloves)	Permethrin	0.05	1.01E-03	2.0%	0.02	<1	Yes
		IPBC	0.2	9.12E-04	0.5%	0.005		
		Propiconazole	0.08	9.12E-04	1.0%	0.01		

A Tier 3B approach is considered since the 3 active substances have target organs in common.

The liver is a target organ common to permethrin, propiconazole and IPBC. The kidney is a target organ common to permethrin, propiconazole and IPBC. Blood is a target organ common to propiconazole. The adrenal is a target organ common to propiconazole and permethrin. The lung is a target organ common to IPBC.

Specific target organ AELS can be derived for each active substance based on the available data in the CARs.

	Permethrin	**Propiconazole**	**IPBC**
General long term AEL	0.05	0.08	0.2
Specific AEL: liver	0.1 (6 months dog)	0.08 (2 generation rat)	0.2 (90 days rat)
Specific AEL: kidney		0.5 (28 days rat)	0.35 (90 days rat)
Specific AEL: Hemato		0.761 (90 days rat)	
Specific AEL: adrenals	0.05 (12 months dog)	0.04 (24 months rat)	
Specific AEL: lungs			0.2 (24 months rat)

Note: AEL was estimated by using a default assessment factor of 100 [10 (interspecies variation) x 10 (intraspecies variation)] obtained from NOAELs values described in active substance's CARs.

The comparison of the exposure for automated dipping and combined automated spraying treatments values with the specific AELs leads to the following results:

- Spraying treatment (combined [4] Tier 4 + [9] Tier 2):

	Permethrin	**IPBC**	**Propiconazole**		
Combined exposure ([4] Tier 5 +[9] Tier 2)	3,20E-02	3,43E-02	3,43E-02		
AEL liver	0,1	0,2	0,08		**HI**
%AEL	32%	17%	43%	92%	0,92
AEL kidney		0,35	0,5		
%AEL		10%	7%	17%	0,17
AEL hematology			0,761		
%AEL			5%	6%	0,06
AEL adrenals	0,05		0,036		
%AEL	64%		95%	159%	**1,58**
AEL Lung		0,2			
%AEL		17		21%	0.21

- Manual dipping treatment (combined [6]):

	Permethrin	**IPBC**	**Propiconazole**
Combined exposure ([6] Tier 4)	1.95E-02	1.76E-02	1.76E-02

AEL liver	0.1	0.2	0.08		HI
%AEL	20%	9%	22%	50%	0.5
AEL kidney		0.35	0.5		
%AEL		5%	4%	9%	0.09
AEL hematology			0.761		
%AEL			2%	4%	0.04
AEL adrenals	0.05		0.036		
%AEL	39%		49%	88%	0.88
AEL Lung		0.2			
%AEL		9		14%	0.14

Local effects

No local effects are needed to be considered from the application of IRUXIL family products under label instructions.

Conclusion

The water-based RTU products from IRUXIL Family products (both IRUXIL W and IRUXIL W-I) containing propiconazole, IPBC, permethrin are used undiluted by professionals for wood preservation by brushing, spraying and manual dipping.

Appropriate PPE (gloves, impermeable coverall (95% protection), eye/face protection) should be used for exposure control is considered for professional users.

Using the RTU product containing 0.225% propiconazole, 0.225% IPBC, 0.25% permethrin, the following risk characterisation is given:

Brushing/ rolling treatment: the risk is acceptable for the RTU IRUXIL Family products, by considering default protective personal equipment (gloves, coverall) for professional users (trained and non-trained).

Spraying: the risk is considered unacceptable for the RTU IRUXIL Family products, even considering default protective personal equipment (new gloves for each work shift, impermeable coverall and masks) for professional users. The exposure of the adrenal glands and liver is deemed at risk.

Manual dipping: the risk is considered acceptable for the RTU IRUXIL Family products, even considering default protective personal equipment (new gloves each work shift, impermeable coverall and masks) for trained professional users. The exposure of the adrenal glands is deemed at risk.

It is important to bear in mind, that the use of new gloves each work shift disclose an acceptable risk for the manual dipping by trained professional users.

2.2.6.3.3 Risk for non-professional users

Non-professional users use the product occasionally over the year so $AEL_{short-term}$ is deemed to establish the risk for this users. According to Guidance on the BPR: Volume III Parts B+C Version 4.0 (2017) no PPE are considered in the risk assessment of non-professional users.

Systemic effects

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Scenario [2] / Mixing and loading of RTU	Tier 1/ no PPE	Permethrin	5	0.5	3.81E-04	0.1%	yes
		IPBC	20	0.35	3.43E-04	0.1%	yes
		Propiconazole	3.6	0.3	3.43E-04	0.1%	yes
Scenario [3] - Brushing /Rolling application	Tier 1/ no PPE	Permethrin	5	0.5	7.21E-04	0.1%	yes
		IPBC	20	0.35	6.49E-04	0.2%	yes
		Propiconazole	3.6	0.3	6.49E-04	0.2%	yes
Scenario [8] - Cleaning brush	Tier 1/ no PPE	Permethrin	5	0.5	3.91E-03	0.8%	yes
		IPBC	20	0.35	3.52E-03	1.0%	yes
		Propiconazole	3.6	0.3	3.52E-03	1.2%	yes
Scenario [11] - Sawing and sanding treated Wood (Secondary exposure)	Tier 1/ no PPE	Permethrin	5	0.5	1.01E-03	0.2%	yes
		IPBC	20	0.35	9.12E-04	0.3%	yes
		Propiconazole	3.6	0.3	9.12E-04	0.3%	yes

Combined scenarios

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Brushing treatment [2] +[3] + [8]	[2] Tier 1 + [3] Tier 1 + [8] Tier 1	Permethrin	5	0.5	5.00E-03	1.0%	Yes
		IPBC	20	0.35	4.49E-03	1.3%	Yes
		Propiconazole	3.6	0.3	4.49E-03	1.5%	Yes

COMBINED EXPOSURE TO SEVERAL ACTIVE SUBSTANCES WITHIN THE BIOCIDAL PRODUCT

According to Guidance on the Biocidal Products Regulation Volume III Human Health Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to each active substances in product has been carried out.

Tier 1:

The decision-making criterion for acceptability of risk remains as in the case of quantitative risk characterization unchanged: the estimated level of exposure to each substance must be lower than its AEL in the considered scenario or the HQ. The Hazard Quotient is defined by the ratio of internal exposure and AEL.

HQ= Internal Exposure / AEL

If HQ <1: the risk from the individual components is considered acceptable and the effects of the biocidal product/mixture must be assessed (as outline in Tier 2 below).

If HQ >1: the risk from the individual components is not considered acceptable and before proceeding to Tier 2 refinement of hazard and/or exposure assessment needs to be performed first so that the HQ <1.

Tier 2:

The effects used to establish the AELs for each of the substances in the mixture/biocidal product are considered concentration or dose-additive. This approach is known to be conservative but corresponds to a pragmatically approach avoiding wasted time in a regulated context with many dossiers to assess. Hazard Quotient is defined by the ratio of internal exposure and AEL:

HQ= Internal Exposure / AEL

HQ for each substance will be used to calculate a HI for the mixture/biocidal product according to the following method:

$HI = \Sigma HQ_{a.s.}$

The HI being the sum of the HQs for each substance. The Hazard Quotient is defined as: estimation of internal exposure/AEL.

If HI ≤1 the risk related to use of the mixture will be considered acceptable;

If HI >1 the risk related to use of the mixture will be considered unacceptable and refinement is needed.

Scenario / task	Tier/ PPE	Active substance	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	HQi	HI=Σ Hqi	Acceptable (Yes/No)
Brushing treatment [2] +[3] + [8]	[2] Tier 2 + [3] Tier 2 + [8] Tier 2	Permethrin	0.5	5.00E-03	1.0%	Yes	<1	Yes
		IPBC	0.35	4.49E-03	1.3%	Yes		
		Propiconazole	0.3	4.49E-03	1.5%	Yes		
Scenario [11] - Sawing and sanding treated Wood (Secondary exposure)	Tier 1/ no PPE	Permethrin	0.5	1.01E-03	0.2%	Yes	<1	Yes
		IPBC	0.35	9.12E-04	0.3%	Yes		
		Propiconazole	0.3	9.12E-04	0.3%	Yes		

Local effects

No local effects are needed to be considered from the application of IRUXIL family products under label instructions.

Conclusion

The water-based RTU products from IRUXIL Family products (both IRUXIL W and IRUXIL W-I) containing propiconazole, IPBC, permethrin shows acceptable risk exposure when they are used undiluted by non-professionals for wood preservation by brushing (use #1).

2.2.6.3.4 Risk for the general public (Secondary exposure)

The risk assessment of general public is done considering the AELshort-term of each active substance. The table below shows the risk obtained for each human group.

Systemic effects

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Sawing and sanding treated Wood / [11] - (acute scenario)	Tier 1/ no PPE	Permethrin	5	0.5	1.01E-04	0.2%	yes
		IPBC	20	0.35	9.12E-04	0.3%	yes
		Propiconazole	3.6	0.3	9.12E-04	0.3%	yes
Chewing wood off-cut / [12] – acute scenario	Tier 1/ no PPE	Permethrin	5	0.5	1.00E-02	2.0%	yes
		IPBC	20	0.35	9.00E-03	2.6%	yes
		Propiconazole	3.6	0.3	9.00E-03	3.0%	yes
Playing on playground structure outdoors and mouthing / [13] – chronic scenario	Tier 1/ no PPE	Permethrin	5	0.05	2.82E-02	56.5%	yes
		IPBC	20	0.2	2.54E-02	12.7%	yes
		Propiconazole	3.6	0.08	2.54E-02	31.8%	yes
Inhalation of volatilized residues / [14] – chronic scenario	Tier 1 / no PPE - adult	IPBC	20	0.2	1.36E-03	0.7%	yes
	Tier 1 / no PPE - child				2.56E-03	1.3%	yes
	Tier 1 / no PPE - todd				4.08E-03	2.0%	yes
	Tier 1 / no PPE - infant				3.45E-03	1.7%	yes

Scenario / task	Tier/ PPE	Active substance	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Laundering work clothes / [15] – chronic scenario	TIER 1 From fully automated dipping	Permethrin	5	0.05	1.03E-01	**205.9%**	no
		IPBC	20	0.2	9.26E-02	46.3%	yes
		Propiconazole	3.6	0.08	9.26E-02	**115.8%**	no
	TIER 2 From brushing scenario	Permethrin	5	0.05	2.14E-05	0.04%	yes
		IPBC	20	0.2	1.93E-05	0.04%	yes
		Propiconazole	3.6	0.08	1.93E-05	0.02%	yes

COMBINED EXPOSURE TO SEVERAL ACTIVE SUBSTANCES WITHIN THE BIOCIDAL PRODUCT

Scenario / task	Tier/ PPE	Active substance	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	HQi	HI=Σ Hqi	Acceptable (Yes/ No)
Sawing and sanding treated Wood / [11] - (acute scenario)	[2] Tier 2 + [3] Tier 2 + [8] Tier 2	Permethrin	0.5	1.01E-04	0.2%	2.0E-03	<1	Yes
		IPBC	0.35	9.12E-04	0.3%	3.0E-03		
		Propiconazole	0.3	9.12E-04	0.3%	3.0E-03		
Chewing wood off-cut / [12] – acute scenario	Tier 1/ no PPE	Permethrin	0.5	1.00E-02	2.0%	2.0E-02	<1	Yes
		IPBC	0.35	9.00E-03	2.6%	2.6E-02		
		Propiconazole	0.3	9.00E-03	3.0%	3.0E-02		
Playing on playground structure outdoors and mouthing / [13] – chronic scenario	Tier 1/ no PPE	Permethrin	0.05	2.82E-02	56.5%	0.57	<1	Yes
		IPBC	0.2	2.54E-02	12.7%	0.13		
		Propiconazole	0.08	2.54E-02	31.8%	0.32		
Inhalation of volatilized residues / [14] – chronic scenario	Tier 1 / no PPE - adult	IPBC	0.2	1.36E-03	0.7%	0.007	<1	Yes
	Tier 1 / no PPE - child			2.56E-03	1.3%	0.013	<1	Yes
	Tier 1 / no PPE - told			4.08E-03	2.0%	0.02	<1	Yes

Scenario / task	Tier/ PPE	Active substance	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	HQi	HI=Σ Hqi	Acceptable (Yes/ No)
	Tier 1 / no PPE - infant			3.45E-03	1.7%	0.017	<1	Yes
Laundering work clothes / [15] – chronic scenario	TIER 1 From fully automated dipping	Permethrin	0.05	1.03E-01	**205.9%**	**2.21**	>1	no
		IPBC	0.2	9.26E-02	46.3%	0.50		
		Propiconazole	0.04	9.26E-02	**115.8%**	**2.48**		
	TIER 2 From brushing scenario	Permethrin	0.05	2.14E-05	0.04%	4.59E-04	<1	Yes
		IPBC	0.2	1.93E-05	0.04%	1.03E-04		
		Propiconazole	0.04	1.93E-05	0.02%	5.16E-04		

Local effects

No local effects are needed to be considered from the application of IRUXIL family products under label instructions.

Conclusion

An acceptable risk exposure is expected for general public by secondary exposure when IRUXIL Family products are applied according to product's label.

Only scenario of laundering work clothes providing from automated dipping process shows unacceptable risk when AELlong-term values are considered. It is important to bear in mind that when dermal absorption used in active substances' CARs are considering in the assessment exposure, an acceptable risk is obtained. On the other hand, if AELshort-term are considered instead of AELlong-term in the risk exposure, acceptable risk is expected regardless the value of dermal absorption used.

2.2.6.3.5 Risk for consumers via residues in food

IRUXIL Family products are not intended to be used in places where food is kept or entrance in contact with food during its application. Therefore, no risk is derived for consumers via residues in food. In addition, in order to avoid any potential risk by its use, the following RMM is set on product's label:

- 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.

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

According to Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017; Annex A: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products, no SoCs have been identified in any formulation of IRUXIL Family products so the risk assessment derived from combined exposure to three active substances is considered sufficient to set the risk of the products.

2.2.7 Risk assessment for animal health

Not applicable. No animal exposure is foreseen

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

IRUXIL Family is a ready to use wood preservative product family containing products applied by brush treatment, spraying and dipping and must be used only for indoor and industrial treatments of wood used in UC 1 (situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting) and UC 2 (situation in which the wood-based product is under cover and fully protected from the weather but where occasional but not persistent wetting may occur), by trained professionals, professionals and general public. It contains Propiconazole 0.225 %, IPBC 0.225 % and Permethrin 0.25 % as active substances. Thus, the emissions to the environment related to the application and storage phase in industrial sites have been calculated, although emissions to the environment due to in situ application indoors are considered negligible (OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2, Revised Emission Scenario Document for Wood Preservatives, 2013).

The active substances Permethrin (Ireland, 2014), Propiconazole (Finland, 2022) and IPBC (Denmark, 2008) were evaluated according to the Regulation (EU) No 528/2012 for its use as wood preservatives (PT 8). Final Competent Authority reports as agreed by the EU Member States and the European Commission are available, to which the applicant has access via Letter of Access.

The PNEC values for IPBC/PBC have been taken from the Assessment Report for PT 8 and also including updates in the Assessment Report for PT13 (January 2015). For Permethrin the PNEC values have been taken from the Assessment Report for PT8 (April 2014). For propiconazole/1,2,4-triazole the PNEC values have been taken from the Assessment Report for propiconazole in PT8 (2022), because new data has been included compared to the Assessment Report for propiconazole in PT8 (December 2007). The other three major soil metabolites of propiconazole (NOA436613, SYN547889, and CGA91305) are not ecotoxicologically relevant.

The following PNEC values were used for the environmental risk assessment:

Summary table on PNEC values for active substances and their relevant metabolites

Substance (- metabolite)	$PNEC_{STP}$ (mg/L)	$PNEC_{water}$ (mg/L)	$PNEC_{sediment}$ (mg/kg_{wwt})	$PNEC_{soil}$ (mg/kg_{wwt})	$PNEC_{bird}$ (mg a.s./kg food	$PNEC_{mammal}$ (mg a.s./kg food)
Permethrin[1]	0.00495	4.7E-07	2.17E-04	0.175	16.7	120
- DCVA[2]	n.r.	0.015	0.012	4.6	-	-
- PBA[3]	n.r.	0.010	0.009	1.44	-	-
Propiconazole[4]	1	0.006	0.054	0.1	3.33	3.33
-1,2,4-Triazole[5]	n.r.	n.r.	n.r.	0.006	-	-
IPBC[6]	0.44	5E-04	Covered by surface water	0.0044	-	-
- PBC[7]	-	0.0413	Covered by surface water	0.149	-	-

n.r. not relevant

[1] Permethrin:

PNECwater: lowest NOEC value from the aquatic invertebrate endpoints of 0.0047 µg/l (AF = 10)

PNECsed: NOEC value from the 5-d *Chironomus riparius* study of 0.1 mg/kg dwt (AF = 100).

PNECsoil: The IE (RMS for permethrin) evaluation of the permethrin confirmatory data was discussed at the BPC Meeting in early March 2017. IE can inform the CG members that an ENV WG e-consultation was requested by BPC Members during the BPC meeting in March, regarding the PNECsoil. The e-consultation concluded on the 13th March.

It was agreed that the conclusions of this e-consultation could be announced at CG-22 in the event of a clear majority opinion. The opinions received from MSs in the e-consultation provided a clear majority opinion in relation to the proposed PNECsoil.

The MSs were in favour of using an AF of 50 and deriving the $PNEC_{soil}$ for permethrin on the soil micro-organism study. The new PNECsoil is 0.198 mg/kg dwt, corresponding to 0.175 mg/kg wwt.

[2] DCVA:

PNECwater: EC_{50} value from the fish study of $\geq$ 14.7 mg/l (AF = 1000).

PNECsed: the PNEC value were calculated using the equilibrium partitioning method

PNECsoil: NOEC value from the *Hypoaspis aculeifer* study of 526 mg/kg dwt (AF = 100)

[3] PBA:

PNECwater: EC50 value from the algae study of > 10 mg/l (AF = 1000)

PNECsed: the PNEC value were calculated using the equilibrium partitioning method.

PNECsoil: FPBA NOEC value from the *Hypoaspis aculeifer* study of 495 mg/kg dwt (AF = 300)

[4] Propiconazole:

PNECwater: EC_{10} value from fish study (*Cyprinodon variegatus*) of 0.06 mg/l (AF = 10)

$PNEC_{STP}$: EC_{50} value of >100 mg/l (AF = 100)

PNECsed: NOEC value from *Chironomus riparius* study of 5.4 mg/ kg wwt (AF = 100)

PNECsoil: NOEC value from earthworm study (*Eisenia fetida*) of 0.998 mg/kg wwt (AF = 10)

The PNECoral of 3.33 mg a.i./kg food was derived from a NOAEC of 100 mg a.i./kg food obtained from a two generation reproduction study with rats and considering an assessment factor of 30. This PNECoral was used for the risk characterisation.

[5] 1,2,4-Triazole:

PNECsoil: NOEC value for soil earthworm of 0.34 mg/kg_{dwt} (AF =50). PNECsoil: 0.0068 mg/kg_{dwt} = 0.006 mg/kg_{ww}

[6]IPBC:

PNECwater: NOEC value from algae study (*Scenedesmus subspicatus*) of 0.0046 mg/L (AF = 10)

PNECsoil: LC50 value from *Avena sativa* study of 4.92 mg/kg dwt (AF = 1000)

[7]PBC:

PNECwater: EC50 value from algae study (*Selenastrum capricomutum*) of 41.3 mg/L (AF = 1000)

PNECsoil: the PNEC value were calculated using the equilibrium partitioning method.

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides. These ED criteria with respect to humans establishes that a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

A. it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
B. it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
C. the adverse effect is a consequence of the endocrine mode of action.

No further ecotoxicological studies are available for IRUXIL FAMILY. The biocidal products within the family were not tested for potential endocrine disruption properties. IRUXIL

FAMILY contains the active substances permethrin, propiconazole and IPBC and various co-formulants (see confidential PAR).

For the active substances, the biocidal product family IRUXIL FAMILY contains the active substance propiconazole, which is considered to have an endocrine mode of action as it shows endocrine activity by interfering steroidogenesis. Thus, propiconazole is considered to have endocrine disrupting properties according to Section B of Regulation (EU) 2017/2100.

The assessment of the endocrine-disrupting (ED) potential of each co-formulant in the biocidal product family composition of IRUXIL FAMILY is provided in the confidential PAR.
During the screening of ED properties of co-formulants, some alerts were rised. However, a conclusion has not yet been agreed for these substances and they are still identified as potential EDs. Based on this information, ES CA considers that the authorisation of the biocidal product family IRUXIL FAMILY can proceed with a post-authorisation condition to, if necessary, reconsider when the conclusion of the ED status has been agreed. Please, see the confidential PAR for futher details.

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

The ecotoxicological effects of the IRUXIL family, consisting of IRUXIL W and IRUXIL W-I, are driven by the active substances permethrin, propiconazole and IPBC for which valid data is available (Ireland, 2014; Finland, 2007; and Denmark, 2008). Co-formulants, which are contained in the biodical product, are not likely to alter the environmental fate or ecotoxicological profile of the active substances and do not affect the classification of the mixture. Synergistic effects between the components are not expected. 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 product itself is not necessary.

The active substances permethrin, propiconazole and IPBC have harmonised classifications with Aquatic Acute 1 and Aquatic Chronic 1. The harmonised M-Factors for these substances are as follows:

- Permethrin: M-Factor = 10000
- Propiconazole: M-Factor (Acute and Chronic) = 1
- IPBC: M-Factor (Acute) = 10; M-Factor (Chronic) = 1

Taking into account the highest concentrations of permethrin (0.25 %), propiconazole (0.225 %), and IPBC (0.225 %), and their corresponding M-Factors, the resulting classification for IRUXIL FAMILY is Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). Hence, the products have to be labelled with the hazard statement H410: Harmful to aquatic life with long lasting effects (H400 may be omitted), the precautionary state-ments P273, P391 and P501, with pictogram for environmental hazard and signal word “Warning”.

Conclusion on the environmental classification and labelling of the product
Classification: Aquatic acute 1 (H400) Aquatic chronic 1 (H410) ***Labelling:***

Warning H410 ***Precautionary statements*** P273 – Avoid release to the environment P391 – Collect spillage P501 – Dispose of contents/container …

PBT-assessment:

According to the PT08-AR of propiconazole (2022), propiconazole and the metabolite 1,2,4-triazole do not fulfil the PBT nor the vPvB criteria. Nonetheless, propiconazole fulfils the P/vP and T[13] criterion and 1,2,4-triazole[14] meets the T-criterion only.

However, propiconazole is not identified as meeting the substitution criteria in accordance with Article 10 (5) of the BPR since the renewal of approval Regulation has still not been passed.

According to the PT8-AR of Permethrin (2014), Permethrin does not fulfil the PBT nor the vPvB criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the *cis* isomer) and therefore fulfill the P criteria.

According to the PT13-AR of IPBC (2015), IPBC and PBC do not fulfil the PBT nor the vPvB criteria.

Further Ecotoxicological studies

No data is available on the product. Please refer to active substances data on AR.

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

No studies were performed or available on the ecotoxicology of the biocidal product family.

For the performance of the environmental exposure and risk assessment only data on the active substances permethrin, IPBC and propiconazole are required. The available data are sufficient to perform the exposure and risk assessment.

Further studies are therefore not required

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

The study does not need to be conducted since the biocidal product is not in the form of bait or granules. The biocidal product is marketed as an aqueous solution and as such, no supervised trials to assess risks to non-target organisms under field conditions or studies on

[13] Propiconazole meets the criteria for classification as toxic for reproduction, Category 1B according to the CLP Regulation (adopted RAC opinion).

[14] According to the RAC opinion (2019) 1,2,4-triazole has an updated harmonised classification of Repr 1B.

acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk have been conducted as it is scientifically unjustified.

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

No new data is deemed neccesary. Please refer to active substances dossier.

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

The study does not need to be conducted since the biocidal product is not intended to be applied to large proportions of a specific habitat. As such, no secondary ecological effect is envisaged.

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

According to intended uses of the biocidal product family and treated wood (Use classes 1 and 2), emissions to the environment can only occur during industrial application of the wood preservative and subsequent storage of the treated structures. In general, emissions to sewage water during applications in joineries and carpentry shops are not likely to occur, because treatment containers are stand-alone devices without direct connection to the sewage. Residues and waste solutions from application containers will be treated as special waste and will not be discharged into the public sewage system. The revised ESD for PT 8 states that the release of wood preservatives from treatment installations to the drain connected to an STP is not permitted in EU countries. Therefore, emission to the SPT is not expected. The same applies to the storage of treated commodities. According to the revised ESD for PT 8 it can be assumed, that most storage places are sealed and run-off from storage places will be collected and disposed of safely. Nevertheless, this scenario is going to be considered in thie risk assessment.

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

[If no data is available, delete the tables and indicate only that no data is available.]
No further tests are deemed necessary since there is sufficient information on the components of the product to enable an environmental fate and behaviour assessment

Leaching behaviour (ADS)

No new data is deemed necessary. The biocidal product family is intended to be used at industrial premises or indoors to treat wood for UC1 and UC2 only, where no exposure to the environment is expected. Only at preventive industrial processes during the product application and storage treatment of treated wood there is a possibility of emission to the environment. However, in order to avoid any emission to the environment, storage area of industrial facilities must be covered and paved.

According to Summary of conclusions of the 2nd EU Leaching Workshop, "*No leaching test is required if no risk is identified for the active substance (AS) and substances of concerns (SoC) for Time 1 and Time 2 by assuming:*

- *50 % leaching during Time 1 and*
- *100 % leaching during Time 2."*

In view of that, the environmental risk assessment of the product focuses on the worst case scenario, 50 % of the active substance is assumed to leach after an initial time period of 30

days and 100 % of the active substance is assumed to leach after a given longer time period. Hence, the average daily flux is estimated as Qa.i. * 50 % / 30 days for Time 1.

Testing for distribution and dissipation in soil (ADS)

No further data is deemed necessary. The composition and the application techniques for these products are not suspected to influence the degradation and transformation or mobility and adsorption properties of the active substance in a way that may considerably alter the conclusions of the risk assessments.

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

No further data is deemed necessary. The environmental exposure and risk assessments, which are based on the data set of the active substances, do not require the performance of further studies.

Testing for distribution and dissipation in air (ADS)

No further data is deemed necessary.

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)

IRUXIL family products are not intended to be sprayed near to surface waters.

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)

IRUXIL Family products are not intended to be sprayed outdoors.

2.2.8.2 Exposure assessment

General information

IRUXIL Family includes water-based products containing permethrin, propiconazole and IPBC as active substances and formulated as a wood preservative for preventive treatment against wood discolouring fungi and insects. The environmental exposure assessment of IRUXIL Family was assessed in accordance with the Guidance on the Biocidal Products Regulation (Volume IV Environment Parts B+C, version 2.0, October 2017), the Revised Emission Scenario Document for Wood Preservatives (OECD, 2013) and the technical agreements for biocides (TAB, February 2021).

The table below shows a summary of the application patterns used in the environmental risk assessment:

Use		**Application method**	**Dose**
Preventive	Industrial (Use classes 1 and 2)	Brushing	200 g/m^2
		Automated spraying	
		Dipping	
		Fully automated dipping	
	Professional (Use classes 1 and 2)	Brushing	
		Spraying	
		Manual dipping	

	General public (Use classes 1 and 2)	Brushing	

According to the OECD Series on Emission Scenario Documents, Nº 2, Part 1 (Emission Scenario Document for Wood Preservatives), potential emissions from indoor treatment by brushing for "Use Class 1" and "Use Class 2" to the environment are considered negligible. Threfore, the following scenarios have been assessed:

Assessed PT	PT8
Assessed scenarios	Stage - Product application and storage before shipping (Industrial) Scenario [1]: Automated dipping treatment Sub-scenario [1.1]: Application Sub-scenario [1.2]: Storage before shipping Scenario [2]: Automated spraying Sub-scenario [2.1]: Application Sub-scenario [2.2]: Storage before shipping
ESD(s) used	Emission Scenario Document for Product Type 8: OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2; Revised Emission Scenario Document for Wood Preservatives (27 September 2013); ENV/JM/MONO(2013)21
Approach	All scenarios by average consumption
Distribution in the environment	Calculated based on: • Emission Scenario Document for Product Type 8: OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2; Revised Emission Scenario Document for Wood Preservatives (27 September 2013); ENV/JM/MONO(2013)21 • Guidance on BPR Vol IV Part B+C (2017) • Technical Agreements for Biocides (TAB) – ENV v.2.1
Groundwater simulation	Initially it was assessed following ESD guidance. No refinement of the results was necessary
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	-

Emission estimation

In accordance with the approach taken in the AR, the Predicted Environmental Concentration (PEC) in surface water, groundwater and sediment were calculated for the industrial intended uses.

The PEC in groundwater is calculated as a direct function of the PEC in soil, and therefore full calculations for both soil and groundwater are presented in the current dossier.

- *Scenario [1] – Automated dipping treatment*

Dipping and immersion are superficial application processes and are typically used in sawmills and carpentry / joinery industries.

The immersion period lasts anything from a very short period of a few minutes to over one hour depending on the end use application of the treated commodity and the application rate of the wood preservative. After the required immersion period the packs or pieces of wood, which are slightly raised at one end to aid liquid run off, are hoisted out of the liquid and usually held above the open tank for excess liquid to fall back into the dipping tank and be re-used. When the excess liquid has been drained, the pieces or packs of wood are moved to a post treatment conditioning location which is usually bounded and the timber is allowed to dry before being moved off-site or used on site. Any further drips are contained and recycled.

As it was mentioned before, no leaching data is regarded because the product is intended to be applied in wood to be used as Use Classes 1 and 2. In addition, a coat of resin product can be applied after the product application in order to increase the retention of the product in the wood during the service life.

Alternatively, it is important to point out that the use of this product (without any coat of resin product) at industrial premises where the storage place is sealed and run-off from storage places will be collected and disposed of by safe means. In that case, the storage place scenario does not need to be considered. In any other case where the sealing of the storage place is not given or unsure, the storage scenario will need to be assessed.

The following table shows the used parameters in the environmental emission assessment for the automated dipping scenario.

Application phase [1.1]

Input parameters for calculating the local emission from automated dipping process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**1.1 – Automated dipping (application)**			
Application rate of biocidal product	8	kg/m^3	S (estimated following TAB ENV 114 (2019)[1]
Quantity of a substance applied per m^3 of wood *(Q_{ai})*			
- Propiconazole	0.018	Kg/m^3	S
- IPBC	0.018	Kg/m^3	S
- Permethrin	0.02	Kg/m^3	S
Volume of wood treated per day (*$VOLUME_{wood\text{-}treated}$*)	100	m^3/d	D
Fraction released to facility drain *($F_{facilitydrain}$)* for IPBC and propiconazole	0.03	[-]	D (water solubility > 100 mg/l)
for permethrin	0.0001	[-]	D (water solubility < 0.25 mg/l)
Fraction released to air for all a.s. *(F_{air})*	0.001	[-]	D (vapour pressure at 20ºC < 0.005Pa)

D=default, S=based on information of applicant

[1] To convert the quantity of a substance applied from kg.m^{-2} to kg.m^{-3} the application rate (0.2 kg.m^{-2}) should be multiplied by a factor of 40 (worst case).

As it was mentioned before the product is intended to be used in wood which are intended to be used as use classes 1 or 2 where the treated wood will be always covered and fully protected from the weather. This entails that storage step (minimum 24 hrs) must be done in sealed places where residues from drain must be collected and disposal by safe means under regional normative in order to avoid any release to the environment. Therefore,

storage of treated wood prior to shipping (including removal processes in the receiving environmental compartment, soil) should not release any residue to the environment so it should not has to be assessed in the current dossier. At anyway in order to cover all worse cases, storage treatment under dipping application process has been also assessed as scenario [1.2.]

- **Calculations**

The local emissions to air and facility drain during the day of application are calculated according to the equations 4.2 and 4.3 from the revised ESD PT8 as following:

$E_{local,air} = Q_{ai} \cdot AREA_{wood\text{-}treated} \cdot (F_{air} + F_{drift})$

$E_{local,facilitydrain} = Q_{ai} \cdot AREA_{wood\text{-}treated} \cdot F_{facilitydrain}$

The results are presented in the following table.

Resulting local emissions		
Active substance	**Local emission ($Elocal_{air}$) [kg·d^{-1}]**	**Local emission ($Elocal_{facilitydrain}$)* [kg·d^{-1}]**
Propiconazole	1.8E-03	5.4E-02
IPBC	1.8E-03	5.4E-02
Permethrin	2E-03	2E-04

*Elocal, facilitydrain = Elocal, wastewater

Storage phase [1.2]

During storage, soil can be exposed – if the label instruction is not followed and storage place is not covered – due to leaching from treated wood via rainfall. In addition, surface water can be exposed via rain run-off from the storage place.

The input parameters for calculating the local emissions and concentrations following leaching are presented in the following table.

Input parameters for calculating the local emission from automated dipping process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**1.2 – Automated dipping (storage)**			
Effective surface area of treated wood, considered to be exposed to rain, per 1 m^2 storage area (i.e. soil) *($AREA_{wood\text{-}expo}$)*	11	m^2.m^{-2}	Default
Surface area of the storage place (*$AREA_{storage}$)*	700	m^2	Default
Duration of the initial assessment period (*TIME1)*	30	d	Default
Duration of a longer assessment period *(TIME2)*	5475	d	Default (15 years)
Average daily flux i.e. the average quantity of a substance that is daily leached out of 1 m^2 of treated wood during 14 day storage period. *($FLUX_{storage,dipp}$)*			Tier 1: worst-case assumption where 50% of the active substance is assumed to leach after an initial time period of 30 days and 100% of the active
- Propiconazole	1.05E-04	kg.m^{-2}·d^{-1}	
- IPBC	1.05E-04	kg.m^{-2}·d^{-1}	

Input parameters for calculating the local emission from automated dipping process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**1.2 – Automated dipping (storage)**			
- Permethrin	1.167E-04	$kg.m^{-2}.d^{-1}$	substance is assumed to leach after a given longer time period = (Qa.i.*50% /30days)*14
Bulk density of wet soil (RHO_{soil})	1700	Kg/m^3	Default
Soil depth ($DEPTH_{soil}$)	0.5	m	Default
Fraction of rainwater running off the storage site (F_{runoff})	0.5	[-]	Default
Flow rate of surface water (creek/river) ($FLOW_{surfacewater}$)	25920	$m^3.d^{-1}$	This value corresponds to 0.3 $m^3.s^{-1}$ which is the default value for a small creek.

D=default, S=based on information of applicant

The cumulative quantities of substance leached over 30 days and 7300 days (Qleach,storage,time) are calculated according to the equations 4.17 and 4.18 from the revised ESD PT8 as following:

Qleach,storage,time1 = FLUXstorage,dip . AREAwood-expo . AREAstorage . TIME 1

Qleach,storage,time2 = FLUXstorage,dip . AREAwood-expo . AREAstorage . TIME 2

The local emissions to surface water during the storage phase are calculated according to the equation 4.21 and 4.22 from the revised ESD PT8 as following:

Elocal,surfacewater,time1 = Qleach,storage time1 . Frunoff / TIME 1

Elocal,surfacewater,time2 = Qleach,storage time2 . Frunoff / TIME 2

The local concentrations into the soil and the surface water are calculated according to the equations 4.19/4.120/4.23/4.24 from the revised ESD PT8 as following:

Clocal,surfacewater,time 1 = Elocal,surfacewater,time1 / FLOWsurfacewater

Clocal,surfacewater,time 2 = Elocal,surfacewater,time2 / FLOWsurfacewater

Clocal,soil,time 1 = Qleach,storage,time1 . (1 – Frunoff) / Vsoil . RHOsoil

Clocal,soil,time 2 = Qleach,storage,time2 . (1 – Frunoff) / Vsoil . RHOsoil

The results are presented in the following table (without considering removal processes).

Resulting cumulative quantity of substance leached		
Active substance	**Cumulative quantity of substance leached over 30 days TIME 1 [kg]**	**Cumulative quantity of substance leached over 15 years TIME 2 [kg]**
Propiconazole	2.43E+01	4.43E+03
IPBC	2.43E+01	4.43E+03
Permethrin	2.7E+01	4.92E+03

Resulting local emissions to surface water compartment		
Active substance	**Local emission due to leaching after 30 days** **TIME 1 [kg·d^{-1}]**	**Local emission due to leaching after 15 years** **TIME 2 [kg·d^{-1}]**
Propiconazole	4.04E-01	4.04E-01
IPBC	4.04E-01	4.04E-01
Permethrin	4.49E-01	4.49E-01

Resulting local concentrations to surface water compartment		
Active substance	**Local concentration into surface water after 30 days** **TIME 1 [mg·L^{-1}]**	**Local concentration into surface water after 15 years** **TIME 2 [mg·L^{-1}]**
Propiconazole	1.56E-02	1.56E-02
IPBC	1.56E-02	1.56E-02
Permethrin	1.73E-02	1.73E-02

Resulting local concentrations to soil compartment		
Active substance	**Local concentration in soil after 30 days** **TIME 1 [kg·kg$_{wwt}^{-1}$]**	**Local concentration in soil after 15 years** **TIME 2 [kg·kg$_{wwt}^{-1}$]**
Propiconazole	2.04E-05	3.72E-03
IPBC	2.04E-05	3.72E-03
Permethrin	2.26E-05	4.13E-03

- *Scenario [2] – Automated spraying*

This type of superficial application process is typically used in sawmills and carpentry / joinery industries. Concentrates of the wood preservative are diluted with water, to prepare a ready for use treatment solution. The wood, whether in debarked logs or fully or partly machined timber are moved through one or more longitudinal or transversal boxes on a continuously moving conveyor system.

The product is applied as a spray which is usually as a coarse spray using a particle spray size to ensure the wetting of the timber with the correct amount of wood preservative.

The spray boxes are relatively contained and splashguards surround the spraying boxes to eliminate any droplets of spray from entering the rest of the mill area and may have local exhaust ventilation.

After the timber has been treated it is stacked or sorted, mechanically either dries on the conveyor belt or in the post treatment drip dry conditioning area before being moved off-site to manufacturers or used on site.

The treatment apparatus is typically established in a contained or bounded area manufactured from materials resistant to the wood preservative product. Provision is made

for the collection, recycling and reuse of wood preservative collected from the conveyor or drip dry area. The release of product's residues from the treating installation or where the treated timber is stored into a surface water drain or drain connected to a Sewage Treatment Plant (STP) is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process.

Following the ESD excel-sheets for automated spraying application, two sub-scenarios have been developed in function of the size of sawmill which has effect in the area of wood treated per day.

The following table shows the used parameters in the environmental emission assessment for the automated dipping scenario.

Application phase [2.1]

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**2.1 – Automated spraying (application)**			
Area of wood treated per day (large plant) *($AREA_{wood\text{-}treated}$)*	20000*	m^2/d	D
Application rate of the product	0.2	kg/m^2	S
Quantity of a substance applied per m^2 of wood *(Q_{ai})*			
- Propiconazole	4.5E-04	Kg/m^2	S
- IPBC	4.5E-04	Kg/m^2	S
- Permethrin	5E-04	Kg/m^2	S
Fraction released to facility drain *($F_{facilitydrain}$)* for IPBC and propiconazole	0.03	[-]	D (water solubility > 100 mg/l)
for permethrin	0.0001	[-]	D (water solubility < 0.25 mg/l)
Fraction released to air for all a.s. *(F_{air})*	0.001	[-]	D (vapour pressure at 20ºC < 0.005Pa)
Fraction of spray drift deposition *(F_{drift})*	0.001	[-]	D

D=default, S=based on information of applicant

*The $AREA_{wood\text{-}treated}$ of 20000 m^2.d-1 (large plant) represents a worst case situation and is therefore used in this risk assessment.

As in the scenario before, the environmental risk derived from the storage of treatment wood during the application and before shipping has been taken in account as a worse case for the automated spraying application.

- **Calculations**

The local emissions to air and facility drain during the day of application are calculated according to the equations 4.2 and 4.3 from the revised ESD PT8 as following:

$$E_{local,air} = Q_{ai} \cdot AREA_{wood\text{-}treated} \cdot (F_{air} + F_{drift})$$

$$E_{local,facilitydrain} = Q_{ai} \cdot AREA_{wood\text{-}treated} \cdot F_{facilitydrain}$$

The results are presented in the following table.

Resulting local emissions		
Active substance	**Local emission ($Elocal_{air}$) [kg·d^{-1}]**	**Local emission ($Elocal_{facilitydrain}$)* [kg·d^{-1}]**
Propiconazole	1.8E-02	2.7E-01
IPBC	1.8E-02	2.7E-01
Permethrin	2E-02	1E-03

*Elocal, facilitydrain = Elocal, wastewater

Storage phase [2.1]

During storage, soil can be exposed – if the label instruction is not followed and storage place is not covered – due to leaching from treated wood via rainfall. In addition, surface water can be exposed via rain run-off from the storage place.

The $AREA_{storage}$ of 790 m^2 (large plant) represents a worst case situation and is therefore used in this risk assessment.

The input parameters for calculating the local emissions and concentrations following leaching are presented in the following table.

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**2.2 – Automated spraying (storage)**			
Effective surface area of treated wood, considered to be exposed to rain, per 1 m^2 storage area (i.e. soil) *($AREA_{wood-expo}$)*	11	m^2.m^{-2}	Default
Surface area of the storage place in a large plant *($AREA_{storage}$)*	790	m^2	Default (worst case)
Duration of the initial assessment period *(TIME 1)*	30	d	Default
Duration of a longer assessment period *(TIME 2)*	5475	d	Default (15 years)
Average daily flux i.e. the average quantity of a substance that is daily leached out of 1 m^2 of treated wood during 3 day storage period. *($FLUX_{storage,spray}$)*			Tier 1: worse-case assumption where 50% of the active substance is assumed to leach after an initial time period of 30 days and 100% of the active substance is assumed to leach after a given longer time period = (Qa.i.*50% /30days)*3
- Propiconazole	2.25E-05	kg.m^{-2}·d^{-1}	
- IPBC	2.25E-05	kg.m^{-2}·d^{-1}	
- Permethrin	2.5E-05	kg.m^{-2}·d^{-1}	
Volume of treated wood stacked per m^2 of storage area (i.e. soil) *($VOLUME_{wood-stacked}$)*	2	m^3.m^{-2}	Default
Bulk density of wet soil *(RHO_{soil})*	1700	Kg/m^3	Default
Soil depth *($DEPTH_{soil}$)*	0.5	m	Default
Fraction of rainwater running off the storage site *(F_{runoff})*	0.5	[-]	Default

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**2.2 – Automated spraying (storage)**			
Flow rate of surface water (creek/river) *($FLOW_{surfacewater}$)*	25920	$m^3.d^{-1}$	This value corresponds to 0.3 $m^3.s^{-1}$ which is the default value for a small creek.

- **Calculations**

The cumulative quantities of substance leached over 30 days and 7300 days (Qleach,storage,time) are calculated according to the equations 4.5 and 4.6 from the revised ESD PT8 as following:

Qleach,storage,time1 = FLUXstorage,spray . AREAwood-expo . AREAstorage . TIME 1

Qleach,storage,time2 = FLUXstorage,spray . AREAwood-expo . AREAstorage . TIME 2

The local emissions to surface water during the storage phase are calculated according to the equation 4.9 and 4.10 from the revised ESD PT8 as following:

Elocal,surfacewater,time1 = Qleach,storage time1 . Frunoff / TIME 1

Elocal,surfacewater,time2 = Qleach,storage time2 . Frunoff / TIME 2

The local concentrations into the soil and the surface water are calculated according to the equations 4.7/4.8/4.11/4.12 from the revised ESD PT8 as following:

Clocal,surfacewater,time 1 = Elocal,surfacewater,time1 / FLOWsurfacewater

Clocal,surfacewater,time 2 = Elocal,surfacewater,time2 / FLOWsurfacewater

Clocal,soil,time 1 = Qleach,storage,time1 . (1 – Frunoff) / Vsoil . RHOsoil

Clocal,soil,time 2 = Qleach,storage,time2 . (1 – Frunoff) / Vsoil . RHOsoil

The results are presented in the following table (without considering removal processes).

Resulting cumulative quantity of substance leached		
Active substance	**Cumulative quantity of substance leached over 30 days TIME 1 [kg]**	**Cumulative quantity of substance leached over 15 years TIME 2 [kg]**
Propiconazole	5.87	1.07E+03
IPBC	5.87	1.07E+03
Permethrin	6.52	1.19E+03

Resulting local emissions to surface water compartment		
Active substance	**Local emission due to leaching after 30 days TIME 1 [$kg \cdot d^{-1}$]**	**Local emission due to leaching after 15 years TIME 2 [$kg \cdot d^{-1}$]**
Propiconazole	9.78E-02	9.78E-02
IPBC	9.78E-02	9.78E-02

Permethrin	1.09E-01	1.09E-01

Resulting local concentrations to surface water compartment		
Active substance	**Local concentration into surface water after 30 days TIME 1 [mg·L^{-1}]**	**Local concentration into surface water after 15 years TIME 2 [mg·L^{-1}]**
Propiconazole	3.77E-03	3.77E-03
IPBC	3.77E-03	3.77E-03
Permethrin	4.19E-03	4.19E-03

Resulting local concentrations to soil compartment		
Active substance	**Local concentration in soil after 30 days TIME 1 [kg·kg$_{wwt}^{-1}$]**	**Local concentration in soil after 15 years TIME 2 [kg·kg$_{wwt}^{-1}$]**
Propiconazole	4.37E-06	7.97E-04
IPBC	4.37E-06	7.97E-04
Permethrin	4.85E-06	8.86E-04

- ***Fate and distribution in exposed environmental compartments***

The fate and distribution in exposed environmental compartments are covered by the active substance data on IPBC, permethrin and propiconazole.

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	yes	yes	n.r.[1]	n.r.	yes	no	yes	yes	n.r.
Scenario 2	yes	yes	n.r.[1]	n.r.	yes	no	yes	yes	n.r.

[1] Risk for seawater is covered by those for fresh water as no additional data on marine organisms is available and therefore PEC/PNEC rations are identical.

n.r. not relevant

In the table below the relevant parameters from the active substance dossiers of all active substances are presented. For a general assessment of the environmental fate and behaviour of all four active substances refer to the active substances CAR.

Input parameters (only set values) for calculating the fate and distribution in the environment					
	Value				
Input	**IPBC***	**Permethrin**[1]	**Propiconazole**[2]	Unit	Remarks
Molecular weight	281.1	391.29	342.2	g/mol	
Melting point	65.8	33	-23	°C	
Vapour pressure	4.5E-03 (at 25°C)	2.155E-06 (at 20°C)	5.6E-05 (at 25°C)	Pa	
Water solubility (at 20°C)	168	< 0.00495	100	mg/l	
Log Octanol/water partition coefficient	2.81	4.67	3.72	Log 10	
Organic carbon/water partition coefficient (Koc)	126	26930	944	l/kg	
Henry's law constant (25ºC)	3.38E-03 (25 ºC)	4.5E-02	9.2E-05	Pa m^3 mol^{-1}	
Biodegradability	readily	no	no		
DT_{50} for degradation in soil	4.7 h (= 0.1958 d)	106	1206	d (at 12ºC)	
DT_{50} for biodegradation in water/sediment	3.1 h (= 0.1292 d) 4.9 h (= 0.204 d)	46.7	82	d (at 12ºC)	

*Values are deduced from the IPBC PT13 AR (January 2015).

[1]Values are deduced from the Permethrin PT8 AR (April 2014) and CAR.

[2]Values are deduced from the Propiconazole PT7 AR (January 2015).

Metabolites

Calculations for metabolites

According to the AR for the active substances, the following major metabolites are identified:

- IPBC: PBC and iodine (all compartments);
- Permethrin: DCVA and PBA (all compartments);
- Propiconazole: 1,2,4-triazole (soil only)

Input parameters (only set values) for calculating the fate and distribution in the environment for the relevant metabolites					
	1.2.4-Triazole	**PBC**	**DCVA**	**PBA**	
Molecular weight	69.1	155.2	209.07	214.22	g/mol
Vapour pressure (at 20 °C)	2.2E-01	1.88E+01	2.6E-01	4.21E-04	Pa
Water solubility (at 20°C)	7.0E+05	2.86E+05	127.6	16.91	mg/l
Organic carbon/water partition coefficient (Koc)	89	198.1	188.53	37.55	l/kg
Molecular weight correction factor	0.202	0.552	0.534	0.547	-
Fraction transformed (soil)	0.43	1	0.113	0.15	-

Calculated PEC values

2.2.8.2.1 Calculated PEC values

The Predicted Environmental Concentration (PEC) calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Guidance on the BPR: Volume IV Environment, Part B+C (2017).

The PECs for Propiconazole, IPBC and Permethrin in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 8.

In the Assessment Report 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 risk of the sediment will not be considered further and the calculation of $PEC_{sediment}$ values is not considered necessary.

Metabolites of IPBC, Propiconazole, and Permethrin are considered to be transient or less persistent than their respective parent, and are less toxic. In the CARs, the risk quotients are more favorable for the metabolites than for the active substances for both the aquatic and terrestrial environment and the metabolites are not considered further in the risks assessment. The only exception concern the metabolites 1,2,4-Triazole and PBC which have a slightly higher PNECsoil than the PNECsoil of its parents.

In general, concentrations of metabolites in the environmental compartments are calculated by multiplying active substances concentrations and amounts leached over the assessment period with the differences in molar weight and the maximal level of formation fraction of the substances in soil.

However, metabolites were not considered in case of release to the sewer as none of the active substances are readily biodegradable and information on the appearance of metabolites during sewage treatment is lacking (e.g. STP simulation studies is not available). Metabolites are therefore assumed to be formed after being released to the aquatic (in effluent) or terrestrial (in sewage sludge) environment.

IPBC is quickly degraded in the environment in iodine, released as iodine radical, which is not stable in soil and can be considered as a "transient metabolite". The final reaction end-products would be iodide and iodate. According to the conclusions of the AR for IPBC PT06 (27/09/2013), a quantitative assessment should not be a requirement for the final reaction end-products of IPBC. Moreover this present evaluation is covered by the qualitative assessment proposed in the AR for IPBC PT06. In addition, the background concentrations

of iodine in the environment (and particularly in the soil compartment: see table below) are much higher than what could be calculated after degradation of the IPBC of the IRUXIL product family.

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

Therefore, emissions and PEC values were calculated for parents only and the PECsoil values were also calculated for the parents and the abovementioned metabolites.

Propiconazole		**PEC_{STP} (mg/L)**	**$PEC_{surface\ water}$ (mg/L)**	**$PEC_{sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	2.41E-02	2.40E-03	5.12E-02	1.01E-02	3.47E-04
	Automated spraying [2.1]	1.20E-01	1.20E-02	2.56E-01	5.03E-02	1.74E-03
Storage phase	Automated dipping [1.2] (Time 1)	-	1.56E-02	3.32E-01	2.04E+01	1.21
	Automated dipping [1.2] (Time 2)	-	1.56E-02	3.32E-01	3.72E+03	2.22E+02
	Automated spraying [2.2] (Time 1)	-	3.77E-03	8.04E-02	4.37	2.60E-01
	Automated spraying [2.2] (Time 2	-	3.77E-03	8.04E-02	7.97E+02	4.75E+01

IPBC		**PEC_{STP} (mg/L)**	**$PEC_{surface\ water}$ (mg/L)**	**$PEC_{sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	2.66E-02	2.66E-03	9.35E-03	4.59E-06	3.27E-07
	Automated spraying [2.1]	1.33E-01	1.33E-02	4.68E-02	2.29E-05	1.63E-06
Storage phase	Automated dipping [1.2] (Time 1)	-	1.56E-02	5.49E-02	2.04E+01	8.71
	Automated dipping [1.2] (Time 2)	-	1.56E-02	5.49E-02	3.72E+03	1.59E+03
	Automated spraying [2.2] (Time 1)	-	3.77E-03	1.33E-02	4.37	1.87
	Automated spraying [2.2] (Time 2	-	3.77E-03	1.33E-02	7.97E+02	3.40E+02

Permethrin		**PEC_{STP} (mg/L)**	**$PEC_{surface\ water}$ (mg/L)**	**$PEC_{sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	2.62E-05	2.51E-06	1.47E-03	2.82E-04	3.89E-07
	Automated spraying [2.1]	1.31E-04	1.26E-05	7.37E-03	1.37E-03	1.87E-06
Storage phase	Automated dipping [1.2] (Time 1)	-	1.73E-02	1.02E+01	2.26E+01	4.76E-02
	Automated dipping [1.2] (Time 2)	-	1.73E-02	1.02E+01	4.13E+03	8.69
	Automated spraying [2.2] (Time 1)	-	4.19E-03	2.46	4.85	1.02E-02
	Automated spraying [2.2] (Time 2	-	4.19E-03	2.46	8.86E+02	1.86

Relevant degradation products and their assessment for the soil compartment

For the permethrin, aquatic metabolites including 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1 cyclopropane)carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA) are far less toxic to soil organisms than the parent active ingredient and are not considered to be ecotoxicologically relevant. In addition, the rates of degradation of permethrin in these two metabolites are rather low and are therefore not taken into account.

Degradation of IPBC yields the primary degradate propargyl butyl carbamate (PBC) as well as iodine. PEC values have been calculated for PBC only for the soil compartment which is the compartment with the higher risk.

The assessment of 1,2,4-triazole for soil compartment takes into account the maximal level of formation fraction of the substances in soil and the molar mass of each component.

1,2,4-Triazole		**PEC_{STP} (mg/L)**	**$PEC_{surface\ water}$ (mg/L)**	**$PEC_{sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	n.r.	n.r.	n.r.	8.74E-04	3.00E-04
	Automated spraying [2.1]	n.r.	n.r.	n.r.	4.37E-03	1.50E-03
Storage phase	Automated dipping [1.2] (Time 1)	-	n.r.	n.r.	1.77	1.05
	Automated dipping [1.2] (Time 2)	-	n.r.	n.r.	3.23E+02	1.91E+02
	Automated spraying [2.2] (Time 1)	-	n.r.	n.r.	3.79E-01	2.25E-01
	Automated spraying [2.2] (Time 2	-	n.r.	n.r.	6.92E+01	4.10E+01

n.r.: not relevant

PBC		PEC$_{STP}$ (mg/L)	PEC$_{surface\ water}$ (mg/L)	PEC$_{sediment}$ (mg/kg$_{wwt}$)	PEC$_{soil}$ (mg/kg$_{wwt}$)	PEC$_{groundwater}$ (mg/L)
Application phase	Automated dipping [1.1]	n.r.	n.r.	n.r.	2.53E-06	1.17E-07
	Automated spraying [2.1]	n.r.	n.r.	n.r.	1.27E-05	5.84E-07
Storage phase	Automated dipping [1.2] (Time 1)	-	n.r.	n.r.	1.13E+01	3.11
	Automated dipping [1.2] (Time 2)	-	n.r.	n.r.	2.05E+03	5.68E+02
	Automated spraying [2.2] (Time 1)	-	n.r.	n.r.	2.41	6.67E-01
	Automated spraying [2.2] (Time 2	-	n.r.	n.r.	4.40E+02	1.22E+02

n.r.: not relevant

Primary and secondary poisoning

2.2.8.2.1.1 PRIMARY POISONING

A direct uptake of the product is unlikely; therefore primary poisoning is not deemed relevant.

2.2.8.2.1.2 SECONDARY POISONING

According to Vol IV, Parts B+C the risk to the fish-eating predators (mammals and/or birds) is calculated as the ratio between the concentration in their food ($PEC_{oral,predator}$) and the no-effect-concentration for oral intake (PNECoral). The calculation of a possible risk to predators via the food chain should be conducted if the active substance shows a potential for bioaccumulation, indicated by a log K_{ow} value >3.

A secondary exposure of fish-eating predators to IPBC can be excluded due to the minimum amount which reaches the soil. In addition, the log Kow is less than 3 and the soil area of concern is very small.

Although the log K_{ow} of Propiconazole (log K_{ow} = 3.7) reveals a slight potential for bioaccumulation, the assessment of secondary poisoning is not requested according to the active substance Assessment Report for the use of propiconazole in wood preservatives.

A log K_{ow} of 4.27 is determined for permethrin, which is above the relevant trigger value of 3 as stated in the BPR Guidance Volume IV Environment – Part B (2015). The BCF_{fish} is 570 L/kg and the $BCF_{earthworm}$ is 15108 L/kg.

In view of that permethrin is the only active substance considered of concern for secondary poisoning and the current assessment is focused on it.

For the risk characterisation the following PNEC-values were used:

- $PNEC_{bird}$ = 16.7 mg a.s./kg food

- $PNEC_{small\ mammal}$ = 120 mg a.s./kg food

For secondary poisoning, the concentration in surface water is used as input for calculating the concentration of Permethrin and DCVA in food (fish) of fish-eating predators ($PECoral_{predator,aquatic}$) according to equation (95) of the Guidance on BPR IV/B+C (2017). An estimated BCF fish of 570 L/kgwwt fish and a BMF of 2 (Kow =4.67) are used for calculations.

For the calculation of the concentration of a.s. in earthworms (Cearthworm = $PEC_{oral,\ predator}$ according equation 99 of the Guidance on BPR IV/B+C, 2017), equation 103c of the guidance is used considering PECsoil averaged over a period of 180 days. Therefore, a BCF earthworm of 15108 L/kgwwt, earthworm and the concentrations in pore water have been used as input parameter to calculate the following PECoral, predator for the terrestrial and aquatic compartment.

For aquatic food chain:

Scenario		**$PEC_{oral,predator}$** [$mg.kg^{-1}_{wet\ fish}$]
Application phase	Automated dipping [1.1]	5.29E-03
	Automated spraying [2.1]	2.54E-02
Storage phase	Automated dipping [1.2] (Time 1)	1.98E+01
	Automated dipping [1.2] (Time 2)	1.98E+01
	Automated spraying [2.2] (Time 1)	4.78
	Automated spraying [2.2] (Time 2	4.78

For terrestrial food chain:

Scenario		**$PEC_{oral,predator}$** [$mg.kg^{-1}_{wet\ earthworm}$]
Application phase	Automated dipping [1.1]	5.29E-03
	Automated spraying [2.1]	2.54E-02
Storage phase	Automated dipping [1.2] (Time 1)	6.49E+02
	Automated dipping [1.2] (Time 2)	1.18E+05
	Automated spraying [2.2] (Time 1)	1.39E+02
	Automated spraying [2.2] (Time 2	2.54E+04

2.2.8.3 Risk characterisation

The environmental risk characterization for biocidal active substances in the context of Article 5 and Annex VI of BPR, Regulation (EU) 528/2012 involves the comparison of PEC and PNEC values for each relevant environmental compartment as well as for non-target organisms. Risk Characterisation Ratios (PEC/PNEC) are derived for the use of the wood preservative. The calculated PEC/PNEC ratios are provided for the STP, the aquatic and terrestrial compartment in the following tables.

If the PEC/PNEC ratio is below 1, this is interpreted as an acceptable risk to the environment. Calculated PEC/PNEC values are summarized below, values above 1 are marked with red colour.

Propiconazole		**PEC/ PNEC$_{STP}$**	**PEC/ PNEC$_{surface\ water}$**	**PEC/ PNEC$_{sediment}$**	**PEC/ PNEC$_{soil}$**	**PEC$_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	2.41E-02	4.01E-01	9.48E-01	1.01E-01	**3.47E-04**
	Automated spraying [2.1]	1.20E-01	**2**	**4.74**	5.03E-01	**1.74E-03**
Storage phase	Automated dipping [1.2] (Time 1)	-	1.56E-02	**6.15**	**2.04E+02**	**1.21**
	Automated dipping [1.2] (Time 2)	-	1.56E-02	**6.15**	**3.72E+04**	**2.22E+02**
	Automated spraying [2.2] (Time 1)	-	3.77E-03	**1.49**	**4.37E+01**	**2.60E-01**
	Automated spraying [2.2] (Time 2	-	3.77E-03	**1.49**	**7.97E+03**	**4.75E+01**

IPBC		**PEC/ PNEC$_{STP}$**	**PEC/ PNEC$_{surface\ water}$**	**PEC/ PNEC$_{sediment}$**	**PEC/ PNEC$_{soil}$**	**PEC$_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	6.04E-02	**5.31**	**-**	1.04E-03	3.27E-07
	Automated spraying [2.1]	4.40E-03	**2.66E+01**	**-**	5.22E-03	1.63E-06
Storage phase	Automated dipping [1.2] (Time 1)	-	**3.12E+01**	**-**	**4.63E+03**	**8.71**
	Automated dipping [1.2] (Time 2)	-	**3.12E+01**	**-**	**8.45E+05**	**1.59E+03**
	Automated spraying [2.2] (Time 1)	-	**7.54**	**-**	**9.93E+02**	**1.87**
	Automated spraying [2.2] (Time 2	-	**7.54**	**-**	**1.81E+05**	**3.40E+02**

Permethrin		**PEC/ PNEC$_{STP}$**	**PEC/ PNEC$_{surface\ water}$**	**PEC/ PNEC$_{sediment}$**	**PEC/ PNEC$_{soil}$**	**PEC$_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	5.28E-03	**5.35**	**6.79**	1.61E-03	3.89E-07
	Automated spraying [2.1]	2.64E-02	**2.67E+01**	**3.40E+01**	7.84E-03	1.87E-06
Storage phase	Automated dipping [1.2] (Time 1)	-	**3.69E+04**	**4.68E+04**	**1.29E+02**	**4.76E-02**

	Automated dipping [1.2] (Time 2)	-	**3.69E+04**	**4.68E+04**	**2.36E+04**	**8.69**
	Automated spraying [2.2] (Time 1)	-	**8.92E+03**	**1.13E+04**	**2.77E+01**	**1.02E-02**
	Automated spraying [2.2] (Time 2	-	**8.92E+03**	**1.13E+04**	**5.06E+03**	**1.86**

1,2,4-Triazole		**PEC/ $PNEC_{STP}$**	**PEC/ $PNEC_{surface\ water}$**	**PEC/ $PNEC_{sediment}$**	**PEC/ $PNEC_{soil}$**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	-	-	-	1.46E-01	3.00E-04
	Automated spraying [2.1]	-	-	-	7.28E-01	1.50E-03
Storage phase	Automated dipping [1.2] (Time 1)	-	-	-	**2.95E+02**	**1.05**
	Automated dipping [1.2] (Time 2)	-	-	-	**5.39E+04**	**1.91E+02**
	Automated spraying [2.2] (Time 1)	-	-	-	**6.32E+01**	**2.25E-01**
	Automated spraying [2.2] (Time 2	-	-	-	**1.15E+04**	**4.10E+01**

PBC		**PEC/ $PNEC_{STP}$**	**PEC/ $PNEC_{surface\ water}$**	**PEC/ $PNEC_{sediment}$**	**PEC/ $PNEC_{soil}$**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	-	-	-	1.70E-05	1.17E-07
	Automated spraying [2.1]	-	-	-	8.50E-05	5.84E-07
Storage phase	Automated dipping [1.2] (Time 1)	-	-	-	**1.13E+03**	**3.11**
	Automated dipping [1.2] (Time 2)	-	-	-	**2.05E+05**	**5.68E+02**
	Automated spraying [2.2] (Time 1)	-	-	-	**2.41E+02**	**6.67E-01**
	Automated spraying [2.2] (Time 2	-	-	-	**4.40E+04**	**1.22E+02**

Atmosphere

Due to the low vapour pressures of IPBC (4.5 x 10^{-3} Pa at 25°C), Permethrin (2.155 x 10^{-6} Pa at 20°C) and Propiconazole (5.6 x 10^{-5} Pa at 25°C) the emission to air seems to be negligible and consequently not relevant. Therefore, the air compartment is not considered for the active substances in the environmental risk assessment.

Sewage treatment plant (STP)

For Sewage Treatment Plant (STP), all PEC/PNEC ratios are lower than 1 for all the evaluated scenarios. So, we can conclude that an unacceptable risk for the STP is not expected from the use of IRUXIL Family products.

Aquatic compartment

For the aquatic compartment (surface-water and sediment), risks were identified during the application phase and during the storage phase for the three active substances. However, those risks should be considered not relevant based on mandatory risk mitigation measures for wood treatments industries. Therefore, an unacceptable risk for the the aquatic compartment is not expected from industrial treatments (application and storage phases) under the RMM application.

Terrestrial compartment

For the soil, the industrial storage scenario provided PEC/PNEC ratios above 1 for TIME 1 and 2 both for the active substances and degradation products. According to the revised ESD for PT 8 it can be assumed, that most storage places are sealed and run-off from storage places will be collected and disposed of safely. However, those risks should be also considered not relevant based on mandatory risk mitigation measures for wood treatments industries. Therefore, an unacceptable risk to the soil compartment from industrial treatments is not expected under the RMM application.

Groundwater

The estimations of releases of active substances and their relevant degradation products for the groundwater compartment disclose unacceptable risk for all scenarios. Groundwater exposure is derived from soil compartment by leaching. Taking into account the mentioned RMM before, where industrial treatments must be developed on sealed facilities that avoid any release to the environment, an unacceptable risk for groundwater is not expected.

Primary and secondary poisoning

Secondary poisoning is relevant only for the active substance permethrin. Therefore, the secondary poisoning was assessed for the service life for wood treated by surface treatment, considered as a worst case. PEC and risk ratios for the risk of secondary poisoning for birds and mammals are summarised in the following table.

Scenario	***Via fish***	***Via earthworm***

		PEC/ PNECbirds	PEC/ PNECmammals	PEC/ PNECbirds	PEC/ PNECmammals
Application phase	Automated dipping [1.1]	1.72E-04	2.39E-05	3.17E-04	4.41E-05
	Automated spraying [2.1]	8.58E-04	1.19E-04	1.52E-03	2.12E-04
Storage phase	Automated dipping [1.2] (Time 1)	**1.18**	1.65E-01	**3.89E+01**	**5.41**
	Automated dipping [1.2] (Time 2)	**1.18**	1.65E-01	**7.09E+03**	**9.87E+02**
	Automated spraying [2.2] (Time 1)	2.86E-01	3.98E-02	**8.33**	**1.16**
	Automated spraying [2.2] (Time 2	2.86E-01	3.98E-02	**1.52E+03**	**2.11E+02**

As it can be observed, the PEC/PNEC ratio is above the threshold balue of 1 for Permethrin for the storage phase, indicating unacceptable risk of secondary poisoning throught the terrestrial food-chain via earthworm and aquatic food chain via fish. However, those risks should be also considered not relevant based on mandatory risk mitigation measures for wood treatments industries. Therefore, unacceptable risk of secondary poisoning observed from industrial storage of treated wood is not expected under the RMM application.

Mixture toxicity

As the biocidal product consists of three active substances and diferent degradation products, 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. As individual risk values are already above 1 for all active substances and degradation products in different environmental compartments, the addition has not been performed.

There is a potential risk derived from industrial treatments, however this risk must not be considered relevant based on mandatory risk mitigation measures for wood treatment industries. Storage must only take place on sealed places or under cover to prevent direct release to soil. This will be stated on the label.

Aggregated exposure (combined for relevant emission sources)

Not relevant

Overall conclusion on the risk assessment for the environment of the product
The risk characterisation indicates that the uses of the biocidal product family IRUXIL by the industrial processes - automated spraying and automated dipping – and by *in situ* processes -brush, spray and dipping for the uses of treated wood in UC 1 and UC 2 should not represent unacceptable risks to the environment if the application follows the label instructions.

2.2.9 Measures to protect man, animals and the environment

See risk mitigation measures for authorized uses

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

3 ANNEXES[15]

3.1 List of studies for the biocidal product FAMILY

List of data submitted in support of the evaluation of the biocidal family IRUXIL										
Section No	Reference No	Author	Year	Title	Owner of data	Letter of access		Data protection claimed		Essential studies for evaluation	
						Yes	No	Yes	No	Yes	No
2.2.2	098771-1-a	[redacted]	[redacted]	Standard Test Method for Viscosity by Ford Viscosity Cup No. 4 (Iruxil W-I)	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.2	095346-2-a	[redacted]	[redacted]	Accelerated Storage Test (CIPAC MT46.3) of Iruxil W product	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		X	
2.2.2	095346-1-a	[redacted]	[redacted]	Environmental Storage Test of Iruxil W product	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.2	095128-2-a	[redacted]	[redacted]	Determination of density, pycnometer method and Standard Test Method for Viscosity by Ford Viscosity Cup No. 4 of IRUXIL W, water based.	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.2	-	[redacted]	[redacted]	Surface tension measurements of several products	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.2	095348-1-a	[redacted]	[redacted]	Environmental Storage Test of Iruxil W-I product	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		X	
2.2.2	095128-1-a	[redacted]	[redacted]	Determination of density, pycnometer method and Standard Test Method for Viscosity by Ford Viscosity Cup No. 4 of IRUXIL W-I, water based.	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.2	095348-2-a	[redacted]	[redacted]	Accelerated Storage Test (CIPAC MT46.3) of Iruxil W-I product	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	

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

List of data submitted in support of the evaluation of the biocidal family IRUXIL											
Section No	**Reference No**	**Author**	**Year**	**Title**	**Owner of data**	**Letter of access**		**Data protection claimed**		**Essential studies for evaluation**	
						Yes	**No**	**Yes**	**No**	**Yes**	**No**
2.2.2	098771-2-a	[redacted]	[redacted]	Standard Test Method for Viscosity by Ford Viscosity Cup No. 4 (Iruxil W)	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.3	A370.2-AEGIS	[redacted]	[redacted]	Evaluación de la corrosividad de los productos "Iruxil W" e "Iruxil W-I"	INDUSTRIAS QUÍMICAS IRURENA, S.A		x	x		x	
2.2.4	098800 – 1a	[redacted]	[redacted]	Validation of the quantitative HPLC –UV method of analysis	INDUSTRIAS QUÍMICAS IRURENA, S.A		x	x		x	
2.2.4	098800 – 2a	[redacted]	[redacted]	Validation of the quantitative HPLC –UV method of analysis	INDUSTRIAS QUÍMICAS IRURENA, S.A		x	x		x	
2.2.5	092354-1-a	[redacted]	[redacted]	Wood preservatives - Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus* (Linnaeus) - Part 1: Application by surface treatment (laboratory method). EN 46-1:2016.	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.5	092354-2-a	[redacted]	[redacted]	Wood preservatives - Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus* (Linnaeus) - Part 1: Application by surface treatment (laboratory method). EN 46-1:2016.	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.5	092354-4-a	[redacted]	[redacted]	Determination of the protective effectiveness of a preservative treatment against blue stain in wood service, according to EN 152:2011 .	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.5	092354-5-a	[redacted]	[redacted]	Determination of the protective effectiveness of a preservative treatment against blue stain in wood service, according to EN 152:2011 .	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.5	Pine wood immersion test	[redacted]	[redacted]	Pine and spruce wood immersion test with IRUXIL W-I	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	

3.2 Output tables from exposure assessment tools

Scenario [2] – Mixing and loading of RTU

Task / Scenario :	mixing and loading		
Model used :	HEEG opinion 1: model mixing and loading 7 for pouring and pumping liquids		
dilución producto (ready-to-use)	100%	TIER 1	TIER 2
Active substance (% w/w) Permetrina	0.250%		
Active substance (% w/w) propiconazol	0.225%		
Active substance (% w/w) IPBC	0.225%		
Body weight (kg)	60	without PPE (HEEG Opinion 1)	Under clothes and gloves (HEEG Opinion 1)
	units		
Potential dermal exposure			
Body			
clothing type			
Indicative value from model	mg/min		
duration	min	10	10
potential dermal deposit	mg	0.00	0.00
clothing penetration from model	%	100%	200%
actual dermal deposit (product)	**mg**	**0.00**	**0.00**
Hands and body exposure			
indica value model under clothes and gloves	mg/min	10.100.000	101.000
duration	min	10	10
potential dermal deposit	g	1010.00	10.10
gloves penetration from model	%	100%	100%
actual hand deposit (product)	**mg**	**1010.0**	**10.10**
Actual dermal exposure			
product	**mg**	**1010.0**	**10.10**
active substance Permetrina	**mg**	**2.53**	**0.025**
active substance propiconazol	**mg**	**2.27**	**0.023**
active substance IPBC	**mg**	**2.27**	**0.023**
Skin penetration Permetrina	%	70%	70%
Skin penetration propiconazol	%	70%	70%
Skin penetration IPBC	%	70%	70%
active substance via the skin Permetrina	**mg**	**1.77E+00**	**1.77E-02**
active substance via the skin propiconazol	**mg**	**1.59E+00**	**1.59E-02**
active substance via the skin IPBC	**mg**	**1.59E+00**	**1.59E-02**
systemic dose via skin Permetrina	**mg/kg bw**	**2.95E-02**	**2.95E-04**
systemic dose via skin propiconazol	**mg/kg bw**	**2.65E-02**	**2.65E-04**
systemic dose via skin IPBC	**mg/kg bw**	**2.65E-02**	**2.65E-04**
Exposure by inhalation			
indicative value from model	mg/m3	0.94	0.94
duration	min	10	10
inhalation rate	m3/min	2.08E-02	2.08E-02
inhaled volume	m3	0.2	0.2
potential inhaled product	mg	0.2	0.2
mitigation factor by RPE	value	1	2
inhaled product through RPE	**mg**	0.195833333	0.391666667
active substance through RPE permetrina	**mg**	4.90E-04	4.90E-04
active substance through RPE propiconazol	**mg**	4.41E-04	4.41E-04
active substance through RPE IPBC	**mg**	4.41E-04	4.41E-04
systemic inhaled dose (ai) permetrina	**mg/kg bw**	**8.16E-06**	**8.16E-06**
systemic inhaled dose (ai) propiconazol	**mg/kg bw**	**7.34E-06**	**7.34E-06**
systemic inhaled dose (ai) IPBC	**mg/kg bw**	**7.34E-06**	**7.34E-06**
Dose			
total	**mg**	**1.768**	**0.018**
systemic dose permetrina	**mg/kg bw**	**2.95E-02**	**3.03E-04**
systemic dose propiconazol	**mg/kg bw**	**2.65E-02**	**2.72E-04**
systemic dose IPBC	**mg/kg bw**	**2.65E-02**	**2.72E-04**

Scenario [3] – Brushing/rolling

Task / Scenario :	Brush application		
Model used :	Recom 6 incluye datos de "Consumer painting model 3" Professional brush treatment (PT8) of Biocides Human Health Methodology		
dilución producto (ready-to-use)	100.00%	TIER 1	TIER 2
Active substance (% w/w) Permetrina	0.250%		
Active substance (% w/w) propiconazol	0.225%		
Active substance (% w/w) IPBC	0.225%		
Body weight (kg)	60	without EPI	with gloves and coverall
	units		
Potential dermal exposure			
Body			
clothing type			
Indicative value from model	mg/m2	0.238200	0.238200
Applicatio area *	m2	31.6	31.6
potential dermal deposit	mg	7.53	7.53
clothing penetration from model	%	100%	10%
actual dermal deposit (product)	**mg**	**7.53**	**0.75**
Hands exposure			
indicative value from model	mg/m2	0.54170	0.54170
Application area *	m2	31.6	31.6
potential dermal deposit	mg	17.12	17.12
gloves penetration from model	%	100%	10%
actual hand deposit (product)	**mg**	**17.12**	**1.71**
Actual dermal exposure			
product	**mg**	**24.64**	**2.46**
active substance permetrina	**mg**	**0.06161**	**0.00616**
active substance propiconazol	**mg**	**0.05545**	**0.00555**
active substance IPBC	**mg**	**0.05545**	**0.00555**
Skin penetration permetrina	%	70%	70%
Skin penetration propiconazol	%	70%	70%
Skin penetration IPBC	%	70%	70%
active substance via the skin permetrina	**mg**	**4.31E-02**	**4.31E-03**
active substance via the skin propiconazol	**mg**	**3.88E-02**	**3.88E-03**
active substance via the skin IPBC	**mg**	**3.88E-02**	**3.88E-03**
systemic dose via skin permetrina	**mg/kg bw**	**7.19E-04**	**7.19E-05**
systemic dose via skin propiconazol	**mg/kg bw**	**6.47E-04**	**6.47E-05**
systemic dose via skin IPBC	**mg/kg bw**	**6.47E-04**	**6.47E-05**
Exposure by inhalation			
indicative value from model	mg/m2	0.0016	0.0016
Application area *	m2	31.6	31.6
inhalation rate	m3/min		
inhaled volume	m3		
potential inhaled product	mg	0.0506	0.0506
mitigation factor by RPE	value	1	1
inhaled product through RPE	**mg**	0.05056	0.05056
active substance through RPE permetrina	**mg**	1.26E-04	1.26E-04
active substance through RPE propiconazol	**mg**	1.14E-04	1.14E-04
active substance through RPE IPBC	**mg**	1.14E-04	1.14E-04
systemic inhaled dose (ai) permetrina	**mg/kg bw**	**2.11E-06**	**2.11E-06**
systemic inhaled dose (ai) propiconazol	**mg/kg bw**	**1.90E-06**	**1.90E-06**
systemic inhaled dose (ai) IPBC	**mg/kg bw**	**1.90E-06**	**1.90E-06**
Dose			
total	**mg**	**0.043**	**0.004**
systemic dose permetrina	**mg/kg bw**	**7.21E-04**	**7.40E-05**
systemic dose propiconazol	**mg/kg bw**	**6.49E-04**	**6.66E-05**
systemic dose IPBC	**mg/kg bw**	**6.49E-04**	**6.66E-05**

Scenario [4] – Spraying application

Task / Scenario :		Spraying model 2			
Model used :		Recommendation 6 of BPC Ad hoc (24 professional spray treatment including M&L) (4-7 bar pressure) PT08. Biocides Human Health Exposure Methodology pag 96			
dilución producto	100%	TIER 1	TIER 2	TIER 3	TIER 4
Active substance (% w/w) permethrin	0.250%				
Active substance (% w/w) propiconazol	0.23%				
Active substance (% w/w) IPBC	0.23%				
Body weight (kg)	60	without EPI	with gloves (including in model)	with gloves (including in model)+ coverall 5%	with gloves (including in model)+ coverall 5%+mask P3
	units				
Potential dermal exposure					
Body					
clothing type					
Indicative value from model	mg/min	222	222	222	222
duration	min	80	80	80	80
potential dermal deposit	mg	17760.00	17760.00	17760.00	17760.00
clothing penetration from model	%	100%	100%	5%	5%
actual dermal deposit (product)	**mg**	**17760.00**	**17760.00**	**888.00**	**888.00**
Hands exposure					
indicative value from model	mg/min	273	7.80	7.80	7.80
duration	min	80	80	80	80
potential dermal deposit	mg	21840.00	624.00	624.00	624.00
gloves penetration from model	%	100%	100%	100%	100%
actual hand deposit (product)	**mg**	**21840.00**	**624.00**	**624.00**	**624.00**
Actual dermal exposure					
product	**mg**	**39600.00**	**18384.00**	**1512.00**	**1512.00**
active substance permetrina	**mg**	**99.00**	**45.96**	**3.78**	**3.78**
active substance propiconazol	**mg**	**89.10**	**41.36**	**3.40**	**3.40**
active substance IPBC	**mg**	**89.10**	**41.36**	**3.40**	**3.40**
Skin penetration permetrina	%	70%	70%	70%	70%
Skin penetration propiconazol	%	70%	70%	70%	70%
Skin penetration IPBC	%	70%	70%	70%	70%
active substance via the skin permetrina	**mg**	**6.93E+01**	**3.22E+01**	**2.65E+00**	**2.65E+00**
active substance via the skin propiconazol	**mg**	**6.24E+01**	**2.90E+01**	**2.38E+00**	**2.38E+00**
active substance via the skin IPBC	**mg**	**6.24E+01**	**2.90E+01**	**2.38E+00**	**2.38E+00**
systemic dose via skin permetrina	**mg/kg bw**	**1.16E+00**	**5.36E-01**	**4.41E-02**	**4.41E-02**
systemic dose via skin propiconazol	**mg/kg bw**	**1.04E+00**	**4.83E-01**	**3.97E-02**	**3.97E-02**
systemic dose via skin IPBC	**mg/kg bw**	**1.04E+00**	**4.83E-01**	**3.97E-02**	**3.97E-02**
Exposure by inhalation					
indicative value from model	mg/m3	76	76	76	76
duration	min	80	80	80	80
inhalation rate	m3/min	2.08E-02	2.08E-02	2.08E-02	2.08E-02
inhaled volume	m3	1.7	1.7	1.7	1.7
potential inhaled product	mg	126.7	126.7	126.7	126.7
mitigation factor by RPE	value	1	1	1	2.50%
inhaled product through RPE	**mg**	1.266.666.667	1.266.666.667	1.266.666.667	3.166.666.667
active substance through RPE permetrina	**mg**	3.17E-01	3.17E-01	3.17E-01	7.92E-03
active substance through RPE propiconazol	**mg**	2.85E-01	2.85E-01	2.85E-01	7.13E-03
active substance through RPE IPBC	**mg**	2.85E-01	2.85E-01	2.85E-01	7.13E-03
systemic inhaled dose (ai) permetrina	**mg/kg bw**	**5.28E-03**	**5.28E-03**	**5.28E-03**	**1.32E-04**
systemic inhaled dose (ai) propiconazol	**mg/kg bw**	**4.75E-03**	**4.75E-03**	**4.75E-03**	**1.19E-04**
systemic inhaled dose (ai) IPBC	**mg/kg bw**	**4.75E-03**	**4.75E-03**	**4.75E-03**	**1.19E-04**
Dose					
total	**mg**	**69.617**	**32.489**	**2.963**	**2.654**
systemic dose permetrina	**mg/kg bw**	**1.16E+00**	**5.41E-01**	**4.94E-02**	**4.42E-02**
systemic dose propiconazol	**mg/kg bw**	**1.04E+00**	**4.87E-01**	**4.44E-02**	**3.98E-02**
systemic dose IPBC	**mg/kg bw**	**1.04E+00**	**4.87E-01**	**4.44E-02**	**3.98E-02**

Scenario [5] – Fully Automated spray application

Task / Scenario :		Spray industrial			
Model used :		Recommendation 6 of BPC Ad hoc (model 21) 2 cycles/day			Handling model 1 water based
dilución producto (worst case)	100,0%				
		TIER 1	TIER 2	TIER 3	TIER 4
Active substance (% w/w) Permetrina	0,250%				
Active substance (% w/w) propiconazol	0,23%				
Active substance (% w/w) IPBC	0,23%				
Body weight (kg)	60				
	units	with gloves (including in model)	with gloves (including in model)+ coverall 5%	with gloves (including in model)+ coverall 5%+mask P3	hand exposure new gloves for each work shift
Potential dermal exposure					
Body					
clothing type					
Indicative value from model	mg/ciclo	8570	8570	8570	8570
duration	ciclos	1	1	1	1
potential dermal deposit	mg	8570,00	8570,00	8570,00	8570,00
clothing penetration from model	%	100%	5%	5%	5%
actual dermal deposit (product)	**mg**	**8570,00**	**428,50**	**428,50**	**428,50**
Hands exposure					
indicative value from model	mg/ciclo	1080,00	1080,00	1080,00	135,00
duration	ciclos	1	1	1	1
potential dermal deposit	mg	1080,00	1080,00	1080,00	135,00
gloves penetration from model	%	100%	100%	100%	100%
actual hand deposit (product)	**mg**	**1080,00**	**1080,00**	**1080,00**	**135,00**
Actual dermal exposure					
product	**mg**	**9650,00**	**1508,50**	**1508,50**	**563,50**
active substance permetrina	**mg**	**24,13**	**3,77**	**3,77**	**1,41**
active substance propiconazol	**mg**	**21,71**	**3,39**	**3,39**	**1,27**
active substance IPBC	**mg**	**21,71**	**3,39**	**3,39**	**1,27**
Skin penetration permetrina	%	70%	70%	70%	70%
Skin penetration propiconazol	%	70%	70%	70%	70%
Skin penetration IPBC	%	70%	70%	70%	70%
active substance via the skin permetrina	**mg**	**1,69E+01**	**2,64E+00**	**2,64E+00**	**9,86E-01**
active substance via the skin propiconazol	**mg**	**1,52E+01**	**2,38E+00**	**2,38E+00**	**8,88E-01**
active substance via the skin IPBC	**mg**	**1,52E+01**	**2,38E+00**	**2,38E+00**	**8,88E-01**
systemic dose via skin permetrina	**mg/kg bw**	**2,81E-01**	**4,40E-02**	**4,40E-02**	**1,64E-02**
systemic dose via skin propiconazol	**mg/kg bw**	**2,53E-01**	**3,96E-02**	**3,96E-02**	**1,48E-02**
systemic dose via skin IPBC	**mg/kg bw**	**2,53E-01**	**3,96E-02**	**3,96E-02**	**1,48E-02**
Exposure by inhalation					
indicative value from model	mg/m3	1,9	1,9	1,9	1,9
duration	min	240	240	240	240
inhalation rate	m3/min	2,08E-02	2,08E-02	2,08E-02	2,08E-02
inhaled volume	m3	5,0	5,0	5,0	5,0
potential inhaled product	mg	9,5	9,5	9,5	9,5
mitigation factor by RPE	value	1	1	2,50%	1
inhaled product through RPE	**mg**	9,5000	9,5000	0,2375	9,5000
active substance through RPE permetrina	**mg**	2,38E-02	2,38E-02	5,94E-04	2,38E-02
active substance through RPE propiconazol	**mg**	2,14E-02	2,14E-02	5,34E-04	2,14E-02
active substance through RPE IPBC	**mg**	2,14E-02	2,14E-02	5,34E-04	2,14E-02
systemic inhaled dose (ai) permetrina	**mg/kg bw**	**3,96E-04**	**3,96E-04**	**9,90E-06**	**3,96E-04**
systemic inhaled dose (ai) propiconazol	**mg/kg bw**	**3,56E-04**	**3,56E-04**	**8,91E-06**	**3,56E-04**
systemic inhaled dose (ai) IPBC	**mg/kg bw**	**3,56E-04**	**3,56E-04**	**8,91E-06**	**3,56E-04**
Dose					
total	**mg**	**16,911**	**2,664**	**2,640**	**1,010**
systemic dose permetrina	**mg/kg bw**	**2,82E-01**	**4,44E-02**	**4,40E-02**	**1,68E-02**
systemic dose propiconazol	**mg/kg bw**	**2,54E-01**	**4,00E-02**	**3,96E-02**	**1,51E-02**
systemic dose IPBC	**mg/kg bw**	**2,54E-01**	**4,00E-02**	**3,96E-02**	**1,51E-02**

Scenario [6] – Manual dipping (industrial)

Model used :		Recommendation 6 of BPC Ad hoc (model 22)			
dilución producto (worst case)	100,0%	**TIER 1**	**TIER 2**	**TIER 3**	**TIER 4**
Active substance (% w/w) Permetrina	0.25%				
Active substance (% w/w) propiconazol	0.225%				
Active substance (% w/w) IPBC	0.225%				
Body weight (kg)	60	(including in model)	(including in	(including in	(including in
	units				
Potential dermal exposure					
Body					
clothing type					
Indicative value from model from application	mg/min	178	178	178	178
duration	min	30	30	30	30
potential dermal deposit	mg	5340,00	5340,00	5340,00	5340,00
clothing penetration from model	%	100%	5%	5%	5%
actual dermal deposit (product)	**mg**	**5340,00**	**267,00**	**267,00**	**267,00**
Hands exposure					
indicative value from pre-application model	mg/min	0.92	0.92	0.92	0.92
duration	min	10	10	10	10
potential dermal deposit	mg	9.2	9.2	9.2	9.2
gloves penetration from model	%	10%	10%	10%	10%
actual hand deposit (product)	**mg**	**0.92**	**0.92**	**0.92**	**0.92**
indicative value from application model	mg/min	25.7	25.7	25.7	13364,00
duration	min	30	30	30	30
potential dermal deposit	mg	771,00	771,00	771,00	400.92
gloves penetration from model	%	100%	100%	100%	100%
actual hand deposit (product)	**mg**	**771,00**	**771,00**	**771,00**	**400.92**
indicative value from pre-application model	mg/min	0.92	0.92	0.92	0.92
duration	min/day	0,33	0,33	0,33	0,33
potential dermal deposit	mg	0,31	0,31	0,31	0,31
gloves penetration from model	%	0,10	0,10	0,10	0,10
actual hand deposit (product)	**mg**	**0,03**	**0,03**	**0,03**	**0,03**
TOTAL HAND deposit (product)		**771,95**	**771,95**	**771,95**	**401,87**
Actual dermal exposure					
product	**mg**	**6111,95**	**1038,95**	**1038,95**	**668,87**
active substance permetrina	**mg**	**15,28**	**2,60**	**2,60**	**1,67**
active substance propiconazol	**mg**	**13,75**	**2,34**	**2,34**	**1,50**
active substance IPBC	**mg**	**13,75**	**2,34**	**2,34**	**1,50**
Skin penetration permetrina	%	70%	70%	70%	70%
Skin penetration propiconazol	%	70%	70%	70%	70%
Skin penetration IPBC	%	70%	70%	70%	70%
active substance via the skin permetrina	**mg**	**1,07E+01**	**1,82E+00**	**1,82E+00**	**1,17E+00**
active substance via the skin propiconazol	**mg**	**9,63E+00**	**1,64E+00**	**1,64E+00**	**1,05E+00**
active substance via the skin IPBC	**mg**	**9,63E+00**	**1,64E+00**	**1,64E+00**	**1,05E+00**
systemic dose via skin permetrina	**mg/kg bw**	**1,78E-01**	**3,03E-02**	**3,03E-02**	**1,95E-02**
systemic dose via skin propiconazol	**mg/kg bw**	**1,60E-01**	**2,73E-02**	**2,73E-02**	**1,76E-02**
systemic dose via skin IPBC	**mg/kg bw**	**1,60E-01**	**2,73E-02**	**2,73E-02**	**1,76E-02**
Exposure by inhalation					
indicative value from model	mg/m3	1	1	1	1
duration	min	30	30	30	30
inhalation rate	m3/min	2,08E-02	2,08E-02	2,08E-02	2,08E-02
inhaled volume	m3	0.625	0.625	0.625	0.625
potential inhaled product	mg	0.625	0.625	0.625	0.625
mitigation factor by RPE	value	1	1	2.5%	2.5%
inhaled product through RPE	**mg**	0.625	0.625	0.015625	0.015625
active substance through RPE permetrina	**mg**	1,56E-03	1,56E-03	3,91E-05	3,91E-05
active substance through RPE propiconazol	**mg**	1,41E-03	1,41E-03	3,52E-05	3,52E-05
active substance through RPE IPBC	**mg**	1,41E-03	1,41E-03	3,52E-05	3,52E-05
systemic inhaled dose (ai) permetrina	**mg/kg bw**	**2,60E-05**	**2,60E-05**	**6,51E-07**	**6,51E-07**
systemic inhaled dose (ai) propiconazol	**mg/kg bw**	**2,34E-05**	**2,34E-05**	**5,86E-07**	**5,86E-07**
systemic inhaled dose (ai) IPBC	**mg/kg bw**	**2,34E-05**	**2,34E-05**	**5,86E-07**	**5,86E-07**
Dose					
total	**mg**				
systemic dose permetrina	**mg/kg bw**	**1,78E-01**	**3,03E-02**	**3,03E-02**	**1,95E-02**
systemic dose propiconazol	**mg/kg bw**	**1,60E-01**	**2,73E-02**	**2,73E-02**	**1,76E-02**
systemic dose IPBC	**mg/kg bw**	**1,60E-01**	**2,73E-02**	**2,73E-02**	**1,76E-02**

Scenario [7] – Automated dipping (industrial)

Task / Scenario :		Automated dipping			
Model used :		Recommendation 6 of BPC Ad hoc (model 19/20 (Fully) automated dipping)		Handling model 1 water based	Handling model 1 water based
dilución producto (worst case)	100,0%				
		TIER 1	TIER 2	TIER 3	TIER 3
Active substance (% w/w) Permetrina	0,250%			Fully automated	Fully automated
Active substance (% w/w) propiconazol	0,225%				
Active substance (% w/w) IPBC	0,225%				
Body weight (kg)	60				
	units	with gloves (including in model)	with gloves (including in model)+ coverall 5%	1/4 (with gloves (including in model)+ coverall 5%)	1/4 (with gloves (including in model)+ coverall 5%+ new gloves)
Potential dermal exposure					
Body					
clothing type					
Indicative value from model	mg/ciclo	8570	8570	8570	8570
duration	ciclos	4	4	4	4
potential dermal deposit	mg	34280,00	34280,00	34280,00	34280,00
clothing penetration from model	%	100%	5%	5%	5%
actual dermal deposit (product)	**mg**	**34280,00**	**1714,00**	**1714,00**	**1714,00**
Hands exposure					
indicative value from model	mg/ciclo	1080,00	1080,00	1080,00	135,00
duration	ciclos	4	4	4	4
potential dermal deposit	mg	4320,00	4320,00	4320,00	540,00
gloves penetration from model	%	100%	100%	100%	100%
actual hand deposit (product)	**mg**	**4320,00**	**4320,00**	**4320,00**	**540,00**
Actual dermal exposure					
product	**mg**	**38600,00**	**6034,00**	**6034,00**	**2254,00**
active substance Permetrina	**mg**	**96,50**	**15,09**	**15,09**	**5,64**
active substance propiconazol	**mg**	**86,85**	**13,58**	**13,58**	**5,07**
active substance IPBC	**mg**	**86,85**	**13,58**	**13,58**	**5,07**
Skin penetration Permetrina	%	70%	70%	70%	70%
Skin penetration propiconazol	%	70%	70%	70%	70%
Skin penetration IPBC	%	70%	70%	70%	70%
active substance via the skin Permetrina	**mg**	**6,76E+01**	**1,06E+01**	**2,64E+00**	**9,86E-01**
active substance via the skin propiconazol	**mg**	**6,08E+01**	**9,50E+00**	**2,38E+00**	**8,88E-01**
active substance via the skin IPBC	**mg**	**6,08E+01**	**9,50E+00**	**2,38E+00**	**8,88E-01**
systemic dose via skin Permetrina	**mg/kg bw**	**1,13E+00**	**1,76E-01**	**4,40E-02**	**1,64E-02**
systemic dose via skin propiconazol	**mg/kg bw**	**1,01E+00**	**1,58E-01**	**3,96E-02**	**1,48E-02**
systemic dose via skin IPBC	**mg/kg bw**	**1,01E+00**	**1,58E-01**	**3,96E-02**	**1,48E-02**

Scenario [8] – Cleaning brush

Limpieza brochas (siguiendo HEEG Opinion 11). **permetrina**

General Exposure Calculator For Washing Out Of Brushes

The systemic dermal exposure is calculated as follows:

Activity and Parameters	Tier 1 No gloves	Tier 2 Gloves	Units
Volume of brush	**200**	**200**	**ml**
Volume of paint remaining on brush after painting (1/8 of 200 ml = 25 ml)	25	25	ml
Density of paint	**1.020**	**1.020**	**g/ml**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	25.50	25.50	g
Concentration of a.s. in paint	**0.250**	**0.250**	**% w/w**
A. Weight of a.s. on brush after painting	637.500	637.500	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	63.750	63.750	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	573.750	573.750	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	31.875	31.875	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore. weight of a.s. available to contaminate the hand (10% of C)	0.3188	0.3188	mg
Penetration of a.s. through gloves	**100**	**10**	**%**
Weight of a.s. on hand	0.31875	0.03188	mg
Dermal absorption of a.s.	**70.00**	**70.00**	**%**
Weight of a.s. entering the body	0.22313	0.02231	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	31.875	31.875	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	0.3188	0.3188	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	28.688	28.688	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0.1594	0.1594	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore. weight of a.s. available to contaminate the hand (10% of F)	0.0159	0.0159	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	0.01594	0.00159	mg
Dermal absorption of a.s.	70.00	70.00	%
Weight of a.s. entering the body	0.01116	0.00112	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (E – F)	0.1594	0.1594	mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	0.0159	0.0159	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	0.1434	0.1434	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	0.0080	0.0080	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore. weight of a.s. available to contaminate the hand (10% of I)	0.0008	0.0008	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	0.00080	0.00008	mg
Dermal absorption of a.s.	70.00	70.00	%
Weight of a.s. entering the body	0.00056	0.00006	mg
Total weight of a.s. entering the body (to 4 decimal places)	**2.35E-01**	**2.35E-02**	**mg**
Body weight	**60**	**60**	**kg**
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE (to 4 decimal places)	**3.91E-03**	**3.91E-04**	**mg a.s./kg bw**

Limpieza brochas (siguiendo HEEG Opinion 11). IPBC

General Exposure Calculator For Washing Out Of Brushes

The systemic dermal exposure is calculated as follows:

Activity and Parameters	Tier 1 No gloves	Tier 2 Gloves	Units
Volume of brush	**200**	**200**	**ml**
Volume of paint remaining on brush after painting (1/8 of 200 ml = 25 ml)	25	25	ml
Density of paint	**1.020**	**1.020**	**g/ml**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	25.50	25.50	g
Concentration of a.s. in paint	**0.225**	**0.225**	**% w/w**
A. Weight of a.s. on brush after painting	573.750	573.750	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	57.375	57.375	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	516.375	516.375	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	28.688	28.688	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore. weight of a.s. available to contaminate the hand (10% of C)	0.2869	0.2869	mg
Penetration of a.s. through gloves	**100**	**10**	**%**
Weight of a.s. on hand	0.28688	0.02869	mg
Dermal absorption of a.s.	**70.00**	**70.00**	**%**
Weight of a.s. entering the body	0.20081	0.02008	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	28.688	28.688	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	0.2869	0.2869	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	25.819	25.819	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0.1434	0.1434	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore. weight of a.s. available to contaminate the hand (10% of F)	0.0143	0.0143	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	0.01434	0.00143	mg
Dermal absorption of a.s.	70.00	70.00	%
Weight of a.s. entering the body	0.01004	0.00100	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (E – F)	0.1434	0.1434	mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	0.0143	0.0143	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	0.1291	0.1291	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	0.0072	0.0072	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore. weight of a.s. available to contaminate the hand (10% of I)	0.0007	0.0007	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	0.00072	0.00007	mg
Dermal absorption of a.s.	70.00	70.00	%
Weight of a.s. entering the body	0.00050	0.00005	mg
Total weight of a.s. entering the body (to 4 decimal places)	**0.2114**	**0.0211**	**mg**
Body weight	**60**	**60**	**kg**
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE (to 4 decimal places)	**3.52E-03**	**3.52E-04**	**mg a.s./kg bw**

Limpieza brochas (siguiendo HEEG Opinion 11). **propiconazol**

General Exposure Calculator For Washing Out Of Brushes

The systemic dermal exposure is calculated as follows:

Activity and Parameters	Tier 1 No gloves	Tier 2 Gloves	Units
Volume of brush	**200**	**200**	**ml**
Volume of paint remaining on brush after painting (1/8 of 200 ml = 25 ml)	25	25	ml
Density of paint	**1.020**	**1.020**	**g/ml**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	25.50	25.50	g
Concentration of a.s. in paint	**0.225**	**0.225**	**% w/w**
A. Weight of a.s. on brush after painting	573.750	573.750	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	57.375	57.375	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	516.375	516.375	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	28.688	28.688	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore. weight of a.s. available to contaminate the hand (10% of C)	0.2869	0.2869	mg
Penetration of a.s. through gloves	**100**	**10**	**%**
Weight of a.s. on hand	0.28688	0.02869	mg
Dermal absorption of a.s.	**70.00**	**70.00**	**%**
Weight of a.s. entering the body	0.20081	0.02008	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	28.688	28.688	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	0.2869	0.2869	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	25.819	25.819	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0.1434	0.1434	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore. weight of a.s. available to contaminate the hand (10% of F)	0.0143	0.0143	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	0.01434	0.00143	mg
Dermal absorption of a.s.	70.00	70.00	%
Weight of a.s. entering the body	0.01004	0.00100	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (E – F)	0.1434	0.1434	mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	0.0143	0.0143	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	0.1291	0.1291	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	0.0072	0.0072	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore. weight of a.s. available to contaminate the hand (10% of I)	0.0007	0.0007	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	0.00072	0.00007	mg
Dermal absorption of a.s.	70.00	70.00	%
Weight of a.s. entering the body	0.00050	0.00005	mg
Total weight of a.s. entering the body (to 4 decimal places)	**0.2114**	**0.0211**	**mg**
Body weight	**60**	**60**	**kg**
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE (to 4 decimal places)	**3.52E-03**	**3.52E-04**	**mg a.s./kg bw**

Scenario [9] - Cleaning spray equipment

Task / Scenario :	Spraying cleaning		
	Recomendation 4 of BPC Ad hoc ("Cleaning of		
	Spray equipment is antifouling use (PT21) see		
Model used :	BPF recommendation no.6		
dilución producto (worst case)	100.0%	TIER 1	TIER 2
Active substance (% w/w) Permetrina	0.250%		
Active substance (% w/w) propiconazol	0.225%		
Active substance (% w/w) IPBC	0.225%		
Body weight (kg)	60	with PPE	with gloves (including in model)+ coverall
	units		
Potential dermal exposure			
Body exposure			
clothing type			
Indicative value from model	mg/min	19.67	19.67
duration	min	20	20
potential dermal deposit	mg	393.40	393.40
clothing penetration from model	%	100%	5%
actual dermal deposit (product)	**mg**	**393.40**	**19.67**
Hands exposure			
indicative value from model	mg/min	35.69	35.69
duration	min	20	20
potential dermal deposit	mg	713.80	713.80
gloves penetration from model	%	100%	10%
actual hand deposit (product)	**mg**	**713.80**	**71.38**
Actual dermal exposure			
product	**mg**	**1107.20**	**91.05**
active substance permetrina	**mg**	**2.77**	**0.23**
active substance propiconazol	**mg**	**2.49**	**0.20**
active substance IPBC	**mg**	**2.49**	**0.20**
Skin penetration permetrina	%	70%	70%
Skin penetration propiconazol	%	70%	70%
Skin penetration IPBC	%	70%	70%
active substance via the skin permetrina	**mg**	**1.94E+00**	**1.59E-01**
active substance via the skin propiconazol	**mg**	**1.74E+00**	**1.43E-01**
active substance via the skin IPBC	**mg**	**1.74E+00**	**1.43E-01**
systemic dose via skin permetrina	**mg/kg bw**	**3.23E-02**	**2.66E-03**
systemic dose via skin propiconazol	**mg/kg bw**	**2.91E-02**	**2.39E-03**
systemic dose via skin IPBC	**mg/kg bw**	**2.91E-02**	**2.39E-03**
Exposure by inhalation			
indicative value from model	mg/m3	0	0
duration	min	0	0
inhalation rate	m3/min	2.08E-02	2.08E-02
inhaled volume	m3	0.0	0.0
potential inhaled product	mg	0.0	0.0
mitigation factor by RPE	value	1	1
inhaled product through RPE	**mg**	0	0
active substance through RPE permetrina	**mg**	0.00E+00	0.00E+00
active substance through RPE propiconazol	**mg**	0.00E+00	0.00E+00
active substance through RPE IPBC	**mg**	0.00E+00	0.00E+00
systemic inhaled dose (ai) permetrina	**mg/kg bw**	**0.00E+00**	**0.00E+00**
systemic inhaled dose (ai) propiconazol	**mg/kg bw**	**0.00E+00**	**0.00E+00**
systemic inhaled dose (ai) IPBC	**mg/kg bw**	**0.00E+00**	**0.00E+00**
Dose			
total	**mg**	**1.938**	**0.159**
systemic dose permetrina	**mg/kg bw**	**3.23E-02**	**2.66E-03**
systemic dose propiconazol	**mg/kg bw**	**2.91E-02**	**2.39E-03**
systemic dose IPBC	**mg/kg bw**	**2.91E-02**	**2.39E-03**

Scenario [10] –Sawing and Sanding treated wood by professional users

Professional sanding treated wood	Permethin	Propiconazol	IPBC	Unidades
AS concentration	0.250%	0.225%	0.225%	
Inhalation				
Volume of wood to be sanded in 1h	4.00E+03	4.00E+03	4.00E+03	cm3
Area of wood to be sanded in 1h surface area	4.03E+03	4.03E+03	4.03E+03	cm2
Rate of product absorbed in wood (dose)	2.00E-01	2.00E-01	2.00E-01	l/m2
Amount of product absorbed in wood	8.06E-02	8.06E-02	8.06E-02	l
Product density	1.02E+00	1.02E+00	1.02E+00	kg/l
Amount of product absorbed in wood sanded in 1h	2.06E-05	2.06E-05	2.06E-05	kg/cm3
Amount of substance absorbed in wood sanded in 1h	5.14E-08	4.63E-08	4.63E-08	kg/cm3 wood
Wood density	4.00E+02	4.00E+02	4.00E+02	mg/cm3
Dust concentration in air (occupational exposure limit for wood dust)	5	5	5	mg/m3
Inhalation rate	1.25	1.25	1.25	m3/h
Exposure duration	6	6	6	h
Dust inhaled	37.5	37.5	37.5	mg/day
Amount of active substance inhaled rate	4.82E-03	4.34E-03	4.34E-03	mg/day
Body weight	60	60	60	kg
Inhalation exposure	**8.03E-05**	**7.23E-05**	**7.23E-05**	**mg/kg/day**
Dermal				
Application rate	2.04E+01	2.04E+01	2.04E+01	mg/cm2
Percentage dislodgeable (%)	2%	2%	2%	
Hand surface	420	420	420	cm2
Transfer to hands (%)	20%	20%	20%	
A.S. Contamination of hand surface	0.0857	0.0771	0.0771	mg a.s.
Dermal absorption (%)	70.00%	70.00%	70.00%	
Dermal exposure	**1.00E-03**	**9.00E-04**	**9.00E-04**	mg a.s/kg bw/d
Total Exposure	1.08E-03	9.72E-04	9.72E-04	mg a.s/kg bw/d

Scenario [11] –Sawing and Sanding treated wood by non-professional users

Professional sanding treated wood	Permethin	Propiconazol	IPBC	Unidades
AS concentration	0.250%	0.23%	0.23%	
Inhalation				
Volume of wood to be sanded in 1h	4.00E+03	4.00E+03	4.00E+03	cm3
Area of wood to be sanded in 1h surface area	4.03E+03	4.03E+03	4.03E+03	cm2
Rate of product absorbed in wood (2l/4m2)	2.00E-01	2.00E-01	2.00E-01	l/m2
Amount of product absorbed in wood	8.06E-02	8.06E-02	8.06E-02	l
Product density	1.02E+00	1.02E+00	1.02E+00	kg/l
Amount of product absorbed in wood sanded in 1h	2.06E-05	2.06E-05	2.06E-05	kg/cm3
Amount of substance absorbed in wood sanded in 1h	5.14E-08	4.63E-08	4.63E-08	kg/cm3 wood
Wood density	4.00E+02	4.00E+02	4.00E+02	mg/cm3
Dust concentration in air (occupational exposure limit for wood dust)	5	5	5	mg/m3
Inhalation rate	1.25	1.25	1.25	m3/h
Exposure duration	1	1	1	h
Dust inhaled	6.25	6.25	6.25	mg/day
Amount of active substance inhaled rate	8.03E-04	7.23E-04	7.23E-04	mg/day
Body weight	60	60	60	kg
Inhalation exposure	**1.34E-05**	**1.20E-05**	**1.20E-05**	**mg/kg/day**
Dermal				
Application rate	2.04E+01	2.04E+01	2.04E+01	mg/cm2
Percentage dislodgeable (%)	2%	2%	2%	
Hand surface	420	420	420	cm2
Transfer to hands (%)	20%	20%	20%	
A.S. Contamination of hand surface	0.0857	0.0771	0.0771	mg a.s.
Dermal absorption (%)	70.00%	70.00%	70.00%	
Dermal exposure	**1.00E-03**	**9.00E-04**	**9.00E-04**	mg a.s/kg bw/d
Total Exposure	1.01E-03	9.12E-04	9.12E-04	mg a.s/kg bw/d

Scenario [12] – Infant chewing wood off-cut

Infant chewing wood composites chips (acute)	permethin	Propiconazol	IPBC	Unidades
AS concentration	0.250%	0.23%	0.23%	
Oral				
Application rate	2.00E+01	2.00E+01	2.00E+01	mg/cm2
A.S.Concentration in treated wood	5.00E-02	4.50E-02	4.50E-02	a.s.mg/cm2
Extraction by chewing	10%	10%	10%	
Size of wood composites chip	16	16	16	cm2
Oral absorption	100%	100%	100%	
Body weight	8	8	8	kg
Systemic exposure	1.00E-02	9.00E-03	9.00E-03	mg/kg bw/d

Scenario [13] – aying on playground structure outdoors and mouthing

Toddler playing on playground structure outdoors and	permethin	Propiconazol	IPBC	Unidades
AS concentration	0.250%	0.23%	0.23%	
Body weight	10	10	10	kg
Dermal				
Application rate	2.00E+01	2.00E+01	2.00E+01	mg/cm2
A.S.Concentration in treated wood	5.00E-02	4.50E-02	4.50E-02	a.s.mg/cm2
Contact surface	2.31E+02	2.31E+02	2.31E+02	cm2
Contaminated area (%)	20%	20%	20%	
Dislogeable fraction (%)	2%	2%	2%	
Amount of a.s on hand	4.63E-02	4.17E-02	4.17E-02	mg
Dermal absorption (%)	70%	70%	70%	
Systemic hand exposure	3.24E-02	2.92E-02	2.92E-02	mg
Systemic dermal exposure	3.24E-03	2.92E-03	2.92E-03	mg/kg bw/day
Oral				
Hand surface area mouthing	5.00E+01	5.00E+01	5.00E+01	cm²
Extraction by chewing	10%	10%	10%	
Oral absorption	100%	100%	100%	
Systemic oral exposure	2.50E-01	2.25E-01	2.25E-01	mg
Systemic oral exposure	2.50E-02	2.25E-02	2.25E-02	mg/kg bw/day
Total exposure				
Systemic total exposure	2.82E-02	2.54E-02	2.54E-02	mg/kg bw/day

Scenario [14] – inhalation residues

		Exposición inhalatoria propiconazol	Adultos	Niños	Toodler	Bebés	Unidades
Presión de vapor s.a.	5.60E-05	Presión de vapor s.a.	5.60E-05	5.60E-05	5.60E-05	5.60E-05	Pa
Pm de s.a.	342.2	Pm de s.a.	342.2	342.2	342.2	342.2	g/mol
Constante de gases	831.451	Constante de gases	831.451	831.451	831.451	831.451	J/mol K
Temperatura (ºK)	298	Temperatura (ºK)	298	298	298	298	K
AEL long term (mg a.s./	0.08	Tasa de inhalación	16	12	8	5.4	m3/día
Constante	0.328	Pc	60	23.9	10	8	Kg
Resultado	7.86E-02	Concentración del vapor saturado	7.73E-08	7.73E-08	7.73E-08	7.73E-08	g/m3
Despreciable	**si**	Exposición inhalatoria	1.24E-03	9.28E-04	6.19E-04	4.18E-04	mg/día
		Exposición sistémica inhalatoria	**2.06E-05**	**3.88E-05**	**6.19E-05**	**5.22E-05**	**mg/kg pc/día**
		Exposición inhalatoria IPBC	Adultos	Niños	Toodler	Bebés	Unidades
Presión de vapor s.a.	4.50E-03	Presión de vapor s.a.	4.50E-03	4.50E-03	4.50E-03	4.50E-03	Pa
Pm de s.a.	281.1	Pm de s.a.	281.1	281.1	281.1	281.1	g/mol
Constante de gases	831.451	Constante de gases	831.451	831.451	831.451	831.451	J/mol K
Temperatura (ºK)	298	Temperatura (ºK)	298	298	298	298	K
AEL long term (mg a.s./	0.2	Tasa de inhalación	16	12	8	5.4	m3/día
Constante	0.328	Pc	60	23.9	10	8	Kg
Resultado	2.07E+00	Concentración del vapor saturado	5.11E-06	5.11E-06	5.11E-06	5.11E-06	g/m3
Despreciable	**no**	Exposición inhalatoria	8.17E-02	6.13E-02	4.08E-02	2.76E-02	mg/día
		Exposición sistémica inhalatoria	**1.36E-03**	**2.56E-03**	**4.08E-03**	**3.45E-03**	**mg/kg pc/día**
		Exposición inhalatoria permetrin	Adultos	Niños	Toodler	Bebés	Unidades
Presión de vapor s.a.	2.16E-06	Presión de vapor s.a.	2.16E-06	2.16E-06	2.16E-06	2.16E-06	Pa
Pm de s.a.	391.29	Pm de s.a.	391.29	391.29	391.29	391.29	g/mol
Constante de gases	831.451	Constante de gases	831.451	831.451	831.451	831.451	J/mol K
Temperatura (ºK)	298	Temperatura (ºK)	298	298	298	298	K
AEL long term (mg a.s./	0.05	Tasa de inhalación	16	12	8	5.4	m3/día
Constante	0.328	Pc	60	23.9	10	8	Kg
Resultado	5.54E-03	Concentración del vapor saturado	3.41E-09	3.41E-09	3.41E-09	3.41E-09	g/m3
Despreciable	**si**	Exposición inhalatoria	5.46E-05	4.09E-05	2.73E-05	1.84E-05	mg/día
		Exposición sistémica inhalatoria	**9.10E-07**	**1.71E-06**	**2.73E-06**	**2.30E-06**	**mg/kg pc/día**

Scenario [15] – Laundering clothes

Task / Scenario :	laundering work cloths	
Model used :		
dilución producto	100%	**TIER 1**
Active substance (% w/w) permetrina	0.250%	
Active substance (% w/w) tebuconazol		
Active substance (% w/w) propiconazol	0.225%	
Active substance (% w/w) IPBC	0.225%	
Body weight (kg)	60	without EPI
	units	
Potential dermal exposure		
Hands exposure		
indicative value from model*	mg/día	677.000
potential dermal deposit	mg	33.85
surface medium-sized coverall	cm2	22700
actual deposit (product)	**mg/cm2**	**0.00149**
Actual dermal exposure		
active substance permetrina	**mg/cm2**	**0.000004**
active substance propiconazol	**mg/cm2**	**0.000003**
active substance IPBC	**mg/cm2**	**0.000003**
Skin penetration permetrina	%	70%
Skin penetration propiconazol	%	70%
Skin penetration IPBC	%	70%
active substance via the skin permetrina	**mg/cm2**	**2.61E-06**
active substance via the skin propiconazol	**mg/cm2**	**2.35E-06**
active substance via the skin IPBC	**mg/cm2**	**2.35E-06**
Skin surface area in contact	**cm2**	1640
Transfer coefficient	**%**	30%
Dose		
systemic dose permetrina	**mg/kg bw**	**2.14E-05**
systemic dose propiconazol	**mg/kg bw**	**1.93E-05**

3.2.1 Environmental Risk Assessment

Outputs from EUSES


Propiconazole_PT8_IRUXIL Family - PAR.xlsx


Permethrin_PT8_IRUXIL Family - PAR.xlsx


IPBC_PT8_IRUXIL Family - PAR.xlsx

Outputs from Simple Treat 4.0:


IPBC.xlsx


Permethrin.xlsx


Propiconazole.xlsx


PBC.xlsx

3.3 New information on the active substance

No new data has been submitted.

3.4 Residue behaviour

No new data has been submitted.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[16]All efficacy

All efficacy test information is summarized in the efficacy table, section 2.2.5.5.

3.6 Other

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