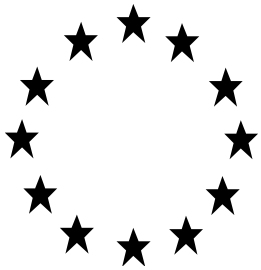
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



Product family identifier in R4BP	Primer TIP
Product type(s):	8 (Wood protection)
Active ingredient(s):	Tebuconazole, IPBC, Permethrin
Case No. in R4BP	BC-NF023903-46
Asset No. in R4BP	DE-0015815-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/08.00017 710-05-08-00017-00-00-00-0000
Date	10.08.2022 (initial assessment)

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1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use products of the product family Primer TIP with the active substances tebuconazole (0.2 % w/w), IPBC (0.5 % w/w) and permethrin (0.06 % w/w) are used by professional and non-professional users for the preventive protection of wood (product-type 8).

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled.

Please find detailed information on the uses appropriate for authorisation and on directions for use of the products in chapter 2.3.

A classification according to Regulation (EC) No 1272/2008[2] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3) has taken the following into consideration:

1. The conclusions and recommendations of the Danish Assessment Report for the approval of the active substance tebuconazole including the “elements to be taken into account by Member States when authorising products” as requested by the Danish CA.
2. The conclusions and recommendations of the Danish Assessment Report for the approval of the active substance IPBC including the “elements to be taken into account by Member States when authorising products” as requested by the Danish CA.
3. The conclusions and recommendations of the Irish Assessment Report for the approval of the active substance permethrin including the “elements to be taken into account by Member States when authorising products” as requested by the Irish CA.
4. The specific provisions from Inclusion Directive for the active substance tebuconazole (Commission Directive 2008/86/EG).

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

5. The specific provisions from Inclusion Directive for the active substance IPBC (Commission Directive 2008/79/EG).
6. The specific provisions from Inclusion Directive for the active substance permethrin (COMMISSION IMPLEMENTING REGULATION 1090/2014).

Approval of the active substance

The active substances tebuconazole, IPBC and permethrin are included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- Tebuconazole
  - In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
  - In addition, products cannot be authorised for the in situ treatment of wood outdoors or for wood that will be in continuous contact with water unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures
- IPBC
  - In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.
  - In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/ or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hardstanding to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
- Permethrin
  - For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
  - Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular: labels and, where provided, safety data sheets of products

authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hardstanding, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

- Products shall not be authorised for wood that will be exposed to frequent weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 19 and Annex VI of Regulation (EU) No 528/2012, if necessary by the application of appropriate risk mitigation measures.
- Products shall not be authorized for treatment of outdoor constructions near or above water or for the treatment of wood that will be used for outdoor constructions near or above water, unless data are submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures.

Composition and formulation

The ready-to-use solvent based products contain the active substances tebuconazole, IPBC and permethrin. “Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics” has been identified as substance of concern. Please refer to chapter 2.2.2 for further information.
Please refer to the confidential annex for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

Physical-chemical hazard(s) were not identified (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The products have been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.3. Please find more information on efficacy of the products in chapter 3.5.

Risk assessment for human health

The substance Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics has been identified as substance of concern. However, the hazards resulting from the substance of concern can be sufficiently reduced to acceptable levels by additional risk mitigation measures.
Accordingly, the human health risk assessment for this product family is based on the active substance(s) and substance of concern (SoC).

A human health risk assessment has been carried out for non-professional/professional/industrial use of the products (see chapter 3.6) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to non-professional/professional/industrial users, bystanders and residents. Regarding non-professional/professional/industrial users health protection, there are no objections against the intended uses if the directions for use according to chapter 2.3 are followed.

Risk assessment for the environment

Since no relevant substance of concern has been identified the risk assessment for the environment for this product family is based on the active substance(s).
A risk assessment for the environment has been carried out for non-professional/professional/industrial use of the products (see chapter 3.8) for all intended uses (see chapter 3).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk for the environment if the directions for use according to chapter 2.3 are followed.

Comparative Assessment

Since the active substance tebuconazole has been identified as a candidate for substitution (see also chapter 2.2.3) a comparative assessment has been necessary (see chapter 3.10). The corresponding Comparative Assessment Report was forwarded to ECHA on 17.07.2020.
The German CA concludes that without the products of the product family - containing tebuconazole, IPBC and permethrin - there is not an adequate chemical diversity.

Addendum after COMMISSION IMPLEMENTING DECISION (EU) 2022/835: According to the information provided by ECHA nowadays (after COM taking its decision in accordance with Article 36 BPR) no longer the active substance Tebuconazole but the Permethrin fulfils the substitution criteria (see chapter 2.2.3 for details). However, this does not change the conclusion of the comparative assessment.

For the comparative assessment Tebuconazol and Permethrin were taken into account. Currently, there are no alternatives in order to replace the products of the BPF Primer TIP. This is because possible

alternatives feature only fungicidal or insecticidal activity while the products of the BPF under authorisation include both the fungicidal active substances (Tebuconazol and IPBC) and the insecticidal active substance permethrin.

2 Summary of the product family assessment

2.1 Administrative information (first information level)

2.1.1 Identifier in R4BP

Primer TIP

2.1.2 Product type(s)

8 (Wood protection)

2.1.3 Manufacturer(s) of the product(s)

Name of manufacturer	LANXESS Deutschland GmbH Material Protection Products
Address of manufacturer	Kennedyplatz 1 D-50569 Köln Germany
Location of manufacturing sites	LANXESS Deutschland GmbH Material Protection Products CHEMPARK, Building Q18 51369 Leverkusen, Germany

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

Active substance	Tebuconazole
Name of manufacturer	Bayer Corp., Agriculture Division
Address of manufacturer	P.O. Box 4913 Hawthorn Road MO 64120-0013 Kansas City USA
Location of manufacturing sites	Hawthorn Road MO 64120-0013 Kansas City USA
Name of manufacturer	Jiangsu Sword Agrochemicals Co., Ltd.
Address of manufacturer	1008, East Guanhua Road

	Postal Code: 224700, Jiangsu, Jianhu County China
Location of manufacturing sites	Jiangsu Sword Agrochemicals Co., Ltd. Binhai Economic Development Zone, Coastal Industrial Park, Binhai County, Jiangsu, P.C. 224500 China

Active substance	IPBC
Name of manufacturer	Shanghai Hui Long Chemicals Co., Ltd.
Address of manufacturer	ZIP: 201815 Dengta Jiazhu Rd. Jiading – district Shanghai China
Location of manufacturing sites	ZIP: 201815 Dengta Jiazhu Rd. Jiading – district Shanghai China
Name of manufacturer	Troy Chemical Europe BV
Address of manufacturer	Uiverlaan 12-E NL 3145 XN Maassluis Netherlands
Location of manufacturing sites	Troy Rheinland GmbH Industriepark 23 D 56593 Horhausen Germany
	Troy Corporation One Avenue L Newark 07105 New Jersey USA

Active substance	Permethrin
Name of manufacturer	Bayer Environmental Science SAS
Address of manufacturer	F-69266 Lyon Cedex 09 France
Location of manufacturing sites	Bayer Vapi Private Limited Plot # 306/3 II Phase, GIDC Vapi – 396 195 Gujarat

	India

2.2 Composition and formulation (first information level)

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Tebuconazole	(RS)-1-p-chlorophenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentan-3-ol	Active substance	107534-96-3	403-640-2	0.2	0.2
IPBC	3-iodo-2-propynyl butylcarbamate	Active substance	55406-53-6	259-627-5	0.5	0.5
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.06	0.06
-	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics	Non-active substance	-	Registration no.: 01-2119457273-39-xxxx	85.71	88.6

- According to the information provided the products in the contain no nanomaterial – as all the products are liquids - as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on technical equivalence

- Are the sources of the active substance(s) the same as the ones 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 ☒ (Jiangsu Sword Agrochemicals Co., Ltd. and Shanghai Hui Long Chemicals Co, Ltd.)

The sources are either the reference sources in the BPD/R dossiers for the actives or have been assessed as technically equivalent to the reference sources:

TAP-D-1252239-29-00/F (Tebuconazole, JIANGSU SWORD AGROCHEMICALS CO.,LTD.)

TAP-D-1255923-24-00/F (IPBC, Shanghai Hui Long Chemicals Co., Ltd, Zip: 201815, Dengta Jiazhu Rd. Jiading, District Shanghai)

2.2.1 Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore, no corresponding regulatory measures are required.

2.2.2 Information on the substance(s) of concern

The following substance(s) of concern was/were identified:

- Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics

➢ (Further) information on the substance(s) of concern is provided in the confidential annex.

2.2.3 Candidate(s) for substitution

The following candidate(s) for substitution was/were identified:

- Permethrin[3]

The following criteria for substitution are met:

- Permerthrin: Toxic, persistent

Permetrhin is not considered a candidate meeting the exclusion criteria according to Article 5(1) BPR.

3 According to the information provided by ECHA nowadays (after COM taking its decision in accordance with Article 36 BPR) no longer the active substance Tebuconazole but the Permethrin fulfils the substitution criteria . However, this does not change the conclusion of the comparative assessment.

2.2.4 Type(s) of formulation

Ready to use: Liquid

2.3 Meta SPC(s) (second information level)

2.3.1 Meta SPC No. 01

2.3.1.1 Administrative information

2.3.1.1.1 Meta SPC identifier

01

2.3.1.1.2 Suffix to the authorisation number

01

2.3.1.1.3 Product type(s) of the products in the meta SPC

8 (Wood protection)

2.3.1.2 Composition and formulation of the products within the meta SPC

2.3.1.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Table 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Tebuconazole	(RS)-1-p-chlorophenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentan-3-ol	Active substance	107534-96-3	403-640-2	0.2	0.2
IPBC	3-iodo-2-propynyl butylcarbamate	Active substance	55406-53-6	259-627-5	0.5	0. 5
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-	Active substance	52645-53-1	258-067-9	0.06	0.06

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
	dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate					
-	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics	Non-active substance	-	Registration no.: 01-2119457273-39-xxxx	86.39	88.05

2.3.1.3 Classification and Labelling according to the Regulation (EC) 1272/2008

Besides the active substances tebuconazole, IPBC and permethrin the substance of concern affects the classification of the biocidal product.

The current harmonised classification of the active substance **tebuconazole** is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):

Acute Tox. 4	H302 Harmful if swallowed.
Repr. 2	H361d Suspected of damaging the unborn child.
Aquatic Acute 1 (M=1)	H400 Very toxic to aquatic life
Aquatic Chronic 1 (M=10)	H410 Very toxic to aquatic life with long-lasting effects

The current harmonised classification of the active substance **IPBC** is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation): The classification and labeling of IPBC is included in Annex VI of the CLP regulation (6th ATP to the CLP Regulation; Commission Regulation (EU) No 605/2014 of 5 June 2014).

Acute Tox. 4	H302 Harmful if swallowed.
Acute Tox. 3	H331 Toxic if inhaled.
Eye Dam.1	H318 Causes serious eye damage.
Skin Sens. 1	H317 May cause an allergic reaction.
STOT RE 1	H372 Causes damage to organs (larynx) through prolonged or repeated exposure.
Aquatic Acute 1 (M=10)	H400 Very toxic to aquatic life
Aquatic Chronic 1 (M=1)	H410 Very toxic to aquatic life with long-lasting effects

The current harmonised classification of the active substance **permethrin** is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Acute Tox. 4	H302 Harmful if swallowed.
Acute Tox. 4	H332 Harmful if inhaled.
Skin Sens. 1	H317 May cause an allergic reaction.
Aquatic Acute 1 (M=1000)	H400 Very toxic to aquatic life
Aquatic Chronic 1 (M=1000)	H410 Very toxic to aquatic life with long-lasting effects

Therefore, a classification of the biocidal product family pursuant to the Regulation (EC) 1272/2008 is required, which results in:
H400 Very toxic to aquatic life
H410 Very toxic to aquatic life with long lasting effects

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.3.1.4 and 2.3.1.5.

Table 3

Classification Hazard classes, Hazard categories	**Hazard statements**	
Asp. 1	H304 - May be fatal if swallowed and enters airways	
Aquatic Acute 1	H400 – Very toxic to aquatic life.	
Aquatic Chronic 1	H410 – Very toxic to aquatic life with long lasting effects.	
Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS08	
	GHS09	
Signal word	-	Danger
Hazard statements	H304	May be fatal if swallowed and enters airways.
	H410	Very toxic to aquatic life with long lasting effects.
Supplemental hazard information	EUH066	Repeated exposure may cause skin dryness or cracking
Supplemental label elements	EUH208	Contains IPBC. May produce an allergic reaction
Precautionary statements	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.
	P260	Do not breathe spray.
	P262	Do not get in eyes, on skin, or on clothing.
	P273	Avoid release to the environment.
	P301 + P330 + P331	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Do NOT induce vomiting.
	P391	Collect spillage.
	P405	Store locked up.
	P501	Dispose of content/container a recognised to waste disposal facility.
Note	-	

According to Article 35 Regulation (EC) No 1272/2008 the packaging – which is supplied to the general public and contains a substance or mixture which meets the requirements in section 3.1.1 of Annex II - shall have a **child-resistant fastening**.

According to Article 35 Regulation (EC) No 1272/2008 the packaging – which is supplied to the general public and contains a substance or mixture which meets the requirements in section 3.2.1 of Annex II - shall bear a **tactile warning of danger**.

2.3.1.4 Use(s) of the products appropriate for authorisation[4]

2.3.1.4.1 Use 1 appropriate for authorisation – brushing/rolling (prof. user)

Product Type(s)	8
Where relevant, an exact description of the use	Wood protection
Target organism(s) (including development stage)	Wood destroying fungi (brown and white rot fungi); wood discolouring fungi; wood boring insects (shown by *Hylotrupes bajulus*)
Field(s) of use	use class 2 and 3 (not in direct contact to soil or surface water), (incl. windows and exterior doors (inner and outer parts)); preventive treatment
Application method(s)	Brush/roll
Application rate(s) and frequency	Softwood: 160 ml/m², 130 g/m²; Hardwood: 225 ml/m², 180 g/m², To be applied by 2-3 coats.
Category(ies) of users	Professional
Pack sizes and packaging material	Up to 25 L (Coated tin cans or HDPE)

2.3.1.4.1.1 Use-specific instructions for use

Application must be conducted by professionals only.

2.3.1.4.1.2 Use-specific risk mitigation measures

1) Use only outdoors or in a well-ventilated area.
2) Keep children and pets away from treated surfaces until dried.
3) Do not apply near bodies of surface water or in the area of water protection zones.
4) During product application to timbers and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.
5) The products of the BPF Primer TIP contain hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics (CAS-No.: -), for which a German Occupational Exposure Level (OEL) according to the German Technical Rules for Hazardous Substances (TRGS 900) is in force.

4 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

6) Provide adequate ventilation (industrial ventilation or cross ventilation by keeping windows and doors open, air change rate at least 5 /h).
7) The wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by brushing and rolling.
The wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for subsequent manual processing of the freshly treated timber.
This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

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

None

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

None

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

None

2.3.1.4.2 Use 2 appropriate for authorisation – brushing/rolling (non-prof. user)

Product Type(s)	8
Where relevant, an exact description of the use	Wood protection
Target organism(s) (including development stage)	Wood destroying fungi (brown and white rot fungi); wood discolouring fungi; wood boring insects (shown by *Hylotrupes bajulus*)
Field(s) of use	use class 2 and 3 (not in direct contact to soil or surface water), (incl. windows and exterior doors (inner and outer parts)); preventive treatment
Application method(s)	Brush/roll
Application rate(s) and frequency	Softwood: 160 ml/m², 130 g/m²; Hardwood: 225 ml/m², 180 g/m², To be applied by 2-3 coats
Category(ies) of users	Non-professional
Pack sizes and packaging material	Up to 5 L (Coated tin cans or HDPE)

2.3.1.4.2.1 Use-specific instructions for use

None

2.3.1.4.2.2 Use-specific risk mitigation measures

1) Use only outdoors or in a well-ventilated area. 2) Keep children and pets away from treated surfaces until dried. 3) Do not apply near bodies of surface water or in the area of water protection zones. 4) During product application to timbers and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

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

None

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

None

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

None

2.3.1.4.3 Use 3 appropriate for authorisation – Automatic dipping

Product Type(s)	8
Where relevant, an exact description of the use	Wood protection
Target organism(s) (including development stage)	Wood destroying fungi (brown and white rot fungi); wood discolouring fungi; wood boring insects (shown by *Hylotrupes bajulus*)
Field(s) of use	use class 2 and 3 (not in direct contact to soil or surface water), (incl. windows and exterior doors (inner and outer parts)); preventive treatment
Application method(s)	Automatic dipping
Application rate(s) and frequency	Softwood: 160 ml/m², 130 g/m²; Hardwood: 225 ml/m², 180 g/m², To be applied by 1-2 coats
Category(ies) of users	Professional and industrial
Pack sizes and packaging material	Up to 25 L, 200L, 1000L (Coated tin cans or HDPE)

2.3.1.4.3.1 Use-specific instructions for use

Application must be conducted by professionals and industrial user only.

2.3.1.4.3.2 Use-specific risk mitigation measures

1) 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).

2) Application by professionals must be conducted within a contained area (indoors or outdoors under roof).
3) Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal.
4) Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber.
5) The products of the BPF Primer TIP contain hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics (CAS-No.: -), for which a German Occupational Exposure Level (OEL) according to the German Technical Rules for Hazardous Substances (TRGS 900) is in force.
6) The product may only be loaded with an automatic dosing system.
7) The wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by automated dipping.
   The wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for subsequent manual processing of the freshly treated timber.
   This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

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

None

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

None

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

None

2.3.1.4.4 Use 4 appropriate for authorisation – Manual dipping

Product Type(s)	8
Where relevant, an exact description of the use	Wood protection
Target organism(s) (including development stage)	Wood destroying fungi (brown and white rot fungi); wood discolouring fungi; wood boring insects (shown by *Hylotrupes bajulus*)
Field(s) of use	use class 2 and 3 (not in direct contact to soil or surface water), (incl. windows and exterior doors (inner and outer parts)); preventive treatment
Application method(s)	Manual dipping
Application rate(s) and frequency	Softwood: 160 ml/m², 130 g/m²; Hardwood: 225 ml/m², 180 g/m², To be applied by 1-2 coats
Category(ies) of users	Professional and industrial
Pack sizes and packaging material	Up to 25 L, 200L, 1000L (Coated tin cans or HDPE)

2.3.1.4.4.1 Use-specific instructions for use

Application must be conducted by professionals and industrial user only.

2.3.1.4.4.2 Use-specific risk mitigation measures

1) 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).
2) Application by professionals must be conducted within a contained area (indoors or outdoors under roof).
3) Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal.
4) Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber.
5) The products of the BPF Primer TIP contain hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics (CAS-No.: -), for which a German Occupational Exposure Level (OEL) according to the German Technical Rules for Hazardous Substances (TRGS 900) is in force.

6) The wearing of chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and coverall of at least type 6 as specified in European Standard EN 13034 is required for application by manual dipping. The wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for subsequent manual processing of the freshly treated timber. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

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

None

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

None

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

None

2.3.1.4.5 Use 5 appropriate for authorisation – Deluge (Spraying in closed devices)

Product Type(s)	8
Where relevant, an exact description of the use	Wood protection
Target organism(s) (including development stage)	Wood destroying fungi (brown and white rot fungi); wood discolouring fungi; wood boring insects (shown by *Hylotrupes bajulus*)
Field(s) of use	use class 2 and 3 (not in direct contact to soil or surface water), (incl. windows and exterior doors (inner and outer parts)); preventive treatment
Application method(s)	Deluge (Spraying in closed devices)
Application rate(s) and frequency	Softwood: 160 ml/m², 130 g/m²; Hardwood: 225 ml/m², 180 g/m², To be applied by 1-2 coats
Category(ies) of users	Professional and industrial
Pack sizes and packaging material	Up to 25 L, 200L, 1000L (Coated tin cans or HDPE)

2.3.1.4.5.1 Use-specific instructions for use

Application must be conducted by professionals and industrial user only.

2.3.1.4.5.2 Use-specific risk mitigation measures

1) 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).
2) Application by professionals must be conducted within a contained area (indoors or outdoors under roof).
3) Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal.
4) Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber.
5) The products of the BPF Primer TIP contain hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics (CAS-No.: -), for which a German Occupational Exposure Level (OEL) according to the German Technical Rules for Hazardous Substances (TRGS 900) is in force.

6) The product may only be loaded with an automatic dosing system. 7) The product may only be used with spray tunnels featuring an automated onward transport of the freshly treated wood with automated stacking or into a drier so as to avoid manual contact with the freshly treated wood. 8) The wearing of chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and coverall of at least type 6 as specified in European Standard EN 13034 is required for application by deluge. The wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for subsequent manual processing of the freshly treated timber. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

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

None

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

None

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

None

2.3.1.5 General directions for use of the products in the meta SPC

2.3.1.5.1 Instructions for use

1) Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer. 2) Do not discharge the biocidal product nor the diluted solution of the biocidal product into the sewage system or the environment. 3) Treated timber must be coated with an appropriate non-biocidal topcoat wood finish after drying of the treated timber. The final top coat should be applied directly after drying of the primer on the

wood surface. A minimum of 24 hours drying time under normal conditions should be allowed after application of a top coat. 4) Respect the conditions of use and use classes of the product.

2.3.1.5.2 Risk mitigation measures

1) Do not use on wood which may come in direct contact with food and feeding stuff and livestock. 2) Keep cats away from treated surfaces due to high sensitivity to permethrin toxicity.

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

First Aid: 1) Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice. (non-professional uses) 2) IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. 3) Do NOT induce vomiting.

2.3.1.5.4 Instructions for safe disposal of the product and its packaging

None

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

1) Product should be stored dry, cool andnot above 40 °C. 2) Shelf life 24 months in coated tin containers and 12 months in HDPE containers.

2.3.1.5.6 Other information

None

2.3.2 Meta SPC No. 02

2.3.2.1 Administrative information

2.3.2.1.1 Meta SPC identifier

02

2.3.2.1.2 Suffix to the authorisation number

02

2.3.2.1.3 Product type(s) of the products in the meta SPC

8 (Wood protection)

2.3.2.2 Composition and formulation of the products within the meta SPC

2.3.2.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Table 4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Tebuconazole	(RS)-1-p-chlorophenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentan-3-ol	Active substance	107534-96-3	403-640-2	0.2	0.2
IPBC	3-iodo-2-propynyl butylcarbamate	Active substance	55406-53-6	259-627-5	0.5	0. 5
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.06	0.06
-	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics	Non-active substance	-	Registration no.: 01-2119457273-39-xxxx	85.81	86.1

2.3.2.2.2 Type(s) of formulation of the products in the meta SPC

Ready to use: Liquid

2.3.2.3 Classification and Labelling according to the Regulation (EC) 1272/2008

See meta 01 (Chapter 2.3.1.3. Page 14).

2.3.2.4 Use(s) of the products appropriate for authorisation

See meta 01 (Chapter 2.3.1.4. Page 17).

2.3.2.5 General directions for use of the products in the meta SPC

See meta 01 (Chapter 2.3.1.5. Page 25).

2.3.3 Meta SPC No. 03

2.3.3.1 Administrative information

2.3.3.1.1 Meta SPC identifier

03

2.3.3.1.2 Suffix to the authorisation number

03

2.3.3.1.3 Product type(s) of the products in the meta SPC

8 (Wood protection)

2.3.3.2 Composition and formulation of the products within the meta SPC

2.3.3.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Table 5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Tebuconazole	(RS)-1-p-chlorophenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentan-3-ol	Active substance	107534-96-3	403-640-2	0.2	0.2
IPBC	3-iodo-2-propynyl butylcarbamate	Active substance	55406-53-6	259-627-5	0.5	0. 5
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.06	0.06
-	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics	Non-active substance	-	Registration no.: 01-2119457273-39-xxxx	85.71	88.6

2.3.3.2.2 Type(s) of formulation of the products in the meta SPC

Ready to use: Liquid

2.3.3.3 Classification and Labelling according to the Regulation (EC) 1272/2008

See meta 01 (Chapter 2.3.1.3. Page 14).

2.3.3.4 Use(s) of the products appropriate for authorisation

See meta 01 (Chapter 2.3.1.4. Page 17).

2.3.3.5 General directions for use of the products in the meta SPC

See meta 01 (Chapter 2.3.1.5. Page 25).

2.4 Individual products in the meta SPC(s) (third information level)

- Information on the specific composition of each individual product is provided in the confidential annex.

2.5 Packaging

Table 6

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Cans	Up to 5 L	Coated* tin or HDPE	-	Non-Professional	Yes
Cans	Up to 25 L	Coated* tin or HDPE	-	Professional	Yes
Canister/IBC	25 L, 200 L, 1000 L	Coated* tin or HDPE	-	Industrial and professional	Yes

*Epoxid pigmentiert / Vinyl

3 Assessment of the product family

3.1 *Intended use(s) as applied for by the applicant*

Meta SPC	Use	PT	Where relevant, an exact description of the use	Target organism(s) (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category(ies) of users	Pack sizes and packaging material
1, 2, 3	1	8	Wood protection	Wood destroying fungi; wood discolouring fungi; wood boring insects	use class 2 and 3 (not in direct contact to soil or surface water), (incl. windows and exterior doors (inner and outer parts)); preventive treatment	Brush/roll	Softwood: 160 ml/m², 130 g/m²; Hardwood: 225 ml/m², 180 g/m², To be applied by 2-3 coats, depending on wood species and surface characteristics.	Professional	Up to 25 L (Coated tin cans or HDPE)
1, 2, 3	2							Non-professional	Up to 5 L (Coated tin cans or HDPE)
1, 2, 3	3					Automatic dipping	Softwood: 160 ml/m², 130 g/m²; Hardwood: 225 ml/m², 180 g/m², To be applied by 1-2 coats, depending on wood species and surface characteristics.	Professional and industrial	Up to 25 L, 200L, 1000L (Coated tin cans or HDPE)
1, 2, 3	4					Manual dipping			
1, 2, 3	5					Deluge (Spraying in closed devices)			

3.2 Physical, chemical and technical properties

Information on the composition of the test products[5] chosen in order to generate data on physical, chemical and technical properties as well as the corresponding justification are provided in the confidential annex.

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

Table 7: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	JJT6310 Batch CH20131112	Liquid	Erstling, K.; 2014; Accelerated and low temperature Storage Stability of JJT 6310
	Visual inspection	JJT6320 Batch CH20140805	Liquid	Erstling, K.; 2014; Accelerated and low temperature Storage Stability of JJT 6320
Colour at 20 °C and 101.3 kPa	Visual inspection	JJT6310 Batch CH20131112	Clear, yellowish	Erstling, K.; 2014; Accelerated and low temperature Storage Stability of JJT 6310
	Visual inspection	JJT6320 Batch CH20140805	Clear, yellowish	Erstling, K.; 2014; Accelerated and low temperature Storage Stability of JJT 6320

[5] JJT 6310 corresponds to Preventol Primer TIP (meta SPC 1 (BP No. 0001)) and JJT 6320 corresponds to Primer TIP A (meta SPC 2 (BP No. 0003))

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Odour at 20 °C and 101.3 kPa	olfactory	JJT6310 Batch CH20131112	slight characteristic	Erstling, K.; 2014; Accelerated and low temperature Storage Stability of JJT 6310
Acidity / alkalinity	CIPAC MT 75 OECD 122	JJT6310 Batch CH20131112	pH = 6.4 (1% solution)	Schlösser, H.-G., 2014; Determination of pH Value in 5 biocide formulations
	CIPAC MT 75 OECD 122	JJT6320 Batch CH20140813	pH = 6.2 (1% solution)	Schlösser, H.-G., 2015; Determination of pH Value in 4 biocide formulations
Relative density / bulk density	EU Method A.3; DIN 51757 oscillating densitimeter	JJT6310 Batch CH20140127	D^{20}_4 = 0.804	Keldenich, H.-P., 2014; Determination of Safety-Relevant Data of JJT6310
Storage stability test – **accelerated storage**	CIPAC MT 46.3 Active substance content analysis: Lanxess method no.:2322-3014801-13	JJT6310 Batch CH20131112 Packaging: 650 mL coated tin can, with coated tin plate cap	The product is found to be stable for 8 weeks at 40°C. The measured values can be found in the table below.	Erstling, K.; 2014; Accelerated and low temperature Storage Stability of JJT 6310
	CIPAC MT 46.3 Active substance content analysis: Lanxess method no.:2322-3014801-13	JJT6310 stored for 8 weeks at 40 °C +/- 2 °C Batch: CH20151113 Packaging: 250 ml HDPE Bottles, Translucent, Wide Mouth with Screw Cap	The product is found to be stable for 8 weeks at 40°C. The measured values can be found in the table below.	Erstling, K., Report no. 2016-03-03, 2016
	CIPAC MT 46.3 Lanxess method no.: 2322-3014901-13	JJT6320 Batch CH20140805 Packaging: 750 ml coated-Pet tin can, with coated tin plate cap	The product is found to be stable for 8 weeks at 40°C. The measured values can be found in the table below.	Erstling, K.; 2014; Accelerated and low temperature Storage Stability of JJT 6320

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – long term storage at ambient temperature	According to GIFAP 17 Active substance content analysis: Lanxess method no.:2322-3014801-13	JJT6310 Batch CH20131112 Packaging: 650 mL coated tin can, with coated tin plate cap	The product is found to be stable for 2 years at ambient temperature. The measured values can be found in the table below.	Erstling, K., Report no. 2016-01-29, 2016
Storage stability test – low temperature stability test for liquids	CIPAC MT 39.3 Active substance content analysis: Lanxess method no.:2322-3014801-13	JJT6310 Batch CH20131112 Packaging: 650 mL coated tin can, with coated tin plate cap	The product is found to be stable for 1 week at 0°C as no phase seperation or crystallistion was observed.	Erstling, K.; 2014; Accelerated and low temperature Storage Stability of JJT 6310
	CIPAC MT 39.3 Active substance content analysis: Lanxess method no.: 2322-3014901-13	JJT6320 Batch CH20140805 Packaging: coated tin can	The product is found to be stable for 1 week at 0°C as no phase seperation or crystallistion was observed.	Erstling, K.; 2014; Accelerated and low temperature Storage Stability of JJT 6320
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The packaging is light-proof. Therefore, the formulations are not exposed to light during storage.	Waiving[6]
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Not applicable because according to the label instructions the biocidal product has to be stored cool, dry and protected from frost in closed, original containers.	Waiving[6]

[6] Data waiving was acceptable (see complete justification(s)/annotation(s) in IUCLID dossier).

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**			The data about the stability of packaging regarding storage stability test are sufficient.	Waiving[6]
Wettability			The formulation type of the product is a ready to use liquid, which is not market with a spray head or in a spraying device. Therefore no technical characteristics are necessary.	Waiving[6]
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				
Persistent foaming				
Flowability/Pourability/Dust ability				
Burning rate — smoke generators				
Burning completeness — smoke generators				
Composition of smoke — smoke generators				
Spraying pattern — aerosols				
Physical compatibility			The biocidal product is not intended to be used with	Waiving[6]
Chemical compatibility				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			other products including other biocidal products.	
Degree of dissolution and dilution stability			The formulation type of the product is a ready to use liquid. Therefore no technical characteristics are necessary.	Waiving[6]
Surface tension	OECD 115, Ring method	JJT6310 Batch CH20140127	24.97 mN/m (undiluted, 25°C)	Keldenich, H.-P., 2014; Determination of Safety-Relevant Data of JJT6310
Viscosity	OECD 114 Rotational viscosimeter	JJT6310 Batch CH20140127	Dynamic: 20°C: 1.71 mPa*s 40°C: 1.2 mPa*s Kinematic (calculated): 20°C: 2.13mm²/s	Keldenich, H.-P., 2014; Determination of Safety-Relevant Data of JJT6310

Table 8: Data regarding storage stability

JJT6310 Batch CH20131112	Start [%]	1 week/0°C [%]	4 weeks/ 40°C [%]	8 weeks/ 40°C [%]	6 months [%]	9 months [%]	12 months [%]	18 months [%]	24 months [%]
IPBC (tin)	0.5	0.48	0.48	0.49	0.5	0.48	0.49	0.48	0.49
Tebuconazole (tin)	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Permethrin (tin)	0.062	0.061	0.061	0.061	0.062	0.059	0.06	0.059	0.064
IPBC (HDPE)	0.51	/	0.50	0.51	Read across to another product. For more information please refer to the condfidential document, section 1.3.4.				
Tebuconazole (HDPE)	0.21	/	0.21	0.22					
Permethrin (HDPE)	0.064	/	0.064	0.068					
Appearance	clear liquid, yellowish	clear liquid, yellowish	clear liquid, yellowish	clear liquid, yellowish	clear liquid, yellowish	clear liquid, yellowish	clear liquid, yellowish	clear liquid, yellowish	clear liquid, yellowish
Odour	slight characteristic	slight characteristic	slight characteristic	slight characteristic	slight characteristic	slight characteristic	slight characteristic	slight characteristic	slight characteristic
weight control			no significant	no significant	no significant	no significant	no significant	no significant	no significant

			weight loss or increase was measured	weight loss or increase was measured	weight loss or increase was measured	weight loss or increase was measured	weight loss or increase was measured	weight loss or increase was measured	weight loss or increase was measured
stability of packaging			no significant interactions were observed	no significant interactions were observed	no significant interactions were observed	no significant interactions were observed	no significant interactions were observed	no significant interactions were observed	no significant interactions were observed

Table 9: Data regarding storage stability

JJT6320 Batch CH20140805	**Start**	**1 week/0°C [%]**	**4 weeks/ 40°C [%]**	**8 weeks/ 40°C [%]**
IPBC	0.5	0.49	0.48	0.47
Tebuconazole	0.21	0.21	0.2	0.21
Permethrin	0.06	0.06	0.057	0.059
Appearance	clear liquid, yellowish	clear liquid, yellowish	clear liquid, yellowish	clear liquid, yellowish
Weight control			no significant weight loss or increase was measured	no significant weight loss or increase was measured
Stability of packaging			no significant interactions were observed	no significant interactions were observed

Table 10

Conclusion on the physical, chemical and technical properties
The biocidal products of the family are clear, yellowish, ready-to-use liquids with slight characteristic odour. The pH of the products is 6.2 respectively 6.4. Based on the provided stability studies a shelf-life of 2 years can be granted.

3.3 Physical hazards and respective characteristics

Information on the composition of the test products[7] chosen in order to generate data on physical hazards and respective characteristics as well as the corresponding justification are provided in the confidential annex.

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

Table 11: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	Regulation (EC) No 440/2008, EU Method A.14	JJT6310 Batch CH20140127	Mechanical sensitivity (drop-weight test): The test item is not sensitive to shock. Mechanical sensitivity (friction-mill test): This test is only applicable to solid materials. Thermal stability (Koenen test):	Meta-SPC 1: No explosive properties according to EU test method A.14. Not classified based on GHS/CLP criteria Meta-SPC 2 and Meta-SPC 3: Product from Meta-SPCs 1 has been tested for explosiveness with negative outcome. Since the composition of the products within Meta-SPCs 2 and 3 is almost identical, read-across between these Meta-SPCs is justified. Moreover, the products of the biocidal product family are petroleum-based formulations. All other	Keldenich, H.-P.; 2014; Determination of Safety-Relevant Data of JJT6310

[7] JJT 6310 corresponds to Preventol Primer TIP (meta SPC 1 (BP No. 0001)) and JJT 6330 corresponds to Primer TIP-P (meta SPC 3 (BP No. 0005))

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
			The test item is not explosive when heated under defined confinement.	components either have no explosive properties based on the criteria of section 6.1, appendix 6 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, or their individual concentrations are so low that a contribution towards explosive properties of the formulation can be excluded.	
Flammable gases				Not applicable The parameter flammable gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas, this test does not need to be performed.	Waiving[8]
Flammable aerosols				Not applicable The parameter flammable aerosols must be determined for biocidal products that are supplied as aerosols. Since the biocidal product is not an aerosol, this test does not need to be performed.	Waiving[8]
Oxidising gases				Not applicable Study does not need to be conducted because products are liquids.	Waiving[8]
Gases under pressure				Not applicable The parameter oxidising gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas, this test does not need to be performed.	Waiving[8]
Flammable liquids	DIN EN ISO 2719	JJT6310	Flash point: 65.0 °C	Meta-SPC 1: Not classified based on GHS/CLP criteria	Keldenich, H.-P.; 2014;

[8] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
	PIN EN ISO 1523	Batch CH20140127 Trade name: Drewnochron Impregnat Grunt R (JJT6330)	Flash point: 61.0 °C	Meta-SPC 3: Not classified based on GHS/CLP criteria Meta-SPC 2: Worst case formulations have been tested for Meta-SPCs 1 and 3, All determined flash points are above 60 °C, thus products in these Meta-SPC do not need to be classified for flammability.	Determination of Safety-Relevant Data of JJT6310 Study No. 2014/00141, Buca, M.; 2016 2016, Determination of the flashpoint and density for Drewnochron Impregnat Grunt R Waiving[8]
Flammable solids				Not applicable The flammability has to be tested for solid biocidal products. Since the biocidal product is liquid, this test does not need to be performed.	Waiving[8]
Self-reactive substances and mixtures	study scientifically not necessary			There are no ingredients with explosive or self-reactive properties present in the biocidal product. Therefore, the formulation is not self-reactive.	Waiving[8]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Pyrophoric liquids	study scientifically not necessary			The study does not need to be conducted as based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected.	Waiving[8]
Pyrophoric solids				Not applicable Test for pyrophoric properties of solid substances does need to be performed, because the biocidal product is liquid.	Waiving[8]
Self-heating substances and mixtures				Not applicable The study does not need to be conducted as the biocidal product is liquid. A liquid shows not self-heating behaviour if it is not absorbed on a large surface.	Waiving[8]
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Based on experience in handling and use and molecular structure of constituents, emission of flammable gases is not expected when the preparation comes in contact with water.	Waiving[8]
Oxidising liquids	study scientifically not necessary			The studies do not need to be conducted, because the products are incapable of reacting exothermically with combustible materials. All constituents of the products either do not contain any oxygen or halogen atoms, or if they contain, they are chemically bonded only to carbon or hydrogen. None of the constituents is classified as an oxidising substance. Hence, the classification procedure does not need to be applied.	Waiving[8]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Oxidising solids				Not applicable The oxidising properties have to be determined for solid biocidal products. Since the biocidal product is liquid, this test does not need to be performed.	Waiving[8]
Organic peroxides	study scientifically not necessary			Since the biocidal product is not an organic peroxide, the test does not need to be performed.	Waiving[8]
Corrosive to metals	UN Test in Part III of the UN-MTC, 37.4	JJT6310 Batch CH20140127	Corrosion rate: < 0.01 mm/year Type of material: Aluminium (7075-T6) steel (1.0037) No localised corrosion was observed by visual inspection.	Not classified based on GHS/CLP criteria	Keldenich, H.-P.; 2014; Determination of Safety-Relevant Data of JJT6310, Study No. 2014/00197
Auto-ignition temperature (liquids and gases)	DIN 51794	JJT6310 Batch CH20140127	Auto-ignition temperature: 225 °C	Meta-SPC 1: 225 °C Meta-SPC 2 and Meta-SPC 3: The auto-ignition temperature has been determined for representative product from Meta-SPC 1. The determined value is 225 °C. Since the composition of the products within Meta-SPCs 1, 2 and 3 is almost identical, read across to the	Keldenich, H.-P.; 2014; Determination of Safety-Relevant Data of JJT6310, Study No. 2014/00141 IUCLID[8]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
				remaining Meta-SPCs is justified. With auto-ignition temperatures > 200 °C and ≤ 300 °C, the formulations fall into temperature class T3, with a maximum allowed surface temperature of 200 °C.	
Relative self-ignition temperature for solids				Not applicable Study does not need to be conducted because products are liquids.	Waiving[8]
Dust explosion hazard				Not applicable The dust explosion hazard must be determined for powders or biocidal products containing, or able to produce, dust. Since the biocidal product is liquid, this test does not need to be performed.	Waiving[8]

Table 12

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. The physical and chemical properties of the biocidal products of the Biocidal Product Family do not fulfil the criteria for a classification according to Regulation (EC) No 1272/2008 and no labelling is required for physical hazards. Therefore, there is no risk expected from the formulated products with regards to the physico-chemical properties.

3.4 Methods for detection and identification

The applicant submitted two studies with validated method for detection of the active substances in two products of the family. Additionally to these two validated method the applicant provided several spectra to indicate that the further constituents of the product family – not tested during method validation- do not interfere the method or coeluate with one of the active substances.

No or only small interferences were visible in the spectra which are not further relevant to the results.

As the SoC “Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics” is not generated during product storage, a fully validated and specific analytical method is not required.

Table 13 Preventol Primer TIP (JJT6310) – example product meta SPC 1, Lanxess method no.: 2322-3014801-13

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
IPBC	HPLC-UV	78 spectra within the peak were compared. No significant interferences were noted. The purity factor is 999.700.	6.45 – 105.12 mg/100 mL (0.3 – 0.7%) R^2: 0.99987	80 and 120% level of active ingredient content Three repeated measurements 0.4000 and 0.6001 % with a recovery of 99.6%	0.4987 – 0.5008%	0.4997%	0.17%		Erstling, K. 2015 Determination of IPBC, PBC, tebuconazole, propiconazole and permethrin in BPR formulations

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
									Meth 2322-3014802-13E
Tebuconazole	HPLC-UV	49 spectra within the peak were compared. No significant interferences were noted. The purity factor is 999.997.	10.02 – 44.97 mg/100 mL (0.2 – 0.3%) R^2: 0.9995	80 and 120% level of active ingredient content Three repeated measurements 0.1600% and 0.2534 % with a recovery of 100.9%	0.2036% - 0.2052%.	0.2046%	0.29%		Erstling, K. 2015 Determination of IPBC, PBC, tebuconazole, propiconazole and permethrin in BPR formulations Meth 2322-3014802-13E
Permethrin	HPLC-UV	Permethrin isomer 1: 82 spectra within the peak were compared. No significant interferences were noted. The purity factor is 999.992. Permethrin isomer 2: 85 spectra within the peak were compared. No significant interferences were	2.00 – 27.02 mg/100 mL (0.06 – 0.4%) R^2: 0.99995	80 and 120% level of active ingredient content Three repeated measurements 0.04806 and 0.07196 % with a recovery of 99.8%					Erstling, K. 2015 Determination of IPBC, PBC, tebuconazole, propiconazole and permethrin in BPR formulations Meth 2322-3014802-13E

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
		noted. The purity factor is 999.964.							
IPBC	HPLC-UV		0.106 – 42.22 mg/100 mL (0.001 – 0.4%) R^2: 0.99998		4.99 – 5.34	5.13	2.87%	Limit of determination: 0.002%; limit of detection: 0.001%	Erstling, K. 2015 Determination of IPBC, PBC, tebuconazole, propiconazole and permethrin in BPR formulations Meth 2322-3014802-13E

For the active substance Permethrin no precision was determined. Based on the data for other products which contain permethrin the applicant justifies the following read across for these data:

In the HPLC method validation 2322-3014802-13E, there are data for precision of the permethrin content available as outlined in the table below:

Table 14

Product	Name of the product (Preventol…)	Permethrin-content / %	Precision	Modified Horwitz criterion	Horwitz criterion fulfilled?
JJT6310	Primer TIP 1 (meta SPC 1)	0.06	no data	RSD < 4.09%	yes (read-across)
JJT6340	Stain TIP	0.06	RSD = 0.40%, n = 6	RSD < 4.09%	yes
JJT6370	Primer PIP	0.06	RSD = 0.75%, n = 6	RSD < 4.09%	yes
JJT6380	Aqua Primer PIP	0.1	no data	RSD < 3.79%	yes (read-across)
JJT6382	Aqua Primer PIP Termites	0.4	RSD = 1.75%, n = 6	RSD < 3.08%	yes

The results obtained for two products with permethrin content 0.06%, as well as for one product with permethrin content 0.4%, fulfil the modified Horwitz criterion: % RSDr < 0.67 * $2^{(1-0.5 \log C)}$ where % RSDr is reproducibility standard deviation and C analyte concentration (W. Horwitz et al, J. Assoc. Off. Anal. Chem. 63 (1980) 1344; W. Horwitz, Anal. Chem. 54 (1982) 67A).
Since all the calculated RSD's are well below the respective Horwitz limit, one can interpolate this finding also to the product with permethrin content 0.1%, i.e. in between 0.06% and 0.4%.
Additionally, at the begin of evaluation the product JJT 6340 was a member of this product family (Preventol Stain TIP Coloured) and at a later time removed from the family. The composition of the product Primer PIP (JJT6370) is beside the use of Propicozole instead of Tebuconazole, and the content of the two solvents Dipropylene glycol monomethyl ether (2.3% instead of 3.59%) and Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (88.93% instead of 87.69%) comparable to Preventol Primer TIP 1.

Table 15 Primer XXX[9] (other name for Primer TIP A, JJT6320) – example product meta SPC 2, Lanxess method no.:2322-3014901-13

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**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
IPBC	HPLC-UV	99 spectra within the peak were compared. No significant interferences were noted. The purity factor is 999.931.	6.45 – 105.12 mg/100 mL (0.3 – 0.7%) R²: 0.99987	80 and 120% level of active ingredient content Three repeated measurements 0.4000 and 0.6001 % with a recovery of 101.9%	0.4653 – 0.4812%	0.4730%	1.51%		Determination of IPBC, PBC, tebuconazole, propiconazole and permethrin in BPR formulation for XXX[9] Erstling, K. 2013 Meth 2322-3014901-13E
Tebuconazole	HPLC-UV	116 spectra within the peak were compared. No significant interferences were noted. The purity factor is 999.964.	10.02 – 44.97 mg/100 mL (0.2 – 0.3%) R²: 0.9995	80 and 120% level of active ingredient content Three repeated measurements 0.1600% and 0.2400 % with a recovery of 102.9%	0.1894% - 0.1959%.	0.1926%	1.60%		

[9] See name of the test product and full title of the method in chapter **Fehler! Verweisquelle konnte nicht gefunden werden.** (page 254) in the confidential annex.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Permethrin	HPLC-UV	Permethrin isomer 1: 107 spectra within the peak were compared. No significant interferences were noted. The purity factor is 999.690. Permethrin isomer 2: 90 spectra within the peak were compared. No significant interferences were noted. The purity factor is 999.972.	2.00 – 27.02 mg/100 mL (0.06 – 0.4%) R^2: 0.99995	80 and 120% level of active ingredient content Three repeated measurements 0.04806 and 0.07196 % with a recovery of 100.6%	0.06689% - 0.06803%.	0.06748%	0.64%		
IPBC	HPLC-UV		0.106 – 42.22 mg/100 mL (0.001 – 0.4%) R^2: 0.99998		4.99 – 5.34	5.13	2.87%	Limit of determination: 0.002%; limit of detection: 0.001%	

An analytical method for the determination of the active substance in an example product of meta SPC 3 was not validated. The reason is that the validated analytical method for meta SPC 1 is considered to cover meta SPC 3. Please see the justication in the confidential annex.

Table 16

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	Tebuconazole	0.1 mg/kg wet soil	$PNEC_{soil}$ AR for PT08, chapter 2.2.2.2., 11/2007
	IPBC	0.05 mg/kg 0.005 mg a.i./ kg wet soil	common limit $PNEC_{soil}$ based on EC_{50} *Avena sativa*: 4.92 mg/kg, AF: 1000 AR; chapter 2.2.2.2.
	Permethrin	0.09 mg/kg wet soil	$PNEC_{soil}$ CAR Doc IIA combined; (PT08+PT18), 11/2013, 4.2.3.5
Drinking water	Tebuconazole	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
	IPBC	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
	Permethrin	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	Tebuconazole	1 µg/L	$PNEC_{water}$ based on NOEC *rainbow trout,* AF: 10 AR for PT08, chapter 2.2.2.2., 11/2007
	IPBC	0.46 µg/L	$PNEC_{water}$ based on NOEC *Scenedesmus subspicatus*: 4.6

Relevant residue definitions for monitoring and levels for which compliance is required			
			µg/L, AF: 10 AR; chapter 2.2.2.2.
	Permethrin	0.47 ng/L	$PNEC_{water}$ based on NOEC *Daphnia magna*: 4.7 ng/L, AF: 10 CAR Doc IIA combined; (PT08+PT18), 11/2013, 4.2.1.6
Air	Tebuconazole	9 µg/m³	AOEL: 0.03 mg/kg bw/d, AR for PT08, list of endpoints, 11/2007
	Not required		IPBC AR; list of endpoints, chapter 5
	Permethrin	15 µg/m³	medium+long-term AEL: 0.05 mg/kg bw/d; AR (PT08), 02/2014, LoEP, AR (PT18), 04/2014, LOEP,
Animal and human body fluids: urine blood and tissues	No relevant residues expected		Tebuconazolnot classified as toxic or very toxic
	IPBC PBC[10] PBC10	0.05 mg/L 0.05 mg/L 0.1 mg/kg	proposed classification: toxic; AR, chapter 2.1.3
	No relevant residues expected		Permethrin Waiver, CAR PT8 Tagros DocIIIA, 4.2.d; 12/2012
Food of plant origin and Food of animal origin	No relevant residues expected		Tebuconazole AR for PT08, 11/2007 IPBC AR; list of endpoints, chapter 5 Permethrin, Waiver; CAR PT8 Bayer/Sumitomo DocIIIA, 4.3; 12/2012 CAR PT8 Tagros DocIIIA, 4.3; 12/2012

[10] In blood and meat IPBC is not stable. See Düsterloh, 2008, doc IIIA, 4.2d/01 for PT06.

Table 17

Analytical methods in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Tebuconazole	GC-NPD, DB-5 column	confirmation included by GC-MS; DB-5MS, m/z 250 but not sufficiently validated	0.01 – 2.01 µg/mL R^2=1.0	GC-NPD 0.01 mg/kg / 5 0.1 mg/kg / 5 GC-MS 0.01 mg/kg / 1 0.1 mg/kg / 1	 94 – 105 % 92 – 95 % 	 100 % 94 % 98 101	 4.3 % 1.2 % - -	0.01 mg/kg	Weeren (2000) CAR, Doc IIIA, 4.2/06
Tebuconazole	LC-MS/MS; LiChroCART Superspher 60 RP-select B, ESI+, m/z: 308→70	no confirmation	0.001 – 0.1 µg/mL R=0.9999	sandy clay loam 5.08 µg/kg / 5 50.8 µg/kg / 5 209 µg/kg / 5 silt loam 5.08 µg/kg / 5 50.8 µg/kg / 5 209 µg/kg / 5 sediment 5.08 µg/kg / 5 50.8 µg/kg / 5	 98.4 – 104 % 102 – 104 % 98.3 – 104 % 96.4 – 114 % 99.5 – 107 % 98.0 – 104 % 79.9 – 85.4 % 75.3 – 77.6 %	 101 % 103 % 101 % 103 % 102 % 101 % 82.0 % 76.5 %	 2.1 % 0.9 % 2.3 % 7.4 % 3.8 % 2.6 % 3.1 % 1.4 %	0.005 mg/kg	Schramel (2001)

Analytical methods in soil									
				209 µg/kg / 5	72.6 – 78.7 %	76.5 %	3.5 %		
IPBC	LC-MS/MS, RP18 column, ESI+	MS transitions not mentioned LC-MS/MS is regarded as highly specific by the eCA, an additional confirmatory method is not presented. In control samples no interfering substances were observed.	0.002 – 0.1 µg/mL R^2=0.9999	0.01 mg/kg / 5 0.1 mg/kg / 5	71.1 – 92.4 % 74.6 – 92.4 %	78.5 % 82.5 %	8.6 % 8.7 %	0.01 mg/kg acceptable for common limit, but LOQ > MRL based on PNEC soil	Bruckhausen (2004) CAR Doc IIIA, 4.2a/01
PBC	LC-MS/MS, RP18 column, ESI+	MS transitions not mentioned LC-MS/MS is regarded as highly specific by the eCA, an additional confirmatory method is not presented. In control samples no interfering substances were observed.	0.002 – 0.1 µg/mL R^2=0.9990	0.01 mg/kg / 5 0.1 mg/kg / 5	73.1 – 88.5 % 69.7 – 96.1 %	80.9 % 83.9 %	8.6 % 14.9 %	0.01 mg/kg	Bruckhausen (2004) CAR Doc IIIA, 4.2a/01
Permethrin	LC MS/MS Synergi 2µ Polar RP		Permethrin	LC MS/MS Synergi 2µ Polar RP column; ESI+		Permethrin	LC MS/MS Synergi 2µ		Permethrin

Analytical methods in soil									
	column; ESI+						Polar RP column; ESI+		

Table 18

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Tebuconazole	GC-MS; DB-5MS, m/z 250	no confirmation, since validation data for a single fragment ion	0.00503 – 0.67 µg/mL R²=0.9994	0.05 µg/L / 5 0.5 µg/L / 5	85 – 105 % 75 – 93 %	97 % 86 %	8.0 % 7.8 %	0.05 µg/L validated in surface water, also accepted for drinking water	Weeren (2000) CAR Doc IIIA, 4.2/08
Tebuconazole	LC-MS/MS; Phenomenex Aqua C18, ESI+, m/z: 308→70, 308→125	confirmation included	0.03 – 5 ng/mL	drinking water m/z: 308→70 0.1 µg/L / 5 1 µg/L / 5 m/z: 308→125 0.1 µg/L / 5 1 µg/L / 5 mineral water m/z: 308→70 0.1 µg/L / 5 1 µg/L / 5		 94 % 137 % 106 % 137 % 111 % 118 %	 14 % 8 % 21 % 8 % 10 % 7 %	0.1 µg/L	Greulich & Alder (2006)

Analytical methods for drinking water									
				m/z: 308→125 0.1 µg/L / 5 1 µg/L / 5		100 % 121 %	14 % 6 %		
IPBC	LC-MS/MS, RP18 column, ESI+	MS transitions not mentioned	IPBC	LC-MS/MS, RP18 column, ESI+	MS transitions not mentioned	IPBC	LC-MS/MS, RP18 column, ESI+	MS transitions not mentioned	IPBC
LC-MS/MS is regarded as highly specific by the eCA, an additional confirmatory method is not presented. In control samples no interfering substances were observed.	0.001 – 0.1 µg/mL		LC-MS/MS is regarded as highly specific by the eCA, an additional confirmatory method is not presented. In control samples no interfering substances were observed.	0.001 – 0.1 µg/mL		LC-MS/MS is regarded as highly specific by the eCA, an additional confirmatory method is not presented. In control samples no interfering substances were observed.	0.001 – 0.1 µg/mL		LC-MS/MS is regarded as highly specific by the eCA, an additional confirmatory method is not presented. In control samples no interfering substances were observed.
Permethrin	LC MS/MS Synergi 2µ Polar RP column; ESI+		Permethrin	LC MS/MS Synergi 2µ Polar RP column; ESI+		Permethrin	LC MS/MS Synergi 2µ Polar RP column; ESI+		Permethrin

Table 19

Analytical methods for surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Tebuconazole	GC-MS; DB-5MS, m/z 250	no confirmation, since validation data for a single fragment ion	0.00503 – 0.67 µg/mL R^2=0.9994	0.05 µg/L / 5 0.5 µg/L / 5	85 – 105 % 75 – 93 %	97 % 86 %	8.0 % 7.8 %	0.05 µg/L	Weeren (2000) CAR Doc IIIA, 4.2/08
IPBC	LC-MS/MS, RP18 column, ESI+	MS transitions not mentioned	IPBC	LC-MS/MS, RP18 column, ESI+	MS transitions not mentioned	IPBC	LC-MS/MS, RP18 column, ESI+	MS transitions not mentioned	IPBC
LC-MS/MS is regarded as highly specific by the eCA, an additional confirmatory method is not presented. In control samples no interfering substances were observed.	0.001 – 0.1 µg/mL		LC-MS/MS is regarded as highly specific by the eCA, an additional confirmatory method is not presented. In control samples no interfering substances were observed.	0.001 – 0.1 µg/mL		LC-MS/MS is regarded as highly specific by the eCA, an additional confirmatory method is not presented. In control samples no interfering substances were observed.	0.001 – 0.1 µg/mL		LC-MS/MS is regarded as highly specific by the eCA, an additional confirmatory method is not presented. In control samples no interfering substances were observed.

Table 20:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Tebuconazole	GC-NPD, CP Wax 52 CB	no confirmation included, but confirmation by GC-MS, HP-1701, EI, m/z 250 (Hellpointner (2000); CAR, Doc IIIA, 3.2/07)	0.017 – 1.701 µg/mL R^2=0.9986	Tenax 1.1 µg/m³ / 4 142 µg/m³ / 4 XAD-2 1.1 µg/m³ / 4 142 µg/m³ / 4	 99.4 – 106 % 89.9 – 104 % 95.3 – 100 % 91.8 – 95.2 %	 104 % 97.1 % 97.9 % 93.6 %	 2.8 % 6.3 % 2.1 % 2.0 %	1.1 µg/m³	Riegner (1992) CAR, Doc IIIA, 4.2/02
Permethrin	LC MS/MS; ESI+ m/z 408→183 m/z 408→ 355	confirmation included by second transition	5 – 500 ng/mL R^2 > 0.997	m/z 408→183 ambient air 5 µg/m³/ 5 48 µg/m³/ 5 warm humid air 4.8 µg/m³/ 5 49 µg/m³/ 5 m/z 408→355 ambient air 5 µg/m³/ 5 48 µg/m³/ 5 warm humid air		 87 % 90 % 92 % 91 % 88 % 90 %	 5 % 4 % 4 % 3 % 6 % 4 %	5 µg/m³	Bacher, 2008 CAR PT8 Bayer/Sumitomo DocIIIA, 4.2 (4); 12/2012

Analytical methods for air									
				4.8 µg/m³/ 5 49 µg/m³/ 5		91 % 90 %	2 % 4 %		
Permethrin	GC-ECD, DB-5 column	confirmation included by GC-MS m/z 127, 163, 183, but no validation data presented in CAR	0.05 – 10 mg/L R=1.0	0.1 µg/m³/ 5 1 µg/m³/ 5		72 % 74 %	1.9 % 3.4 %	0.1 µg/m³	Sathiyanarayanan, 2006 CAR PT8 Tagros DocIIIA, 4.2.b; 12/2012
Stoddard solvent, naphtha and mineral spirits	Samples collection: charcoal tubes. Desorbtion with carbon disulfide (CS_2) Analysis: GC-FID					97.7%	± 3.53%.	0.77 mg/sample (260 mg/m³)	OSHA Method ORG-48 | November 1984 NIOSH Manual of Analytical Methods, 2nd ed.
Kerosene	Analysis: GC-FID					mean recovery for the wet samples: 100.5%, recovery at the LOQ was 93.2%		Recommended air volume and sampling rage: 20 L at 0.1 L/min, LOQ: 4.79 mg/m³	OSHA Method PV2139, NIOSH Manual of Analytical Methods, 4th ed.
Hydrocarbon substances (naphthas: Petroleum	Sample collection: SOLID SORBENT TUBE (coconut shell							LOD: 0.1 mg per sample	NIOSH Method 1550, issue 2: Naphthas

Analytical methods for air									
ether (benzin), rubber solvent, petroleum naphtha, VM&P naphtha, mineral spirits, Stoddard solvent, kerosene (kerosine), coal tar naphtha.)	charcoal, 100 mg/50 mg). Analysis: GC-FID								NIOSH Manual of Analytical Methods, 4th ed.

Table 21

Analytical methods for body fluid blood									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
PBC	LC-MS/MS, RP18 column, (primary method); Phenyl hexyl column (confirmatory method), ESI+	MS transitions not mentioned validation data for primary and confirmatory method	0.5 – 12.5 ng/mL R^2=0.9994	Primary method: 0.05 mg/L / 4 0.5 mg/L / 5 Confirmatory method: 0.05 mg/L / 3 0.5 mg/L / 2	81 - 109 % 96 - 114 % 73 - 104 % 106 %, 106 %	93 % 103 % 93 % 106 %	13 % 6 % 15 % -	0.05 mg/L	Düsterloh (2008) IPBC- PT6 CAR Doc IIIA, 4.2d/01

Table 22

Analytical methods for body fluid urine									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
IPBC	LC-MS/MS, RP18 column, (primary method); Phenyl hexyl column (confirmatory method), ESI+	MS transitions not mentioned validation data for primary and confirmatory method	0.5 – 12.5 ng/mL R^2=0.9981	Primary method: 0.05 mg/L / 5 0.5 mg/L / 5 Confirmatory method: 0.05 mg/L / 3 0.5 mg/L / 2	72 - 79 % 67 - 76 % 95 - 105 % 99 %, 103 % 	76 % 70 % 100 % 101 %	3 % 5 % 4 % -	0.05 mg/L	Düsterloh (2008) IPBC- PT6 CAR Doc IIIA, 4.2d/01
PBC	LC-MS/MS, RP18 column, (primary method); Phenyl hexyl column (confirmatory method), ESI+	MS transitions not mentioned validation data for primary and confirmatory method	0.5 – 12.5 ng/mL R^2=0.9994	Primary method: 0.05 mg/L / 5 0.5 mg/L / 5 Confirmatory method: 0.05 mg/L / 3 0.5 mg/L / 2	60 - 67 % 73 - 87 % 74 - 88 % 82 %, 78 %	63 % 77 % 83 % 80 %	4 % 7 % 8 % -	0.05 mg/L	Düsterloh (2008) CAR IPBC-PT6 Doc IIIA, 4.2d/01

Table 23

Analytical methods tissue meat									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
PBC	LC-MS/MS, RP18 column, (primary method); Phenyl hexyl column (confirmatory method), ESI+	MS transitions not mentioned validation data for primary and confirmatory method	0.5 – 12.5 ng/mL R^2=0.9994	Primary method: 0.1 mg/kg / 5 1.0 mg/kg / 5 Confirmatory method: 0.1 mg/kg / 3 0.5 mg/L / 2	84 - 117 % 76 - 99 % 80 - 96 % 95 %, 88 %	99 % 86 % 87 % 91 %	11 % 10 % 8 % -	0.1 mg/kg	Düsterloh (2008) CAR IPBC-PT6 Doc IIIA, 4.2d/01

Table 24

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.1 substance of concern. Data waiving was accepted for “Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics” 2. 5.2.2. Air: Data waving was accepted for residues of IPBC. 3. 5.2.4 Body fluids and tissues: Data waving was accepted for tebuconazole and permethrin. 4. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant: Data waving was accepted for tebuconazole, IPBC and permethrin.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 25

Conclusion on the methods for detection and identification
The methods provided regarding the active substances, residues and substance of concern were acceptable. The methods provided regarding the residues of the active substances IPBC, tebuconazole and permethrin were acceptable. Please note: The method for determination of permethrin in surface water is not sufficient for monitoring the limit of 0.47 ng/L based on the PNEC water, but the presented method was accepted in the CAR. The method for determination of IPBC in soil is not sufficient for monitoring the limit of 0.005 mg/kg based on the PNEC soil, but the presented method was accepted in the CAR. For residues of IPBC in drinking water, surface water and soil the validation data for second MS/MS transitions should be added for confirmatory purposes. For residues of tebuconazole in surface water a sufficiently validated confirmatory method should be added in the context of the next active substance renewal according to Regulation (EU) No 528/2012. Methods regarding residues of the substance of concern were not necessary.

3.5 Efficacy against target organisms

Information on the composition of the test products chosen in order to generate data on the efficacy against target organisms as well as the corresponding justification are provided in the confidential annex.
The test products chosen, the corresponding justification and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.
Therefore, the efficacy assessment for Meta SPC 1 in this chapter also covers Meta SPC 2 and 3.

3.5.1 Function and field of use

Products are designed for preventive treatment of wood by surface application against wood discolouring fungi (blue stain), wood rotting fungi (brown and white rot) and wood boring insects. Application methods are brushing when used by professional or non-professional users. Application methods of dipping and spraying in closed devices are for industrial professionals and professionals only.

Products are designed as primers for use class 2 and use class 3. When used in use class 2 and 3 against wood discolouring fungi and in use class 3 against wood rotting fungi they must always be over-coated with an appropriate coating.

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

Products are ready for use formulations and are effective against wood discolouring fungi, wood destroying basidiomycetes and wood boring insect larvae. The products are for use on timbers not in ground contact, either exposed to the weather (use class 3) or protected from the weather but subject to occasional wetting (use class 2). In situations where treated timber would be exposed to weathering (use class 3), the treated timber must always be over-coated after drying with a suitable top coat. Against wood discolouring fungi, a top coat is required both in use class 2 and 3.

3.5.3 Effects on target organisms, including unacceptable suffering

Growth of discolouring fungi is suppressed either completely or to the level of insignificantly blue-stained the most. Growth of wood destroying basidiomycetes is prevented with almost no measurable mass

loss. Development of insect larvae is stopped after contact with treated wood followed by 100 % mortality after no more than 12 weeks.

3.5.4 Mode of action, including time delay

Tebuconazole
Tebuconazole inhibits in the ergosterol biosynthesis of fungi, thus prohibiting formation of cell walls.

IPBC
IPBC is a carbamate fungicide. The target sites of carbamates in fungi are cell membrane permeability and fatty acids, which leads to disruption of basic cell functions.

Permethrin
As an insecticide, permethrin when formulated as a wood preservative is an axonic poison, binding to voltage-gated sodium channels in nerves. By binding to these channels, the substance group of pyrethroids prevent the channels from closing which cause prolonged sodium channel activation. The nervous system is irreversibly damaged leading to death.

The biocidal product is used preventively. Time delay is not relevant in these uses.

3.5.5 Efficacy data

General
The label claim against discolouring fungi is supported by two key studies according to EN 152-1 in combination with either a 4 weeks artificial weathering or a 26 weeks natural exposure of the treated wood in the field prior to laboratory testing. The label claim against wood destroying basidiomycetes is supported by four key studies according EN 113 against brown rot fungi on pine wood as well as by two key studies against white rot fungi on beech. Tests were carried out after artificial ageing according to EN 73 (evaporation), which is relevant for use class 2 and use class 3, as well as after artificial ageing according to EN 84 (leaching), which is relevant for use class 3. Efficacy against wood boring insect larvae is supported by four studies according to EN 46-1. Two tests were carried out after artificial ageing according to EN 73 (evaporation), which is relevant for use class 2 and use class 3, and two tests were carried out after artificial ageing according to EN 84 (leaching), which is relevant for use class 3.

Wood discolouring fungi

Tests for efficacy against wood discolouring fungi were carried out with test products JJT 6311 and JJT 6320. Both test products were solvent-based ready for use formulations tested via surface application through brushing. Both test products had equal amounts of IPBC, and Tebuconazole, as well as similar alkyd resin (binder) contents. JJT 6311 was missing Permethrin when compared to the products of Meta SPC 1. Because the efficacy against wood discolouring fungi is caused by the presence of IPBC and Tebuconazole in the products, the presence of Permethrin is not relevant to evaluate anti blue stain activity. Since the concentrations of IPBC and Tebuconazole in the reference products (test products) are the same as in the products for Meta SPC 1 and all products are solvent-based formulations, read-across to demonstrate efficacy against wood discolouring fungi is justified. The binder contents vary slightly, but differences are not regarded as relevant for efficacy evaluation. The same applies for all other constituents of the formulations. The EN 152-1 test results with JJT 6320 demonstrated efficacy as a preventive wood preservative against blue stain fungi (*Aureobasidium pullulans* and *Sydowia polyspora*) at application rates of min. 148.6 mL/m² (mean 150.5 mL/m²). The tested treatment fulfilled the requirements given in EN 599-1. No test specimen had a blue stain rating higher than 1 (insignificantly blue-stained) and the minimum blue-stain free zone was 4.5 mm with a mean of 5.9 mm. The validity criteria of EN 152 were fulfilled, so the test is considered valid.The test was carried out after 4 weeks of artificial weathering with JJT 6320 being covered by a top coat. In the second test according to EN 152-1, test results with JJT 6311 demonstrated efficacy as a preventive wood preservative against blue stain fungi *(Aureobasidium pullulan*s and *Sydowia polyspora*) at application rates of min. 146 mL/m² (mean not provided). The tested treatment fulfilled the requirements given in EN 599-1. No test specimen had a blue stain rating higher than 1 (insignificantly blue-stained) and the minimum blue-stain free zone was 3.5 mm with a mean of 4.3 mm. The validity criteria of EN 152 were fulfilled, so the test is considered valid. The test was carried out after 26 weeks of natural weathering with JJT 6311 being covered by a top coat.

Therefore, efficacy of the recommended dosages of 160 mL/m² for softwood and 225 mL/m² for hardwood for products in Meta SPC 1 against discolouring fungi was demonstrated for use class 2 and use class 3. An appropriate top coat has to be applied.

Wood rotting fungi

Tests for efficacy against wood destroying basidiomycetes were carried out with test products JJT 6311 and JJT 6320. Both test products were solvent-based concentrated formulations tested in various dilutions via pressure impregnation. Both test products had equal amounts of IPBC, and Tebuconazole, as well as similar alkyd resin (binder) contents. JJT 6311 was missing Permethrin when compared to the products of Meta SPC 1. Because the efficacy against wood destroying basidiomycetes is caused by the presence of IPBC and Tebuconazole in the products, the presence of Permethrin is not relevant to evaluate anti basidiomycete activity. Since the concentrations of IPBC and Tebuconazole in the

reference products (test products) are the same as in the products for Meta SPC 1 and all products are solvent-based formulations, read-across to demonstrate efficacy against wood destroying basidiomycetes is justified. The binder contents vary slightly, but differences are not regarded as relevant for efficacy evaluation. The same applies for all other constituents of the formulations.

The test product JJT 6320 showed sufficient efficacy against wood destroying basidiomycetes, namely against *Coniophora puteana*, *Poria placenta* and *Gloeophyllum trabeum* (brown rot) as well as against *Trametes (Coriolus) versicolor* (white rot). Efficacy was shown in tests according to EN 113 in combination with evaporative ageing procedure EN 73 and leaching procedure EN 84 respectively. The critical value (c.v.) is the highest biological reference value (b.r.v.) from all of the biological tests carried out. Therefore, from the studies after evaporation and after leaching, the c.v. is 41.4 kg/m³ against brown rotting fungi and 88.1 kg/m³ against white rotting fungi. EN 599-1 states that, for superficial treatments in use class 2, the b.r.v. in grams per square metre shall be deemed to be equivalent to twice the b.r.v. established in kilograms per cubic metre. On this basis, the c.v. of 41.4 kg/m³ against brown rotting fungi is equivalent to an application rate of 82.8 g product/m² (corresponds to 103 mL/m²) and the c.v. of 88.1 kg/m³ against white rotting fungi is equivalent to an application rate of 176.2 g product/m² (corresponds to 219 mL/m²). The same assumption can be applied for use class 3 if the superficial treatments are covered by an appropriate top-coat after drying. In the second test the test product JJT 6311 showed sufficient efficacy against wood destroying brown rot basidiomycetes, namely against *Coniophora puteana*, *Poria placenta* and *Gloeophyllum trabeum*. White rot basidiomycetes were not tested with JJT 6311. Efficacy was shown in tests according to EN 113 in combination with evaporative ageing procedure EN 73 and leaching procedure EN 84 respectively. The critical value (c.v.) is the highest biological reference value (b.r.v.) from all of the biological tests carried out. Therefore, from the two studies after evaporation and after leaching against brown rotting fungi, the c.v. is 44 kg/m³. EN 599-1 states that, for superficial treatments in use class 2, the b.r.v. in grams per square metre shall be deemed to be equivalent to twice the b.r.v. established in kilograms per cubic metre. On this basis, the c.v. of 44 kg/m³ against brown rotting fungi is equivalent to an application rate of 88 g product/m² (corresponds to 109 mL/m²). The same assumption can be applied for use class 3 if the superficial treatments are covered by an appropriate top-coat after drying.
Therefore, efficacy of the recommended dosages of 160 mL/m² for softwood and 225 mL/m² for hardwood for products in Meta SPC 1 against wood destroying basidiomycetes was demonstrated for use class 2 and use class 3. When used in use class 3, an appropriate top coat has to be applied.

Wood destroying beetle larvae

Tests for efficacy against wood boring insect larvae were carried out with test products JJT 6310 and JJT 6320. Both test products were solvent-based ready for use formulations, tested via surface application through brushing, containing 0.5 % IPBC, 0.2% Tebuconazole, 0.06 % Permethrin as well as similar alkyd resin (binder) contents. Since the concentrations of Permethrin in the reference products (test products) are the same as in the products for Meta SPC 1 and all products are solvent-based formulations, read-across to demonstrate efficacy against wood boring insect larvae is justified. The binder contents vary slightly, but differences are not regarded as relevant for efficacy evaluation. The same applies for all other constituents of the formulations. In two studies conducted with JJT 6310 according to test standard EN 46-1, the test product was tested for efficacy against wood destroying beetle larvae of *Hylotrupes bajulus*. From both studies, after evaporation according to EN 73 as well as after leaching according to EN 84, respectively, the minimum effective retention for 100 % mortality of larvae was 152.7 mL/m². In the other two studies conducted with JJT 6320 according to test standard EN 46-1, the test product was also tested for efficacy against wood destroying beetle larvae of *Hylotrupes bajulus*. From both of these studies, after evaporation according to EN 73 as well as after leaching according to EN 84, respectively, the minimum effective retention for 100 % mortality of larvae was 150.2 mL/m².

Therefore, efficacy of the recommended dosages of 160 mL/m² for softwood and 225 mL/m² for hardwood for products in Meta SPC 1 against *Hylotrupes bajulus* was demonstrated for use class 2 and use class 3. According to the Transitional Guidance on Efficacy Assessment for Product Type 8 Wood Preservatives (March 2015), which was in force when the application for authorisation of Primer TIP was submitted, efficacy against *Hylotrupes bajulus* is sufficient to cover a general claim against wood boring beetles for preventive treatment. New data against other beetle species have to be submitted at the renewal stage.

Table 26

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Fungicide; Preventive effectiveness against wood destroying fungi	Wood preservative in use class 2 and 3	JJT 6311 0.5% IPBC and 0.2% Tebuconazole	*Coniophora puteana*, BAM Ebw 15, *Poria placenta* FPRL 280, *Gloeophyllum trabeum*, BAM Ebw 109	EN 113 (1996) in combination with leaching procedure (EN 84, 1997)	**Laboratory method**, Wood species: scotch pine sapwood (*Pinus sylvestris* L.) **Treatment:** Vacuum pressure, mean target retention of product: 0-26-33-40-49-61 kg/m^3, concentrations tested: 0-5.4-6.6-8-9.8-12 %; conditioning: at least 28 days, accelerated ageing: 14 days, method of sterilization: ionising radiation, 16 weeks of incubation, Replicates: 4	Down to the lowest uptake of about 25 to 26 kg product/m³ protective efficacy was shown for three fungi *Poria placenta and Gloeophyllum trabeum*, and *Coniophora puteana.* In the untreated controls mass losses were between 29 and 47 %.	Morsing & Klamer, 2013a
Fungicide; Preventive effectiveness against wood destroying fungi	Wood preservative in use class 2 and 3	JJT 6311 0.5% IPBC and 0.2% Tebuconazole	*Coniophora puteana*, BAM Ebw 15	EN 113 (1996) in combination with accelerated ageing	**Laboratory method**, Wood species: scotch pine sapwood (*Pinus sylvestris* L.)	Down to the lowest uptake of about 40-48 kg product/m³ protective	Morsing & Klamer, 2014a

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
			Poria placenta, FPRL 280 *Gloeophyllum trabeum*, BAM Ebw 109	procedure (EN 73, 1988	**Treatment:** Vacuum pressure, target retention of product: 0-26-32-40-48-60 kg/m^3, concentrations tested0-5.4-6.6-8-9.8-12 %; conditioning: at least 28 days, ageing: 12 weeks, method of sterilization: ionising radiation,16 weeks of incubation, Replicates: 4	efficacy was shown for the test fungi *Poria placenta,* with 25 kg product/m^3 for *Gloeophyllum trabeum* , and with 32-40 kg product/m^3 for *Coniophora puteana.* In the untreated controls mass losses were between 23 and 43%. The mean corrected mass loss for the highest concentration without protective effect was 6.6%.	
Fungicide; Preventive effectiveness against wood destroying fungi	Wood preservative in use class 2 and 3	JJT 6320 0.5% IPBC and 0.2% Tebuconazole	*Coniophora puteana*, BAM Ebw 15,	EN 113 (1996) in combination with leaching procedure (EN 84, 1997)	**Laboratory method**, Wood species: scotch pine sapwood (*Pinus sylvestris* L.)	Down to the lowest uptake of about 40.8 kg product/m³ protective	Schumacher & Fennert, 2013a

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		and 0,06 % Permethrin	*Poria placenta* FPRL 280, *Gloeophyllum trabeum*, BAM Ebw 109		**Treatment:** Vacuum pressure, mean target retention of product: 0-40-50-60-70-80 kg/m^3, concentrations tested: 0-8.2-10.2-12.2-14.3-16.1 %; conditioning: at least 28 days, accelerated ageing: 14 days, method of sterilization: ionising radiation, 16 weeks of incubation, Replicates: 4	efficacy was shown for the test fungi *Poria placenta,* with 41.4 kg product/m^3 for *Gloeophyllum trabeum* , and with 41,3 kg product/m^3 for *Coniophora puteana.* In the untreated controls mass losses were between 22 and 38 % (mean values). The mean corrected mass loss for the highest concentration without protective effect was below 8.2 %.	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Fungicide; Preventive effectiveness against wood destroying fungi	Wood preservative in use class 2 and 3	JJT 6320 0.5% IPBC and 0.2% Tebuconazole and 0,06 % Permethrin	*Coniophora puteana*, BAM Ebw 15 *Poria placenta*, FPRL 280 *Gloeophyllum trabeum*, BAM Ebw 109	EN 113 (1996) in combination with accelerated ageing procedure (EN 73, 1988	**Laboratory method**, Wood species: scotch pine sapwood (*Pinus sylvestris* L.) **Treatment:** Vacuum pressure, target retention of product: 0-40-50-60-70-80 kg/m^3, concentrations tested: 0-8.2-10.2-12.2-14.3-16.1 %; conditioning: at least 28 days, ageing: 12 weeks, method of sterilization: ionising radiation,16 weeks of incubation, Replicates: 4	Down to the lowest uptake of about 40.8 kg product/m³ protective efficacy was shown for the test fungi *Poria placenta,* with 41.4 kg product/m^3 for *Gloeophyllum trabeum* , and with 40.9 kg product/m^3 for *Coniophora puteana.* In the untreated controls mass losses were between 26 and 48% (mean values). The mean corrected mass loss for the highest concentration without	Schumacher & Fennert, 2014a

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						protective effect was below 8.2 %.	
Fungicide; Preventive effectiveness against wood destroying fungi	Wood preservative in use class 2 and 3	JJT 6320 0.5% IPBC and 0.2% Tebuconazole and 0,06 % Permethrin	*Coriolus versicolor*, CTB 863 A	EN 113 (1996) in combination with leaching procedure (EN 84, 1997)	Laboratory method, Wood species: Beech (*Fagus sylvatica* L.) **Treatment:** Full impregnation, target retention of product: 0-50-60-70-80-90 kg/m³, concentrations tested: 0-13.8-16.5-19.3-22.1-24.8%; conditioning: at least 28 days, accelerated ageing: 14 days, method of sterilization: ionising radiation, 16 weeks of incubation, Replicates: 4	Down to the lowest uptake of about 50.6 kg product/m³ protective efficacy was shown for *Coriolus versicolor*. In the untreated controls mass losses were 30 % (mean values).	Schumacher & Fennert, 2013b
Fungicide; Preventive effectiveness against wood destroying fungi	Wood preservative in use class 2 and 3	JJT 6320 0.5% IPBC and 0.2% Tebuconazole and 0,06 % Permethrin	*Coriolus versicolor*, CTB 863 A	EN 113 (1996) in combination with accelerated ageing	Laboratory method, Wood species: Beech (*Fagus sylvatica* L.) **Treatment:** Full impregnation, target	Down to the lowest uptake of about 82.4 to 93.8 kg product/m³ protective	Schumacher & Fennert, 2014b

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
				procedure (EN 73, 1988	retention of product: 0-50-60-70-80-90 kg/m^3, concentrations tested: 0-13.8-16.5-19.3-22.1-24.8%; conditioning: at least 28 days, accelerated ageing: 12 weeks, method of sterilization: ionising radiation, 16 weeks of incubation, Replicates: 4	efficacy was shown for *Coriolus versicolor*. In the untreated controls mass losses were 36 % (mean values).	
Fungicide; Protective effectiveness against blue stain	Wood preservative in use class 2 and 3	JJT 6311 0.5% IPBC and 0.2% Tebuconazole	*Aureobasidium pullulans*, P268 *Sydowia polyspora*, S231	ÖNORM EN 152:2012, system Type A (fungicidal preparation used with unspecified top) after 6 months of field testing	**Laboratory method**, Wood species: scotch pine sapwood (*Pinus sylvestris L.*) **Treatment:** brushing 146-151 mL/m², 3 x alkyd standard top coat, conditioning: at least 7 days, natural weathering: 6 months, method of sterilization: ionising	6 Blocks treated with 146-151 mL/m² Blue stain on surface: max. 1 Zone width free of blue stain Minimum (mm): 3.5 Mean (mm): 4.3	Pfabigan & Gründlinger, 2014a

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					radiation, 6 weeks of incubation, Replicates: 6		
Fungicide; Protective effectiveness against blue stain	Wood preservative in use class 2 and 3	JJT 6320 0.5% IPBC and 0.2% Tebuconazole and 0,06 % Permethrin	*Aureobasidium pullulans*, P268 *Sydowia polyspora*, S231	EN 152:2011, system Type A (fungicidal preparation used with unspecified top) after 4 weeks artificial weathering	**Laboratory method**, Wood species: scotch pine sapwood (*Pinus sylvestris L.*) **Treatment:** brushing 140-160 mL/m², 3 x alkyd standard top coat, conditioning: at least 7 days, artificial weathering: 4 weeks, method of sterilization: ionising radiation, 6 weeks of incubation, Replicates: 6	6 Blocks treated with 140-160 mL/m² Blue stain on surface: max. 1 Zone width free of blue stain Minimum (mm): 4.5 Mean (mm): 5.9	Schumacher & Fennert, 2013c
Insecticide; Preventive effectiveness against wood destroying beetles	Wood preservative in use class 2 and 3	JJT 6320 0.5% IPBC and 0.2% Tebuconazole and 0,06 % Permethrin	*Hylotrupes bajulus*	EN 46-1 (2009) in combination with leaching procedure (EN 84, 1997)	Laboratory method, Wood species: scotch pine sapwood (*Pinus sylvestris* L.) **Treatment:** surface application through brushing, target retention 140 to 160	Down to the lowest effective uptake 150.2 ml product/m³ protective efficacy was shown for *Hylotrupes bajulus*.	Schumacher & Fennert, 2013d

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					ml/m²; 4 weeks of exposure to insects, Replicates: 6		
Insecticide; Preventive effectiveness against wood destroying beetles	Wood preservative in use class 2 and 3	JJT 6320 0.5% IPBC and 0.2% Tebuconazole and 0,06 % Permethrin	*Hylotrupes bajulus*	EN 46-1 (2009) in combination with leaching procedure (EN 73, 1988)	Laboratory method, Wood species: scotch pine sapwood (*Pinus sylvestris* L.) **Treatment:** surface application through brushing, target retention 140 to 160 ml/m²; 4 weeks of exposure to insects, Replicates: 6	Down to the lowest effective uptake 150.2 ml product/m³ protective efficacy was shown for *Hylotrupes bajulus*.	Schumacher & Fennert, 2013e
Insecticide; Preventive effectiveness against wood destroying beetles	Wood preservative in use class 2 and 3	JJT 6310 0.5% IPBC and 0.2% Tebuconazole and 0,06 % Permethrin	*Hylotrupes bajulus*	EN 46-1 (2009) in combination with leaching procedure (EN 84, 1997)	Laboratory method, Wood species: scotch pine sapwood (*Pinus sylvestris* L.) **Treatment:** surface application through brushing, target retention 140 to 160 ml/m²; 4 weeks of exposure to insects, Replicates: 6	Down to the lowest effective uptake 152.7 ml product/m³ protective efficacy was shown for *Hylotrupes bajulus*.	Arancon 2013a
Insecticide; Preventive	Wood preservative in	JJT 6310	*Hylotrupes bajulus*	EN 46-1 (2009) in	Laboratory method,	Down to the lowest effective	Arancon 2013b

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
effectiveness against wood destroying beetles	use class 2 and 3	0.5% IPBC and 0.2% Tebuconazole and 0,06 % Permethrin		combination with leaching procedure (EN 73, 1988)	Wood species: scotch pine sapwood (*Pinus sylvestris* L.) **Treatment:** surface application through brushing, target retention 140 to 160 ml/m²; 4 weeks of exposure to insects, Replicates: 6	uptake 150.5 ml product/m³ protective efficacy was shown for *Hylotrupes bajulus*.	

3.5.6 Occurrence of resistance and resistance management

Tebuconazole:
As other triazole fungicides Tebuconazole inhibits the C 14 demethylation step in the ergosterol biosynthesis of fungi. All demethylation inhibitors including Tebuconazole have a similar resistance risk but resistance factors may be different. Resistance of Tebuconazole to target organisms in wood preservation is not officially reported or known up to the time being. Due to the specific application fields, the nature of the organisms and the frequency of treatment it is unlikely that resistance will be built-up by the target organisms in a short time.

IPBC:
The risk of resistance formation against Carbamate fungicides is regarded to be low to medium by FRAC. This applies to the use of Carbamate fungicides in agriculture, where annual applications are performed. With respect to the use of Carbamates in wood preservation, there is a small potential in the formation of resistance. The number of treatments to a wooden structure is generally low. In many cases, only one application is made per lifetime of timber structures, resulting in a low selection pressure. In the present biocidal products family, IPBC is used in combination with Tebuconazole. Both active substances have different modes of action. For this reason, the low risk of resistance formation is further reduced.

Permethrin:
There are no reported cases of development of resistance involving the use of Permethrin in wood preservation. However, cases of resistance have been documented in a wide variety of insects when Permethrin has been used as a general insecticide (PT18 product). The level of resistance is less than ten-fold in some of the species but high levels of resistance have been observed in others such as cockroaches. In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms.
Thus, authorisation holders and professional end-users should report any observed resistance incidents to the Competent Authorities. Additionally, pest management strategies are advised in the use of Permethrin for wood preservation in order to combat any potential for the onset of resistance.
Preventive efficacy resulted in 100 % mortality, therefore any kind of tolerance cannot be inherited.

3.5.7 Known limitations

Reference products for Meta SPC 1 were covered with a top-coat when tested for efficacy against discolouring fungi. Therefore, products for Meta SPC 1, 2 and 3 are not effective against discolouring fungi in use class 2 and use class 3 when not covered by an appropriate top coat. Products in Meta SPC 1, 2 and 3 are not effective against wood destroying basidiomycetes in use class 3 when not covered by an appropriate top coat.

3.5.8 Evaluation of the label claims

The label discloses the following claims:

- The products within the product family contains active ingredients effective against wood destroying and wood discolouring fungi as well as against wood boring insects.
- Effective against wood destroying fungi, blue stain and wood boring insects at 160 ml/m^2.

The German CA considers the efficacy of the products within the product family Primer TIP against wood destroying and wood discolouring fungi as well as against wood boring insects (shown by *Hylotrupes bajulus*) at an application rate of 160 ml/m^2 on softwood as proved by the data provided. However, hardwood can only be claimed with the higher application rate of 225 ml/m^2. Furthermore, while demonstration of efficacy against *H. bajulus* was sufficient for a general preventive claim against wood boring beetles based on the guidance applicable at submission of this application for authorisation, new data against other beetle species have to be submitted at the renewal stage.

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

As the products are not intended to be authorised for use with other biocidal product(s), there is no need for information at this point.

3.5.10 Data waiving and conclusion

Table 27

Data waiving was acceptable for the following information requirements

Information requirement	No data waiving.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 28

Conclusion on the efficacy
With the application rate of 160 ml/m^2 (preventive use, surface application via brushing, dipping and spraying) sufficient preventive efficacy on softwood against wood discolouring fungi (blue stain), wood rotting fungi and wood boring insects can be assumed and the biocidal product family “Primer TIP” can be authorised. Efficacy for wood boring insects has only be shown on the beetle type *Hylotrupes bajulus*. New data against other beetle species have to be submitted at the renewal stage. Hard wood can only be claimed with the higher application rate of 225 ml/m^2. An appropriate top coat is necessary in use class 2 and 3 when used against wood discolouring fungi and in use class 3 when used against wood rotting fungi.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 29

Tebuconazole	Value	Study	Safety factor
AEL long-term	0.03 mg/kg bw/d	1-yr dog; Porter et al. (1989 & 1993) Assessment Report (RMS Denmark (2007) derived as AOEL (Operator/Worker Exposure)	100
AEL medium-term	0.03 mg/kg bw/d	1-yr dog; Porter et al. (1989 & 1993) Assessment Report (RMS Denmark (2007) derived as AOEL (Operator/Worker Exposure)	100
AEL acute	0.03 mg/kg bw/d	EFSA Scientific Report (2008) 176, 1-109 (2008-09-25)	300

Table 30

Tebuconazole	Value	Reference
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Assessment Report (RMS Denmark (2007)
Dermal absorption	75 % for products containing ≤ 5 %; 25 % for products containing > 5 %	Default value (EFSA Journal 2012)
	~50 % (0.04 - 40 mg/ml in ethanol)	Assessment Report (RMS Denmark (2007))
	16 % (0.63 % w/w in JJT 3582 organic solvent based formulation) 4 % (0.65 % w/w in JJT 3583 water based formulation)	Human skin *in vitro*; Toner (2006), TM IV 2012 Human skin in vitro; Toner (2006), TM IV 2012
	Testformulierung 1 „Primer“; Meta-SPC 1, 2, 3: **37 %**	Craig, S. (2015)

Table 31

IPBC	Value	Study	Safety factor
AEL long-term	0.2 mg/kg bw/d	2-yr rat; Mulhem et al. (1989), Draft Assessment-Report (RMS Denmark (2013))	100
AEL medium-term	0.35 mg/kg bw/d	90-d rat; Bien (2002), Draft Assessment-Report (RMS Denmark (2013))	100
AEL acute	0.35 mg/kg bw/d	90-d rat; Bien (2002), Draft Assessment-Report (RMS Denmark (2013))	100
ADI	0.2 mg/kg bw/d	2-yr rat; Mulhem et al. (1989), Draft Assessment-Report (RMS Denmark (2013))	
ARfD	0.35 mg/kg bw/d	90-d rat; Bien (2002), Draft Assessment-Report (RMS Denmark (2013))	

Table 32

IPBC	Value	Reference
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Ampofo (1994), Draft Assessment-Report (RMS Denmark (2013))
Dermal absorption	75 %: formulations containing < 0.5 % - 0.6 % IPBC and untested formulations containing ≤ 5 % IPBC	Default value, EFSA Journal 2012;10(4): 2665
	30 % (0.6 % IPBC in Hickson Vascol 2651) 10 % (2.4 % IPBC in Microtech) 1.6 % (17 % IPBC in Troysan Polyphase EC)	Human skin *in vitro* Jack and Dunsire, 1995, Assessment-Report (RMS Denmark (2013))
	25 %: untested formulations containing > 5 % IPBC 75 % default for solutions containing < 0.5 % - 0.6 % IPBC	Default value EFSA Journal 2012;10(4):2665
	Formulierung B „Primer“, Meta-SPC 1, 2, 3: **54 %**	Maas, W.J.M. (2013)

Table 33

Permethrin	Value	Study	Safety factor
AEL long-term	0.05 mg/kg bw/d	12-month dog study. Bayer (Kalinowski *et al*., 1982), Assessment-Report (RMS Ireland (2014))	100
AEL medium-term	0.05 mg/kg bw/d	12-month dog study. Bayer (Kalinowski *et al*, 1982), Assessment-Report (RMS Ireland (2014))	100
AEL acute	0.5 mg/kg bw	Rat 2 year oral study (acute effect), Bayer (Ishmael and Litchfield, 1988), Assessment-Report (RMS Ireland (2014))	100

Table 34

Permethrin	Value	Reference
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Assessment Report (RMS Ireland (2014))
Dermal absorption	3 %	Assessment Report (RMS Ireland (2014)) Human dermal penetration study
	10 %	Webbley, K. (2015)

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 35

Data waiving was acceptable for the following information requirements	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	A skin irritation study performed with biocidal products of this family is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.1 “Skin corrosion or skin irritation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 2.1, 2017), “testing on the biocidal products 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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” Sufficient information on skin-irritating/skin corrosion properties of

	the components of the biocidal products is available. Information on synergistic effects is not available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary.

Table 36

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Meta-SPC 1, 2, 3: Not irritating to the skin. May cause skin dryness and cracking. May cause paresthesia.
Justification for the value/conclusion	Evaluation and classification is based on the toxicological properties of the single components. The content of components classified for skin irritation or corrosion is below the limits for classification. The biocidal products contain naphtha (petroleum, hydrotreated heavy, CAS No. 64742-48-9) and other hydrocarbons, which are labelled with EUH066 (acc. to Annex VI of Regulation (EC) No 1272/2008 and SDS submitted by the applicant) in maximum concentrations of approximately 90 %. Thus, also the biocidal product has to be labelled accordingly. Pyrethroids like the active substance permethrin in the biocidal product can cause paresthesia.
Classification of the product according to CLP	Meta-SPC 1, 2, 3: Classification for skin irritation/corrosivity is not required. EUH066 Repeated exposure may cause skin dryness and cracking. May cause paresthesia.

3.6.2.2 Eye irritation

Table 37

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	An eye irritation study performed with biocidal products of this family is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.2 “Eye irritation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 2.1, 2017), “testing on the biocidal products 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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” Sufficient information on eye-irritating/eye damage properties of the components of the biocidal products is available. Information on synergistic effects is not available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary. Based on the results of the eye irritation studies with the active substances and information on the hazards of the single components eye irritation of the biocidal products can be predicted.

Table 38

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Best and worst case: Meta-SPC 1, 2, 3: Not irritating to the eyes.
Justification for the value/conclusion	Meta-SPC 1, 2, 3: The concentration of components classified with Eye Dam. 1 or Eye Irrit. 2 is below the corresponding concentration limits.
Classification of the product according to CLP	Maximum and minimum classification Meta-SPC 1, 2, 3: Not classified

3.6.2.3 Respiratory tract irritation

Table 39

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, “other endpoints”
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal products do not contain components classified for respiratory irritation in relevant concentrations.

Table 40

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Meta-SPC 1, 2, 3: Not irritating to the respiratory tract.
Justification for the value/conclusion	Meta-SPC 1, 2, 3: Based on intrinsic properties of individual components and their concentration in the formulations the biocidal products are not irritating to the respiratory tract.
Classification of the product according to CLP	Meta-SPC 1, 2, 3: Classification for respiratory tract irritation is not required.

3.6.2.4 Skin sensitisation

Table 41

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the biocidal products are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.3 “Skin sensitisation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 2.1, 2017), “testing on the biocidal products 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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal products the compositions are known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the products. Information on synergistic effects is not available.

Table 42

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Meta-SPC 1, 2, 3: Not skin.sensitising
Justification for the value/conclusion	Meta-SPC 1, 2, 3: The active substances IPBC and permethrin are classified for skin sensitisation. However, their concentrations are below the limit for classification. Based on the content of IPBC the EUH208 is required. IPBC (0.5 %, w/w): Skin Sens. 1 [1)] (H317: C ≥ 1 %; EUH208: C > 0.1 %) [2)] Permethrin (0.06 %): Skin Sens. 1 [1)] (H317: C ≥ 1 %; EUH208: C > 0.1 %) [2) 3)]
Classification of the product according to CLP	Meta-SPC 1, 2, 3: Classification for skin sensitisation is not required. Labelling with EUH208 (Contains IPBC. May produce an allergic reaction.)

[1)] According to Annex VI of Regulation (EC) No 1272/2008
[2)] According to Regulation (EC) No 1272/2008
[3)] According to the active substance evaluation permethrin is not skin-sensitising. A CLH intention to remove this entry has been submitted. However, a final decision is not available. Thus, the current classification is legally binding.

3.6.2.5 Respiratory sensitisation (ADS)

Table 43

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	Data on respiratory sensitisation for the biocidal products or their components are not available.

Table 44

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Respiratory sensitisation is not expected.
Justification for the value/conclusion	Data on respiratory sensitisation for the biocidal products or their components with the corresponding concentration are not available.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 45

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	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 2.1, 2017), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal products the compositions are known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the biocidal products can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 46

Value used in the Risk Assessment – Acute oral toxicity	
Value	Meta-SPC 1, 2, 3: Not acutely toxic via the oral route. Causes human aspiration toxicity.
Justification for the selected value	Meta-SPC 1, 2, 3: Based on the oral LD_{50} available for the single components the oral LD_{50} of the biocidal products is estimated as > 2000 mg/kg bw. Additional information on non-active substances: Naphtha, petroleum, hydrotreated heavy (ShellSol D60; max app. 90 %, w/w) Asp. 1 [1)], (concentration limit for Asp. 1: ≥ 10 %; kinematic viscosity (40 °C) ≤ 20.5 mm^2/s) [2)] The biocidal products contain also other components (hydrocarbons), which contribute to this classification.
Classification of the product according to CLP	Meta-SPC 1, 2, 3: Classification for acute oral toxicity is not required. Asp. 1; H304 (May be fatal if swallowed and enters airways.)

[1)] According to Annex VI of Regulation (EC) No 1272/2008

[2)] According to Regulation (EC) No 1272/2008. Meta-SPC 1, 2, 3 (representative test formulation): The kinematic viscosity at 20 °C is 2.13 mm²/s (section 3.2). Thus, it can be concluded that the kinematic viscosity at 40 °C is also far below the limit value. Meta-SPC 3 to 6 (representative test formulation): The kinematic viscosity at 20 °C is 16.8 mm²/s (section 3.2).

3.6.2.6.2 Acute toxicity by inhalation

Table 47

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	A study on acute inhalation toxicity of the biocidal products is not required. 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 2.1, 2017), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal products the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the biocidal products can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 48

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Meta-SPC 1, 2, 3: Not acutely toxic via the inhalation route.
Justification for the selected value	Meta-SPC 1, 2, 3: Based on the inhalation LC_{50} available for the single components the inhalation LC_{50} of the biocidal product is estimated as > 5 mg/L.
Classification of the product according to CLP	Meta-SPC 1, 2, 3: Classification for acute inhalation toxicity is not required.

3.6.2.6.3 Acute toxicity by dermal route

Table 49

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	Meta-SPC 1, 2, 3: A study on acute dermal toxicity of the biocidal products is not required. 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 2.1, 2017), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal products the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the biocidal products can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 50

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Meta-SPC 1, 2, 3: Not acutely toxic via the dermal route.
Justification for the selected value	Meta-SPC 1, 2, 3: Based on the dermal LD_{50} available for the single components the dermal LD_{50} of the biocidal product is estimated as > 2000 mg/kg bw.
Classification of the product according to CLP	Meta-SPC 1, 2, 3: Classification for acute dermal toxicity is not required.

3.6.2.7 Information on dermal absorption

Table 51

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Age/Sex, Localisation, No. Number of skin samples and donors tested per dose, exposure and post-exposure time, oOther relevant information about the study**	**Test substance, Formulation details incl. identify and concentration Doses (total volume/mass applied per area, amount of a.s. applied per area)**	**Absorption data for each compartment (mean and SD as percentage of dose), absorption (percentage of dose) calculated in accordance with EFSA Guidance on Dermal Absorption (2012) and final absorption value**	**Remarks (e.g. major deviations statements on variability and time-course, justification of non-inclusion of certain compartments, other relevant information, e.g. receptor fluid)**	**Reference**
OECD 428 GLP: yes Reliability: 1	Species: Human Age/Sex: 42 – 52, female Localisation: breast and abdomen Number of skin samples and donors tested per dose: 4 donors 2 per donor and dose 8 samples, one sample excluded Exposure time: 6 h Post exposure time: 18 h	Test substance: **IPBC** Solvent based formulation B (JJT 6464 Solvent-Borne Primer (Blank) + radio labelled test compound (IPBC); practically identical to biocidal product, contains same amount of IPBC but not the other a. s., slightly higher amount of non-polar solvent	Receptor fluid: 36.38 % ± 9.93 % Receptor compartment wash: 0.08 % ± 0.02 % Absorbed dose: 36.45 % ± 9.94 % Stripped skin: 2.68 % ± 0.75 % Total Absorbable dose: 39.13 % ± 9.86 % Normalised: 43.27 % ± 11.22 % Correction for high variation (> 25 %): 54.49 % **Rounded dermal absorption value:** **54 %**	All tape strips were excluded from the absorbable dose since the total absorption during the first half exceeds 75 %. Due to the low recovery (< 95 % for all samples) in the study normalisation of the absorbable dose was performed. Since the variation of the absorbable dose (28 %) was higher than 25 % one SD was added. The dermal absorption study consists of 6 independent experiments with three	Maas, W.J.M. (2013)

		Concentration IPBC: 0.3 % Dose: 6.4 µL/ 0.64 cm^2 =10 µL/cm^2		different formulations. Studies with the test formulations, which are not representative for the biocidal product, were not evaluated. The second study with the representative test formulation results in a significantly lower dermal absorption but also in a lower total recovery. As proposed by the applicant this experiment was not considered for derivation of the dermal absorption.	
OECD 428 GLP: yes Reliability: 1	Species: Human Age/Sex: 28-68, male/female Localisation: breast and abdomen Number of skin samples and donors tested per dose: 4 donors 2 per donor and dose 8 samples Exposure time: 6 h Post exposure time: 18 h	Test substance: **Permethrin** Solvent based formulation Preventol Primer TIP+ radio labelled test compound (permethrin); similar to biocidal product family Concentration permethrin: 0.07 % Dose: 15 µL/1.77 cm^2 =8.47 µL/cm^2	Receptor fluid: 0.57 % ± 0.16 % Absorbed dose: 0.57 % ± 0.16 % Stripped skin: 1.93 % ± 1.72 % Tape strips (excl. 1 and 2): 4.13 ± 3.15 Total Absorbable dose: 6.63 % ± 3.79 % Normalised: not required Correction for high variation (> 25 %): 10.42 % Rounded dermal absorption value: 10 %	Only tape strips 1 + 2 were excluded from the absorbable dose since the total absorption during the first half was below 75 %. (60 % ± 3 %) Since the variation of the absorbable dose (57 %) was higher than 25 % one SD was added. The target concentration during preparation of the test formulation was 0.06 %. However, the measured concentration was 0.07 %. One sample was excluded due to a low mass balance considerably deviating from	Webbley, K. (2015)

				the mass balance of all other samples.	
OECD 428 GLP: yes Reliability: 1	Species: Human Age/Sex: 31-63, male/female Localisation: breast and abdomen Number of skin samples and donors tested per dose: 5 donors 2 per donor and dose 10 samples Exposure time: 6 h Post exposure time: 18 h	Test substance 1: **Tebuconazole** Solvent based formulation Preventol Primer TIP+ radio labelled test compound (tebuconazole); similar to the primer in this biocidal product family Concentration tebuconazole: 0.2 % Dose: 6.4 µL/0.64 cm^2 =9.98 µL/cm^2	Receptor fluid (incl. rinse and wash): 4.26 % ± 2.46 % Absorbed dose: 4.26 % ± 2.46 % Stripped skin: 9.24 % ± 6.92 % Tape strips (excl. 1 and 2): 12.94 % ± 3.66 % Total Absorbable dose: 26.44 % ± 8.92 % Normalised: 27.39 % ± 9.15 % Correction for high variation (> 25 %): 36.54 % Rounded dermal absorption value: 37 %	Values from cells No. 38 and 40 were excluded since it must be assumed that these cells were leaking during the experiment (low recovery, significant higher values for donor wash and unexposed skin). Only tape strips 1 + 2 were excluded from the absorbable dose since the total absorption during the first half was below 75 % (64 % ± 12 %) Absorption values of 4 samples were normalised since the recovery was below 95 %. Since the variation of the absorbable dose (33 %) was higher than 25 % one SD was added. The target concentration during preparation of the test formulation was 0.2 %. However, the measured concentration was 0.226 %.	Craig, S. (2015)

Note: The dermal absorption studies for IPBC and tebuconazole contains experimental data for a primer formulation and a stain formulation. Regarding this application only data for primer formulations were evaluated.

Table 52

Data waiving was acceptable for the following information requirements	
Information requirement	Data waiving for the dried biocidal product. 8.6. Information on dermal absorption.
Justification	No dermal absorption studies are available for the dried biocidal product on/in wood. Thus, the default value of 75 % from the EFSA Guidance on Dermal Absorption (2012) should be used for all active substances.

Value(s) used in the Risk Assessment – Dermal absorption			
Substance exposure scenario(s)	IPBC 1 Ready-to-use product 2. Dried films on treated wood	Permethrin 1 Ready-to-use product 2 Dried films on treated wood	Tebuconazole 1. Ready-to-use product 2. Dried films on treated wood
Value(s)	1. 54 % 2. 75 %	1. 10 %2. 75 %	1. 37 % 2. 75 %
Justification for the selected value(s)	1. Dermal absorption study with a similar formulations 2. EFSA Guidance on Dermal Absorption, 2012	1. Dermal absorption study with a similar formulation 2. EFSA Guidance on Dermal Absorption, 2012	1. Dermal absorption study with a similar formulations 2. EFSA Guidance on Dermal Absorption, 2012

IPBC:

In a study submitted by the applicant dermal absorption values of a primer and of a stain were determined. The identity of both test formulations is presented in the confidential annex. The primer formulation is sufficiently similar to the corresponding members of the biocidal product family. The concentration of the active substance is for both test formulations in the lower range of the relevant members of the biocidal product family. The concentrations of the solvents, binders and other auxiliaries are in the same ranges. In the absence of appropriate dermal absorption studies the default of 75 % according to the EFSA Guidance on Dermal Absorption (2012) should be applied for indirect exposure to dried biocidal products.

Note: The applicant proposed to use a dermal absorption value of 1.6 % for IBPC if the biocidal product is dried. He argues that it is a well-accepted fact that dermal absorption of an active substance in a solid formulation (e.g. powder, granule) is distinctly lower than in a water-based formulation and even lower than in an organic solvent-based formulation. Thus, the dermal absorption value obtained with a high concentrated solvent-based formulation represents a worst case.

This position is not shared. Dried fluids on wood are not comparable with solid formulations or solvent-based formulations. The amounts of active substance transferred from wood to skin are normally far

below the dose tested for dermal absorption. The dose of an active substance on a skin surface is a dominant factor influencing skin absorption and often inversely related to the concentration. It is also known that dermal absorption depends also on co-formulants and therefore even solid formulations may have a higher dermal absorption than liquid formulations.
Thus, in the absence of specific data for dried fluids on wood a dermal absorption value of 75 % should be used.

Permethrin:
For permethrin the dermal absorption value of 10 % resulting from a study with a comparable formulation (primer) can be applied for primary exposure. The identity of the test formulation is presented in the confidential annex. The test formulation is sufficiently similar to the members of this biocidal product family. The concentration of the active substance is in the lower range of the biocidal product family. The concentrations of the solvents, binders and other auxiliaries are in the same ranges.
In the absence of appropriate dermal absorption studies the default of 75 % according to the EFSA Guidance on Dermal Absorption (2012) should be applied for indirect exposure to dried biocidal products.

Tebuconazole:
In a study submitted by the applicant dermal absorption values of a primer was determined. The identity of the test formulation is presented in the confidential annex. The test formulation is sufficiently similar to the corresponding members of the biocidal product family. The concentration of the active substance in the test formulation is in the lower range of the relevant members of the biocidal product family. The concentrations of the solvents, binders and other auxiliaries are in the same ranges.
In the absence of appropriate dermal absorption studies the default of 75 % according to the EFSA Guidance on Dermal Absorption (2012) should be applied for indirect exposure to dried biocidal products.

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

For labelling with EUH066 refer to section 3.6.2.1.
For classification with Asp. 1, H304 refer to section 3.6.2.6.1.

Toxicology and metabolism –substances of concern

Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (ShellSol D60; CAS No.: -, EC No.: -),

Limits and other Values for Human Health Risk Assessment

Summary	*Value*	*Study/Source*	*AF*
AEL	Not established		
DNEL		REACH Registration Dossier no. 01-2119486659-16-0000 (date accessed: 30/01/2020),	
Worker, inhalation, long-term	838 mg/m^3	Respiratory tract	6
Worker, inhalation, acute/short-term	1067 mg/m^3	Respiratory tract (higher value for neurotoxicity: 1286 mg/m^3)	9
Worker, dermal	Not derived	-	
General population, inhalation, long-term	179 mg/m^3	Respiratory tract	10
General population, inhalation, acute/short-term	640 mg/m^3	Respiratory tract (higher value for neurotoxicity: 1152 mg/m^3)	15
General population, dermal and oral	Not derived	-	
AGW for C9 – C15 aliphatics	250 mg/m^3	TRGS 900 (07/06/2018), Technische Regeln für Gefahrstoffe	-
MAK value (2009) for hydrotreated heavy naphtha (petroleum)	300 mg/m^3 (50 mL/m^3)[1]	4-hr human volunteer inhalation study, Lammers et al. (2007), NOAEC: 600 mg/m^3 (CNS impairment)	2
Inhalative absorption	50 % [2]	Default assumption for volatiles	
Oral absorption	100 %	Default, REACH Registration Dossier Reg. No. 01-2119486659-16-0000	
Dermal absorption	25 %	Default, (EFSA Guidance on Dermal Absorption (2012))	

[1] Peak limitation: Category II, excursion factor = 2 (corr. to a permissible short term concentration of 600 mg/m^3); Pregnancy Risk Group D; Source: The MAK-Collection Part I, MAK Value Documentations 2015, DFG, Deutsche Forschungsgemeinschaft, Wiley-VCH Verlag GmbH & Co. KGaA, 2015.
[2] Inhalative absorption may be lower for individual components. Refer to REACH Registration Dossiers Reg. No. 01-2119486659-16-0000 and 01-2119457273-39

i) Toluene is classified acc. to Table 3.1 of the CLP regulation as STOT SE3, STOT RE2, Repr. 2 with the lowest concentration limit at 3 % (w/w). The concentration of aromatics in hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (ShellSol D60; CAS No.: -, EC No.: -) as reported in the MSDS for ShellSol D60 is below 2 %. Thus, no hazard classification results for the SoC.
ii) n-hexane is classified acc. to Table 3.1 of the CLP regulation as Skin Irrit. 2, Asp. Tox. 1, STOT SE3, STOT RE2 and Repr. 2 with the lowest concentration limit at 3 % (w/w). Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (ShellSol D60) contains mainly C10-13 hydrocarbons and n-hexane does not trigger classification for the SoC. The content of n-hexane may be specified as below 3 %.
iii) For Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2 % aromatics (ShellSol D60; CAS No.: -, EC No.: -) a harmonised classification does currently not exist. Naphtha (petroleum), hydrotreated heavy (CAS No.: 64742-48-9) is classified as Asp. Tox. 1, Muta. 1B and Carc. 1B according to Annex VI of the CLP regulation. However, according to Note P for this entry, classification as Muta. 1B and Carc. 1B does not apply when the substance contains less than 0.1 % (w/w) benzene (EINECS No 200-753-7). Thus, the SoC would not need to be classified for Muta. 1B and Carc. 1B if levels of benzene are below 0.1 %. This may also be included in the specification.
Overall, classification for Asp. Tox. 1 results for this SoC.
Classification as STOT SE 3 for narcotic effects [currently not foreseen for neither Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (ShellSol D60; CAS No.: -, EC No.: -) nor naphtha (petroleum), hydrotreated heavy (CAS No.: 64742-48-9) by CLP regulation Table 3.1] does not relate to the substance potency. Neuro(psycho)logical effects of the SoC have been discussed above and can be used as starting point for quantitative assessment of “narcotic” effects of hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (ShellSol D60; CAS No.: -, EC No.: -) if needed.

Classification	
Current, with regard to toxicological data, according to Annex VI Table 3.1 of Reg. 1272/2008 for naphtha (petroleum), hydrotreated heavy (CAS No.: 64742-48-9)	Danger; Asp. Tox. 1, *Muta. 1B, Carc. 1B* *Note P: Muta. 1B and Carc. 1B need not apply if it can be shown that the substance contains less than 0.1 % w/w benzene (EINECS No 200-753-7)* H304 May be fatal if swallowed and enters airways *(H340 May cause genetic defects)* *(H350 May cause cancer)*
Additional / deviating, with regard to toxicological data, according to the criteria in Reg. 1272/2008	EUH066 Repeated exposure may cause skin dryness of cracking

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

Not available.

3.6.2.11 Summary of effects assessment

Table 53

Endpoint	Brief description
Skin corrosion and irritation	Meta-SPC 1, 2, 3: Based on the intrinsic properties of single components. Not classified for skin irritation or corrosion. Repeated exposure may cause skin dryness or cracking. Labelling with EU066 is required. Skin exposure may cause paresthesia.
Eye irritation	Based on the intrinsic properties of single components. Meta-SPC 1, 2 ,3: Not irritating to the eyes (not classified).
Respiratory tract irritation	Meta-SPC 1, 2, 3: Based on the intrinsic properties of single components. Not irritating to the respiratory tract (not classified).
Skin sensitisation	Based on the intrinsic properties of single components. Meta-SPC 1, 2, 3: Not skin-sensitising (not classified), labelling with EUH208 for IPBC.
Respiratory sensitization (ADS)	Meta-SPC 1, 2, 3: Based on the known intrinsic properties of single components. Not sensitising to the respiratory tract (not classified).
Acute toxicity by oral route	Meta-SPC 1, 2, 3: Based on the known intrinsic properties of single components. Oral LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw. Classification with Asp. 1, H304 is required due to the toxicological properties of co-formulants and their concentration in the biocidal products and their viscosity.
Acute toxicity by inhalation	Meta-SPC 1, 2, 3: Not classified for acute inhalation toxicity. Inhalation LC_{50} calculated from information on the ingredients: > 5.0 mg/L.
Acute toxicity by dermal route	Meta-SPC 1, 2, 3: Not classified for acute dermal toxicity. Dermal LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw
Information on dermal absorption	Based on dermal absorption studies with representative formulations or default values according to EFSA Guidance on Dermal Absorption (2012) IPBC: 54 % for application scenarios and 75 % for dried films on treated wood. Permethrin: 10 % for application scenarios and 75 % for dried films on treated wood. Tebuconazole: 37 % for application scenarios and 75 % for dried films on treated wood.
Available toxicological data relating to non-active substance(s)	Single target organ toxicity, repeated exposure (CNS) Based on the known intrinsic properties of single components. Meta-SPC 1, 2, 3: Classification is not required.
Available toxicological data relating to a mixture	Not relevant
Other relevant information	Not available

3.6.3 Exposure assessment

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

Table 54

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	Yes	Yes	yes	n.a.
Dermal	Yes	Yes	yes	Yes	Yes	yes	n.a.
Oral	Not applicable	Not applicable	yes	Not applicable	Not applicable	yes	no

List of scenarios

Table 55

Summary table: scenarios				
Scenario number	**Use number***	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure Description of scenario**	**Exposed group (e.g. professionals, non-professionals, bystanders)**
1.	2	Application	Brushing, outdoors, acute exposure	Non-professional users
2.	2	Application	Cleaning brush, acute exposure	Non-professional users
3.	-	Post-application	Secondary exposure, acute: adult - sanding treated wood, inhalation and dermal exposure	General public, adults
4.	-	Post-application	Secondary exposure, acute: toddler - chewing treated wood off-cut, oral exposure	General public, toddlers, (adults)
5.	-	Post-application	Secondary exposure, long-term, toddler (represents worst case for older children and adults) - inhalation of volatilised residues in doors, inhalation exposure	General public, toddlers, (adults)
6.	-	Post-application	Secondary exposure, long-term, toddler - playing on treated structure and mouthing, superficial treatment (dermal, oral)	General public, toddlers, (adults)
7.	1	Brush treatment	Primary exposure of workers resulting from application of the b.p. using hand held equipment such as a brush or a roller and cleaning of equipment.	Professional
8.	3	Immersion (automated dipping)	Primary exposure of workers resulting from mixing and loading, automated dipping processes in industrial scale treatment units entailing cycles of loading, waiting, unloading and removal of treated timber to storage and maintenance work.	Professional, industrial

Summary table: scenarios				
Scenario number	**Use number***	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure Description of scenario**	**Exposed group (e.g. professionals, non-professionals, bystanders)**
9.	4	Dip treatment (manual dipping)	Primary exposure of workers resulting from mixing and loading, manual dipping processes followed by placing treated wood on storage yards and cleaning.	Professional, industrial
10.	5	Deluge treatment	Primary exposure of workers resulting from mixing and loading, deluge processes in industrial scale treatment units entailing loading, waiting, unloading and removal of treated timber to storage and maintenance work.	Professional, industrial
11.	-	Secondary exposure: Mechanical processing of treated wood	Secondary exposure of workers resulting from mechanical processing of treated wood, i.e. sawing or sanding preventively treated wood.	Professional, industrial

3.6.3.1.1 Industrial exposure

- **Scenario 8 – Immersion (automated dipping)**

For a detailed description of this scenario, please see chapter 3.6.3.1.2.

- **Scenario 9 – Dip treatment (manual dipping)**

For a detailed description of this scenario, please see chapter 3.6.3.1.2.

- **Scenario 10 – Deluge treatment**

For a detailed description of this scenario, please see chapter 3.6.3.1.2.

- **Scenario 11 – Secondary exposure: Mechanical processing of treated wood**

For a detailed description of this scenario, please see chapter 3.6.3.1.2.

3.6.3.1.2 Professional exposure Meta-SPC 1, 2 and 3

- **General considerations for the product family**

The biocidal product family (BPF) Primer TIP is a biocidal product family of solvent-based liquid wood preservatives comprising three meta-SPCs 1, 2, 3

All members of meta-SPCs 1, 2, 3 are ready-to-use wood preservatives containing the three active substances (a.s.) IPBC (CAS-No.: 55406-53-6), tebuconazole (CAS-No.: 107534-96-3) and permethrin (CAS-No.: 52645-53-1). They also contain the substance of concern (soc) hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (CAS-No.: -). The products of meta-SPCs 1, 2, 3 intended for professional use are marketed in package sizes of up to 25 L, 200 L, and 1000 L (for brushing, only up to 25 l packages are foreseen).

The products of meta-SPCs 1, 2, 3 are applied for the preventive treatment of wooden structures by the same application techniques, i.e., brushing, immersion (automated dipping), dip treatment (manual dipping), and deluge treatment. These application techniques and the respective exposure models will be described in individual subsections of the current section. The exposures to the three a.s. and the soc are assessed separately for the different application techniques. They are usually based on the harmonised document “Biocides Human Health Exposure methodology (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007. The inhalation exposures to the soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics resulting from the different application techniques are assessed using the consumer exposure model ConsExpo, which is applicable to assess this volatile substance.

The products of meta-SPCs 1, 2 and 3 contain the same concentrations of the three a.s.. The concentration of the soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics is almost identical in meta-SPCs 1, 2, 3, ranging from 88.05 % – 88.60 %.

Since the concentrations of the three a.s. in products of meta-SPC 1, 2 and 3 do not differ, and the concentrations of the soc are also almost identical, the parameters, calculations and results laid out in this chapter will be applicable to all products of meta-SPCs 1, 2 and 3. For the SoC, the highest concentration of 88.60 % will be considered as a worst-case.

Detailed exposure calculations for the professional user for meta-SPCs 1, 2 and 3 are laid out in annex 4.2.1. For risk characterisation, see chapter 3.6.4.5.

- **Scenario 7 – Brush treatment**

Description

A harmonised approach for exposure assessment of brush treatment is described in the *Biocides Human Health Exposure Methodology document* (October 2015, version 1). The assessment laid out in this PAR follows this approach.

The products of meta-SPCs 1, 2, 3 are ready-to-use wood preservatives, which are applied using hand-held equipment such as brush or roller for brush application.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

For the application phase, no appropriate exposure model for professional brushing is available, therefore the dermal exposure is assessed using the BfR “Summary Report - Human Exposure to Wood Preservatives”, which is recommended by the harmonised document “Biocides Human Health Exposure Methodology (October 2015, version 1)”. The application process significantly contributes to the total dermal exposure.

Additionally, exposure of hands during cleaning of the brush is considered, although it represents a minor part of the total dermal exposure. As a worst case assumption this post-application phase is calculated on the basis of a Human Exposure Expert Group opinion (HEEG, endorsed TM III 2010) dealing with washing paint out of a brush.

Exposure by inhalation

For the application phase, exposure to aerosols has been calculated using indicative values of the German BfR-study. This is in line with the harmonised document “*Biocides Human Health Exposure Methodology”* (October 2015, version 1). In this study, inhalation exposure has been detected, but exposure to aerosols was not mentioned in detail. On this account, it is assumed that the values given by this study might overestimate the exposure by inhalation towards the non-volatile a.s. Exposure to aerosols during post-application is not expected.

In addition, inhalation exposure to vapour was calculated for the volatile soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (CAS-No.: -) using ConsExpo.
In contrast to the non-volatile a.s., the exposure to aerosols of the volatile soc is assessed to be negligible in relation to the exposure to the vapours.

Summary of exposure assessment

The results of the calculations for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) for meta-SPCs 1, 2 and 3 are summarised in Table 61. For risk characterisation, see chapter 3.6.4.5. Details of the exposure calculations for the professional user are laid out in annex 4.2.1.

A risk was identified in Tier 1. Thus, a refined exposure assessment was performed in Tier 2. For risk assessment, the dermal contact to the active substances and the inhalation exposure towards the SoC

hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics are most relevant for the application by brushing. In Tier 1, it was demonstrated that exceedance of the German OEL (8h TWA and 15 min STEL) is likely. Therefore, for the refined exposure assessment in Tier 2, a reduction of the exposure to vapours by improved ventilation was considered. For reduction of the dermal contact, protective gloves were required.

Table 56

	Details of Scenario 7 – Brush treatment	
	Parameters	**Value**
Tier 1	Concentration a.s. IPBC	0.50%
	Concentration a.s. tebuconazole	0.21%
	Concentration a.s. permethrin	0.06%
	Concentration of soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics in b.p.*	88.6 %*
	Concentration of the b.p. the in application liquid	100 %
	Density of the b.p.	0.804 g/cm³ (20 °C)
	Amount of b.p. applied to the wood	5.7 kg
	Air exchange rate**	0.5 /h
	Duration of stay in the treated area**	480 min
Tier 2	Air exchange (Improved ventilation: cross ventilation)	5 /h
	Chemical protective gloves (EN 374), protection factor	90%

* The concentration of this soc differs slightly between meta-SPC 1 (88.05 %), meta SPC 2 (88.11%) and meta-SPC 3 (88.6 %); for this calculation, the highest concentration of meta-SPC 3 was used as worst-case.

** Used for calculation of exposure to vapours of the soc with ConsExpo.

- **Scenario 8 – Immersion (automated dipping)**

Description

A harmonised approach for exposure assessment of automated dipping is described in the *Biocides Human Health Exposure Methodology* document (October 2015, version 1). The assessment laid out in this PAR follows this approach.

Immersion/automated dipping is a batch process using industrial scale treatment units. The treatment itself is carried out in open dip tanks. The wood is lowered by fork lift truck into the dipping tank. Alternatively, the dip tank unit can feature hydraulic lifting equipment. Application includes all stages in preservation, from loading the dip tanks to stacking the treated wood to dry. The job entails a cycle of loading, waiting, unloading and removal of treated timber to storage. Fresh and treated wood is usually moved using lift trucks, however, the operators are closely involved with handling restraining straps and treatment machinery, in removing fallen wood and sawdust sludge.

The products of meta-SPCs 1, 2, 3 are ready-to-use wood preservatives which are transferred into a dip tank. For this process, the operator has to connect the transfer lines only.

The duration of dipping cycles and in consequence the number of dipping cycles performed per day depends on different factors (e.g. application rate, type of wood, humidity of wood, economic situation). In practice, the companies take into account the different influencing factors and decide on the duration of one dipping cycle and the performed number of cycles per day. As shown by a questionnaire in Germany (see also “HEEG opinion 8 - "Defaults and appropriate models to assess human exposure for dipping processes (PT8)”) the number of dipping cycles can range between 1 and more than 20 cycles per day. In cases of short term dipping with dipping durations in the range of minutes it is likely that more than 4 cycles are performed per day. In contrast, for long term automated dipping with durations in the range of hours it is reasonable to assume less than 4 cycles per day. To decide on a general basis about the variations of dipping durations and cycles the mean value of 4 dipping cycles is used. This is also in line with HEEG opinion 8 and the *Biocides Human Health Exposure Methodology document* (October 2015, version 1).

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

Exposure to hands is expected for the loading phase during connecting transfer lines of the Intermediate Bulk container (IBC) to the dip tank. An appropriate model is recommended by the Human Exposure Expert Group (HEEG) and is used to calculate the hand exposure. This phase has a minor impact on the total dermal exposure.

For the application phase, exposure to hands and body is assessed using “Handling model 1” for liquid formulations (*Biocides Human Health Exposure Methodology*). There is no generic model data available for the immersion process, however according to "HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT8)” as well as “HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping“, “Handling model 1” reflects the procedures listed above most accurately. As a reasonable default value, a number of 4 cycles is calculated for the application phase. If there is no risk identified for this assessment there are no additional restrictions for the process necessary.

If a risk for the Tier 1 assessment is identified, the process is restricted to a “fully automated dipping process” due to HEEG opinion 18 - in line with the *Biocides Human Health Exposure Methodology document (October 2015, version 1)* - as follows:
“The biocidal product must only be used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place including when the treated articles are transported through the dip tank to 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. The latter statement excludes the use of fork lift trucks for lowering the wood into the dipping tank.

With these restrictions, the exposure is expected to decrease by a factor of 4 (in Tier 2).

Professional post-application exposure constitutes system maintenance and is not considered a daily, but rather a weekly process (expert judgement). Therefore, the indicative value of “Handling model 1” for one cycle (*Biocides Human Health Exposure Methodology*) is used to assess weekly dermal exposure.

Exposure by inhalation

According to the Human Exposure Expert Group (HEEG) opinion mentioned above, inhalation exposure to aerosols can be considered negligible. However, inhalation exposure to vapours was calculated for the volatile soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics using ConsExpo.

Summary of exposure assessment

The results of the calculations for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 61. For details on the calculation of dermal and inhalation exposure, please refer to Annex 4.2.1 of this PAR. For risk characterisation, see chapter 3.6.4.5.

No risk was identified in Tier 1, however, since hand exposure resulting from the application phase was assessed based on data which was measured under protective gloves, this risk reduction measure is considered necessary for safe application. In addition, an automatic dosing device was considered necessary for filling of the vessel.

For information, a Tier 2 calculation was performed taking a fully automated dipping process together with use of protective gloves for all phases of the immersion process into account.

Table 57

	Details of Scenario 8 – Immersion (automated dipping)	
	Parameters	**Value**
Tier 1	Concentration a.s. IPBC	0.50%
	Concentration a.s. tebuconazole	0.21%
	Concentration a.s. permethrin	0.06%
	Concentration of the soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics in b.p.*	88.6 %
	Concentration of the b.p. in the application liquid	100 %
	Density of the b.p.	0.804 g/cm³ (20 °C)
	Amount of b.p. applied to the wood	181 kg
	Air exchange rate**	10 / h
	Duration of stay in the treated area**	30 min
	Number of cycles performed per day	4
Tier 2	Technical protection factor resulting from restriction to fully automated dipping***	4
	Chemical protective gloves (EN 374), protection factor****	90%

* The concentration of this soc differs slightly between meta-SPC 1 (88.05 %), meta SPC 2 (88.03%) and meta-SPC 3 (88.6 %); for this calculation, the highest concentration of meta-SPC 3 was used as worst-case.
** Used for calculation of exposure to vapours of the soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics with ConsExpo.
*** Only for information, not required for safe use
**** Chemical protective gloves are included in Tier 1 for the application and post-application phase (actual exposure data), in Tier 2 protective gloves have also been considered for the mixing and loading phase

- **Scenario 9 – Dip treatment (manual dipping)**

Description

A harmonised approach for exposure assessment of dip treatment is described in the *Biocides Human Health Exposure Methodology* document (October 2015, version 1). The assessment laid out in this PAR follows this approach related to the application phase.

The products are ready-to-use wood preservatives which can be pumped or poured manually into the dipping tank. As a worst case, the assessment considers a manual filling operation, which results in higher exposure compared to using an automatic dosing pump.

The application phase consists of dipping the wood piles into the treatment solution for a short time (minutes to hours, usually 1 to 10 minutes). The dipping process is done manually and is followed by placing the wood on the storage yard to drip off.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

For the loading phase, exposure to hands is expected during manual filling of the dipping tank. It is assumed that frequent (daily) loading will only involve filling up the dipping tank with limited quantities of up to 20 l of b.p., while a complete refilling of the dipping tank will take place as a less frequent maintenance operation (*vide infra*). . An appropriate model for manual pouring is recommended by Human Exposure Expert Group (HEEG) and is used to calculate the hand exposure. This phase has a minor impact on the total dermal exposure.

The application phase covers different steps of handling: manual dipping of wood in a tank followed by manual removing the treated wood for storage. Exposure to hands and body is considered to occur and is calculated using “Dipping model 1” (*Biocides Human Health Exposure Methodology*) taking into account a duration of 30 minutes per day according to the Human Exposure Expert Group (HEEG) opinion on “Defaults and appropriate models to assess human exposure for dipping processes (PT8)”. The model provides measurement data of potential body and actual hand exposure (measurements of hand exposure inside gloves) and is recommended by the harmonised document “Biocides Human Health Exposure Methodology (October 2015, version 1)”. The application process significantly contributes to the total dermal exposure.

Additionally, exposure to hands and body during post-application, i.e., maintenance of the dipping tank, has to be considered. The maintenance essentially consists of draining the old product from the tank and refilling it with fresh product. This process can be performed manually (draining using a hose) or with a pump. As a worst case, a manual process was considered here. An elaborated cleaning step is not expected.

Exposure by inhalation

Inhalation exposure may occur when leaning over the open tank to immerse and rotate the timber. Therefore, inhalation exposure to aerosols has been calculated for the application phase using indicative values of “Dipping model 1”. Exposure to aerosols during mixing/loading and post-application are not expected to occur. In addition, inhalation exposure to vapours was calculated for the volatile soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (CAS-No.: -) using ConsExpo. In contrast to the non-volatile a.s., the exposure to aerosols of this volatile soc is assessed to be negligible in relation to the exposure to the vapours.

Summary of exposure assessment
The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 61. For details on the calculation of dermal and inhalation exposure, please refer to Annex 4.2.1 of this PAR. For risk characterisation, see chapter 3.6.4.5.

In Tier 2, a refined exposure assessment is performed due to the risk identified in Tier 1. Since the dermal exposure to the a.s. IPBC and tebuconazole are most relevant, protective gloves and a protective coverall (type 6) are taken into account as risk reduction measures for Tier 2.

Table 58

	Details of Scenario 9 – Dip treatment	
	Parameters	**Value**
Tier 1	Concentration a.s. IPBC	0.50%
	Concentration a.s. tebuconazole	0.21%
	Concentration a.s. permethrin	0.06%
	Concentration of the soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics in b.p.*	88.6 %
	Concentration of the b.p. in the application liquid	100 %
	Density of the b.p.	0.804 g/cm³ (20 °C)
	Application duration per day**	30 min
	Amount of b.p. applied to the wood	18.1 kg
	Air exchange rate***	2 / h
	Duration of stay in the treated area ***	240 min
Tier 2	Chemical protective gloves (EN 374), protection factor****	90%
	Protective coverall (type 6, EN 13034), protection factor	90%

* The concentration of this soc differs slightly between meta-SPC 1 (88.05 %), meta SPC 2 (88.03%) and meta-SPC 3 (88.6 %); for this calculation, the highest concentration of meta-SPC 3 was used as worst-case.
** Value reflects work carried out directly at the dipping vessel and is considered for assessment of dermal exposure and exposure to aerosols.
*** Vapours are considered to disperse throughout the room, therefore this value is used for calculation of exposure to vapours of the soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics with ConsExpo.
****Chemical protective gloves have also been included in Tier 1 for the application and post-application phase (actual exposure data), in Tier 2 protective gloves have also been considered for the mixing and loading phase.

- **Scenario 10 – Deluge treatment**

Description

A harmonised approach for exposure assessment of deluge treatment is described in the *Biocides Human Health Exposure Methodology* document (October 2015, version 1). The assessment laid out in this PAR follows this approach.

The products are ready-to-use wood preservatives.

For deluge treatment, the products are pumped into the deluge tunnel throughout the application process. The operator connects the transfer lines to the container containing the b.p.

During application, timber is passed through a tunnel (on a conveyor) in which the wood preservative is applied from various types of spray jets. On the exit conveyor the freshly treated wood leaves the tunnel and has to be handled manually for lifting it onto the deposit station for drying. This scenario is assessed in the following section as worst case (Tier 1).

If risks for professional users were identified in Tier 1, the assessment could be refined by restricting the application to systems featuring an automatic piling device. In these systems, the freshly treated wood, which leaves the tunnel on the exit conveyor, is automatically piled up and then transported to storage using forklift trucks, thereby reducing dermal exposure.

Since the tunnel may be used with different types of wood preservatives on one day and to prevent jamming of the spray jets, extensive cleaning procedures have to be carried out after each pass and on each working day, respectively. However, it is expected that regular cleaning is included in the application process, thus no additional post-application phase is considered for exposure assessment.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

For the loading phase, exposure to hands is expected during connecting transfer lines of the IBC to the automatic dosing system. An appropriate model is recommended by Human Exposure Expert Group (HEEG) and is used to calculate the hand exposure. This phase has a minor impact on the total dermal exposure.

The application phase covers different steps of manual handling: handling treated timber coming out of the deluge tunnel and placing it on the deposit station. Exposure to hand and body is considered to occur. There is no generic model data available for the deluge treatment, however “Dipping model 1” (*Biocides Human Health Exposure methodology*) is used because the tasks described in this model most accurately reflect the procedures listed above. The model provides measurement data of potential body and actual hand exposure (measurements of hand exposure inside gloves). 60 min (two cycles of 30 min each) per day are taken into account for the deluge treatment. This is based on experience of the RMS collected during onsite visits of deluge treatment plants and on the assumption that much more treated wood is handled for deluge treatment than for manual dipping; furthermore this approach is in accordance with the *Biocides Human Health Exposure methodology document* (October 2015, version 1). The application process significantly contributes to the total dermal exposure.

In Tier 2, the exposure assessment can be refined by restricting the application to systems featuring an automatic piling device. This approach is based on the agreed assessment of immersion systems featuring “fully automatic dipping” (see “HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping“).

Exposure by inhalation

Due to the construction type of the deluge tunnel, exposure to aerosols cannot be excluded for the worker operating next to the tunnel unit. Therefore, inhalation exposure to aerosols has been calculated for the application phase using indicative values of “Dipping model 1”. Exposure to aerosols during loading and post-application are not expected to occur. In addition, inhalation exposure to vapour was calculated for the volatile soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (CAS-No.: -) using ConsExpo. In contrast to the non-volatile a.s., the exposure to aerosols of the volatile soc is assessed to be negligible in relation to the exposure to vapours.

Summary of exposure assessment

The results of the calculations for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 61. For risk characterisation, see 3.6.4.5. Details of the exposure calculations for the professional user are laid out in annex 4.2.1.

In Tier 2, a refined exposure assessment is performed due to the risk identified in Tier 1. Since the dermal exposure to the a.s. IPBC and tebuconazole is most relevant, a restriction to spray tunnels featuring an automated onward transport of the freshly treated wood with automated stacking or into a drier (“automated piling system”) was considered, which reduces the manual contact with the freshly treated wood. In addition, protective gloves and a protective coverall (type 6) are taken into account as risk reduction measures for Tier 2.

Table 59

	Details of Scenario 10 – Deluge treatment	
	Parameters	**Value**
Tier 1	Concentration a.s. IPBC	0.50%
	Concentration a.s. tebuconazole	0.21%
	Concentration a.s. permethrin	0.06%
	Concentration of the soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics in b.p.*	88.6 %
	Concentration of the b.p. in the application liquid	100 %
	Density of the b.p.	0.804 g/cm³ (20 °C)
	Amount of b.p. applied to the wood	90.4 kg
	Air exchange rate**	5 / h
	Number of cycles per day***	2 cycles (30 min each)
	Duration of stay in the treated area**	480 min
Tier 2	Technical protection factor resulting from restriction to spray tunnels featuring an automated piling system	2
	Chemical protective gloves (EN 374), protection factor****	90%
	Protective coverall (type 6, EN 13034), protection factor	90%

* The concentration of this soc differs slightly between meta-SPC 1 (88.05 %), meta SPC 2 (88.03%) and meta-SPC 3 (88.6 %); for this calculation, the highest concentration of meta-SPC 7 was used as worst-case.
** Used for calculation of exposure to vapours of the soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics with ConsExpo.
*** Value reflects work carried out near the spray tunnel and is considered for assessment of dermal exposure and exposure to aerosols; it is nevertheless assumed that the spray tunnel runs throughout the entire shift, which is considered relevant for estimation of exposure to vapours.
****Chemical protective gloves have also been included in Tier 1 for the application and post-application phase (actual exposure data), in Tier 2 protective gloves have also been considered for the mixing and loading phase.

- **Scenario 11 – Secondary exposure: Mechanical processing of treated wood**

Description

Secondary exposure due to mechanical processing of treated wood produced by application via brushing, immersion, deluge or dip treatment cannot be excluded. Therefore, the inhalation exposure to wood dust and dermal exposure during handling of treated wood and resulting from transfer of wood preservative to the skin are estimated here.

Inhalation exposure for mechanical processing of treated wood is assessed taking the limit value for wood dust concentration of 2 mg/m^3 into account - according to the German Hazardous Substances Ordinance "Gefahrstoffverordnung" and the Technical Rules for Hazardous Substances (TRGS 553). For calculation of the concentration of the a.s./soc within the wood dust, it is assumed that the applied application liquid is distributed within a thin layer at the wood surface. Sanding, as a worst case, releases wood dust created entirely from this layer. The density of the wood is taken from the Technical Agreements for Biocides (TAB, 2016, version 1).

Since the a.s. are not chemically fixed to the wood it cannot be ruled out that the substances can be released when the surface is wet, for instance. Therefore, it is reasonable that during the mechanical processing of treated wood dermal exposure could occur due to transfer of wood preservative to the hand. For exposure assessment, it is assumed that 20 % of both palms are exposed.

Summary of exposure assessment
The results of the calculation for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 61 (for risk characterisation, see 3.6.4.5). Details of the exposure calculations for the professional user are laid out in annex 4.2.1.

In Tier 2, a refined exposure assessment is performed due to the identified risk in Tier 1. Since the dermal exposure to the a.s. tebuconazole is most relevant, protective gloves as a risk reduction measure are taken into account for Tier 2.

Table 60

	Details of Scenario 11 – Secondary exposure: Mechanical processing of treated wood	
	Parameters	**Value**
Tier 1	Concentration a.s. IPBC	0.50%
	Concentration a.s. tebuconazole	0.21%
	Concentration a.s. permethrin	0.06%
	Concentration of b.p. in application liquid	100 %
	Density of the b.p.	0.804 g/cm³ (20 °C)
	Concentration b.p. in treated wood surface*	90.45 kg/m^3
	Hand area: palms of both hands	410 cm^2
	Contaminated hand surface	20 %
	Exposed hand area	82 cm^2
Tier 2	Chemical protective gloves (EN 374), protection factor	90%

* assumed penetration depth (outer layer): 0.002 m; expert judgement.

Further information and considerations

The volatile soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics is not considered relevant for secondary exposure, since it is expected to be evaporated before the wood is further processed.

Table 61

Summary table: estimated exposure from professional uses for meta-SPC 1, 2 and 3								
Exposure scenario	**Tier/ PPE**	**a.s. IPBC**		**a.s. tebuconazole**		**a.s. permethrin**		**soc hydrocarbons, C10-13, n-alkanes, isoalkanes, cyclics, < 2% aromatics**
		external inhalation exposure	**external dermal exposure [mg/day]**	**external inhalation exposure**	**external dermal exposure [mg/day]**	**external inhalation exposure**	**external dermal exposure [mg/day]**	**external inhalation exposure [mg/m³]**
1: Brush treatment	Tier 1	$2.53 \cdot 10^{-2}$ mg/day	10.43	$1.06 \cdot 10^{-2}$ mg/day	4.38	$3.03 \cdot 10^{-3}$ mg/day	1.25	8h TWA: 639 15 min STEL: 1031
	Tier 2	$2.53 \cdot 10^{-2}$ mg/day	3.76	$1.06 \cdot 10^{-2}$ mg/day	1.58	$3.03 \cdot 10^{-3}$ mg/day	0.45	8h TWA: 114 15 min STEL: 157
3: Immersion - automated dipping	Tier 1	not expected, no aerosol	daily: 6.76	not expected, no aerosol	daily: 2.84	not expected, no aerosol	daily: 0.81	daily, 8h TWA: 29 daily, 15 min STEL: 138
			weekly: 1.68		weekly: 0.71		weekly: 0.20	Weekly, 8h TWA: 7 Weekly, 15 min STEL: 138
	Tier 2		daily: 1.68		daily: 0.71		daily: 0.20	daily, 8h TWA: 29 daily, 15 min STEL: 138
			weekly: 1.68		weekly: 0.71		weekly: 0.20	Weekly, 8h TWA: 7 Weekly, 15 min STEL: 138
4: Dip treatment - manual dipping	Tier 1	$3.13 \cdot 10^{-4}$ mg/m³	46.68	$1.31 \cdot 10^{-4}$ mg/m³	19.60	$3.75 \cdot 10^{-5}$ mg/m³	5.60	8h TWA: 191 15 min STEL: 457
	Tier 2	$3.13 \cdot 10^{-4}$ mg/m³	7.46	$1.31 \cdot 10^{-4}$ mg/m³	3.13	$3.75 \cdot 10^{-5}$ mg/m³	0.89	8h TWA: 191 15 min STEL: 457
5: Deluge treatment	Tier 1	$6.25 \cdot 10^{-4}$ mg/m³	49.17	$2.63 \cdot 10^{-4}$ mg/m³	20.65	$7.50 \cdot 10^{-5}$ mg/m³	5.90	8h TWA: 76 15 min STEL: 150
	Tier 2	$3.13 \cdot 10^{-4}$ mg/m³	5.25	$1.31 \cdot 10^{-4}$ mg/m³	2.20	$3.75 \cdot 10^{-5}$ mg/m³	0.63	8h TWA: 76 15 min STEL: 150
6: Secondary Exposure: Mechanical processing of treated wood	Tier 1	$2.26 \cdot 10^{-3}$ mg/m³	7.42	$9.50 \cdot 10^{-4}$ mg/m³	3.12	$2.71 \cdot 10^{-4}$ mg/m³	0.89	not expected
	Tier 2	$2.26 \cdot 10^{-3}$ mg/m³	0.74	$9.50 \cdot 10^{-4}$ mg/m³	0.31	$2.71 \cdot 10^{-4}$ mg/m³	0.09	

- **Combined scenarios**

Within the different application methods the mixing and loading, application and post-application phases were combined if applicable. A combination of exposure resulting from different active substances was not performed.

3.6.3.1.3 Non-professional exposure

Meta-SPC 1, 2, 3

- **Scenario [1]**

Table 62

Description of Scenario [1]		
Primary acute exposure by application, brushing, outdoor, non-professional user, dermal and inhalation exposure: The biocidal product is for non-professional use and will be applied outdoors by brushing. According to the label provided by the applicant the biocidal product is also applied on the inner surface of window frames and doors. Since windows and doors has to be disassembled or at least opened before application this use can also be considered as outdoor use and no separate exposure scenario has to be assessed. Exposure assessment is based on exposure data summarised in the HEAdhoc recommendation No. 10 (The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling, 2016). According to this recommendation indicative values derived from the Austrian/BfR study (Humanexposition bei Holzschutzmitteln - (Human exposure to wood preservatives), Federal Institute for Risk Assessment, Berlin, 2005) and from the Consumer Product Painting Model 3 (Biocides Human Health Exposure Methodology, 2015, Brushing sheds and fences, outdoor (direct from can), Ann. Occup. Hyg. 44: 421-426, 2000) are used for dermal and inhalation exposure, respectively.		
	Parameters	Value
Tier 1	Indicative exposure value, hands, dermal, solvent-based (HEAdhoc recommendation No. 10, 2016)	9.14 µL BP/min
	Indicative exposure value, body, dermal, solvent-based (HEAdhoc recommendation No. 10, 2016)	1.12 µL BP/min
	Indicative exposure value, inhalation (HEAdhoc recommendation No. 10, 2016)	1.63 mg BP/m^3
	Density primer (applicant)	0.804 g/mL
	Max. concentration IPBC (applicant)	0.5 % (w/w)
	Max. concentration permethrin (applicant)	0.06 % (w/w)
	Max. concentration tebuconazole (applicant)	0.2 % (w/w)

Description of Scenario [1]		
	Exposure duration (TNsG on Human Exposure, 2002; Ann. Occup. Hyg. 44: 421-426, 2000)	150 min
	Dermal absorption IPBC (refer to chapter 3.6.2.7 Information on dermal absorption)	54 %
	Dermal absorption permethrin (refer to chapter 3.6.2.7 Information on dermal absorption)	10 %
	Dermal absorption tebuconazole (refer to chapter 3.6.2.7 Information on dermal absorption)	37 %
	Inhalation absorption (default for all active substances, CAR)	100 %
	Inhalation rate, adult (HEEG opinion No. 17, short-term exposure)	1.25 m^3/h
	Body weight, adult (HEEG opinion No. 17)	60 kg

Calculations for Scenario [1]

Systemic exposure

$Exposure_{dermal}$ = (dermal exposure hands + dermal exposure body) x density x concentration a.s. x exposure duration x dermal absorption / body weight adult

$Exposure_{inhalation}$ = inhalation exposure x concentration a.s. x exposure duration x inhalation rate x inhalation absorption / body weight adult

IPBC

$Exposure_{dermal}$ = (9.14 µL BP/min + 1.12 µL BP/min) x 0.804 g/mL x 0.5 % x 150 min x 54 % / 60 kg
= 0.0557 mg/kg bw

$Exposure_{inhalation}$ = 1.63 mg/m^3 x 0.5 % x 150 min x 1.25 m^3 / 60 min x 100 % / 60 kg
= 0.0004 mg/kg bw

Total systemic exposure = 0.0561 mg a.s./kg bw

Permethrin

$Exposure_{dermal}$ = (9.14 µL BP/min + 1.12 µL BP/min) x 0.804 g/mL x 0.06 % x 150 min x 10 % / 60 kg

= 0.00124 mg/kg bw

$Exposure_{inhalation}$ = 1.63 mg/m^3 x 0.06 % x 150 min x 1.25 m^3 / 60 min x 100 % / 60 kg
= 0.00005 mg/kg bw

Total systemic exposure = 0.00129 mg a.s./kg bw

Tebuconazole

$Exposure_{dermal}$ = (9.14 µL BP/min + 1.12 µL BP/min) x 0.804 g/mL x 0.2 % x 150 min x 37 % / 60 kg
= 0.0153 mg/kg bw

$Exposure_{inhalation}$ = 1.63 mg/m^3 x 0.2 % x 150 min x 1.25 m^3 / 60 min x 100 % / 60 kg
= 0.0002 mg/kg bw

Total systemic exposure = 0.0154 mg a.s./kg bw

- **Scenario [2]**

Table 63

Description of Scenario [2]		
Primary acute exposure by cleaning the brush, outdoors, non-professional user, dermal exposure. Dermal exposure by cleaning of the used brush is assessed according to the HEEG opinion No. 11 Exposure model Primary exposure scenario – washing out of a brush which has been used to apply a paint (2010) using the attached Excel sheet (section 4.2.2)		
	Parameters	Value
Tier 1	Volume of paint remaining on brush after painting (1/8 of 200 ml = 25 ml, HEEG opinion No. 11, 2010)	25 mL
	Max. concentration IPBC (applicant)	0.5 % (w/w)
	Max. concentration permethrin (applicant)	0.06 % (w/w)
	Max. concentration tebuconazole (applicant)	0.2 % (w/w)
	Density biocidal product (applicant)	0.804 g/mL
	Penetration factor gloves (no gloves)	100 %
	Dermal absorption IPBC (refer to chapter 3.6.2.7 Information on dermal absorption)	54 %
	Dermal absorption permethrin (refer to chapter 3.6.2.7 Information on dermal absorption)	10 %
	Dermal absorption tebuconazole (refer to chapter 3.6.2.7 Information on dermal absorption)	37 %
	Frequency of washing (HEEG opinion No. 11, 2010)	3

Description of Scenario [2]		
	Body weight, adult (HEEG opinion No. 17, 2013)	60 kg

Calculations for Scenario [2]

For detailed exposure calculations refer to the corresponding extract from the excel sheet (as presented in the HEEG opinion No. 11, 2011) in section 4.2.2.

Systemic exposure

IPBC

$Exposure_{dermal}$ = **0.00476 mg/kg bw**

Permethrin

$Exposure_{dermal}$ = **0.00011 mg/kg bw**

Tebuconazole

$Exposure_{dermal}$ = **0.00130 mg/kg bw**

Table 64 IPBC

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw [/d])**	**Estimated dermal uptake (mg/kg bw [/d])**	**Estimated oral uptake (mg/kg bw [/d])**	**Estimated total uptake (mg/kg bw [/d])**
Scenario [1]	1	0.0004	0.0557	-	0.0561
Scenario [2]	1	-	0.00476	-	0.00476

Table 65 Permethrin

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw [/d])**	**Estimated dermal uptake (mg/kg bw [/d])**	**Estimated oral uptake (mg/kg bw [/d])**	**Estimated total uptake (mg/kg bw [/d])**
Scenario [1]	1	0.00005	0.00124	-	0.00129
Scenario [2]	1	-	0.00011	-	0.00011

Table 66 Tebuconazole

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw [/d])**	**Estimated dermal uptake (mg/kg bw [/d])**	**Estimated oral uptake (mg/kg bw [/d])**	**Estimated total uptake (mg/kg bw [/d])**
Scenario [1]	1	0.0002	0.0153	-	0.0154
Scenario [2]	1	-	0.00130	-	0.00130

- **Combined scenarios**

Table 67 IPBC

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**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])**
Scenarios [1] + [2]	0.0004	0.0605	-	0.0609

Table 68 Permethrin

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**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])**
Scenarios [1] + [2]	0.00005	0.00135	-	0.00140

Table 69 Tebuconazole

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**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])**
Scenarios [1] + [2]	0.0002	0.0166	-	0.0168

3.6.3.1.4 Secondary exposure of the general public

Meta-SPC 1, 2, 3

- **Scenario [3]**

Table 70

Description of Scenario [3]		
Secondary acute exposure, adult - sanding treated wood, inhalation and dermal exposure The exposure estimates for the general public to active substances of this biocidal product in treated wood by sanding is based on the recommendations of the TNsG on Human Exposure (2002). Some parameters have been adapted due to more recent guidance. It is assumed that an adult sands a wooden post with a dimension of 4 cm x 4 cm x 250 cm. The long sides of the post are treated with biocidal product (4000 cm^2). It is assumed that the biocidal product is evenly distributed in the 1-cm outer layer. The corresponding wood volume is 3000 cm^3. Hence, the concentration of the active substances in the wood can be calculated from the application rate, the density, the treated surface and the volume of wood with biocidal product. The transfer coefficient and the percentage of the hand getting in contact have not been adopted from the TNsG on Human Exposure (2002) but amended in accordance to the HEAdhoc recommendation No. 5 Non-professional use of antifouling paints: exposure assessment for a toddler (2015). Although these parameters are for exposure of toddlers to antifouling paints it is expected that they also represent a worst case for adults getting in contact with wood preservatives.		
	Parameters	Value
Tier 1	Application rate (applicant)	225 mL/m^2 = 22.5 $\mu L/cm^2$
	Density biocidal product (applicant)	0.804 g/mL
	Max. concentration IPBC (applicant)	0.5 % (w/w)
	Max. concentration permethrin (applicant)	0.06 % (w/w)
	Max. concentration tebuconazole (applicant)	0.2 % (w/w)
	Dimension of wooden post to be sanded (TNsG on Human Exposure (2002) Part 3, Page 50),	4 cm x 4 cm x 250 cm = 4000 cm^3
	Surface of wooden post treated with the biocidal product (long sides only)	4000 cm^2
	Volume of wood treated with biocidal product (biocidal product is in the 1-cm-outer-layer (TNsG on Human Exposure (2002) Part 3, Page 50)	3000 cm^3
	Concentration a.s. in the treated wood: Application rate x density x concentration a.s. x surface treated wood / volume treated wood	IPBC: 0.1206 mg a.s./cm^3 Permethrin: 0.01447 mg a.s./cm^3 Tebuconazole: 0.04824 mg a.s./cm^3

Description of Scenario [3]		
	Hand inner surface (both hands), adult (HEEG opinion No. 17, 2013), half of both hands	410 cm^2
	Percentage of hand surface getting in contact to the biocidal product (HEAdhoc recommendation No. 5, 2015)	40 %
	Transfer coefficient, rough sawn wood, dried fluid (Biocides Human Health Exposure Methodology, 2015 and HEAdhoc recommendation No. 5, 2015)	3 %
	Dermal absorption all active substances (refer to chapter 3.6.2.7, Information on dermal absorption)	75 %
	Body weight, adult (HEEG opinion No. 17, 2013)	60 kg
	Wood dust concentration in the air during sanding (EU, OEL, 2004)	5 mg/m^3
	Exposure duration (TNsG on Human Exposure (2002) part 3, page 50)	60 min
	Inhalation rate adult, short-term (HEEG opinion No. 17, 2013)	1.25 m^3/h
	Wood density (MOTA, 2013 from TM III, 2008)	0.4 g/cm^3
	Inhalation absorption (default for all active substances, CAR of all a.s.)	100 %

Calculations for Scenario [3]

Systemic exposure

$Exposure_{dermal}$ = concentration a.s. in the treated wood x hand inner surface of both hands x percentage contaminated skin x transfer coefficient x dermal absorption / body weight adult

$Exposure_{inhalation}$ = concentration a.s. in the treated wood x aerial wood dust concentration / density wood dust x exposure duration x inhalation rate / body weight adult

IPBC

$Exposure_{dermal}$ = 0.1206 mg a.s./cm^3 x 410 cm^2 x 40 % x 3 % x 75 % / 60 kg

= 0.00742 mg a.s./kg bw

$Exposure_{inhalation}$ = 0.12301 mg a.s./cm^3 x 5 mg/m^3 x 1 h x 1.25 m^3/h / (0.4 g/cm^3 x 60 kg)
= 0.00003 mg a.s./kg bw

Total systemic exposure = 0.00745 mg a.s./kg bw

Permethrin

$Exposure_{dermal}$ = 0.01447 mg a.s./cm^3 x 410 cm^2 x 40 % x 3 % x 75 % / 60 kg
= 0.000890 mg a.s./kg bw

$Exposure_{inhalation}$ = 0.01447 mg a.s./cm^3 x 5 mg/m^3 x 1 h x 1.25 m^3/h / (0.4 g/cm^3 x 60 kg)
= 0.000004 mg a.s./kg bw

Total systemic exposure = 0.000894 mg a.s./kg bw

Tebuconazole

$Exposure_{dermal}$ = 0.04824 mg a.s./cm^3 x 410 cm^2 x 40 % x 3 % x 75 % / 60 kg
= 0.00297 mg a.s./kg bw

$Exposure_{inhalation}$ = 0.04824 mg a.s./cm^3 x 5 mg/m^3 x 1 h x 1.25 m^3/h / (0.4 g/cm^3 x 60 kg)
= 0.00001 mg a.s./kg bw

Total systemic exposure = 0.00298 mg a.s./kg bw

- **Scenario [4]**

Table 71

Description of Scenario [4]		
Secondary acute exposure, toddler - chewing treated wood cut-off, oral exposure. The exposure estimates are based on the recommendations of the TNsG on Human Exposure (2002). It is based on the assumption that a toddler mouth and chew a piece of wood of 4 cm x 4 cm x 1 cm, which can be considered as 1 cm-cut-off of a wooden post as described in Scenario 8. Hence, four surfaces of 1 cm x 4 cm are treated with the biocidal product resulting in a total surface of 16 cm^2. The concentration of the active substance on the wood surface is calculated from application rate and the density. The total amount of a.s. available for extraction is calculated from the treated surface and the application rate.		
	Parameters	Value
Tier 1	Application rate (applicant)	225 mL/m^2 = 22.5 $\mu L/cm^2$
	Density biocidal product (applicant)	0.804 g/cm^3
	Max. concentration IPBC (applicant)	0.5 % (w/w)
	Max. concentration permethrin (applicant)	0.06 % (w/w)
	Max. concentration tebuconazole (applicant)	0.2 % (w/w)
	Concentration a.s. on the surface	IPBC: 0.09045 mg a.s./cm^2 Permethrin: 0.01085 mg a.s./cm^2 Tebuconazole: 0.03618 mg a.s./cm^2
	Dimension of the wood cut off (TNsG Human Exposure to Biocidal Products (2002) Part 3, page 50, Infant acute, Chewing wood off-cut)	4 cm x 4 cm x 1 cm = 16 cm^3
	Surface treated with the biocidal product (for calculation see above)	4 x 4 cm x 1 cm = 16 cm^2
	Total amount a.s. on/in wood (= surface treated with the biocidal product x concentration a.s. on the surface)[1)]	IPBC: 1.4472 mg a.s. Permethrin: 0.1737 mg a.s. Tebuconazole: 0.5789 mg a.s.
	Extraction coefficient (TNsG Human Exposure to Biocidal Products (2002) Part 3)	10 %
	Oral absorption (CAR/AR of all a.s., default)	100 %
	Body weight, toddler (HEEG opinion No. 17, 2013)	10 kg

[1)] It is assumed that the whole amount applied to the surface is potentially available for oral exposure

Calculations for Scenario [4]

Systemic exposure

$Exposure_{oral}$ = Total amount a.s. in/on wood x extraction coefficient x oral absorption / body weight toddler

IPBC

$Exposure_{oral}$ = 1.4472 mg a.s. x 10% x 100 % / 10 kg

= 0.0145 mg/kg bw

Permethrin

$Exposure_{oral}$ = 0.1737 mg a.s. x 10% x 100 % / 10 kg

= 0.00174 mg/kg bw

Tebuconazole

$Exposure_{oral}$ = 0.5789 mg a.s. x 10% x 100 % / 10 kg

= 0.0579 mg/kg bw

- **Scenario [5]**

Table 72

Description of Scenario [5]		
Secondary long-term exposure, toddler - inhalation of volatilised residues indoors, inhalation exposure. This scenario is based on a proposal from the TNsG on Human exposure (2002) and the more specified recommendations in the HEEG opinion No. 13 “Assessment of Inhalation Exposure of Volatilised Biocide Active Substance”. The estimation of air concentrations by saturated vapour pressure is a conservative but very simple approach. Since the major use of the biocidal product will be outdoors the potential risk by inhalation exposure is limited to a small number of applications. A human health risk is identified for IPBC. Hence, exposure assessment was refined for this active substance using the evaporation model of Consexpo 4.1. The product amount was calculated from the application rate (225 mL/m^2) and the density (0.803 g/cm^3) assuming that the inner side of a door and the window frames has a surface of 4 m^2. This surface is considered as a realistic worst case for a room with a volume of 20 m^3 (Default room volume acc. to Consexpo General Fact Sheet, 2012). The application duration was calculated from the median application duration of 7.6 min/m^2 reported in a publication of Garrod et al. (Ann. occup. Hyg., (2000) 44, 421-126, Potential Exposure of Amateurs (Consumers) through Painting Wood Preservative and Antifoulant Preparations). The default for the mass transfer rate was estimated according to Langmuir method, which (according to Consexpo) generally overestimates the evaporation rate. For the molecular weight of the matrix in the Consexpo model the average molecular weight of the solvent as given in the CLH report for White Spirit was chosen. Other minor components are considered to be not relevant. This exposure assessment for toddlers represents also a worst case for other members of the general public.		
	Parameters	Value
,Tier 1	Molecular weight IPBC (CAR/AR, 2008)	281.1 g/mol
	Vapour pressure IPBC (25 °C, CAR/AR, 2008)	4.5 x 10^{-3} Pa
	Molecular weight permethrin (CAR/AR, 2014)	391.3 g/mol
	Vapour pressure permethrin (25 °C, CAR/AR, 2014)	2.155 x 10^{-6} Pa
	Molecular weight tebuconazole (CAR/AR, 2007)	307.8 g/mol
	Vapour pressure tebuconazole (25 °C, CAR/AR, 2007)	1.7 x 10^{-6} Pa
	Gas constant (Atkins Physical Chemistry, 5th Edition)	8.31451 J/mol/K
	Temperature (assumed room temperature = 20 °C HEEG opinion No. 13, 2011)	293 K
	Saturated vapour pressure IPBC (calculated acc. to HEEG opinion No. 13, 2011)	5,19 x 10^{-1} mg/m^3
	Saturated vapour pressure permethrin (calculated acc. to HEEG opinion No. 13, 2011)	3.46 x 10^{-4} mg/m^3
	Saturated vapour pressure tebuconazole (calculated acc. to HEEG opinion No. 13, 2011)	2.15 x 10^{-4} mg/m^3
	Exposure duration (worst case, HEEG opinion No. 13, 2011)	24 h

Description of Scenario [5]		
	Inhalation rate, toddler (HEEG opinion No. 17, 2013, long-term exposure)	8 m^3/24 h
	Inhalation absorption (CAR/AR of all a.s., default)	100 %
	Body weight, toddler (HEEG opinion No. 17, 2013)	10 kg
Tier 2 (for IPBC only)	Product amount for treatment of 4 m^2 (225 mL/m^2 x 0.804 g/cm^3 (density) x 4 m^2)	724 g
	Concentration IPBC	0.51 % (w/w)
	Room volume (default, Consexpo General Fact Sheet, 2012)	20 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2012)	0.6 h^{-1}
	Release area adult (expert judgement)	4 m^2
	Application duration (Ann. Occup. Hyg., (2000) 44, 421-126)	30 min (rounded)
	Mass transfer rate (Langmuir, Consexpo)	2.23 x 10^3 m/min
	Molecular weight matrix (estimated for the main solvent ShellSol D60)	150 g/mol
	For other parameters refer to Tier 1	

Calculations for Scenario [5]

Systemic exposure

$Exposure_{inhalation}$ = saturated vapour concentration a.s. x inhalation rate x inhalation duration x inhalation absorption / body weight toddler

IPBC

$Exposure_{inhalation}$ = 5.19 x 10^{-1} mg/m^3 x 8 m^3/d x 1 d x 100 % / 10 kg
= 0.4154 mg a.s./kg bw/d

Permethrin

$Exposure_{inhalation}$ = 3.46 x 10^{-4} mg/m^3 x 8 m^3/d x 1 d x 100 % / 10 kg
= 0.000277 mg a.s./kg bw/d

Tebuconazole

$Exposure_{inhalation}$ = 2.15 x 10^{-4} mg/m^3 x 8 m^3/d x 1 d x 100 % / 10 kg
= 0.000172 mg a.s./kg bw/d

Tier 2 (Consexpo)

For IPBC only

For details refer to the corresponding Consexpo Report in section 4.2.2

Systemic exposure

$Exposure_{inhalation}$ = 0.00111 mg a.s./kg bw/d

- **Scenario [6]**

Table 73

Description of Scenario [6]		
Secondary long-term exposure, toddler - playing on treated structure and mouthing, dermal and oral exposure A first recommendation for assessment of secondary long-term exposure of a toddler playing on treated structures is provided in the TNsG on Human Exposure (2002). This exposure assessment was amended in accordance to the Recommendation No. 5 of the BPC Ad hoc Working Group on Human Exposure (HEAdhoc) “Non-professional use of antifouling paints: exposure assessment for a toddler” (2015). It is assumed that dried wood preservatives and antifoulings have similar properties in this context. This exposure assessment for toddlers represents also a worst case for other members of the general public.		
	Parameters	Value
Tier 1	Application rate (applicant)	225 mL/m^2 = 0.0225 mL/cm^2
	Density biocidal product (applicant)	0.804 g/cm^3
	Max. concentration IPBC (applicant)	0.5 % (w/w)
	Max. concentration permethrin (applicant)	0.06 % (w/w)
	Max. concentration tebuconazole (applicant)	0.2 % (w/w)
	Amount a.s. available on wood surface for transfer to skin (Application rate x density x concentration a.s.)	IPBC: 0.09045 mg a.s./cm^2 Permethrin: 0.01085 mg a.s./cm^2 Tebuconazole: 0.03618 mg a.s./cm^2
	Hand surface (toddler, palms of both hands, HEEG opinion No. 17, 2013)	115.2 cm^2
	Proportion of palms of hand in contact with the b.p., percentage contaminated skin (Headhoc recommendation No. 5, 2015)	40 %
	Transfer coefficient of biocidal product from dried b.p. to hand (Headhoc recommendation No. 5, 2015)	3 %

Description of Scenario [6]		
	Transfer coefficient of paint from hand to mouth for dried paint (Headhoc recommendation No. 5, 2015, based on Pest Control Fact Sheet, 2.2.7, 2006)	50 %
	Dermal absorption (default, EFSA Guidance on Dermal Absorption, 2012)	75 %
	Oral absorption (CAR/AR of all a.s.)	100 %
	Body weight, toddler (HEEG opinion No. 17, 2013)	10 kg

Calculations for Scenario [6]

Systemic exposure

$Exposure_{dermal}$ = application rate b.p. x concentration a.s. in b.p. x density x hand inner surface of both hands x proportion of palms of hand in contact with the b.p. x transfer coefficient dried b.p. to hands x dermal absorption / body weight

$Exposure_{oral}$ = application rate b.p. x concentration a.s. in b.p. x density x hand inner surface of both hands x transfer coefficient x percentage contaminated skin x transfer coefficient hand to mouth x oral absorption / body weight

IPBC

$Exposure_{dermal}$ = 22.5 µL/cm² x 0.804 g/cm³ x 0.5 % x 115.2 cm² x 3 % x 40 % x 75 % / 10 kg
= 0.00938 mg a.s./kg bw

$Exposure_{oral}$ = 22.5 µL/cm² x 0.804 g/cm³ x 0.5 % x 115.2 cm² x 3 % x 40 % x 50 % x 100 % / 10 kg
= 0.00625 mg a.s./kg bw

Total systemic exposure = 0.01563 mg a.s./kg bw

Permethrin

$Exposure_{dermal}$ = 22.5 µL/cm² x 0.804 g/cm³ x 0.06 % x 115.2 cm² x 3 % x 40 % x 75 % / 10 kg
= 0.00113 mg a.s./kg bw

$Exposure_{oral}$ = 22.5 µL/cm² x 0.804 g/cm³ x 0.06 % x 115.2 cm² x 3 % x 40 % x 50 % x 100 % / 10 kg
= 0.00075 mg a.s./kg bw

Total systemic exposure = 0.00188 mg a.s./kg bw

Tebuconazole

$Exposure_{dermal}$ = 22.5 µL/cm² x 0.804 g/cm³ x 0.2 % x 115.2 cm² x 3 % x 40 % x 75 % / 10 kg
= 0.00375 mg a.s./kg bw

$Exposure_{oral}$ = 22.5 µL/cm² x 0.804 g/cm³ x 0.2 % x 115.2 cm² x 3 % x 40 % x 50 % x 100 % / 10 kg
= 0.00250 mg a.s./kg bw

Total systemic exposure = 0.00625 mg a.s./kg bw

Table 74 IPBC

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw[/d])**	**Estimated dermal uptake (mg/kg bw[/d])**	**Estimated oral uptake (mg/kg bw[/d])**	**Estimated total uptake (mg/kg bw[/d])**
Scenario [3], adult, sanding treated wood	1	0.00003	0.00742	-	0.00745
Scenario [4], toddler, chewing treated wood cut-off	1	-	-	0.01447	0.01447
Scenario [5], toddler, inhalation volatilised residues	1	0.41539	-	-	0.41539
Scenario [5], toddler, inhalation volatilised residues	2	0.00111	-	-	0.00111
Scenario [6], toddler, dermal contact to treated surface	1	-	0.00938	0.00625	0.01563

Table 75 Permethrin

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw[/d])**	**Estimated dermal uptake (mg/kg bw[/d])**	**Estimated oral uptake (mg/kg bw[/d])**	**Estimated total uptake (mg/kg bw[/d])**
Scenario [3], adult, sanding treated wood	1	0.000004	0.000890	-	0.000894
Scenario [4], toddler, chewing treated wood cut-off	1	-	-	0.00174	0.00174
Scenario [5], toddler, inhalation volatilised residues	1	0.000277	-	-	0.000277
Scenario [6], toddler, dermal contact to treated surface	1	-	0.00113	0.00075	0.00188

Table 76 Tebuconazole

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw[/d])**	**Estimated dermal uptake (mg/kg bw[/d])**	**Estimated oral uptake (mg/kg bw[/d])**	**Estimated total uptake (mg/kg bw[/d])**
Scenario [3], adult, sanding treated wood	1	0.00001	0.00297	-	0.00298
Scenario [4], toddler, chewing treated wood cut-off	1	-	-	0.00579	0.00579
Scenario [5], toddler, inhalation volatilised residues	1	0.000172	-	-	0.000172
Scenario [6], toddler, dermal contact to treated surface	1	-	0.00375	0.00250	0.00625

- **Combined scenarios**

Table 77 IPBC

Summary table: combined systemic exposure of the general public				
Scenarios combined	**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])**
Scenarios [5, Tier 2 + 6]	0.001141	0.00938	0.00625	0.01677

Table 78 Permethrin

Summary table: combined systemic exposure of the general public				
Scenarios combined	**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])**
Scenarios [5 + 6]	0.000277	0.00113	0.00075	0.00216

Table 79 Tebuconazole

Summary table: combined systemic exposure of the general public				
Scenarios combined	**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])**
Scenarios [5 + 6]	0.00017	0.00375	0.00250	0.00642

3.6.3.2 Dietary exposure

The intended use descriptions of the IPBC, permethrin and tebuconazole-containing biocidal products of meta-SPCs 1, 2, 3 for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The products are to be used for the preservation of wood that does not come into direct contact with food, feedstuff or livestock animals.

Table 80

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference values**
1.	Veterinary use	Permethrin is authorized as pharmacologically active substance used as antiparasitic agent/agent against ectoparasites.	MRLs in foodstuffs of animal origin are set with Reg. (EU) 37/2010 for edible tissue and milk from bovine (fat: 0.5 mg/kg, muscle, liver, kidney, milk: 0.05 mg/kg).
2.	Plant Protection Products	Permethrin has been used as active substance in plant protection products but is currently not authorized in the EU (Reg. 2000/817/EC). Tebuconazole is authorised in the EU as fungicide (Reg. 2008/125/EC).	MRLs for permethrin in food of plant and animal origin are set with Reg. (EU) 2017/623. For bovine edible tissue and milk the VMP MRLs have been included (fat: 0.5 mg/kg, muscle, liver, kidney, milk: 0.05 mg/kg), while for all other commodities the respective LOQ applies (0,05* mg/kg or 0,1* mg/kg). MRLs for tebuconazole are set with Reg. (EU) 2018/1514 for various food commodities of plant and animal origin between 0.05 mg/kg (e.g. tree nuts) and 40 mg/kg (e.g. hops).
3.	Consumer products	IBPC is used as preservative in cosmetics and personal care products, as well as in perfumes and fragrances (Reg. (EC) 1223/2009).	The maximum threshold is set between 0.0075 % and 0.02 % (Reg. (EC) 1223/2009).

3.6.3.3 Aggregated exposure

Not applicable.

3.6.3.4 Summary of exposure assessment

For professional/industrial user please refer to Summary Table 61 (Meta SPC 1, 2 and 3).

Meta-SPC 1, 2, 3

Table 81 IPBC

Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake (mg/kg bw[/d])
1.	Non-professional user	1	0.0561
2.	Non-professional user	1	0.00476
3.	General public	1	0.0745
4.	General public	1	0.0145
5.	General public	1	0.4154
5.	General public	2	0.00114
6.	General public	1	0.0156

Table 82 Permethrin

Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake (mg/kg bw[/d])
1.	Non-professional user	1	0.00129
2.	Non-professional user	1	0.00011
3.	General public	1	0.00089
4.	General public	1	0.00174
5.	General public	1	0.00028
6.	General public	1	0.00188

Table 83 Tebuconazole

Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake (mg/kg bw[/d])
1.	Non-professional user	1	0.0154
2.	Non-professional user	1	0.00130
3.	General public	1	0.00298
4.	General public	1	0.00579
5.	General public	1	0.00017
6.	General public	1	0.00625

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in Table 84.

Table 84

Tebuconazole	Value	Study	Safety factor
AEL long-term	0.03 mg/kg bw/d	1-yr dog; Porter et al. (1989 & 1993) Assessment Report (RMS Denmark (2007) derived as AOEL (Operator/Worker Exposure)	100
AEL medium-term	0.03 mg/kg bw/d	1-yr dog; Porter et al. (1989 & 1993) Assessment Report (RMS Denmark (2007) derived as AOEL (Operator/Worker Exposure)	100
AEL acute	0.03 mg/kg bw/d	EFSA Scientific Report (2008) 176, 1-109 (2008-09-25)	300

Table 85

IPBC	Value	Study	Safety factor
AEL long-term	0.2 mg/kg bw/d	2-yr rat; Mulhem et al. (1989), Draft Assessment-Report (RMS Denmark (2013))	100
AEL medium-term	0.35 mg/kg bw/d	90-d rat; Bien (2002), Draft Assessment-Report (RMS Denmark (2013))	100
AEL acute	0.35 mg/kg bw/d	90-d rat; Bien (2002), Draft Assessment-Report (RMS Denmark (2013))	100
ADI	0.2 mg/kg bw/d	2-yr rat; Mulhem et al. (1989), Draft Assessment-Report (RMS Denmark (2013))	
ARfD	0.35 mg/kg bw/d	90-d rat; Bien (2002), Draft Assessment-Report (RMS Denmark (2013))	

Table 86

Permethrin	Value	Study	Safety factor
AEL long-term	0.05 mg/kg bw/d	12-month dog study. Bayer (Kalinowski *et al*., 1982), Assessment-Report (RMS Ireland (2014))	100
AEL medium-term	0.05 mg/kg bw/d	12-month dog study. Bayer (Kalinowski *et al*, 1982), Assessment-Report (RMS Ireland (2014))	100
AEL acute	0.5 mg/kg bw	Rat 2 year oral study (acute effect), Bayer (Ishmael and Litchfield, 1988), Assessment-Report (RMS Ireland (2014))	100

3.6.4.2 Maximum residue limits or equivalent

Table 87

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL (permethrin)	Reg. (EC) 2017/623	all	0.05* or 0.1* mg/kg Bovine: - fat: 0.5 mg/kg muscle, liver, kidney, milk: 0.05 mg/kg
MRL (permethrin)	Reg. (EC) 37/2010	bovine edible tissues	fat 0.5 mg/kg muscle, liver, kidney, milk: 0.05 mg/kg
MRL (tebuconazole)	Reg. (EU) 2018/1514	all	Variable (between 0.05 mg/kg (e.g. tree nuts) and 40 mg/kg (e.g. hops))

* MRL set at LOQ

3.6.4.3 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.6.4.4 Risk for industrial users

The risk for industrial users is described in chapter 3.6.4.5.

3.6.4.5 Risk for professional users

The occupational risk assessment for the biocidal product family Primer TIP takes into account systemic effects of the active substances tebuconazole, IPBC and permethrin. In the biocidal product family Primer TIP Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (CAS: -; EC: -) is identified as a substance of concern based on classification according to Annex VI of Regulation (EC) No 1272/2008 with H304 (Asp. Tox. 1). The occupational risk assessment takes into account systemic and local effects of the substance of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics.
Exposure of professional users to biocidal products generally takes place via the inhalation and/or dermal route and is usually assessed by means of external inhalation and/or dermal exposure values. For many substances (both active substances and substances of concern) external reference values such as occupational exposure limits (OELs) are available. By contrast, internal reference values (AELs) normally exist for active substances only. Therefore, external reference values will preferably be the basis for the risk characterisation of biocidal products as chemical mixtures. In case only internal reference values are available, they will be converted to external reference values in order to allow for a comparison with external exposure values.

3.6.4.5.1 Risk for professional users for meta SPC 1

Systemic effects

Tebuconazole

The primary toxic effects of the active substance tebuconazole in a one-year dog study were unspecific effects like histopathological alterations in the adrenal cortex. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to tebuconazole resulting from use of the biocidal products covered by meta SPC 1. As reference value the AEL of 0.03 mg/kg bw/day is used.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from exposure of professional users to tebuconazole from the biocidal products covered by meta SPC 1, inhalation and dermal exposure to tebuconazole is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ (0.03 mg/kg bw/d) of tebuconazole is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of tebuconazole, the corresponding $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) and an external dermal reference value (RV_{derm}) according to the following equations:

RV_{inhal} (in mg/m^3) = $AEL_{long\text{-}term}$ of tebuconazole (in mg/kg bw/d) x 60 kg / 10 m^3 x100 % / 100 %-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{long\text{-}term}$ of tebuconazole (in mg/kg bw/d) / 37 % and 75 %-dermal absorption x 100%.

By this means RV_{inhal} equivalent to 0.18 mg/m^3 and RV_{derm} equivalent to 0.08 mg/kg bw/d and 0.04 mg/kg bw/d are calculated for tebuconazole.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the active substance tebuconazole.

Dermal absorption rate

As dermal absorption of the active substance tebuconazole the value of 37 % derived from a study that is further described in the confidential annex of the PAR is used for the products covered by meta SPC 1 in scenarios ‘brush treatment’, ‘immersion (automated dipping)’ daily and weekly, ‘dip treatment (manual dipping)’ and ‘deluge treatment’.
Valid data are not available for dried films on treated wood. Therefore, the default value of 75 % for active substance concentration below 5 % (according to the EFSA Guidance on Dermal Absorption, 2012) has to be taken into consideration for risk assessment of secondary exposure.

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for the inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the active substance tebuconazole resulting from use of the biocidal products covered by meta SPC 1 is determined according to the following equations:

RQ_{inhal} = inhalation exposure to tebuconazole (in mg/m³) / RV_{inhal} of tebuconazole (in mg/m³).

RQ_{derm} = dermal exposure to tebuconazole (in mg/kg bw/d) / RV_{derm} of tebuconazole (in mg/kg bw/d).

Dermal exposure to tebuconazole given in mg/kg bw/d is calculated from dermal exposure to tebuconazole given in mg/person through division by 60 kg/person.

The summation of RQ_{inhal} and RQ_{derm} for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 88 gives a detailed overview of the risk assessment results referring to the active substance tebuconazole for the biocidal products covered by meta SPC 1. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 88. However, the underlying calculations are based on unrounded exposure values.
A risk for professional users referring to the active substance tebuconazole resulting from the use of the biocidal products covered by meta SPC 1 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 88, the scenarios ‘brush treatment’, ‘immersion (automated dipping)’ daily and weekly yield RIs of less than 1 already in TIER 1. By contrast, the RI of the scenarios ‘dip treatment (manual dipping), ‘deluge treatment’ and ‘secondary exposure: mechanical processing of treated wood’ exceed the value of 1 after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenarios. However when additional risk mitigation measures are implemented the risk characterisation results consistently yield RI of less than 1 in TIER 2.

Table 88: Overview of detailed risk assessment results referring to the active substance tebuconazole for the biocidal products covered by meta SPC 1

Scenario		inhalation external			dermal external					
		potential / actual exposure	RV_{inhal}	RQ_{inhal}	potential / actual exposure		RV_{derm}	RQ_{derm}	RI	Acceptable
		mg/m³	mg/m³		mg/person	mg/kg bw/d	mg/kg bw/d			
Brush treatment	Tier 1	$1.06x10^{-3}$	0.18	$5.89x10^{-3}$	4.38	0.07	0.08	0.90	0.91	**yes**
	Tier 2	$1.06x10^{-3}$	0.18	$5.89x10^{-3}$	1.58	0.03	0.08	0.32	0.33	yes
Immersion (automated dipping)- daily	Tier 1	not expected, no aerosol			2.84	0.05	0.08	0.58	0.58	**yes**
	Tier 2				0.71	0.01	0.08	0.15	0.15	yes
Immersion (automated dipping)- weekly	Tier 1	not expected, no aerosol			0.71	0.01	0.08	0.15	0.15	**yes**
	Tier 2				0.71	0.01	0.08	0.15	0.15	yes
Dip treatment (manual dipping)	Tier 1	$1.31x10^{-4}$	0.18	$7.29x10^{-4}$	19.60	0.33	0.08	4.03	4.03	no
	Tier 2	$1.31x10^{-4}$	0.18	$7.29x10^{-4}$	3.13	0.05	0.08	0.64	0.64	**yes**
Deluge treatment	Tier 1	$2.63x10^{-4}$	0.18	$1.46x10^{-3}$	20.65	0.34	0.08	4.24	4.25	no
	Tier 2	$1.31x10^{-4}$	0.18	$7.29x10^{-4}$	2.20	0.04	0.08	0.45	0.45	**yes**
Secondary exposure: Mechanical processing of treated wood	Tier 1	$9.50x10^{-4}$	0.18	$5.28x10^{-3}$	3.12	0.05	0.04	1.30	1.30	no
	Tier 2	$9.50x10^{-4}$	0.18	$5.28x10^{-3}$	0.31	$5.19x10^{-3}$	0.04	0.13	0.14	**yes**

RV_{inhal}: reference value for the inhalation route
RQ_{inhal}: risk quotient for the inhalation route
RV_{derm}: reference value for the dermal route
RQ_{derm}: risk quotient for the dermal route
RI: substance specific risk index

Conclusion

Based on the risk assessment of the active substance tebuconazole via the inhalation and dermal route, a risk for professional users resulting from the intended uses ('brush treatment', 'immersion (automated dipping)' daily and weekly), 'dip treatment (manual dipping)' and 'deluge treatment' with the biocidal products covered by meta SPC 1 as well as from secondary exposure ('mechanical processing of treated wood') is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 at least after TIER 2 consideration. Regarding occupational safety, there are no objections against the intended uses as well as secondary exposure taking into account the provisions described in 2.3.1.4 of this PAR.

IPBC

The primary toxic effect of the active substance IPBC in chronic toxicity studies are histopathological changes in the gastrointestinal tract. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to IPBC resulting from use of the biocidal products covered by meta SPC 1. As reference value the $AEL_{long\text{-}term}$ of 0.20 mg/kg bw/day is used.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from exposure of professional users to IPBC from the biocidal products covered by meta SPC 1, inhalation and dermal exposure to IPBC is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ (0.20 mg/kg bw/d) of IPBC is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of IPBC, the corresponding $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) and an external dermal reference value (RV_{derm}) according to the following equations:

RV_{inhal} (in mg/m³) = $AEL_{long\text{-}term}$ of IPBC (in mg/kg bw/d) x 60 kg / 10 m³ x100 % / 100 %-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{long\text{-}term}$ of IPBC (in mg/kg bw/d) / 54 % and 75 %-dermal absorption x 100%.

By this means RV_{inhal} equivalent to 1.20 mg/m³ and RV_{derm} equivalent to 0.37 mg/kg bw/d and 0.27 mg/kg bw/d are calculated for IPBC.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the active substance IPBC.

Dermal absorption rate

As dermal absorption of the active substance IPBC the value of 54 % derived from a study that is further described in the confidential annex of the PAR is used for the products covered by meta SPC 1 in scenarios ‘brush treatment’, ‘immersion (automated dipping) daily and weekly’, ‘dip treatment (manual dipping)’ and ‘deluge treatment’.

Valid data are not available for dried films on treated wood. Therefore, the default value of 75 % for active substance concentration below 5 % (according to the EFSA Guidance on Dermal Absorption, 2012) has to be taken into consideration for risk assessment of secondary exposure.

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for the inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the active substance IPBC resulting from use of the biocidal products covered by meta SPC 1is determined according to the following equations:

RQ_{inhal} = inhalation exposure to IPBC (in mg/m^3) / RV_{inhal} of IPBC (in mg/m^3).

RQ_{derm} = dermal exposure to IPBC (in mg/kg bw/d) / RV_{derm} of IPBC (in mg/kg bw/d).

Dermal exposure to IPBC given in mg/kg bw/d is calculated from dermal exposure to IPBC given in mg/person through division by 60 kg/person.

The summation of RQinhal and RQderm for a substance within a scenario gives the corresponding substance specific risk index (RI).

Table 89 gives a detailed overview of the risk assessment results referring to the active substance IPBC for the biocidal products covered by meta SPC 1. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 89.

However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance IPBC resulting from the use of the biocidal products covered by meta SPC 1 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 89, the scenarios ‘brush treatment’, ‘immersion (automated dipping) – daily and weekly’ and ‘secondary exposure: mechanical processing of treated wood’ yield RIs of less than 1 already in TIER 1. By contrast, the RI of the scenarios ‘dip treatment (manual dipping)’ and ‘deluge treatment’ exceed the value of 1 after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenarios.

However when additional risk mitigation measures are implemented the risk characterisation results consistently yield RIs of less than 1 in TIER 2.

Table 89: Overview of detailed risk assessment results referring to the active substance IPBC for the biocidal products covered by meta SPC 1

Scenario		inhalation external			dermal external				RI	Acceptable
		potential / actual exposure	RV_{inhal}	RQ_{inhal}	potential / actual exposure		RV_{derm}	RQ_{derm}		
		mg/m³	mg/m³		mg/person	mg/kg bw/d	mg/kg bw/d			
Brush treatment	Tier 1	$2.53x10^{-3}$	1,20	$2.11x10^{-3}$	10.43	0. 17	0.37	0.47	0.47	**yes**
	Tier 2	$2.53x10^{-3}$	1.20	$2.11x10^{-3}$	3.76	0.06	0.37	0.17	0.17	yes
Immersion (automated dipping)- daily	Tier 1	not expected, no aerosol			6.76	0.11	0.37	0.30	0.30	**yes**
	Tier 2				1.68	0.03	0.37	0.08	0.08	yes
Immersion (automated dipping)- weekly	Tier 1	not expected, no aerosol			1.68	0.03	0.37	0.08	0.08	**yes**
	Tier 2				1.68	0.03	0.37	0.083	0. 083	yes
Dip treatment (manual dipping)	Tier 1	$3.13x10^{-4}$	1.20	$2.60x10^{-4}$	49.17	0.82	0.37	2.21	2.21	no
	Tier 2	$3.13x10^{-4}$	1.20	$2.60x10^{-4}$	10.50	0.17	0.37	0.47	0.47	**yes**
Deluge treatment	Tier 1	$6.25x10^{-4}$	1.20	$5.21x10^{-4}$	49.17	0.82	0.37	2.21	2.21	no
	Tier 2	$3.13x10^{-4}$	1.20	$2.60x10^{-4}$	5.25	0.09	0.37	0.24	0.24	**yes**
Secondary exposure: Mechanical processing of treated wood	Tier 1	$2.26x10^{-3}$	1.20	$1.88x10^{-3}$	7.42	0.12	0.27	0.46	0.47	**yes**
	Tier 2	$2.26x10^{-3}$	1.20	$1.88x10^{-3}$	0.74	0.01	0.27	0.05	0.05	yes

RV_{inhal}: reference value for the inhalation route
RQ_{inhal}: risk quotient for the inhalation route
RV_{derm}: reference value for the dermal route
RQ_{derm}: risk quotient for the dermal route
RI: substance specific risk index

Conclusion

Based on the risk assessment of the active substance IPBC via the inhalation and dermal route, a risk for professional users resulting from the intended uses ('brush treatment', 'immersion (automated dipping)' daily and weekly, 'dip treatment (manual dipping)', 'deluge treatment' with the biocidal products covered by meta SPC 1 as well as from secondary exposure ('mechanical processing of treated wood') is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 at least after TIER 2 consideration. Regarding occupational safety, there are no objections against the intended uses as well as secondary exposure taking into account the provisions described in 2.3.1.4 of this PAR.

Permethrin

The primary toxic effect of the active substance permethrin in repeated dose toxicity studies is increased liver weights. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to permethrin resulting from use of the biocidal products covered by meta SPC 1. As reference value the $AEL_{long\text{-}term}$ of 0.05 mg/kg bw/day is used.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from exposure of professional users to permethrin from the biocidal products covered by meta SPC 1, inhalation and dermal exposure to permethrin is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ (0.05 mg/kg bw/d) of permethrin is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of permethrin, the corresponding $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) and an external dermal reference value (RV_{derm}) according to the following equations:

RV_{inhal} (in mg/m^3) = $AEL_{long\text{-}term}$ of permethrin (in mg/kg bw/d) x 60 kg / 10 m^3 x100 % / 100 %-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{long\text{-}term}$ of permethrin (in mg/kg bw/d) / 10 % and 75 %-dermal absorption x 100%.

By this means RV_{inhal} equivalent to 0.30 mg/m^3 and RV_{derm} equivalent to 0.50 mg/kg bw/d and 0.07 mg/kg bw/d are calculated for permethrin.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the active substance permethrin.

Dermal absorption rate

As dermal absorption of the active substance permethrin the value of 10 % derived from a study that is further described in the confidential annex of the PAR is used for the products covered by meta SPC 1 in scenarios ‘brush treatment’, ‘immersion (automated dipping)’ daily and weekly, ‘dip treatment (manual dipping)’ and ‘deluge treatment’.

Valid data are not available for dried films on treated wood. Therefore, the default value of 75 % for active substance concentration below 5 % (according to the EFSA Guidance on Dermal Absorption, 2012) has to be taken into consideration for risk assessment of secondary exposure.

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for the inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the active substance permethrin resulting from use of the biocidal products covered by meta SPC 1 is determined according to the following equations:

RQ_{inhal} = inhalation exposure to permethrin (in mg/m³) / RV_{inhal} of permethrin (in mg/m³).

RQ_{derm} = dermal exposure to permethrin (in mg/kg bw/d) / RV_{derm} of permethrin (in mg/kg bw/d).

Dermal exposure to permethrin given in mg/kg bw/d is calculated from dermal exposure to permethrin given in mg/person through division by 60 kg/person.

The summation of RQ_{inhal} and RQ_{derm} for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 90 gives a detailed overview of the risk assessment results referring to the active substance permethrin for the biocidal products covered by meta SPCs 1. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 90. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance permethrin resulting from the use of the biocidal products covered by meta SPC 1 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 90, each scenario assessed (‘brush treatment’, ‘immersion (automated dipping)’ daily and weekly, ‘dip treatment (manual dipping)’, ‘deluge treatment’ and ‘secondary exposure: mechanical processing of treated wood’) yields RIs of less than 1 already in TIER 1.

Table 90: Overview of detailed risk assessment results referring to the active substance permethrin for the biocidal products covered by meta SPC 1

Scenario		inhalation external			dermal external					
		potential / actual exposure	RV_{inhal}	RQ_{inhal}	potential / actual exposure		RV_{derm}	RQ_{derm}	RI	Acceptable
		mg/m³	mg/m³		mg/person	mg/kg bw/d	mg/kg bw/d			
Brush treatment	Tier 1	$3.03x10^{-4}$	0.30	$1.01x10^{-3}$	1.25	0.02	0.50	0.04	0.04	**yes**
	Tier 2	$3.03x10^{-4}$	0.30	$1.01x10^{-3}$	0.45	$7.53x10^{-3}$	0.50	0.02	0.02	yes
Immersion (automated dipping) - daily	Tier 1	not expected, no aerosol			0.81	0.01	0.50	0.03	0.03	**yes**
	Tier 2				0.20	$3.37x10^{-3}$	0.50	$6.74x10^{-3}$	$6.74x10^{-3}$	yes
Immersion (automated dipping) - weekly	Tier 1	not expected, no aerosol			0.20	$3.36x10^{-3}$	0.50	$6.72x10^{-3}$	$6.72x10^{-3}$	**yes**
	Tier 2				0.20	$3.36x10^{-3}$	0.50	$6.72x10^{-3}$	$6.72x10^{-3}$	yes
Dip treatment (manual dipping)	Tier 1	$3.75x10^{-5}$	0.30	$1.25x10^{-4}$	5.60	0.09	0.50	0.19	0.19	**yes**
	Tier 2	$3.75x10^{-5}$	0.30	$1.25x10^{-4}$	0.89	0.01	0.50	0.03	0.03	yes
Deluge treatment	Tier 1	$7.50x10^{-5}$	0.30	$2.50x10^{-4}$	5.90	0.10	0.50	0.20	0.20	**yes**
	Tier 2	$3.75x10^{-5}$	0.30	$1.25x10^{-4}$	0.63	0.01	0.50	0.02	0.02	yes
Secondary exposure: Mechanical processing of treated wood	Tier 1	$2.71x10^{-4}$	0.30	$9.05x10^{-4}$	0.89	0.01	0.07	0.22	0.22	**yes**
	Tier 2	$2.71x10^{-4}$	0.30	$9.05x10^{-4}$	0.09	$1.48x10^{-3}$	0.07	0.02	0.02	yes

RV_{inhal}: reference value for the inhalation route
RQ_{inhal}: risk quotient for the inhalation route
RV_{derm}: reference value for the dermal route
RQ_{derm}: risk quotient for the dermal route
RI: substance specific risk index

Conclusion

Based on the risk assessment of the active substance permethrin via the inhalation and dermal route, a risk for professional users resulting from the intended uses ('brush treatment', 'immersion (automated dipping)' daily and weekly, 'dip treatment (manual dipping)' and 'deluge treatment') with the biocidal products covered by meta SPC 1 as well as from secondary exposure ('mechanical processing of treated wood') is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 after TIER 1 consideration. Regarding occupational safety, there are no objections against the intended uses as well as secondary exposure taking into account the provisions described in 2.3.1.4 of this PAR.

Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (CAS: -; EC: -)

The primary toxic effect of the substance of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics in short-term and long-term studies is neurotoxicity. The quantitative risk characterisation for professional users takes into account inhalation exposure to Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics resulting from use of the biocidal product.

As no systemic reference values for Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics are established the risk characterisation is based on the German OEL.

The OEL for Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (250 mg/m³) is determined based on the *Reciprocal Calculation-based Procedure – RCP* for hydrocarbon mixtures as stated in the Technical Rules for Hazardous Substances (TRGS) 900. Details of the calculation are provided below.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics from the biocidal products covered by meta SPC 1, inhalation exposure to Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics is assessed.

For this, the German OEL (250 mg/m³, 8 h TWA) for Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics is calculated as shown below and used as external inhalation reference value (RV_{inhal}) that is directly compared with airborne concentrations of Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics.

In addition, the German short-term OEL (500 mg/m³, 15 min STEL) must be complied with to limit the exposure peaks. Thus for assessment of exposure peaks the German short-term OEL (500 mg/m³, 15 min) of Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics is calculated as shown below and used as external inhalation reference value that is directly compared with airborne

concentrations of exposure peaks to as well as Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the substance of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics.

Calculation of the German OEL according to the *Reciprocal Calculation-based Procedure – RCP* as stated in the TRGS900

For determination of the OEL for the substance of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics as a worst case a fraction of 98 % C10-C13 aliphates (group reference value for C9-C14 aliphates of 300 mg/m³ applies) and a fraction of 2 % aromatics (group reference value for C9-C14 aromatics of 50 mg/m³ applies) is assumed:

> 1 / OEL (mg/m³) = fraction of C9-C14 aliphates / group reference value for C9-C14 aliphates + fraction of C9-C14 aromates / group reference value for C9-C14 aromatics
>
> 1 / OEL (mg/m³) = 0.98 / 300 mg/m³ + 0.02 / 50 mg/m³ = 0.00367
>
> OEL = 1 / 0.00367 = 272.72 mg/m³ → 250 mg/m³ (Rounding rule: > 100 mg/m³: round up or down to the nearest full 50)

By this means an OEL equivalent to 250 mg/m³ is calculated for Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics.

Calculation of the German short-term OEL

The short-term OEL for the substance of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics is determined as follows:

Short-term OEL (mg/m³) = OEL (in mg/m³) * excursion factor

Short-term OEL (mg/m³) = 250 mg/m³ * 2

An excursion factor of 2 is applied for substances with systemic effects when no further substance specific data justifying a higher factor are available.
By this means an short-term OEL equivalent to 500 mg/m³ is calculated for Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics.

Calculation of risk quotients (RQ) and substance specific risk index (RI)
The risk index for inhalation route (RQ_{inhal}) referring to the substances of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics resulting from use of the biocidal products covered by meta SPC 1 is determined for Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics according to the following equations:

RI (8 h TWA) = inhalation exposure to Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (in mg/m^3) / German OEL of Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (in mg/m^3).

RI (15 min STEL) = inhalation peak exposure to Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (in mg/m^3) / German short-term OEL of Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (in mg/m^3).

In this case where only inhalation exposure to Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics is assessed for the professional user, the RQ_{inhal} is identical with the corresponding substance specific risk index (RI). Table 91 gives a detailed overview of the risk assessment results referring to the substance of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 91. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the substance of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics resulting from the use of the biocidal products covered by meta

SPC 1 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 91 the scenarios ‘immersion (automated dipping)’ daily and weekly, ‘dip treatment (manual dipping)’ and ‘deluge treatment’ yield RIs of less than 1 already in TIER 1. By contrast, the RI of the scenario ‘brush treatment’ exceeds the value of 1 after TIER 1 consideration after 8 h as well as short-term exposure. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenarios. However when additional risk mitigation measures are implemented the risk characterisation results consistently yield RI of less than 1 in TIER 2.

Table 91: Overview of detailed risk assessment results for inhalation route referring to the substance of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics for the biocidal products covered by meta SPC 1

Scenario		inhalation external (8 h)		RI_{TWA}	Acceptable	inhalation external (15 min)		RI_{STEL}	Acceptable
		potential / actual exposure	German OEL			potential / actual exposure	German shortterm OEL		
		mg/m³	mg/m³			mg/m³	mg/m³		
Brush treatment	Tier 1	639.00	250.00	2.56	no	1030.85	500.00	2.06	no
	Tier 2	114.00	250.00	0.46	**yes**	156.73	500.00	0.31	**yes**
Immersion (automated dipping) - daily	Tier 1	28.75	250.00	0.12	**yes**	137.82	500.00	0.28	**yes**
	Tier 2	28.75	250.00	0.12	yes	137.82	500.00	0.28	yes
Immersion (automated dipping) - weekly	Tier 1	7.19	250.00	0.03	**yes**	137.82	500.00	0.28	**yes**
	Tier 2	7.19	250.00	0.03	yes	137.82	500.00	0.28	yes
Dip treatment (manual dipping)	Tier 1	190.50	250.00	0.76	**yes**	456.60	500.00	0.91	**yes**
	Tier 2	190.50	250.00	0.76	yes	456.60	500.00	0.91	yes
Deluge treatment	Tier 1	76.30	250.00	0.31	**yes**	149.69	500.00	0.30	**yes**
	Tier 2	76.30	250.00	0.31	yes	149.69	500.00	0.30	yes

RI_{TWA}: substance specific risk index regarding TWA (time-weighted average, 8 h)
RI_{STEL}: substance specific risk index regarding STEL (short-term exposure limit, 15 min)

Conclusion

Based on the risk assessment of the substance of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics via the inhalation route, a risk for professional users resulting from the intended uses ('brush treatment', 'immersion (automated dipping)' daily and weekly, 'dip treatment (manual dipping)', and 'deluge treatment') with the biocidal products covered by meta SPC 1 is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 at least after TIER 2 consideration. Regarding occupational safety, there are no objections against the intended uses taking into account the provisions described in 2.3.1.4 of this PAR.

Local effects

Qualitative local risk characterisation

The substance of concern Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics triggers the classification of the biocidal products covered by meta SPC 1 with H304 (May be fatal if swallowed and enters airways) and is therefore assigned in hazard classification band A according to the Guidance on substances of concern (SoC) (Annex A to ECHA Guidance Vol III Part B, version 4.0). This guidance states that for these SoC appropriate risk mitigation measures in the form of the precautionary (P)-statements should be applied. It is assumed that the application of the precautionary statements associated with the concerned hazard statement H304 and the provisions described in 2.3.1.5.2 are sufficient to minimise the risk for professional users.

4.6.4.5.2 Risk for professional users for meta SPC 2

The systemic risk assessment for professional users for biocidal products of meta SPC 2 is covered by the risk assessment as presented in section 3.6.4.5 for biocidal products of meta SPC 1. For details refer to this section.

4.6.4.5.3 Risk for professional users for meta SPC 3

The systemic risk assessment for professional users for biocidal products of meta SPC 2 is covered by the risk assessment as presented in section 3.6.4.5 for biocidal products of meta SPC 1. For details refer to this section.

Overall conclusion for Meta-SPC 1, 2, 3

In summary, a risk for professional users resulting from the use of the biocidal products of the biocidal product family Primer TIP is unlikely for the intended uses ‘brush treatment’, ‘immersion (automated dipping)’ daily and weekly, ‘dip treatment (manual dipping)’and ‘deluge treatment’ as well as from secondary exposure (‘mechanical processing of treated wood’). Risk mitigation measures described in 2.3.1.4 have to be taken into account in order to ensure safe use of the biocidal product family Primer TIP.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

For the components “unknown compoments, not listed in the MSDS”, “alkyd resin” and “polysiloxane preparation” contained in the biocidal products of the biocidal product family Primer TIP the compositions and substance identifiers (CAS-No.) are not (fully) known. The risk assessment is based on the assumption that the biocidal product contains no further substances relevant for evaluation.

3.6.4.6 Risk for non-professional users

Meta-SPC 1, 2, 3

Table 92: Systemic effects IPBC

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw[/d])	AEL (mg/kg bw[/d])	Estimated uptake (mg/kg bw[/d])	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1, Brushing outdoors	1	35	0.35	0.0561	16	yes
2 Cleaning brush	1	35	0.35	0.0048	1.4	yes

Table 93: Combined scenarios IPBC

Scenarios combined	Tier	Systemic NOAEL (mg/kg bw[/d])	AEL (mg/kg bw[/d])	Estimated uptake (mg/kg bw[/d])	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 + 2	1	35	0.35	0.0609	17	yes

Table 94: Systemic effects Permethrin

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw[/d])	AEL (mg/kg bw[/d])	Estimated uptake (mg/kg bw[/d])	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1, Brushing outdoors	1	50	0.5	0.00129	0.3	yes
2 Cleaning brush	1	50	0.5	0.00011	0.02	yes

Table 95: Combined scenarios Permethrin

Scenarios combined	Tier	Systemic NOAEL (mg/kg bw[/d])	AEL (mg/kg bw[/d])	Estimated uptake (mg/kg bw[/d])	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 + 2	1	50	0.5	0.00140	0.3	yes

Table 96: Systemic effects Tebuconazole

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw[/d])	AEL (mg/kg bw[/d])	Estimated uptake (mg/kg bw[/d])	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1, Brushing outdoors	1	30	0.03	0.0154	51	yes
2 Cleaning brush	1	30	0.03	0.0013	4.3	yes

Table 97: Combined scenarios Tebuconazole

Scenarios combined	Tier	Systemic NOAEL (mg/kg bw[/d])	AEL (mg/kg bw[/d])	Estimated uptake (mg/kg bw[/d])	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 + 2	1	30	0.03	0.0167	56	yes

- **Local effects**

The biocidal product contains the pyrethroid permethrin. Pyrethroids are known to cause paresthesia, which are normally transient and do not persist. Hence, an appropriate labelling on the packaging is required to inform susceptible persons.

The biocidal products are labelled with EUH066. Based on the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation 4.3.2.5 this labelling leads to the hazard category “low” for local effects. Hence, a quantitative assessment is not required. Due to the low application frequency and the fact that the solvent, which triggers this labelling evaporates rapidly further risk mitigation measures for the general public are not required.

Conclusion

Based on the quantitative exposure and risk assessment for active substances application of biocidal products of Meta-SPC 1, 2, 3 is considered safe for the non-professional user if used as intended.

Due to the permethrin content a specific labelling for the potential occurrence of paraesthesia is necessary.

A quantitative assessment for non-professional users and the general public from exposure to hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (Shellsol D60) and other similar hydrocarbons was not performed since agreed reference values for these groups do not exist. However, it is known that high concentrations of this compound are unpleasant and may lead to drowsiness. Thus, the biocidal product should only be used in well-ventilated areas. A corresponding labelling is required.

3.6.4.7 Risk for the general public

Meta-SPC 1, 2, 3

Table 98: Systemic effects IPBC

Task/ Scenario	Tier	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, adult - sanding treated wood	1	35	0.35	0.00745	2.1	yes
Scenario 4: toddler - chewing treated wood off-cut,	1	35	0.35	0.01447	4.1	yes
Scenario 5, toddler inhalation of volatilised residues in doors,	1	20	0.2	0.4154	208	no
Scenario 5, toddler inhalation of volatilised residues in doors,	2	20	0.2	0.00111	0.6	yes
Scenario 6, toddler - playing on treated structure and mouthing,	1	20	0.2	0.0156	7.8	yes

Table 99: Combined scenarios IPBC

Scenarios combined	Tier	Systemic NOAEL (mg/kg bw[/d])	AEL (mg/kg bw[/d])	Estimated uptake (mg/kg [bw/d])	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 5 and 6	1/2	20	0.2	0.0167	8.4	yes

Table 100: Systemic effects Permethrin

Task/ Scenario	Tier	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, adult - sanding treated wood	1	50	0.5	0.00089	0.2	yes
Scenario 4: toddler - chewing treated wood off-cut,	1	50	0.5	0.00174	0.3	yes
Scenario 5, toddler inhalation of volatilised residues in doors,	1	5	0.05	0.000277	0.6	yes
Scenario 6, toddler - playing on treated structure and mouthing,	1	5	0.05	0.00188	3.8	yes

Table 101: Combined scenarios Permethrin

Scenarios combined	Tier	Systemic NOAEL (mg/kg bw[/d])	AEL (mg/kg bw[/d])	Estimated uptake (mg/kg bw[/d])	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 5 and 6	1	5	0.05	0.00216	4.3	yes

Table 102: Systemic effects Tebuconazole

Task/ Scenario	Tier	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, adult - sanding treated wood	1	30	0.03	0.00298	9.9	yes
Scenario 4: toddler - chewing treated wood off-cut,	1	30	0.03	0.00579	19	yes
Scenario 5, toddler inhalation of volatilised residues in doors,	1	4	0.03	0.00017	0.6	yes
Scenario 6, toddler - playing on treated structure and mouthing,	1	4	0.03	0.00625	21	yes

Table 103: Combined scenarios Tebuconazole

Scenarios combined	Tier	Systemic NOAEL (mg/kg bw[/d])	AEL (mg/kg bw[/d])	Estimated uptake (mg/kg bw[/d])	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 5 and 6	1	4	0.03	0.00642	21	yes

- **Local effects**

The biocidal products contain the pyrethroid permethrin. Pyrethroids are known to cause paraesthesia, which are normally transient and do not persist. Hence, an appropriate labelling on the packaging is required to inform susceptible persons.

The biocidal products are labelled with EUH066. Based on the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation 4.3.2.5 this labelling leads to the hazard category “low” for local effects. Hence, a quantitative assessment is not required. Due to the low application frequency and the fact that the solvent, which triggers this labelling evaporates rapidly further risk mitigation measures for the general public are not required.

Conclusion

Based on the exposure and risk assessment application of biocidal products of this family is considered safe for the general public. Since the secondary exposure and risk assessment for the general public is based on the assumption that treated wood is dried, the user of the biocidal product has to be informed accordingly.

Due to the permethrin content a specific labelling for the potential occurrence of paraesthesia is necessary.

A quantitative assessment for non-professional users and the general public from exposure to hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2 % aromatics (Shellsol D60) and other similar hydrocarbons was not performed since agreed reference values for these groups do not exist. However, it is known that high concentrations of this compound are unpleasant and may lead to drowsiness. Thus, the biocidal products should only be used in well-ventilated areas. A corresponding labelling is required.

3.6.4.8 Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

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

Cumulative risk assessment (also "*risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product*") follows a tiered approach as described in Chapter 4.4.1 of the BPR Guidance Volume III Parts B+C. Following risk characterisation for the individual active substances (**tier 1**), this approach foresees a step-wise procedure starting with the lowest level of refinement in tier 2. The approach is based on the assumption of dose additivity and thus limited to cases where there is no indication for synergistic effects between the active substance(s) and/or the SoC(s).

Tier 2: There is no specific information showing synergistic effects between permethrin, tebuconazole, IPBC and/or Naphtha. Thus Tier 2 is considered applicable. The hazard index (HI) is calculated by

addition of the individual hazard quotient (HQ, the ratio of exposure-to-reference value) for each active substance / the SoC.

Tier 3: For exposure scenarios where Tier 2 cannot demonstrate safe use, further refinement of the cumulative risk assessment is performed.

Tier 3a is based on the assumption that cumulative risk assessment can be limited to substances with common target organs. For all scenarios where a safe use could not be demonstrated in tier 2, a target organ specific hazard index (HIto) is calculated separately for each common target organ by addition of the HQs for all substances affecting this particular target organ. It is considered sufficiently conservative to include only those tissues as target organs that were responsive at doses not higher than ten times the effective dose in the most sensitive organ. Here, the following common target organs were identified.
Group 1: The liver is a target organ common to permethrin, tebuconazole and IPBC.
Group 2:Respiratory irritation is common to IPBC and Naphtha.
Group 3: Neurotoxicity is reported for permethrin and Naphtha. Tebuconazol is currently not included in this group as data on (developmental) neurotoxicity was contradictory with effects at higher doses only. In principle, another group may be defined with kidneys as target organ common to permethrin and IPBC, but this is not required as both substances are already represented in group 1.
Reference values for Tier 3a are available from chapters 3.6.1 and 3.6.2.8.

Tier 3b: For exposure scenarios and target organs where Tier 3a cannot demonstrate safe use, further refinement is performed by adjusting the HIto considering the target organ specific potency of each substance in a group. E.g. when a reference value was derived based on toxicity to the liver as the most sensititve target organ and neurotoxic effects were observed only at a threefold higher dose compared to liver, an adjusted AEL that is threefold higher may be used for that particular substance when calculating adjusted target-organ specific HI (aHIto).

Group 1:
For permethrin, reference values were based on liver effects. No adjustment can be made for these substances.
For tebuconazol, AEL long-term and medium-term (as well as ADI) were based on toxicity to the adrenals in a one-year dog study. However, according to the data reported in the CAR, onset of liver toxicity was observed in the same dose range with a NOAEL / LOAEL of 1.6 / 8 mg/kg bw/d in the one-year dog study (von Keutz Schilde, 1987b) (The CAR also states NOAEL liver of 3 mg/kg bw/d elsewhere). Thorough re-analysis of the data provided in the original study reports would be necessary

to further elaborate the potential of refinement of the target organ specific cumulative risk assessment for tebuconazol if such is needed.
For IPBC, reference values were derived based on gastrointestinal effects with histopathology in the stomach, forestomach and salivary glands also leading to reduced body weight (gain). For assessment of liver effects of IPBC, the 90 day study in rats (Bien, 2002, Doc. No. 533-005, Doc. IIIA, Section A6.4.1/01) can provide a suitable starting point with an NOAEL of 35 mg/kg bw/d. The long-term study in rats (Mulhern et al., 1989, Doc. No. 537-001, Doc. IIIA, Section A6.7/01) demonstrated that there was no increase in sensitivity with longer exposure duration. The following adjustment can be performed for IPBC in group 1 (liver):

Table 104

Time frame	AEL	Adjusted value	Study	Safety factor
long-term	0.2 mg/kg bw/d	0.35 mg/kg bw/d	90-d rat; Bien (2002) /2-yr rat; Mulhem et al. (1989)	100
medium-term	0.35 mg/kg bw/d	0.35 mg/kg bw/d	No refinement possible	-
acute	0.35 mg/kg bw/d	0.35 mg/kg bw/d	No refinement possible	-

It is noted that no significant liver toxicity is expected for acute exposures and cumulative risk assessment for this time frame is thus not essential for group 1.

Group 2:
A NOAEC of 1.16 mg/m^3 was derived for local effects in the respiratory system of IPBC (see also chapter 3.6.1). A reference MOE of 25 could be applied for risk characterisation.
For Naphtha, no agreed reference values concerning the enpoint respiratory irritation exist.

Group 3:
Mammals may be significantly less sensitive to the neurotoxic effects of permethrin than its liver toxicity. However, presentation of the data in the CAR / AR was not performed in a way that is considered suitable for refinement of cumulative risk assessment for the nervous system. A thorough re-analysis of the data provided by the different applicants for permethrin would be necessary if such is needed.
For Naphtha, a national OEL does exist (250 mg/m³] and was used for the systemic risk assessment of the professional user.

Cumulative risk characterisation for the non-professional user

Table 105: Cumulative systemic risk assessment for non-professional users and the general public

Task/ Scenario	Tier	Exposure [mg/kg bw(/d)]		AEL [mg/kg bw(/d)]		Hazard index	Acceptable (yes/no)
Scenario [1], Brushing outdoors	**1**	IPBC: Permethrin: Tebuconazol:	0.0561 0.00129 0.0154	IPBC: Permethrin: Tebuconazol:	0.35 0.5 0.03	0.68	yes
Scenario [2], Cleaning brush	**1**	IPBC: Permethrin: Tebuconazol:	0.00476 0.00011 0.00130	IPBC: Permethrin: Tebuconazol:	0.35 0.5 0.03	0.06	yes
Scenario [3], Sanding treated wood	1	IPBC: Permethrin: Tebuconazol:	0.00475 0.00089 0.00298	IPBC: Permethrin: Tebuconazol:	0.35 0.5 0.03	0.11	yes
Scenario [4], Mouthing treated wood	1	IPBC: Permethrin: Tebuconazol:	0.0145 0.00174 0.00579	IPBC: Permethrin: Tebuconazol:	0.35 0.5 0.03	0.23	yes
Scenario [5], inhalation volatilised residues	1/2	IPBC: Permethrin: Tebuconazol:	0.00111 0.00028 0.00017	IPBC: Permethrin: Tebuconazol:	0.2 0.05 0.03	0.02	yes
Scenario [5], Contact to treated surfaces	1	IPBC: Permethrin: Tebuconazol:	0.0156 0.00188 0.00625	IPBC: Permethrin: Tebuconazol:	0.2 0.05 0.03	0.32	yes

No human health risk from systemic effects is identified for non-professional users and the general public from cumulative exposure to the active substances IPBC, permethrin and tebuconazole if the biocidal product is used as intended.

Cumulative risk characterisation for the professional user

Table 106: Cumulative risk assessment for the professional user for the active substances tebuconazole, IPBC and permethrin

Scenario		HI[1]	acceptable (yes/no)
Brush treatment	Tier 1	1,42	no
	Tier 2	0,52	**yes**
Immersion - automated dipping daily	Tier 1	0,91	**yes**
	Tier 2	0,23	yes
Immersion - automated dipping	Tier 1	0,23	**yes**

weekly	Tier 2	0,23	yes
Dip treatment - manual dipping	Tier 1	6,32	no
	Tier 2	1,01	**no**
Deluge treatment	Tier 1	6,66	no
	Tier 2	0,71	**yes**
Mechanical processing of treated wood	Tier 1	1,99	no
	Tier 2	0,21	**yes**

[1]: HI: Hazard Index; sum of the Hazard Quotients (HQs) for each substance. HQ: estimation of internal exposure/AEL. Acceptable, if HI ≤ 1

A risk is identified for the scenario “Dip treatment – manual dipping” even with risk mitigation measures in TIER 2. Therefore a refinement is necessary.

The refined assessment uses a liver-specific AEL for IPBC of 0.35 mg/kg bw/d (instead of the regular AEL of 0.2 mg/kg bw/d) for calculation of the Hazard Index (HI) and the result is shown in **Table 107**.

Table 107: Cumulative risk assessment for the professional user for the active substances tebuconazole, IPBC and permethrin (using the liver-specific AEL of 0.35 mg/kg bw/d for IPBC)

Scenario		**HI_{liver}[1,2]**	**acceptable** (yes/no)
Brush treatment	Tier 1	1,22	no
	Tier 2	0,44	**yes**
Immersion - automated dipping daily	Tier 1	0,78	**yes**
	Tier 2	0,20	yes
Immersion - automated dipping weekly	Tier 1	0,20	**yes**
	Tier 2	0,20	yes
Dip treatment - manual dipping	Tier 1	5,42	no
	Tier 2	0,87	**yes**
Deluge treatment	Tier 1	5,71	no
	Tier 2	0,61	**yes**
Mechanical processing of treated wood	Tier 1	1,79	no
	Tier 2	0,19	**yes**

[1]: HI: Hazard Index; sum of the Hazard Quotients (HQs) for each substance. HQ: estimation of internal exposure/AEL. Acceptable, if HI ≤ 1;

[2]: HI calculated using the liver-specific AEL of 0.35 mg/kg bw/d for IPBC and the standard-AELs for tebuconazole and permethrin

After consideration of the liver-specific AEL for the active substance IPBC an acceptable HI of 0.87 in Tier 2 results for the scenario “Dip treatment – manual dipping”.

Conclusion

Based on the combined/cumulative risk assessment a risk for professional users resulting from the intended uses (‘brush treatment’, ‘immersion (automated dipping)’ daily and weekly, ‘dip treatment (manual dipping)’ and ‘deluge treatment’) with the biocidal products covered by meta SPC 1 as well as from secondary exposure (‘mechanical processing of treated wood’) is unlikely since the respective risk characterisation consistently yields hazard indices (HI) of less than 1 at the latest after TIER 2 consideration and application of the liver-specific AEL for IPBC. Regarding occupational safety, there are no objections against the intended uses as well as secondary exposure taking into account the provisions described in 2.3.1.4 of this PAR.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

The risk for industrial users is described in chapter 3.6.4.5.

3.6.4.10.2 Summary of risk characterisation for professional user

Please refer to the summary tables of the active substances and SoC (Table 88, Table 89 and Table 90 Table 91) and the cumulative risk assessment (chapter 3.6.4.9**)** relevant for Meta-SPC 1, 2, 3.

3.6.4.10.3 Summary of risk characterisation for non-professional user

Meta-SPC 1, 2, 3

Table 108 IPBC

Scenario, Tier	Relevant reference value (mg/kg bw [/d])	Estimated uptake (mg/kg bw[/d])	Estimated uptake/ reference value (%)	Acceptable (yes/no)
Scenario 1, Tier 1	0.35	0.0561	16	yes
Scenario 2, Tier 1	0.35	0.00476	1.4	yes

Table 109 Permethrin

Scenario, Tier	Relevant reference value (mg/kg bw [/d])	Estimated uptake (mg/kg bw [/d])	Estimated uptake/ reference value (%)	Acceptable (yes/no)
Scenario 1, Tier 1	0.5	0.00129	0.3	yes
Scenario 2, Tier 1	0.5	0.00011	0.02	yes

Table 110 Tebuconazole

Scenario, Tier	Relevant reference value (mg/kg bw [/d])	Estimated uptake (mg/kg bw [/d])	Estimated uptake/ reference value (%)	Acceptable (yes/no)
Scenario 1, Tier 1	0.03	0.0154	51	yes
Scenario 2, Tier 1	0.03	0.00130	4.3	yes

3.6.4.10.4 Summary of risk characterisation for indirect exposure

Meta-SPC 1, 2, 3

Table 111 IPBC

Scenario, Tier	Relevant reference value (mg/kg bw [/d])	Estimated uptake (mg/kg bw[/d])	Estimated uptake/ reference value (%)	Acceptable (yes/no)
Scenario 3, Tier 1	0.35	0.00745	2.1	yes
Scenario 4, Tier 1	0.35	0.01447	4.1	yes
Scenario 5, Tier 1	0.2	0.4154	208	no
Scenario 5, Tier 2	0.2	0.00111	0.6	yes
Scenario 6, Tier 1	0.2	0.0156	7.8	yes

Table 112 Permethrin

Scenario, Tier	Relevant reference value (mg/kg bw [/d])	Estimated uptake (mg/kg bw [/d])	Estimated uptake/ reference value (%)	Acceptable (yes/no)
Scenario 3, Tier 1	0.5	0.00089	0.2	yes
Scenario 4, Tier 1	0.5	0.00174	0.3	yes
Scenario 5, Tier 1	0.05	0.00028	0.6	yes
Scenario 6, Tier 1	0.05	0.00188	3.8	yes

Table 113 Tebuconazole

Scenario, Tier	Relevant reference value (mg/kg bw [/d])	Estimated uptake (mg/kg bw [/d])	Estimated uptake/ reference value (%)	Acceptable (yes/no)
Scenario 3, Tier 1	0.03	0.00298	9.8	yes
Scenario 4, Tier 1	0.03	0.00579	19	yes
Scenario 5, Tier 1	0.03	0.00017	0.6	yes
Scenario 6, Tier 1	0.03	0.00625	21	yes

3.7 Risk assessment for animal health

The toxicological information submitted by the applicant, the Competent Authority Report (CAR) and the Assessment Report (AR), as well as the current scientific literature was evaluated with regard to indications for increased susceptibility of relevant animal species to the active substance(s).

In particular, information on major differences in effect levels and types of effects / target organs when compared to findings in laboratory animals were considered as relevant. In addition, information on major qualitative and quantitative differences in pathways of absorption, distribution, metabolism and excretion (i.e. toxico-kinetics) was included.

There were the following findings:

Conclusion on risk assessment for animal health
Due to the lack of an appropriate guidance, a specific exposure and risk assessment for pets and domestic animals is not performed. However, it is expected that animals can be exposed to the active substances after treatment particularly by contact to treated surfaces. It is assumed that the health risk for these animals (except cats) is comparable to those of toddlers and children. Therefore, no specific measures are required for these animals if the biocidal product is used as intended. However, cats are more sensitive against pyrethroids. Due to a slower metabolisation (lethal) intoxications by pyrethroids are common. Hence, contact of pets, particularly cats, to treated surfaces should be avoided.

3.8 Risk assessment for the environment

Please note, this part of the assessment is applicable for meta-SPCs No. 1, 2, 3.

3.8.1 General information

Primer TIP is a solvent-borne biocidal product family (BPF) for use in PT 8, containing tebuconazole, IPBC and permethrin. The products are intended for use on timbers in use classes 2 and 3, i.e. outdoors for wood, which is not in direct contact to the ground or water, but continually exposed to the weather or subject to frequent wetting.

The modes of application include brushing/rolling by amateurs and professionals as well as dipping in special facilities and spraying in closed devices for professionals and industrial users. During industrial treatment, the biocidal products (b.p.) are applied to timbers or in industrial manufacturing plants.
The environmental risk assessment (ERA) focusses on the use in use class 3 as relevant emissions to environmental compartments are likely to occur when wooden structures are exposed to frequent wetting outdoors, or outdoor in-situ treatment leads to losses to soil and/or surface water during the application.
The risk assessment for the BPF Primer TIP after application is based on data of the active substances tebuconazole, IPBC and permethrin, including relevant metabolites.

For Meta-SPC 1, 2, 3 the representative and worst-case product with regard to the environment is Primer TIP (JJT 6310). Therefore, the risk assessment for the environment in this chapter for Primer TIP is applicable to all products included in the Meta-SPC 1, 2, 3. The environmental risk assessment is done for application of Primer TIP on hardwood due to the higher application rate of the b.p. for hardwood compared to the application rate for softwood. The application of Primer TIP on hardwood can be seen as a worst-case application that covers also the use of Primer TIP on softwood.

3.8.2 Effects assessment

Effects assessment is performed based on the active substances in the products. For active substances tebuconazole, IPBC and permethrin, as well as their metabolites, the evaluation is adapted from respective risk assessment reports of the active substances in the products:

- IPBC CAR 2008 PT 8, CAR 2013 PT 6 and CAR 2013 PT 13 (Denmark)[11],
- Tebuconazole CAR 2007 PT 8, CAR 2013 PT 7 and CAR 2013 PT 9 (Denmark)[11]

[11] The lists of endpoints concerning environmental effects assessment are identical for these CARs.

- Permethrin CAR 2014, PT8 and PT 18; (Ireland)

For Permethrin in PT 8 and PT 18 a new study has been provided for soil arthropod *Folsomia candida*, which was currently evaluated by eCA IE with regard to active substance approval. The outcome of the MS e-consultation concerning the derivation of PNECsoil was still pending at the stage of product assessment. Therefore, the effect assessment of the BPF is initially based on the data available in the CAR of 2014 associated with the corresponding assessment factor. The new PNECsoil was available with the addendum to the AR in March 2017 (0.175 mg/kg ww). It does not affect the outcome of the risk assessment in comparison to the old PNECsoil used in this assessment.

3.8.2.1 Mixture toxicity

As the BPF consists of more than one active substance, the risk assessment for the BPF can be based on data of the active substances, when considering the mixture toxicity assessment for biocidal products (Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C) 2017).

Screening step

- **Screening Step 1: Identification of concerned environmental compartments**

The screening step identifies, if exposure of environmental compartments can be expected from the application of the BPF and if so, which environmental compartments are likely to be at risk.
The wood treated with the products of meta SPC 1 of BPF Primer TIP is not considered for use in direct contact with soil or water when used in use class 2 and 3. However; in use class 3 (wood not covered, not in contact with ground, exposed to the weather or subject to frequent wetting) the active substances might enter the environment during in-situ treatment and/or leaching from treated wood during service life. Therefore, the risk assessment for the BPF Primer TIP is based on data of the active substances, including the mixture toxicity assessment for products.

- **Screening Step 2: Identification of relevant substances**

The BPF Primer TIP contains three active substances. The maximum concentrations in meta SPC 1 for the RTU products are 0.5 % for IPBC, 0.2% for tebuconazole and 0.06% for permethrin. For the assessment of mixture toxicity, the respective relevant metabolites have to be considered as well.
Some ingredients of the BPF contain substances, which are classified as hazardous to the environment according to regulation (EC) No 1272/2008. However, none of these substances are considered as SoCs. Concluding, as no SoCs were identified for the product family, the relevant substances for mixture toxicity assessment are the active substances and calculation of relative toxic units is not necessary.

- **Screening Step 3: Screen on synergistic interactions**

The product contains 3 active substances (IPBC, tebuconazole and permethrin) and no substances of concern for the environment. The toxicity of the single active substances is known. Potential indications for synergistic interactions/effects are summarised in Annex 3 of the Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C) 2017. In this Annex possible synergistic effects are described for fungicides, which act as ergosterol biosynthesis inhibitors (EBI fungicides) and pyrethroids. As tebuconazole belongs to the class of EBI fungicides and permethrin is a pyrethroid substance, literature was screened on indications of synergisms between these substances. The literature research revealed one study[12] on *Daphnia magna* with tebuconazole and a pyrethroid (alpha-cypermethrin), showing no synergistic interaction, but additive behaviour. Furthermore, the tested concentrations of tebuconazole were far above the environmental concentrations expected from the use of the product Primer TIP.

Four other studies on EBI fungicides and pyrethroids[13] were found, which incorporated either alpha-cypermethrin or other pyrethroid substances instead of permethrin and/or prochloraz as EBI fungicide instead of tebuconazole. The tests showing synergism were conducted using either *Daphnia magna, Vibrio fischeri* or *Apis mellifera* as test organisms. The seen synergistic interactions in those tests most likely resulted from the type of the used azole fungicide- unlike tebuconazole, procloraz is an imidazole which is generally more toxic due to higher bioaccumulation and exhibits a higher potency as a synergist compared to other triazoles, according to Dalhoff et al. (2016). All tests were conducted using alpha-cypermethrin and in one case lambda-cyhalothrin, which are type-2 pyrethroids, while permethrin is a type-1 pyrethroid. The eCA suggests that this structural difference might affect the potency as synergist for different pyrethroid substances similarly as shown for the EBI fungicides. Furthermore, synergistic effects only occured at exposure concentrations far above the environmental concentrations expected from the use of Primer TIP for at least one of the combined substances. Therefore it seems unlikely, that the two active substances tebuconazole and permethrin will exhibit synergistic effects in the environment, at concentrations potentially released to environment from the use of the product.

12 Nørgaard and Cedergreen 2010: Pesticide cocktails can interact synergistically on aquatic crustaceans. Environ. Sci Pollut Res (2010) 17:957-967 and references therein

13 Kretschmann et al. 2015 **(**https://doi.org/10.1016/j.aquatox.2015.02.011**);** Dalhoff et al. 2016 (https://doi.org/10.1016/j.aquatox.2015.12.007); Bjergager et al. 2011 **(**https://doi.org/10.1016/j.aquatox.2010.11.004**);** Pilling et al. 1995 (https://doi.org/10.1002/ps.2780390407)

Table 114

Screening step	
Y	Significant exposure of environmental compartments? Yes, because the products of BPF Primer TIP are used in use class 3 (wood not covered, not in contact with ground, exposed to the weather or subject to frequent wetting). Therefore, the active substances might enter the environment during in-situ treatment and/or leaching from treated wood during service life.
Y	Number of relevant substances >1? Yes, the BPF Primer TIP contains three active substances: IPBC, tebuconazole and permethrin.
N	Indication for synergistic effects for the product or its constituents in the literature? No, see above.

Tiered approach

- **Tier 1 PEC/PNEC summation**

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

$(PEC/PNEC)_{product} = \Sigma\ (PEC/PNEC)_{individual\ substances}$ for each environmental compartment.

$(PEC/PNEC)_{product\_metabolites} = \Sigma\ (PEC/PNEC)_{metabolites}$ for each environmental compartment.

The summations regarding each environmental compartment are documented in chapter3.8.5.

Conclusion of mixture toxicity

According to the Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C, 2017), the summation of the active substances as well as the summation of the relevant metabolites showed only an unacceptable risk for the environment for the scenarios “in-situ application” for the house and bridge-over-pond scenario, respectively. The unacceptable risk for mixture toxicity is triggered by the input-values of each single a.s. or metabolite, which already showed PEC/PNEC-values >1. These risks can be reduced by the requirement that (1) the ground should be covered before painting with the products of the BPF Primer TIP and (2) application of the products of the BPF Primer TIP is not allowed near surface waters, hence direct emissions during the application are avoided. In summary, an unacceptable risk for soil and water organisms due to the use of products of the BPF Primer TIP is not indicated, if the RMMs are considered. Since no unacceptable risk for the environment is expected for the mixture after Tier 1 due to imposed RMMs, no refinement of the mixture toxicity assessment is necessary.

3.8.2.2 Aquatic compartment (including sediment and STP)

- **Acute aquatic toxicity**

Active substance IPBC and its metabolite PBC

Data for environmental effects assessment was taken from the CAR for PT 8 and PT 13 (2008 and 2015) for the active substance IPBC. For risk assessment a $PNEC_{water}$ = 0.0005 mg/L was derived for IPBC and for the metabolite PBC a $PNEC_{water, PBC}$= 0.0413 mg/L was derived. A summary is included in the chapters below.

Active substance tebuconazole and its metabolite 1,2,4-triazole

Data for the environmental effect assessment and PNEC derivation of the active substance tebuconazole was taken from the CARs for the active substance tebuconazole in PT 8. For the metabolite 1,2,4-triazole no PNEC was derived in the respective active substance CARs, because its toxicity is much lower compared to the parent compound. Thus, the PNEC of tebuconazole covers the toxicity of the metabolite.

Active substance permethrin and its metabolites DCVA and PBA

Data for the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolite DCVA and PBA was taken from the CAR for active substance permethrin in PT8 and PT18 (2014).

Table 115

Conclusion used in Risk Assessment – aquatic toxicity	
IPBC and its metabolite PBC	
Value/conclusion	IPBC: $PNEC_{water}$ = 0.0005 mg/L; PBC: $PNEC_{water}$ = 0.0413 mg/L;
tebuconazole and its metabolites 1,2,4-triazole	
Value/conclusion	Tebuconazole: PNECwater = 0.001 mg/L metabolite covered by PNEC of parent compound
permethrin and its metabolites DCVA and PBA	
Value/conclusion	Permethrin: $PNEC_{water}$ = 0.00047 µg/L; DCVA: $PNEC_{water}$ = 0.015 mg/L; PBA: $PNEC_{water}$ >0.010 mg/L;

- **Sediment toxicity**

Active substance IPBC and its relevant metabolite PBC

No studies on sediment toxicity are available for IPBC. Usually, the PNEC for the sediment is calculated using the equilibrium method in this case. However, in the Danish CAR for PT13 (2013) for IPBC it was concluded that it is not necessary to make these calculations, as IPBC has a log Kow < 5. It was agreed that $PNEC_{sed}$ is covered by $PNEC_{water}$. For further details please refer to CAR for PT13 (2013).

PBC was identified as a relevant metabolite in water, sediment and soil >10%. IPBC is by several orders of magnitude more toxic than PBC regards the aquatic data. Due to DT50 of 31, 31 and 10 d in water, sediment and soil, respectively, PBC was regarded as a transient metabolite.

Active substance tebuconazole and its metabolite 1,2,4 – triazole

Detailed data on environmental effects assessment for tebuconazole and its major metabolite 1,2,4-triazole is given in the CAR for PT 8 (2007). For risk assessment of tebuconazole a PNECsed = 0.55 mg/kg dwt was derived. For the metabolite 1,2,4-triazole, no $PNEC_{sed}$ was derived, as its ecotoxicity is much lower than that of the parent compound. Thus, environmental risk assessment of the parent compound also covers the metabolite.

Active substance permethrin and its metabolites DCVA and PBA

Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolite DCVA and PBA can be found in the CAR for PT8 and PT18 (2014). For risk assessment of Permethrin, a $PNEC_{sed}$ = 0.001 mg/kg dwt (2.17 x 10-4 wwt) was derived. For the metabolites DCVA and PBA a $PNEC_{sed,DVCA}$ = 0.055 mg/kg dwt (0.012 mg/kg wwt) and $PNEC_{sed,PBA}$ = 0.042 mg/kg dwt (0.009 mg/kg wwt) was derived respectively.

Table 116

Conclusion used in Risk Assessment – Sediment toxicity	
IPBC and its metabolite PBC	
Justification for the value/conclusion	Not calculated.
Tebuconazole	
Justification for the value/conclusion	tebuconazole: PNECsed = 0.55 mg/kg metabolite covered by PNEC of parent compound
Permethrin and its metabolites DCVA and PBA	
Justification for the value/conclusion	Permethrin: $PNEC_{sed}$ = 0.001 mg/kg dwt (2.17 x 10^{-4} wwt) DCVA: $PNEC_{sed}$ = 0.055 mg/kg dwt (0.012 mg/kg wwt) PBA: $PNEC_{sed}$ = 0.042 mg/kg dwt (0.009 mg/kg wwt)

- **Inhibition of microbial activity (aquatic)**

For each of the three active substances their effect on aerobic biological sewage treatment processes was assessed according to OECD 209 by determining respiration inhibition of the micro-organisms present in activated sludge following 3 hours contact.

For **tebuconazole** the EC_{50} of 32 mg a.i./L was obtained for activated sludge (the solubility of tebuconazole is 32 mg/L). According to the TGD for Risk Assessment (EC, 2003) for such tests an assessment factor of 100 should be applied to the available EC50. Therefore, the PNEC $_{microorganisms\ (STP)}$ presented in the AR (2013) for PT 7 was **0.32 mg/L**.

The EC_{50} (3h) value measured for **IPBC** was 44 mg/l. The PNEC $_{microorganisms\ (STP)}$ of **0.44 mg/l** was derived by dividing 44 mg/l by an assessment factor of 100 (AR, 2016, PT 13).

Since for **permethrin** testing was conducted using concentrations above the water solubility and no inhibition was observed, the NOEC is set equal to the water solubility of **4.95 µg/l**. The PNEC $_{microorganisms\ (STP)}$ reported in the AR (2016, PT 8) was 4.95 µg/l.

Table 117

Conclusion used in Risk Assessment – Microbial toxicity	
Value/conclusion	IPBC and PBC
Justification for the value/conclusion	$PNEC_{STP}$ = 440 µg/L;
Value/conclusion	Tebuconazole
Justification for the value/conclusion	$PNEC_{STP}$ = 0.32 mg/L;
Value/conclusion	Permethrin and its metabolite DCVA and PBA (CAR 2014)
Justification for the value/conclusion	$PNEC_{STP}$ = 4.95 µg/L;

3.8.2.3 Terrestrial compartment (including groundwater)

Regarding terrestrial toxicity, no data are available for the product “Primer TIP” itself. Considering the mixture toxicity approach as given above, the risk assessment for the product can be based on data of the active substances. The PNEC values for tebuconazole, IPBC, permethrin and their relevant metabolites have been taken from the Assessment Reports for the active substances and are summarized below.

Active substance IPBC and its relevant metabolite PBC

Detailed data on the environmental effect assessment and PNEC derivation of the active substance IPBC and the metabolite PBC can be found in the CAR for PT8 and PT13 (2008 and 2015).

The metabolite PBC was identified as a relevant metabolite in water, sediment and soil >10%. IPBC is by several orders of magnitude more toxic than PBC with regards to the aquatic data. Due to DT50 of 31, 31 and 10 d in water, sediment and soil, respectively, PBC was regarded as a transient metabolite.

Although the active substance has a high mobility potential, it rapidly dissipates in all compartments, according to the CAR. Thus, it is not expected to reach groundwater. In the case of industrial treatment plants, risk mitigation measures should be applied.

Active substance tebuconazole and its metabolite 1,2,4 – triazole

Detailed data on the environmental effect assessment and PNEC derivation of the active substance and it's metabolite 1,2,4-triazole is given in the CAR for PT 8 (2007): $PNEC_{soil}$ = 0.11 mg/kg soil dwt (0.1 mg/kg soil wwt).

For the metabolite 1,2,4-triazole, no $PNEC_{soil}$ was derived, as its ecotoxicity is much lower than that of the parent compound. Thus, environmental risk assessment of the parent compound also covers the metabolite.

The low mobility potential of the active substance indicates a low probability of groundwater contamination.

Active substance permethrin and its metabolites DCVA and PBA

Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolites DCVA and 3-Phenoxybenzoic Acid (PBA) can be found in the CAR for PT8 and PT18 (2014): $PNEC_{soil}$ = > 0.099 mg/kg dwt (> 0.0876 mg/kg soil wwt).[14]

For the active substance approval of permethrin in PT8 / PT18 a new study has been provided for the compartment soil (November 2016), which is currently evaluated by eCA IRE. As the outcome of the evaluation is still pending, the effect assessment of the product "Primer TIP" is initially based on the data currently available in the CAR (2014) associated with the corresponding AF:

$PNEC_{soil;\ DCVA}$= 5.2 mg/kg soil dwt (4.6 mg/kg soil wwt)

$PNEC_{soil,PBA.}$ = 1.63 mg/kg soil dwt (1.44 mg/kg soil wwt)

An overview on the PNECs used for risk assessment in soil is given in Table 118.

[14] Please note that a new PNECsoil for Permethrin is available from the Addendum to the AR (March 2017) with 0.175 mg/kg ww which was not considered in this assessment, as agreement was pending when the product family was assessed and the outcome of the risk assessment would not be affected when applying the new PNECsoil.

Table 118

Conclusion used in Risk Assessment – Soil toxicity	
IPBC and its metabolite PBC	
Justification for the value/conclusion	$PNEC_{soil}$ = 0.006 mg/kg soil dwt Metabolites covered by PNEC for IPBC
Tebuconazole and its metabolite 1,2,4-triazole	
Justification for the value/conclusion	$PNEC_{soil}$ = 0.11 mg/kg soil dwt Metabolite covered by PNEC for parent compound
Permethrin and its metabolites DCVA and PBA	
Justification for the value/conclusion	Permethrin: $PNEC_{soil}$ = >0.099 mg/kg soil dwt DCVA: $PNEC_{soil; DCVA}$= 5.2 mg/kg soil dwt PBA: $PNEC_{soil,PBA.}$ = 1.63 mg/kg soil dwt

3.8.2.4 Atmosphere

Exposure to the atmosphere is not considered relevant for the biocidal product family Primer TIP, due to low vapour pressures of the three active substances:

Active substance IPBC

Exposure to the atmosphere is not considered relevant because the vapour pressure (2.36-4.5 x 10^{-3} Pa (25 °C)) of IPBC is very low (CAR 2007).

Active substance tebuconazole

Calculations of the chemical lifetime in the troposphere resulted in a half-life of 3.8 days. Although according to these results (DT_{50} > 2d), tebuconazole could be suspect of accumulation in the atmosphere, air will not be an environmental compartment of concern for use in PT 8. Based on the vapour pressure (1.7 x 10^{-6} Pa) and the Henry's Law constant (1 x 10^{-5} Pa×m³/mol), volatilisation of tebuconazole is considered to be negligible.

Active substance permethrin

Exposure to the atmosphere is not considered relevant for permethrin, due to low vapour pressure (2.16 x 10^{-6} Pa (20 °C)) of permethrin, low Henry's Law constant and high adsorption potential. Calculations indicate that if permethrin were present in the atmosphere it would be expected to degrade rapidly, mainly via gas phase reaction with photo-chemically generated hydroxyl radicals (CAR 2014).

3.8.2.5 Non-compartment specific effects

Bioaccumulation and secondary poisoning

Assessment of bioaccumulation potential and secondary poisoning was provided for the active substances tebuconazole, permethrin and IPBC in the respective CARs (tebuconazole PT8, 2007; permethrin PT 8 & 18, 2013 & 2014; IPBC PT8, 2008). Accordingly, $BCF_{tebuconazole}$ = 78 and BCF_{IPBC} was not derived, as the substance has a logKow below 3. According to the data presented, neither bioaccumulation nor secondary poisoning are considered relevant for these active substances.
For permethrin log Kow = 4.7 and reveals a potential for bioaccumulation. Moreover, according to the CAR 2012, some of the estimated BCF values indicate a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) and subsequently bioaccumulate through the food chain. Therefore, the assessment of secondary poisoning is requested. For a summary of relevant BCF values taken into account for secondary poisoning reference is made to the permethrin CAR PT8, 2014. For the derivation of $PNEC_{oral\ bird}$ = 16.7 mg a.s./kg food the NOEC from the one-generation study with the Northern Bobwhite (*Colinus virginianus*) and an AF30 was used. For derivation of $PNEC_{oral\ mammal}$ = 120 mg a.s./kg food the $NOEC_{mammal}$,= 3600 mg/kg food and an AF of 30 was used (CAR 2014).

3.8.2.6 Summary of effects assessment

All PNEC values used for the risk assessment of the product family “Primer TIP” are summarised in Table 119.

Table 119

Summary table on calculated PNEC values	
Compartment	**PNEC**
Aquatic	IPBC:0.0005 mg/L PBC: 0.0413 mg/L Tebuconazole: 0.001 mg/L Permethrin: 0.00047 µg/L DCVA: 0.015 mg/L PBA > 0.01 mg/L
Sediment	IPBC: covered by $PNEC_{aquatic}$ Tebuconazole 0.55 mg/kg dw Permethrin: 0.001 mg/kg dw DCVA: 0.055 mg/kg dw PBA: 0.042 mg/kg dw
STP	IPBC and PBC: 440 µg/L Tebuconazole: 320 µg/L Permethrin and DCVA and PBA (CAR 2014): 4.95 µg/L
Soil	IPBC: 0.005 mg/kg ww Tebuconazole: 0.1 mg/kg ww Permethrin: > 0.0876 mg/kg ww DCVA: 4.6 mg/kg ww PBA: 1.44 mg/kg ww

3.8.3 Fate and behaviour

For the general assessment of the environmental fate and behaviour of tebuconazole, IPBC and permethrin, please refer to the Assessment Reports of the BPD and BPR Dossiers[15]. A summary of the relevant parameters used in the risk assessment is given in Table 120.

15 (EU 1038/2013) Assessment Report Tebuconazole, Product type 7, September 2013
(EU 1090/2014) Assessment Report Permethrin, Product type 8, May 2016
(EU 2015/1728) Assessment Report IPBC, Product type 13, January 2016

Table 120: Parameters of active substances and its metabolites used for the environmental risk assessment

Parameter	Unit	Tebuconazole	1,2,4-Triazole *	IPBC	PBC**	Permethrin	DCVA***	PBA***
Molecular mass	g/mol	307.8	69.07	281.1	155.2	391.3	209.1	214.2
Vapour pressure	Pa	1.7-06 (20°C)	2.20 x 10^{-1} (25°C)	4.50 x 10^{-3} (25 °C)		2.155 x 10^{-6} (20°C)	0.26	4.21 x 10^{-4}
Henry's law constant	Pa·m^3·mol^{-1}	1.00 x 10^{-5}		6.45 x 10^{-3} (25°C)	1.02	<4.5 x 10^{-2}	-	-
Water solubility	mg/L	29 (pH 7. 20°C)	700.000	168 (pH 7, 20°C)		<0.00495 (20°C)	127.6 (25°C)	16.91 (25°C)
Log Pow		3.49 (20°C)		2.81 (25°C)	1.64	4.67 (25°C)	-	-
Hydrolysis		Stable at 25°C		Stable	-	Hydrolysed at pH>9	-	-
Aqueous photolysis		Stable at pH 7		Stable	-	Stable	-	-
Readily biodegradable		No		No	-	No	-	-
DT50soil (12°C)	d	77	Slow phase: 115.5 Fraction: 0.511 Fast phase 3.19 Fraction: 0.489	0.196	9.5	106	175	2.5
DT50 surface water (12°C)	d	198		0.129	31.2	46.7 (whole system)	188.8	61.8
DT50 sediment (12°C)	d	default 1000		0.204	31.4			
DT50 air	d	<2		<2		<2		
Koc	L/kg	992	69	126	198.1	73441	93.2	141.2
Distribution in STP from simple treat		89.1% water 10.9% sludge	99% water 1% sludge	98.4% water 1.5% sludge	1%air 97%water 2%sludge	16.3%water 83.8%sludge	0.4% air 98.4% water 1.1% sludge	98.3% water 1.7% sludge

* refer additionally to the active substance dossier for propiconazol – PT 8, Doc. II B, 2007

** refer to the active substance dossier for IPBC – PT8, Doc. II A, 2007

***refer additionally active substance dossier for permethrin – PT8, Doc. II B, 2014

Biodegradation / Metabolites

Apart from the post approval submission of an aerobic water/sediment degradation study (OECD 308) for the permethrin metabolite DCVA no new data regarding biodegradation behaviour of the three active substances tebuconazole, IPBC and permethrin were delivered by the applicant for authorisation of the biocidal product family Primer TIP. Therefore, the data presented in the respective Competent Authority Reports are used for the exposure and risk assessment. No further data are required.

Tebuconazole is not readily biodegradable.

In soil studies the geometric mean DT_{50} (12 °C) value was determined to be 77 days and this value was subsequently used for calculation of PECsoil. The decomposition of tebuconazole in aerobic soil proceeds via the formation of 1,2,4-triazole. According to DOC II (CAR tebuconazole PT 7) 1,2,4-triazole was identified as a relevant metabolite of tebuconazole in soil, because it was found in soil degradation studies at concentrations up to 9%, which is close to the limit value of 10%. Due to the shorter half-life of 1,2,4-triazole in soil compared to that of tebuconazole, 1,2,4-triazole can be regarded as a transient metabolite. Furthermore, the ecotoxicity of 1,2,4-triazole was found to be significantly lower than that described for tebuconazole (see Doc IIA). Therefore, an exposure assessment and risk assessment on 1,2,4-triazole for surface water, fresh-water sediment and soil is not considered further in the CAR. The metabolite 1,2,4-triazole is also a metabolite of the a.s. propiconazole. In the trilateral discussions on CAR of propiconazole in PT 7 it was raised that the UK RMS made a PPPD review on propiconazole in January 2014 indicating that the DT_{50} of the metabolite 1,2,4-triazole in soil at 20 °C should be 60.5 days. Due to the metabolite's behaviour in soil (fast and slow degradation phases) the DT_{50} is 1.68 d for the fast fraction (48.9%) and 60.5 days for the slow fraction (51.1%). BPC Working Group on environmental issues decided that the DT_{50} of 60.5 days corresponding to a DT_{50} of 115 days at 12 °C from the slow fraction should be used for worst case PECsoil calculations. For groundwater assessment a bi-phasic approach including a fast phase as well as a slow phase degradation should be employed according to FOCUS guidance.

For risk refinement purposes in the aquatic compartment the whole water/ sediment system first order $DegT_{50}$ value at 12 °C of 198 days was used.

IPBC is not readily biodegradable. However, IPBC was shown to be primarily biodegradable in a Zahn-Wellens Test (OECD 302B) in which IPBC degrades rapidly (within 2 hours) to propargyl butyl carbamate (PBC) and iodine. Together with data from the soil degradation studies indicating a DT_{50} value of 4.7 hours at 12 °C and also that 75% is mineralized after 21 days IPBC is assumed to be inherently biodegradable (k= 0.1 h^{-1} by default in STP).
Environmental exposure and risk assessment for the soil compartment is based on results from aerobic laboratory degradation studies in soil. For risk refinement purposes a DT_{50} (12 °C) value of 4.7 h corresponding to 0.196 days was used. PBC was identified as a relevant metabolite of IPBC with a DT_{50} (12 °C) value of 9.5 days.
Environmental exposure and risk assessment for the water/sediment system is based on results from an anaerobic laboratory water/sediment degradation study. For risk refinement purposes a DT_{50} (12 °C) value of 3.1 h corresponding to 0.129 days was used for the water compartment.

Permethrin is not readily biodegradable. For environmental exposure and risk assessment results from both aerobic laboratory degradation studies in soil as well as from aerobic water/ sediment studies were considered.
The range of reliable SFO DT_{50} values in several soils ranged from 77 d to ~141 d at 12 °C. The corresponding geomean DT_{50} was 106 d. The *cis* isomer degraded more slowly than the *trans* isomer. The geomean DT_{50} is derived from permethrin samples containing 50-78% of the *trans*- isomer. It can be expected that a DT_{50} value of 106 days is conservative enough to represent the degradation in soil at 12 °C of permethrin samples containing a *cis:trans* ratio of 25:75.
In the soil compartment permethrin breaks down to form DCVA (max 11.3 % AR, SFO DT_{50} 33.1- ~175 d at 12 °C) and PBA (max 15.0 % AR, DT_{50} 1.7-2.5 d at 12 °C), and ultimately converts to CO_2. For risk refinement purposes worst case DT_{50} (12 °C) values of 175 days resp. 2.5 days were used for the two metabolites DCVA resp. PBA.
In the aquatic environment, permethrin whole water/ sediment system first order degradation DT_{50} values at 12 °C ranged from 21.1 days to 46.1 days for vinyl-label treatment and 46.7 to 46.7 days for phenoxyphenyl-treatment. For risk refinement purposes the worst case DT_{50} value of 46.7 days was used.
In line with the request for further information after active substance approval, a confirmatory water/ sediment degradation study for the permethrin metabolite DCVA investigating the route and rate of degradation of [cyclopropane-1-14C] DCVA in two water/ sediment systems under aerobic laboratory conditions according to OECD 308 has been submitted by the applicant 2016 post-approval for PT 8 and PT 18. For refinement of exposure assessment the use of these new data is still awaiting the final outcome of the EU evaluation of the eCA IE and approval of BPC.

A summary of the relevant metabolites and the compartments where they occur are given in Table 121.

Table 121

Metabolite/transformation- or reaction product	Compartment
1,2,4-Triazole	Soil*, Groundwater
PBC	Soil, Groundwater, Water
DCVA	Soil, Groundwater, Water, Sediment
PBA	Soil, Groundwater, Water, Sediment

*for completeness regarding mixture toxicity

3.8.3.1 Leaching behaviour (ADS)

A leaching test for the BPF-assessment has been performed with an exemplary product representing the meta SPCs 1, 2, 3 containing Primer TIP products to evaluate the released active substances into the environment. The exemplary product has the identification number JJT6310.

Semi-field leaching tests

The leaching of tebuconazole, IPBC and permethrin from treated timber was investigated in a semi-field study for a period of 2 years (Wegner, R., 2015) at MPA-Eberswalde (Materialprüfanstalt Brandenburg GmbH). A summary of the test report is included in the IUCLID dossier. The test design is in accordance with NT Build 509 “Leaching of active components from preservative treated timber – semi-field testing (approved 2005-03)”, but the exposed wood surface was 0.8155 m^2 according to DIN CEN/TR 16663:2014. *Pinus sylvestris* was treated with JJT6310, containing 0.5% IPBC, 0.2 % tebuconazole, and 0.06% permethrin. The product was applied by brushing (2 times) without a top coat, resulting in final product retention of mean 129 g/m² (160 mL/m²), corresponding to 0.26 g tebuconazole/m², 0.64 g IPBC/m^2 and 0.077 g permethrin/m^2. One untreated test set and three preservative treated test set-ups were established, each consisting of 7 replicates. The timber panels were exposed outdoor above ground vertically facing south-west. Run-off leachates were continuously collected after each major rain event and analyzed for tebuconazole, IPBC (including PBC) and permethrin. Leachates were collected from 30 September 2013 to 30 September 2015 (730 days since start).

The maximum retention applied for during product authorization is 160 mL/m^2 for softwood and 225 mL/m^2 for hardwood. Therefore, for environmental risk assessment of the products used for hardwood a correction factor of 1.406 has to be applied during calculation of cumulative leaching amounts.

The calculated leaching rates based on the leaching test are summarised below. The detailed calculations are presented in chapter 4.2.3.

Table 122: Leaching rates for Primer TIP

Leaching rates for Primer TIP						
Active substance	**Softwood** [mg/m²/d]			**Hardwood** [mg/m²/d]		
	TIME 1 (30days)	**TIME 2a (5 years)**	**TIME 2b (15 years)**	**TIME 1 (30days)**	**TIME 2a (5 years)**	**TIME 2b (15 years)**
Tebuconazole	0.073	0.007	0.003	0.102	0.010	0.004
IPBC (incl. PBC)	0.075	0.007	0.003	0.106	0.010	0.004
Permethrin	1.95×10^{-5}	1.07×10^{-5}	1.07×10^{-5}	2.74×10^{-5}	1.50×10^{-5}	1.50×10^{-5}

The leaching rates resulting from the leaching study were accepted for the environmental risk assessment of all intended uses. It is assumed that leaching from treated wood after brush treatment would be the worst case compared to the industrial/professional dipping or spraying application.

3.8.3.2 Bioconcentration

IPBC

The LogKow of IPBC is 2.81 at 25 °C following the OECD 107 Guideline. Moreover, IPBC degrades rapidly in the environment to PBC. Like IPBC, the degradation product PBC dissipates rapidly in the environment. Therefore, no accumulation is expected (CAR 2007).

Tebuconazole

The assessment of secondary poisoning is not requested according to the Assessment Report for the use of tebuconazole in wood preservatives, as the BCF of the active substance is 78.

Permethrin

The reported LogKow values for permethrin range from 4.6 to 6.1 (CAR April 2014 for PT8 & PT18), indicating it is a fat-soluble molecule with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms). The CAR April 2014 for PT8 & PT18 provides BCF value for fish (BCF 570 L/kg). However, the half-life for depuration of tissue residues in fish was approximately 4-5 days with approximately 80% of the accumulated residues depurated within 14 days. Therefore, it was concluded that bioconcentration in fish tissues would not significantly occur and any residues accumulated are readily eliminated. Moreover, exposure of organisms to permethrin is expected to be low. The treated wood is not in direct contact with soil or water since Primer TIP is used up to use class 3 only.

3.8.4 Exposure assessment

3.8.4.1 General information

The biocidal products (b.p.s) of meta SPC 1 of the BPF Primer TIP are solvent-borne RTU products containing **0.2% tebuconazole**, **0.5% IPBC**, and **0.06% permethrin** (BPR Product Type 8) used for wood outdoors in use classes 2 and 3. The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting. The biocidal products of meta SPC 1 of the BPF Primer TIP are applied in use class 2 and 3 at a rate of 160 mL/m^2 (approx. 129 g/m^2) for softwood and **225 mL/m² (approx. 181 g/m²) for hardwood**. This results in maximum total applied amounts of **0.37 g tebuconazole/m², 0.9 g IPBC/m^2 and 0.11 g permethrin/m^2** wood, respectively.
The modes of application include brushing by amateurs and professionals as well as professional and industrial dipping and spraying.
Emissions to the environment from Primer TIP can occur during professional/industrial application, storage of freshly treated wood after professional/industrial application, during in-situ treatment and during the service life of the treated wood. In accordance with the 'Revised Emission Scenario Document for Wood Preservatives' (OECD, 2013[16]) and the 'BPR guidance Vol IV part B' (2015) a quantitative approach is performed assessing 3 main scenarios (refer to Table 123) in order to estimate potential tebuconazole, IPBC and permethrin emissions to environmental compartments, arising from the use of Primer TIP as preservatives for wooden structures. Predicted Environmental Concentrations (PECs) are calculated accordingly. The derived PECs are compared with the Predicted No Effect Concentrations (PNEC). The professional/industrial application and storage of freshly treated wood after professional/industrial application are assessed qualitatively.

Regarding iodine, IPBC emissions into the environmental compartments surface water and soil, respectively, have been converted to iodine and concentrations have been calculated for surface water, soil and groundwater. 100% transformation of IPBC into iodine is assumed.
Under environmental conditions iodine react quickly, forming iodide (I^-) and iodate (IO_3^-), which become part of the natural iodine circle and are ubiquitious in the environment.
At TM II 2012 it was decided that a formation of 100% iodide and of 100% iodate from iodine in water shall be considered for the environmental risk assessment as a worst-case approach. For calculation of soil concentrations, it was agreed that it can be assumed that the total iodine concentration in soil is

[16] OECD (2013): Revised Emission Scenario Document for Wood Preservatives. OECD Series on Emission Scenario Documents No2OECD, Environmental Directorate, Paris.

transformed into 14% iodide and 100% iodate. It is expected that much less than 100% of the different iodine species will be present in the environmental compartments.

Environmental concentration of iodine, iodate and iodide were calculated by applying the transformation rates above and considering a molecular weight correction to the PECs calculated for IPBC (without degradation):

- The molecular weight of one iodine molecule (I_2) is a factor 0.4514 lower than the molecular weight of two IPBC molecules.
- The molecular weight of 2 iodide ions corresponds to the molecular weight of one iodine molecule, consequently the PECs for iodide are the same as for iodine (factor 1).
- The molecular weight of 2 iodate ions is a factor of 1.3782 higher than the molecule weight of one iodine molecule, therefore the PECs for iodate were calculated by multiplying the PECs of iodine by this factor.

The resulting iodine, iodate and iodide concentrations have been compared to background concentrations found in the environment (according to the Iodine CAR 2013). Please refer to chapter 3.8.5.1 and 3.8.5.2 for the results.

Iodine background concentrations are as follows:

- Soil contains approximately 5 mg/kg iodine (average) worldwide with a range of 0.5-20 mg/kg dry weight (peat contains up to 98 mg/kg)
- In freshwater background concentrations are reported to be between 0.5 and 20 µg/L
- In groundwater, the mean concentration of iodine is 1 µg/L. Ranges of < 1-70 µg/L are reported

Besides tebuconazole, IPBC and permethrin the product does not contain substances of concern with respect to the environment.

During the Arona Leaching Workshop in June 2005, it was agreed that a long-term assessment of in-service uses of wood should be carried out. For brushing treatments an assessment of cumulative leaching from treated wood in-service over a 5 year period is applied. Hence, for these uses the assessment times are 30 days (TIME 1) for short term consideration and 5 years (service life) for the longer time period (TIME 2). Regarding the professional/industrial dipping and spraying application, an assessment of cumulative leaching from treated wood in-service over a 15 year period is applied.

If an unacceptable risk is identified for TIME 1, a further TIME 1b value of 365 days is calculated as well (not used for decision making, but sent to ECHA) as agreed by the BPC Working Group Environment.

Please refer to section “Fate and distribution in exposed environmental compartment” for further details.

Table 123

Assessed PT	PT 8
Assessed scenarios	**Scenario 1:** **In-situ brush application by amateur users** - Bridge over pond - Timber cladded house **Scenario 2:** **In-situ brush application by professional user** - Bridge over pond - Timber cladded house **Scenario 8:** **In-service leaching from treated wood** - Bridge over pond - Timber cladded house - Noise barrier Where appropriate the aggregated risks of emissions from application and in-service leaching are assessed.
ESD(s) used	ESD for PT 8: Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013)
Approach	Scenarios 1-3: Average consumption
Distribution in the environment	BPR guidance Vol IV part B (2015)
Groundwater simulation	FOCUS Pearl version 4.4.4
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation: No Use (application): Yes Storage: Yes (qualitatively) Service life: Yes
Remarks	No remarks

Formulation of the biocidal product

The production of Primer TIP is done in a closed system, unacceptable emissions to the environment can be excluded and therefore, no risk assessment was conducted for this life cycle stage. Furthermore, this step is already covered under other EU legislation.

Professional/Industrial application of the biocidal product

Emissions to the environment can occur during professional/industrial application (dipping and spraying) of the wood preservative and subsequent storage of the treated timbers. A state of the art report for wood preservatives and the environment published by the Deutsche Bauchemie (Dt. Bauchemie,

2002[17]) refers to the safe operation of timber treatment installations. Save use can be achieved through a number of measures, both technical and organisational. To avoid or minimise harm to health and damage to the environment, additional preventive measures must be taken into account in the event of an accident. For instance, to achieve a high degree of safety, regular control measures are scheduled for the operation of closed impregnation facilities like pressure impregnation. These include checks for leaks in the facility as well as proper functioning of the leak monitoring devices. Exactly defined measures for procedures ensure that the impregnation process runs safely. Just as with pressure procedures, the tightness of facilities for pressureless procedures is of utmost importance. While control instruments are also checked in closed facilities to ensure safety, the functioning of overflow safety devices is continuously monitored in open tank facilities (Dt. Bauchemie, 2012[18]).

A risk of contaminating the direct surrounding area of an impregnation facility exists, for example, if the preservative escapes through run off. When a facility is built, local conditions and prerequisites are taken into consideration first. Such facilities are not constructed in the vicinity of lakes, dams or in areas that are used as a water supply. The construction of collecting basins, not only for the impregnation facility itself but also for storing preservatives, practically eliminates the risk of ground, groundwater and surface water contamination.

The design and safe operation of timber treatment installations are regulated by national laws which implement EU directives and correspond to the current state of technique and scientific knowledge. A detailed description for the safety measures of timber treatment installations is given in a European Code of Practice for their Safe Design and Operation (EWPM, 2011[19]). The document provides generic guidance on environmental, safety and health aspects relevant to all companies in the European Union engaged in the activity of industrial wood preservation.

The principle of total containment should be followed during site design and applied to processing plant, wood preservative storage area and the holding area for treated timber. A covered and/or contained and impermeable dripping area for freshly treated timber should be provided and be situated adjacent to the plant and the storage tank bund. Treated timber will be further processed, i.e., they are basically not stored in an open outdoor area. Especially treated timber foreseen for use class 1 and 2 applications

17 Wood Preservative and the Environment, State-of-the-Art Report 2002, 2nd Edition, March 2002, Deutsche Bauchemie

18 Fachgerechte Tränkung von Bauholz – Planung und Ausführung zum Schutz von Holz im Nichtdruckverfahren, 1. Ausgabe, März 2012, Deutsche Bauchemie.

19 Timber Treatment Installations, European Code of Practice for their Safe Design and Operation, Issue 1, 2011, European Wood Preservative Manufacturers Group (EWPM)

should not be exposed to rain to avoid any leaching of the product. It is recommended that bulk quantities of dry treated timber be stored under cover and/or on an impermeable surface to prevent possible contamination of surface and / or groundwater.

In general, emissions to sewage water system during applications in treatment plants are not likely to occur, because treatment containers are stand-alone devices without direct connection to the sewage. It has to be stated that at impregnation plants the redundant preservative solution will be collected and recycled into the process whenever possible. Furthermore, residues like sludge, debris from tanks and other materials from application will be classified as hazardous waste, and require to be disposed of accordingly.

The professional application of Primer TIP by dipping and spraying may be undertaken indoors or outdoors under roof in a contained area in timber treatment installations (e.g. saw mills, joineries). In professional timber treatment installations, safety measures are implemented in order to prevent contamination of the environment. Consequently, only negligible emissions caused by professional application are expected.

In addition, potential emissions to the environment during professional/industrial treatment can be controlled by implementation of appropriate risk mitigation measures like: “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)” and “Application by professionals must be conducted within a contained area (indoors or outdoors under roof).”

Conclusion: During industrial treatment of the BPF Primer TIP, no significant emissions to the environment (air, soil and water) will occur, since the treatment processes take place in an industrial, discontinuous batch system with safety measures being on the state of the art of the chemical industry. The same conclusion applies to professional treatment by dipping and spraying. In addition, potential emissions to the environment during professional/industrial treatment can be controlled by implementation of appropriate risk mitigation measures. Thus, no exposure/risk assessment of the life cycle step application (industrial and professional) is derived.

Storage of treated wood

Emissions to the environment can potentially occur during storage after industrial/professional application of products of the BPF Primer TIP. As it can be concluded from the respective CAR on tebuconazole, IPBC and permethrin storage of treated timber will pose a risk to soil and groundwater unless risk mitigation measures are undertaken. Consequently, the inclusion directives demand an appropriate risk mitigation measure to protect these compartments. The risk mitigation measure has

been rephrased (WG-V-2016, BPC-17) to the following harmonized version: “Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal.” Thus, only negligible emissions to the environment are expected. Therefore, no emission and exposure calculation during storage is performed.

Conclusion: Potential emissions to the environment during storage of treated timber can be controlled by implementation of a risk mitigation measure. Thus, no exposure assessment is conducted.

Outdoor in-situ applications

Outdoor in-situ applications of the BPF by brushing/rolling will be undertaken by amateurs and professionals. Product losses can occur due to spills and drips and will end up in the soil (and groundwater) or the surface water if treated commodities are located close to surface water bodies. For applications by amateurs and professionals, product losses of 5% and 3% to soil or surface water, respectively, are assumed according to the ESD for PT 8 (2013).

In-service life

Emissions may take place due to leaching from constructions being in-situ treated with products of the BPF Primer TIP or built from industrially treated wood.
During the Arona Leaching Workshop in June 2005 (EC, 2005[20]), it was agreed that besides a short-term assessment (30 days) a long-term assessment should be carried out which is linked to the in-service life of the treated wood. For brushing treatment a service life of 5 years was proposed. For other superficially treated wood (automated spraying and dipping) a service life of 15 years should be taken into account.

3.8.4.2 Fate and distribution in exposed environmental compartments

In Table 124 the environmental compartments are summarized, which might potentially be exposed to the a.s. tebuconazole, IPBC and permethrin due to the use of the b.p. of the BPF Primer TIP.
The compartments marked with 'Yes' are those of concern for which predicted emissions and local concentrations have been determined.

[20] European Commission (2005): Report of the Arona Leaching Workshop (open session). Arona, Italy, 13 and 14 June 2005. European Commission Joint Research Centre, EUR 21878.

Table 124

Identification of relevant receiving compartments based on the exposure pathway							
Scenario		**Fresh-water**	**Freshwater sediment**	**STP**	**Soil**	**Ground-water**	**Air**
Scenario 1 and 2: In-situ application	**Brushing: Bridge over pond**	Yes	Yes	No	No	No	Not relevant
	Brushing: House	No	No	No	Yes	Yes	Not relevant
Scenario 8: Service life	**Bridge over pond**	Yes	Yes	No	No	No	Not relevant
	House	No	No	No	Yes	Yes	Not relevant
	Noise barrier	Yes	Yes	Yes	Yes	Yes	Not relevant

Calculation of PEC values

The Predicted Environmental Concentration (PEC) calculations follow the available guidance (revised Emission Scenario Document for Wood Preservatives (OECD, 2013); BPR guidance Vol. IV part B (2015). The PECs for tebuconazole, 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, taking into account degradation processes and/or dilution (where applicable). The PEC values presented in the following tables are rounded values from EXCEL spread sheets. The calculations for the different PECs within EXCEL are always carried out with unrounded values.

The calculation of PEC values for Meta-SPC 1 is based on the b.p. Primer TIP used for hardwood.

3.8.4.3 Aquatic compartment (including sediment and STP)

- **<u>Emission estimation</u>**

PECs for sewage treatment plants (STPs)

Losses to STPs are calculated for the in-service leaching from the surfaces of the noise barrier (constructed from industrial treated timber).

For tebuconazole, IPBC and permethrin, the STP effluent concentrations do represent PECs for this compartment. The distribution of the compounds to air, water and sludge is listed in Table 120.

The following tables contain the PEC values for STPs (active substances).

Table 125

Summary of PECs for STP Primer TIP hardwood					
			Tebuconazole	IPBC	Permethrin
SCENARIO			PEC STP [µg/L]	PEC STP [µg/L]	PEC STP [µg/L]
Noise Barrier	Leaching in-service via STP after dipping or automated spraying	30 days	1.08×10^{-1}	1.12×10^{-1}	2.88×10^{-5}
		15 years	4.38×10^{-3}	4.37×10^{-3}	1.57×10^{-5}

PECs for surface water

Emissions to surface water are assessed either indirectly from the noise barrier scenario via the STP or directly via the bridge over pond scenario. The calculated PEC values for surface water are presented in Table 126 (active substances) and Table 127 (metabolites). Unless otherwise noted, the values include degradation.

Table 126

Summary of PECs for surface water Primer TIP hardwood						
				Tebuconazole	IPBC	Permethrin
SCENARIO				PEC surface water [µg/L]	PEC surface water [µg/L]	PEC surface water [µg/L]
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days*	3.90 x 10^{-3}	1.12 x 10^{-2}	4.23 x 10^{-7}
			15 years*	3.90 x 10^{-4}	4.37 x 10^{-4}	2.31 x 10^{-7}
Bridge over pond	Application in-situ	Amateur	1 day*	1.82 x 10^{-1}	4.56 x 10^{-1}	5.50 x 10^{-2}
		Professional	1 day*	1.09 x 10^{-1}	2.73 x 10^{-1}	3.30 x 10^{-2}
	Leaching in-service after brushing, dipping or spraying		30 days	1.50 x 10^{-2}	1.96 x 10^{-4}	3.57 x 10^{-6}
			5 years	2.50 x 10^{-2}	1.90 x 10^{-5}	9.71 x 10^{-6}
			15 years	1.10 x 10^{-2}	7.74 x 10^{-6}	9.98 x 10^{-6}
	Application in-situ + leaching in service	Amateur	30 days	1.88 x 10^{-1}	3.03 x 10^{-3}	4.40 x 10^{-2}
			5 years	5.30 x 10^{-2}	6.55 x 10^{-5}	6.80 x 10^{-4}
		Professional	30 days	1.18 x 10^{-1}	1.89 x 10^{-3}	2.70 x 10^{-2}
			5 years	4.20 x 10^{-2}	4.68 x 10^{-5}	4.09 x 10^{-4}

*without degradation

Table 127

Summary of PECs for surface water for metabolites Primer TIP hardwood						
				IPBC metabolite	Permethrin metabolites	
				PBC	DCVA	PBA
SCENARIO				PEC surface water [µg/L]	PEC surface water [µg/L]	PEC surface water [µg/L]
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days*	6.16 x 10^{-3}	1.25 x 10^{-3}	1.29 x 10^{-3}
			15 years*	2.41 x 10^{-4}	7.72 x 10^{-4}	7.91 x 10^{-4}
Bridge over pond	Application in-situ	Amateur	1 day*	2.52 x 10^{-1}	2.94 x 10^{-2}	3.01 x 10^{-2}
		Professional	1 day*	1.51 x 10^{-1}	1.76 x 10^{-2}	1.81 x 10^{-2}
	Leaching in-service after brushing, dipping or spraying		30 days*	1.76 x 10^{-2}	4.40 x 10^{-6}	4.50 x 10^{-6}
			5 years*	1.03 x 10^{-1}	1.46 x 10^{-4}	1.50 x 10^{-4}
			15 years*	1.26 x 10^{-1}	4.39 x 10^{-4}	4.50 x 10^{-4}
	Application in-situ + leaching in service	Amateur	30 days*	2.69 x 10^{-1}	2.94 x 10^{-2}	3.01 x 10^{-2}
			5 years*	2.54 x 10^{-1}	2.95 x 10^{-2}	3.03 x 10^{-2}
		Professional	30 days*	6.16 x 10^{-3}	3.06 x 10^{-2}	3.14 x 10^{-2}
			5 years*	1.78 x 10^{-2}	3.02 x 10^{-2}	3.09 x 10^{-2}

*without degradation

PECs for sediment

For tebuconazole and permethrin $PEC_{sediment}$ values are calculated for the "bridge over pond" scenario taking into account degradation/dissipation in the water phase, where appropriate. For IPBC and PBC no sediment risk assessment was carried out as the log Kow of both IPBC and PBC are < 3 and hence the surface water risk assessment also covers sediment.

The predicted concentration in sediment is deduced from the $PEC_{surfacewater}$ by a partition of the a.s. between suspended matter and the water phase. The sediment values are derived from initial surface water concentrations, biodegradation is considered where appropriate.

The calculated PEC values for sediment are presented in Table 128 (active substances) and Table 129 (metabolites).

Table 128

Summary of PECs for sediment Primer TIP hardwood						
				Tebuconazole	IPBC	Permethrin
SCENARIO				PEC sediment [µg/kg wwt]	PEC sediment [µg/kg wwt]	PEC sediment [µg/kg wwt]
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days*	8.94×10^{-2}	n.a.	6.76×10^{-4}
			15 years*	8.72×10^{-3}	n.a.	3.69×10^{-4}
Bridge over pond	Application in-situ	Amateur	1 day*	4.07	n.a.	87.9
		Professional	1 day*	2.44	n.a.	52.7
	Leaching in-service after brushing, dipping or spraying		30 days	3.35×10^{-1}	n.a.	5.70×10^{-3}
			5 years	5.59×10^{-1}	n.a.	1.55×10^{-2}
			15 years	2.46×10^{-1}	n.a.	1.59×10^{-2}
	Application in-situ + leaching in service	Amateur	30 days	4.01	n.a.	70.3
			5 years	1.13	n.a.	1.09
		Professional	30 days	2.51	n.a.	43.1
			5 years	8.95×10^{-1}	n.a.	6.53×10^{-1}

*without degradation

Table 129

Summary of PECs for sediment for metabolites Primer TIP hardwood					
				Permethrin	
				DCVA	PBA
SCENARIO				PEC sediment [µg/kg wwt]	PEC sediment [µg/kg wwt]
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days*	3.51 x 10^{-3}	4.97 x 10^{-3}
			15 years*	2.17 x 10^{-3}	3.05 x 10^{-3}
Bridge over pond	Application in-situ	Amateur	1 day*	4.94 x 10^{-2}	1.16 x 10^{-1}
		Professional	1 day*	8.25 x 10^{-2}	7.71 x 10^{-2}
	Leaching in-service after brushing, dipping or spraying		30 days*	1.24 x 10^{-5}	1.73 x 10^{-5}
			5 years*	4.10 x 10^{-4}	5.78 x 10^{-4}
			15 years*	1.23 x 10^{-3}	1.73 x 10^{-3}
	Application in-situ + leaching in service	Amateur	30 days*	4.94 x 10^{-2}	1.16 x 10^{-1}
			5 years*	4.98 x 10^{-2}	1.17 x 10^{-1}
		Professional	30 days*	8.25 x 10^{-2}	7.71 x 10^{-2}
			5 years*	8.29 x 10^{-2}	7.77 x 10^{-2}

*without degradation

3.8.4.4 Terrestrial compartment (including groundwater)

PECs for soil

Emissions to soil are assessed for the noise barrier scenario and the house scenario. The calculated PEC values for soil are summarized in Table 130 and

Table 131. Unless otherwise noted, the values include degradation.

Table 130

Summary of PECs for soil Primer TIP hardwood						
				Tebuconazole	IPBC	Permethrin
SCENARIO				PEC soil [mg/kg wwt]	PEC soil [mg/kg wwt]	PEC soil [mg/kg wwt]
Noise Barrier	Leaching in-service after dipping or automated spraying		30 days*	2.40×10^{-2}	6.35×10^{-5}	8.88×10^{-6}
			15 years*	9.82×10^{-4}	2.49×10^{-6}	4.86×10^{-6}
House	Application in-situ	Amateur	1 day*	1.03×10^{-1}	2.58×10^{-1}	3.10×10^{-2}
		Professional	1 day*	6.20×10^{-2}	1.55×10^{-1}	1.90×10^{-2}
	Leaching in-service after brushing, dipping or spraying		30 days	6.40×10^{-2}	1.70×10^{-4}	2.37×10^{-5}
			5 years	6.44×10^{-3}	1.63×10^{-5}	1.29×10^{-5}
			15 years	2.62×10^{-3}	6.65×10^{-6}	1.30×10^{-5}
	Application in-situ + leaching in service	Amateur	30 days	9.80×10^{-2}	2.60×10^{-3}	2.80×10^{-2}
			5 years	1.20×10^{-2}	4.03×10^{-5}	2.61×10^{-3}
		Professional	30 days	6.20×10^{-2}	1.63×10^{-3}	1.70×10^{-2}
			5 years	9.81×10^{-3}	4.05×10^{-5}	1.60×10^{-3}

*without degradation

Table 131

Summary of PECs for soil for metabolites Primer TIP hardwood							
				IPBC metabolite	Permethrin metabolites		Tebuconazol metabolite
				PBC	DCVA	PBA	1,2,4-triazol
SCENARIO				PEC soil [mg/kg wwt]	PEC soil [mg/kg wwt]	PEC soil [mg/kg wwt]	PEC soil [mg/kg wwt]
Noise Barrier	Leaching in-service after dipping or automated spraying		30 days	2.40 x 10^{-2}*	6.35 x 10^{-5}*	8.88 x 10^{-6}*	1.46 x 10^{-3}*
			15 years	9.82 x 10^{-4}	2.49 x 10^{-6}*	4.86 x 10^{-6}*	3.22 x 10-^{4}
	Application in-situ	Amateur	1 day*	1.03 x 10^{-1}*	2.58 x 10^{-1}*	3.10 x 10^{-2}*	2.31 x 10^{-2}*
		Professional	1 day*	6.20 x 10^{-2}*	1.55 x 10^{-1}*	1.90 x 10^{-2}*	1.39 x 10^{-2}*
	Leaching in-service after brushing, dipping or spraying		30 days	6.40 x 10^{-2}	1.70 x 10^{-4}*	2.37 x 10^{-5}*	3.81 x 10^{-3}*
			5 years	6.44 x 10^{-3}	1.63 x 10^{-5}*	1.29 x 10^{-5}*	2.16 x 10^{-3}
			15 years	2.62 x 10^{-3}	6.65 x 10^{-6}*	1.30 x 10^{-5}*	8.83 x 10^{-4}
	Application in-situ + leaching in service	Amateur	30 days	9.80 x 10^{-2}	2.60 x 10^{-3}*	2.80 x 10^{-2}*	2.69 x 10^{-2}*
			5 years	1.20 x 10^{-2}	4.03 x 10^{-5}*	2.61 x 10^{-3}*	4.69 x 10^{-2}*
		Professional	30 days	6.20 x 10^{-2}	1.63 x 10^{-3}*	1.70 x 10^{-2}*	1.77 x 10^{-2}*
House			5 years	9.81 x 10^{-3}	4.05 x 10^{-5}*	1.60 x 10^{-3}*	3.77 x 10^{-2}*

*without degradation

Groundwater assessment

The groundwater assessment is described in detail in chapter 3.8.5.2

3.8.4.5 Atmosphere

Based on the vapour pressure (1.7 x 10^{-6} Pa at 20 °C) and the Henry`s Law constant (1 x 10^{-5} Pa×m³/mol), volatilisation of tebuconazole can be regarded as negligible.

For IPBC the volatilization is considered to be negligible based on the vapour pressure (4.5 x 10^{-3} Pa at 25 °C) and the Henry`s Law constant (6.45 x 10^{-3} Pa·m³/mol)

Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.16 x 10^{-6} Pa at 20 °C) and the Henry`s Law constant (>4.5 x 10^{-2} Pa·m³/mol).

Therefore, the calculation of PEC values for the atmosphere (PEC_{air}) is of no relevance and air is not regarded as a compartment of concern for this Product-Type and proposed use patterns.

3.8.4.6 Aggregated exposure (combined for relevant emission sources)

Biocidal active substances (a.s.) are used in various applications and are often contained in many different products. The environmental exposure assessment of single uses may therefore underestimate the actual concentrations of a.s. to be found in the environment.

According to the “Decision tree on the need for estimation of aggregated exposure” (Figure 1), it is checked if aggregated exposure estimations are required for the active substances in the BPF Primer TIP.

The present exposure and risk assessment does not consider the whole amount of IPBC, tebuconazole and permethrin which the environment could be exposed to due to the use of different biocidal products containing these active substances. Furthermore, transformation of permethrin in the environment leads to the major metabolites DCVA (3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate and PBA (3-phenoxybenzyl alcohol to 3-phenoxybenzoic acid) which are common transformation products of several active substances of the group of pyrethroids. As pyrethroids are common insecticides, future risk assessments of permethrin containing biocidal products should take the possible aggregated exposure of not only the parent but also of the transformation products into account.

All a.s. of Primer TIP can be used in different PTs:

- IPBC: PT 6, 7, 8, 9, 10, 13
- Tebuconazole: PT, 7, 8, 10
- Permethrin: PT 8, 18

Therefore, the possibility is given that overlapping emissions in time and space of the a.s. containing products can occur and an aggregated exposure assessment should be done.

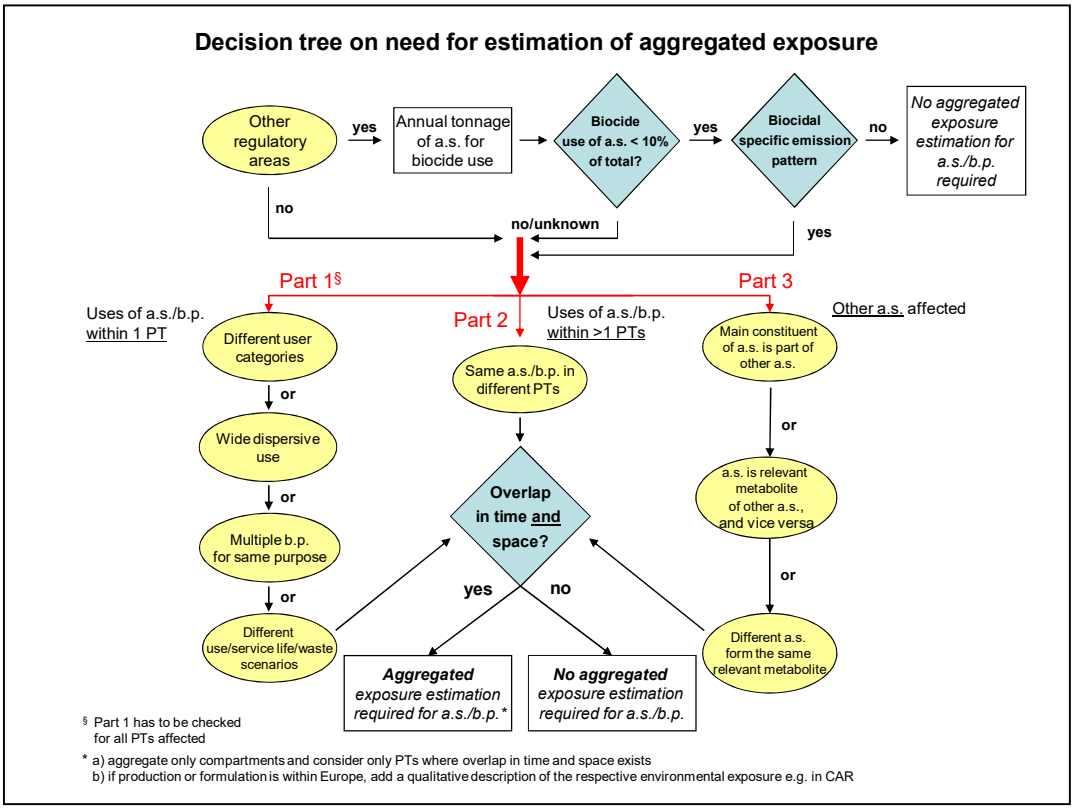


Figure 1: Decision tree on the need for estimation of aggregated exposure

However, currently a guideline on how an aggregated exposure assessment shall be performed is in development. Therefore, in this PAR the aggregated exposure has not yet been assessed.

3.8.5 Risk characterisation

The environmental risk characterisation for biocidal active substances in the context of Annex VI of the Biocidal Products Regulation (Regulation (EU) No 528/2012) involves the comparison of PEC and PNEC values for each relevant environmental compartment as well as for non-target organisms. For this purpose Risk Characterisation Ratios (PEC/PNEC) are derived for the use of the wood preservative BPF Primer TIP. Exceptions are the assessments of the professional/industrial application of the biocidal product and the storage of treated wood, which were done qualitatively (refer to chapter 3.8.4.1).

The PNEC values for tebuconazole, IPBC and permethrin have been taken from the Assessment Reports for the active substances when used for PT 8 purposes, the values are summarized in Table 119.

The calculated PEC/PNEC ratios are provided for the aquatic (incl. sediment) and the terrestrial compartment. If the PEC/PNEC ratio is equal or below 1, this is interpreted as an acceptable risk to the environment.

3.8.5.1 Aquatic compartment (sediment and STP)

Sewage treatment plant

Losses to STPs are calculated for the in-service leaching from the surfaces of the noise barrier (constructed from industrial treated timber).

The following table contains the PEC/PNEC ratios for the substances as well as a mixture toxicity assessment, comprising the addition of the PEC/PNEC values for tebuconazole, IPBC and permethrin. Synergistic effects of the substances are not reported and are therefore not further assessed.

Table 132

Summary of PEC/PNECs for STP Primer TIP hardwood						
			Tebuconazole	IPBC	Permethrin	
			PNEC STP = 320 µg/L	PNEC STP = 440 µg/L	PNEC STP = 4.95 µg/L	MixTox
SCENARIO			PEC/PNEC	PEC/PNEC	PEC/PNEC	PEC/PNEC
Noise Barrier	Leaching in-service via STP after dipping or automated spraying	30 days	3.36×10^{-4}	2.53×10^{-4}	5.82×10^{-6}	5.95×10^{-4}
		15 years	1.37×10^{-5}	9.92×10^{-6}	3.18×10^{-6}	2.68×10^{-5}

Conclusion

The requirements for acceptable risk according to the BPR guidance Vol IV part B (2015) are met for all scenarios for each active substances and the mixture for Primer TIP hardwood application. Therefore, these requirements are also met for all scenarios for softwood application.

Surface water

The following tables contain the PEC/PNEC ratios for the single substances /metabolites as well as a mixture toxicity assessment, comprising the addition of the PEC/PNEC values of tebuconazole, IPBC and permethrin. Synergistic effects of the substances are not reported and are therefore not further assessed. Unless otherwise noted, the values consider degradation of the active substance in surface water.

Table 133

Summary of PEC/PNECs for surface water Primer TIP hardwood							
				Tebuconazole	IPBC	Permethrin	
				PNEC surface water = 1 µg/L	PNEC surface water = 0.5 µg/L	PNEC surface water = 4.7 x 10^{-4} µg/L	MixTox
SCENARIO				PEC/PNEC	PEC/PNEC	PEC/PNEC	PEC/PNEC
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days*	3.78 x 10^{-3}	1.16 x 10^{-2}	9.09 x 10^{-4}	1.63 x 10^{-2}
			15 years*	3.79 x 10^{-4}	8.68 x 10^{-4}	4.68 x 10^{-4}	1.72 x 10^{-3}
Bridge over pond	Application in-situ	Amateur	1 day*	1.82 x 10^{-1}	9.12 x 10^{-1}	**117.02**	**118.12**
		Professional	1 day*	1.09 x 10^{-1}	5.46 x 10^{-1}	**70.21**	**70.87**
	Leaching in-service after brushing, dipping or spraying		30 days	1.50 x 10^{-2}	3.92 x 10^{-4}	7.59 x 10^{-3}	2.30 x 10^{-2}
			5 years	2.50 x 10^{-2}	3.80 x 10^{-5}	2.07 x 10^{-2}	4.57 x 10^{-2}
			15 years	1.10 x 10^{-2}	1.55 x 10^{-5}	2.12 x 10^{-2}	3.22 x 10^{-2}
	Application in-situ + leaching in service	Amateur	30 days	1.88 x 10^{-1}	6.05 x 10^{-3}	**93.62**	**93.81**
			5 years	5.30 x 10^{-2}	1.31 x 10^{-4}	**1.45**	**1.50**
		Professional	30 days	1.18 x 10^{-1}	3.78 x 10^{-3}	**57.45**	**57.57**
			5 years	4.20 x 10^{-2}	9.37 x 10^{-5}	8.71 x 10^{-1}	9.13 x 10^{-1}

*without degradation

Table 134

Summary of PEC/PNECs for surface water for metabolites for Primer TIP hardwood							
				IPBC metabolite	Permethrin metabolites		
				PBC	DCVA	PBA	
SCENARIO				PNEC surface water = 41.3 µg/L PEC/PNEC	PNEC surface water = 15 µg/L PEC/PNEC	PNEC surface water = 10 µg/L PEC/PNEC	MixTox PEC/PNEC
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days*	1.49×10^{-4}	8.33×10^{-5}	8.60×10^{-5}	3.18×10^{-4}
			15 years*	5.84×10^{-6}	5.15×10^{-5}	5.27×10^{-5}	1.10×10^{-4}
Bridge over pond	Application in-situ	Amateur	1 day*	6.10×10^{-3}	1.96×10^{-3}	2.01×10^{-3}	1.01×10^{-2}
		Professional	1 day*	3.65×10^{-3}	1.18×10^{-3}	1.20×10^{-3}	6.03×10^{-3}
	Leaching in-service after brushing, dipping or spraying		30 days*	4.25×10^{-4}	2.93×10^{-7}	3.00×10^{-7}	4.26×10^{-4}
			5 years*	2.49×10^{-3}	9.74×10^{-6}	9.98×10^{-6}	2.51×10^{-3}
			15 years*	3.04×10^{-3}	2.93×10^{-5}	3.00×10^{-5}	3.10×10^{-3}
	Application in-situ + leaching in service	Amateur	30 days*	6.52×10^{-3}	1.96×10^{-3}	2.01×10^{-3}	1.05×10^{-2}
			5 years*	6.14×10^{-3}	1.97×10^{-3}	2.02×10^{-3}	1.01×10^{-2}
		Professional	30 days*	1.49×10^{-4}	2.04×10^{-3}	2.09×10^{-3}	4.28×10^{-3}
			5 years*	4.31×10^{-4}	2.01×10^{-3}	2.06×10^{-3}	4.50×10^{-3}

*without degradation

Conclusion

The in-service scenarios yield PEC/PNEC ratios below one for all scenarios and the single substances as well as the mixture of active substances, indicating acceptable risk for surface water organisms. An unacceptable risk was identified for in-situ application for the bridge over pond scenario (and, therefore, also if in-situ application and in-service is taken into account together). These risks are due to the high toxicity of permethrin to aquatic organisms. These risks can be reduced to an acceptable level by the following risk mitigation measure: “Do not apply near bodies of surface water or in the area of water protection zones.” Taking this RMM into account, an unacceptable risk for surface water organisms due to the use of the products of meta SPC 1 of BPF Primer TIP is not indicated.

Beside the above-mentioned metabolites, iodine and its transformation products iodide and iodate might reach the aquatic environment as inorganic transformation products of IPBC and are therefore assessed separately. For the iodine risk assessment the bridge over pond scenario in-situ application has been chosen as a worst case since it represents an intake into a static water body. Iodine as an inorganic compound is not biodegradable, so it was assumed that the whole IPBC emissions might accumulate. Molecular weight transformation results in both 0.206 µg/L iodine and iodide and 0.284 µg/L iodate. These values are below the iodine background concentration of 0.5 – 20 µg/L in surface water.

Sediment

According to the Danish CAR for PT13 (2015) the risk of IPBC to the sediment is the same as that described for surface water. Therefore, the following table contains the PEC/PNEC ratios for single substances as well as a mixture toxicity assessment, comprising the addition of the $PEC/PNEC_{sediment}$ values of tebuconazole and permethrin and the $PEC/PNEC_{surfacewater}$ values of IPBC. Moreover, as modelled levels of iodine, iodide and iodate are below background levels in the surface water, these were not assessed in the sediment.

Synergistic effects of the substances are not reported and are therefore no matter of concern. Unless otherwise noted, the sediment values are based on surface water values without including degradation.

Table 135

Summary of PEC/PNECs for sediment Primer TIP hardwood							
				Tebuconazole	IPBC	Permethrin	
				PNEC sediment = 550 µg/kg wwt	PNEC surface water = 0.5 µg/L	PNEC sediment = 0.217 µg/kg wwt	MixTox
SCENARIO				PEC/PNEC	PEC/PNEC	PEC/PNEC	PEC/PNEC
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days*	1.63×10^{-4}	1.16×10^{-2}	3.12×10^{-3}	1.49×10^{-2}
			15 years*	1.59×10^{-5}	8.68×10^{-4}	1.70×10^{-3}	2.58×10^{-3}
Bridge over pond	Application in-situ	Amateur	1 day*	7.40×10^{-3}	9.12×10^{-1}	**405.07**	**405.99**
		Professional	1 day*	4.44×10^{-3}	5.46×10^{-1}	**242.86**	**243.41**
	Leaching in-service after brushing, dipping or spraying		30 days	6.09×10^{-4}	3.92×10^{-4}	2.63×10^{-2}	2.73×10^{-2}
			5 years	1.02×10^{-3}	3.80×10^{-5}	7.14×10^{-2}	7.25×10^{-2}
			15 years	4.47×10^{-4}	1.55×10^{-5}	1.31×10^{-2}	1.35×10^{-2}
	Application in-situ + leaching in service	Amateur	30 days	7.29×10^{-3}	6.05×10^{-3}	**323.96**	**323.98**
			5 years	2.05×10^{-3}	1.31×10^{-4}	**5.02**	**5.03**
		Professional	30 days	4.56×10^{-3}	3.78×10^{-3}	**198.62**	**198.63**
			5 years	1.63×10^{-3}	9.37×10^{-5}	**3.01**	**3.01**

*without degradation

Table 136

Summary of PEC/PNECs for sediment for metabolites Primer TIP hardwood						
				Permethrin		
				DCVA	PBA	
				PNEC sediment = 1.2 x 10^{-2} µg/kg wwt	PNEC sediment = 9 x 10^{-3} µg/kg wwt	MixTox
SCENARIO				PEC/PNEC	PEC/PNEC	PEC/PNEC
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days*	2.93 x 10^{-1}	5.52 x 10^{-1}	8.45 x 10^{-1}
			15 years*	1.81 x 10^{-1}	3.39 x 10^{-1}	5.20 x 10^{-1}
Bridge over pond	Application in-situ	Amateur	1 day*	**4.12**	**12.89**	**17.01**
		Professional	1 day*	**6.88**	**8.57**	**15.44**
	Leaching in-service after brushing, dipping or spraying		30 days*	1.03 x 10^{-3}	1.92 x 10^{-3}	2.96 x 10^{-3}
			5 years*	3.42 x 10^{-2}	6.42 x 10^{-2}	9.84 x 10^{-2}
			15 years*	1.03 x 10^{-1}	1.92 x 10^{-1}	2.95 x 10^{-1}
	Application in-situ + leaching in service	Amateur	30 days*	**4.12**	**12.89**	**17.01**
			5 years*	**4.15**	**12.995**	**17.10**
		Professional	30 days*	**6.88**	**8.57**	**15.44**
			5 years*	**6.91**	**8.63**	**15.54**

*without degradation

Conclusion

For the sediment, the same scenarios result in unacceptable PEC/PNEC ratios as for surface water. Therefore, the same conclusions and requirements apply. The risks can be reduced to an acceptable level by the following risk mitigation measure: “Do not apply near bodies of surface water or in the area of water protection zones.” Taking this RMM into account, an unacceptable risk for sediment organisms due to the use of the products of meta SPC 1 of BPF Primer TIP is not indicated.

3.8.5.2 Terrestrial compartment (Soil/Groundwater)

Soil

The following tables contain the PEC/PNEC ratios for the single substances/metabolites as well as a mixture toxicity assessment, comprising the addition of the PEC/PNEC values of tebuconazole, IPBC and permethrin. Synergistic effects of the substances are not reported and are, therefore, no matter of concern. Unless otherwise noted, the values include degradation.

Table 137

Summary of PEC/PNECs for soil Primer TIP hardwood							
				Tebuconazole	IPBC	Permethrin	
				PNEC soil = 0.1 mg/kg wwt	PNEC soil = 0.005 mg/kg wwt	PNEC soil = 0.0876 mg/kg wwt	MixTox
SCENARIO				PEC/PNEC	PEC/PNEC	PEC/PNEC	PEC/PNEC
Noise Barrier	Leaching in-service after dipping or automated spraying		30 days*	2.40×10^{-1}	6.75×10^{-3}	1.01×10^{-4}	2.47×10^{-1}
			15 years*	9.82×10^{-3}	5.03×10^{-4}	5.54×10^{-5}	1.04×10^{-2}
House	Application in-situ	Amateur	1 day*	**1.03**	**51.60**	3.54×10^{-1}	**52.98**
		Professional	1 day*	6.20×10^{-1}	**31.00**	2.17×10^{-1}	**31.84**
	Leaching in-service after brushing. dipping or spraying		30 days	6.40×10^{-1}	3.39×10^{-2}	2.71×10^{-4}	6.74×10^{-1}
			5 years	6.44×10^{-2}	3.27×10^{-3}	1.48×10^{-4}	6.78×10^{-2}
			15 years	2.62×10^{-2}	1.33×10^{-3}	1.48×10^{-4}	2.77×10^{-2}
	Application in-situ + leaching in service	Amateur	30 days	9.80×10^{-1}	5.20×10^{-1}	3.20×10^{-1}	**1.82**
			5 years	1.20×10^{-1}	8.07×10^{-3}	2.98×10^{-2}	1.58×10^{-1}
		Professional	30 days	6.20×10^{-1}	3.26×10^{-1}	1.94×10^{-1}	**1.14**
			5 years	9.81×10^{-2}	8.10×10^{-3}	1.83×10^{-2}	1.25×10^{-1}

*without degradation

Table 138

Summary of PEC/PNECs for soil for metabolites for Primer TIP hardwood								
				IPBC metabolite	Permethrin metabolites		Tebuconzaol metabolite	
				PBC	DCVA	PBA	1,2,4-triazol	
				PNEC soil = 0.149 mg/kg wwt	PNEC soil = 4.6 mg/kg wwt	PNEC soil = 1.44 mg/kg wwt	PNEC soil = 0.01 mg/kg wwt	MixTox
SCENARIO				PEC/PNEC	PEC/PNEC	PEC/PNEC	PEC/PNEC	PEC/PNEC
Noise Barrier	Leaching in-service after dipping or automated spraying		30 days	2.50×10^{-2}*	2.02×10^{-7}*	6.63×10^{-7}*	1.46×10^{-1}	1.71×10^{-1}
			15 years	2.03×10^{-4}	2.02×10^{-5}*	6.61×10^{-5}*	3.22×10^{-2}*	3.24×10^{-2}
House	Application in-situ	Amateur	1 day	9.56×10^{-1}*	3.60×10^{-3}*	1.18×10^{-2}*	**2.31***	**3.28**
		Professional	1 day	5.74×10^{-1}*	2.21×10^{-3}*	7.22×10^{-3}*	**1.39***	**1.98**
	Leaching in-service after brushing. dipping or spraying		30 days	3.05×10^{-2}	5.41×10^{-7}*	1.77×10^{-6}*	3.81×10^{-1}*	4.12×10^{-1}
			5 years	2.93×10^{-3}	1.79×10^{-5}*	5.87×10^{-5}*	2.16×10^{-1}	2.19×10^{-1}
			15 years	1.19×10^{-3}	5.39×10^{-5}*	1.77×10^{-4}*	8.83×10^{-2}	8.97×10^{-2}
	Application in-situ + leaching in service	Amateur	30 days	**1.02***	3.60×10^{-3}*	1.18×10^{-2}*	**2.69***	**3.73**
			5 years	**1.35***	3.62×10^{-3}*	1.18×10^{-2}*	**4.69***	**6.05**
		Professional	30 days	9.81×10^{-1}*	3.60×10^{-3}*	1.18×10^{-2}*	**1.77***	**2.77**
			5 years	**1.13***	3.62×10^{-3}*	1.19×10^{-2}*	**3.77***	**4.92**

*without degradation

Conclusion

Unacceptable risks for soil organisms are identified for in-situ application regarding IPBC, tebuconazole and the mixture.

These risks can be reduced to an acceptable level by the requirement that the ground should be covered before painting timber with the products of Meta SPC 1 of BPF Primer TIP: “During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way”

The in-service leaching scenarios showed no unacceptable risks for all a.s. and the mixture.

Unacceptable risks for soil organisms are identified for in-situ application plus leaching in-service regarding PBC, 1,2,4-triazol and the mixture. These risks can be reduced to an acceptable level by the requirement that the ground should be covered before painting with the products of Meta SPC 1 of BPF Primer TIP; hence direct emissions during the application are avoided. The in-service leaching scenario showed no unacceptable risks for all metabolites and the mixture. Therefore, in summary, an unacceptable risk for soil organisms due to the use of products of meta SPC 1 of BPF Primer TIP is not indicated if the RMM is taken into account.

With reference to the iodine risk assessment for soil, the same procedure as for surface water has been followed. Considering the RMM above, the worst-case scenario if no degradation is considered is the house scenario with a service life of 15 years. The calculated IPBC concentration of 0.129 mg/kg wet weight soil is molecular weight corrected, yielding 0.058 mg/kg wet weight soil iodine, 0.080 mg/kg wet weight soil iodate and 0.008 mg/kg wet weight soil iodide. These values are even below the background concentration of 0.5 – 20 mg/kg and pose therefore no unacceptable risk for the soil.

- **Groundwater**

The fate and behaviour for IPBC suggest that it is not expected to reach groundwater since this compound has been shown to have a half-life in soil of 0.196 days at 12 °C. Therefore, an exposure assessment for groundwater on IPBC is not considered further for the use phase, but for its metabolite PBC FOCUS PEARL 4.4.4 was run.

However, iodine as a metabolite of IPBC and its transformation products iodide and iodate might reach groundwater. It is not appropriate to take over the approach used for soil and static surface water since groundwater is a ‘flowing’ system, moving through soil and bedrock and being diluted. Therefore, as a starting point IPBC worst-case soil concentrations immediately after an in-situ application by an amateur have been taken, accounting for 0.258 mg IPBC/kg soil. This value has been used for calculating potential IPBC porewater concentrations. The porewater calculation according to the BPR guidance Vol IV part B (2015) (using IPBC parameter for the Henry’s law constant and the Koc since no iodine values are available) results in an IPBC concentration of 110 µg/L and concentrations of both iodine and iodide of 49.7 µg/L and of iodate of 68.4 µg/L after molecular weight correction. These values are within the

background concentration of <1 - 70 µg/L. The expected concentrations can be reduced by the requirement that the ground should be covered before painting with the products of BPF Primer TIP; hence direct emissions during the application are avoided.

For tebuconazole and permethrin (and the metabolites that are more mobile) risk in groundwater could be expected. Hence the PECgw has been calculated with FOCUS PEARL 4.4.4. It has been taken into account the PT 08 scheme: a density of 16 treated houses per ha and a leachable area of 125 m² per house, resulting in a total leachable area of 2000 m² per ha. According to the supplement to Appendix 4 of the ESD for PT 8 (2013) 10 application events can be considered (10 January, 15 February, 24 March, 29 April, 5 June, 11 July, 17 August, 22 September, 29 October, 4 December). The crop type is alfalfa/grass and the application mode is “to the soil surface” (no plant uptake).

Tebuconazole:

From the leaching study, the experimental leaching rate for tebuconazole is 0.01 mg/m^2/d in 5 years (Table 122). The total amount of leached a.s. per ha per year and per application event is 7.5 x 10^{-4} kg. For ground water assessment of the metabolite of tebuconazole (1,2,4-triazole) the transformation of the a.s. into 1,2,4-triazole in soil in a slow (DT_{50} = 60.5 d) and a fast (DT_{50} = 1.68 d) degrading compartment was taken into account.

Table 139

Tebuconazole and 1,2,4-triazole inputs			
Input parameter	**Unit**	**Tebuconazole**	**1,2,4-Triazole**
Water solubility	mg/L	29	700,000
Vapour pressure	Pa	1.7 x 10^{-6}	2.20 x 10^{-1} (20 °C)
Kom (Koc/1.724)	L/Kg	575.4	51.6
Freundlich exponent (default)		0.9	0.9
DT50 soil (20°C)	days	77 (12°C)	Slow phase: 60.5. Fraction 0.511
			Fast phase: 1.68. Fraction 0.489

Table 140

PECgw Tebuconazole results		
Scenario	**PECgw (µg/L) Tebuconazole**	**PECgw (µg/L) 1.2.4-Triazole**
Chateaudun	<0.0001	0.0011
Hamburg	<0.0001	0.0027
Joikoinen	<0.0001	0.0008
Kremsmuester	<0.0001	0.0014
Okehampton	<0.0001	0.0024
Piacenza	<0.0001	0.0028
Porto	<0.0001	0.0017
Sevilla	<0.0001	0.0003
Thiva	<0.0001	0.0007

Permethrin:

Considering the leaching study for permethrin and assuming a service life of 5 years an emission rate of 1.07 x 10^{-5} mg/m^2 has been taken (Table 122). According to the PT 08 scheme, the total amount of leached a.s. per ha per year is 1.09 x 10^{-6} kg (considering 10 application events evenly distributed over the year).

Table 141

Permethrin and metabolites inputs				
Input parameter	**Unit**	**Permethrin**	**DCVA**	**PBA**
Water solubility	mg/L	4.95 x 10^{-3}	127.6	16.9
Vapour pressure	Pa	2.16 x 10^{-6}	0.26	4.21 x 10^{-4}
Kom (Koc/1.724)	L/Kg	42599	54.1	81.9
Freundlich exponent (default)		0.9	0.9	0.9
DT50 soil (20°C)	days	56.1	92.2	1.3
Formation Fraction*		-	1	1

*The formation fractions are not available from degradation studies in soil in the assessment report, therefore f=1 has been taken as worst case.

Table 142

PECgw Permethrin, DCVA, PBA results			
Scenario	PECgw (µg/L)		
	Permethrin	**DCVA**	**PBA**
Chateaudun	<0.0001	<0.0001	<0.0001
Hamburg	<0.0001	<0.0001	<0.0001
Joikoinen	<0.0001	<0.0001	<0.0001
Kremsmuester	<0.0001	<0.0001	<0.0001
Okehampton	<0.0001	<0.0001	<0.0001
Piacenza	<0.0001	<0.0001	<0.0001
Porto	<0.0001	<0.0001	<0.0001
Sevilla	<0.0001	<0.0001	<0.0001
Thiva	<0.0001	<0.0001	<0.0001

(I)PBC:

Considering the worst-case with 100% leaching of IPBC + PBC, the total amount of leached a.s. per ha per year is 7.5 x 10^{-4} kg (considering 10 application events evenly distributed over the year).

Table 143

IPBC and metabolites inputs			
Input parameter	**Unit**	**IPBC**	**PBC**
Water solubility	mg/L	168 (20°C)	Same as a.s.
Vapour pressure	Pa	4.5 x 10^{-5} (25°C)	Same as a.s.
Kom (Koc/1.724)	L/Kg	73.09	114.9
Freundlich exponent (default)		0.9	0.9
DT50 soil (20°C)	days	0.196	9.592.2
Formation Fraction*		-	1

*The formation fractions are not available from degradation studies in soil in the assessment report, therefore f=1 has been taken as worst case.

Table 144

PECgw IPBC, PBC results		
Scenario	PECgw (µg/L)	
	IPBC	**PBC**
Chateaudun	<0.0001	<0.0001
Hamburg	<0.0001	<0.0001
Joikoinen	<0.0001	<0.0001
Kremsmuester	<0.0001	<0.0001
Okehampton	<0.0001	<0.0001
Piacenza	<0.0001	<0.0001
Porto	<0.0001	<0.0001
Sevilla	<0.0001	<0.0001
Thiva	<0.0001	<0.0001

Conclusion

The PECgroundwater is below the quality standard of 0.1 µg/L for pesticides and biocidal products according to the Directives 98/83/EC and 2006/118/EC for the all active substances permethrin, tebucconazole, IPBC as well as the metabolites DCVA and PBA, 1,2,4-triazole and PBC for all scenarios. Iodine, iodide and iodate as transformation product of IPBC show no unacceptable risk for the environment, too. Therefore, the use of products of meta SPC 1 of BPF Primer TIP does not present an unacceptable risk for groundwater.

3.8.5.3 PBT assessment

IPBC

P

The **P criterion for IPBC and PBC is not fulfilled** since the half-lives from both the aerobic soil degradation study and the aerobic water-sediment study are well below the trigger values.

B

IPBC and PBC do not fulfil the B criterion. The bioaccumulation potentials are not significant based on a logPow value of 2.8 for IPBC and 1.64 for PBC (CAR for PT13, 2015).

T

The T criterion is fulfilled as a chronic NOEC below 0.01 mg/L is found for IPBC ($NOEC_{algae}$ = 0.0046 mg/l.).

Tebuconazole

P

Tebuconazole **fulfils the persistence criterion to be very persistent (vP).**

B

Tebuconazole **does not fulfil the B criterion**.

T

Tebuconazole **fulfils the T criterion** as **it** meets the criteria for classification as toxic for reproduction, category 2 according to the CLP Regulation (CAR PT 7 & 10, 2013).

Tebuconazole is regarded as candidate for substitution because it fulfils the vP and T criterion.

Permethrin

P

According to the decision at BPC-40 (2021), Permethrin **is considered to fulfil the P criterion**.
At the ENV WG-III-2019 follow-up WebEx (11/06/2019), the working group agreed that cis-permethrin exceeds both the 'P' and the 'vP' criterion for the sediment compartment with a DT_{50} of 180.2 days at 12°C (whole system). Also, the soil P trigger of 120 days was exceeded by the isomeric permethrin mixtures (containing 50-78% of the trans-isomer) in two of the soils tested. Because cis-permethrin is degraded more slowly than trans-permethrin, it can possibly be assumed that the cis-isomer could generally fulfill the P-criterion in the soil compartment. As the P status has already been agreed upon by the conclusion on the sediment compartment, no further data is needed for the soil compartment.
For further detailed information please refer to Permethrin CAR 2021, PT 8/ PT18; Rapporteur: Ireland; October 2021;

B

Permethrin does not fulfil the B criterion. BCF_{fish} and $BCF_{chironomid}$ values are < 2000. For further detailed information please refer to Permethrin CAR 2014, PT 8/ PT18; Rapporteur: Ireland; April 2014;

T

Permethrin meets the criteria for toxicity. The measured NOEC values for aquatic organisms are all lower than the specified T criterion trigger value of 0.01 mg/L.

3.8.5.4 Endocrine disrupting properties

The three active substances in the BPF Primer TIP are not classified as an identified ED substance in wildlife:

IPBC

IPBC and PBC are not classified as an identified ED substance in wildlife. (CAR; PT13; 2015)

Tebuconazole

Tebuconazole may have the potential to cause endocrine disruption based on suspected properties for the azole group (CAR; PT8; 2007). However, tebuconazole is included in table 4 (substances classified as HPV and/or persistent and/or exposure expected in humans and wildlife, with insufficient data) (CAR PT 7 & 10, 2013).

Permethrin

Permethrin is not a classified as an identified ED substance in wildlife. For further details please refer to CAR 2014.

A comprehensive ED-assessment for all three active substances according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage.

Non-active substances

The full composition of the BPF is listed in the confidential annex. There are no indications that a non-active substance of the product may have endocrine disrupting properties on environmental non-target organisms based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation, the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards or ECHA's endocrine disruptor assessment list. For none of the co-formulants indications on potential ED effects on environmental non-target organisms were found in scientific literature. More detailed information regarding the assessment is given in the condifental annex 2.

3.8.5.5 Summary of risk characterisation

- **Overall conclusion on the risk assessment for the environment of the product**

The BPF Primer TIP is a solvent-borne Ready To Use product family containing tebuconazole, IPBC and permethrin (BPR Product-Type 8) used for wood outdoors in use classes 2 and 3. The BPF is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.
The modes of application include brushing and rolling by amateurs and professionals as well as dipping and spraying in closed facilities for professional and industrial uses. During industrial treatment, Primer TIP is applied to timbers in industrial manufacturing plants.
During industrial treatment of the BPF Primer TIP, no significant emissions to the environment (air, soil and water) will occur, since the treatment processes take place in an industrial, discontinuous batch system with safety measures being on the state of the art of the chemical industry. The same conclusion applies to professional treatment by dipping and spraying. In addition, potential emissions to the environment during professional/industrial treatment can be controlled by implementation of appropriate risk mitigation measures. Thus, no quantitative risk assessment of the life cycle step industrial and professional application is derived.

For the storage of treated timber no exposure/risk assessment is conducted. Potential emissions to the environment during storage of treated timber can be controlled by implementation of the risk mitigation measure “Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal.”

Regarding the aquatic compartment (including sediment), in-service scenarios yield PEC/PNEC ratios below one for all single substances as well as the mixture of active substances and metabolites, respectively, indicating acceptable risk for aquatic compartment (incl. sediment).

Unacceptable risks were identified for in-situ application of the b.p. for the bridge over pond scenario. These risks can be reduced by the requirement that the products of BPF Primer TIP should not be used in the immediate proximity of waters; hence direct emissions during the application are avoided. Therefore, an unacceptable risk for surface water organisms due to the use of products of BPF Primer TIP is not indicated if the risk mitigation measure is taken into account.

Unacceptable risks could be identified for soil organisms for in-situ application regarding the house scenario. These risks can be reduced by the requirement that the ground should be covered before painting with the products of BPF Primer TIP; hence direct emissions during the application are avoided. All in-service leaching scenarios are without any unacceptable risk. In summary, an unacceptable risk for soil organisms due to the use of products of BPF Primer TIP is not indicated if the risk mitigation measure is taken into account.

BPF Primer TIP possesses acceptable risks for groundwater and secondary poisoning because all the requirements are met according to the BPR guidance Vol IV part B (2015) for all scenarios, for each active substance, its metabolites and the mixture, respectively.

Therefore, it could be concluded that for BPF Primer TIP acceptable risk for the environment are assessed taking into account risk mitigation measures regarding the prof./industrial application, storage of freshly treated timber and the in-situ application.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

3.10.1 Background

The products contain - in addition to IPBC and permethrin - the active substance tebuconazole, which meets the criteria for substitution under Article 10 of the Biocides Regulation (EU) No 528/2012[21] (BPR).[22] Tebuconazole is considered to be very persistent (vP) and toxic (T) and therefore meets two of the criteria for being PBT. Therefore, in line with Article 23 (1) of the BPR the German CA has conducted a comparative assessment for the product 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-May-15-Doc-4.3a-Final-TNG on comparative assessment.doc).
For this comparative assessment the German CA used the data from R4BP (dated 06.06.2019).

In accordance with the Technical Guidance Note on comparative assessment of biocidal products (CA-May-15-Doc-4.3a-final) the products were only compared to the alternatives authorised in Germany as the R4BP3 is not yet populated with searchable SPCs and no search tool has been provided by ECHA yet.

3.10.2 Application administrative details

Procedure: National Authorisation (NA)
Purpose: Authorisation
Case Number in R4BP: BC-NF023903-46
Evaluating Competent Authority: Germany (BAuA)
Applicant: Lanxess Deutschland GmbH
(Prospective) Authorisation holder: Lanxess Deutschland GmbH

3.10.3 Administrative information

Trade name: Primer TIP

[21] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.
[22] According to the information provided by ECHA nowadays (after COM taking its decision in accordance with Article 36 BPR) no longer the active substance Tebuconazole but the Permethrin fulfils the substitution criteria (see chapter 2.2.3 for details). However, this does not change the conclusion of the comparative assessment.

Product type: 8 (Wood protection)
Active substance: Tebuconazole, IPBC, permethrin

3.10.4 Intended use(s)

The products are wood protection products (PT8) which contain the active substances tebuconazole, IPBC, permethrin. The products are used by non-professional, professionals and industrial users to protect wood in use class 2 and 3 against wood destroying fungi, wood discolouring fungi and wood boring insects.
Table 145 lists the intended uses of the biocidal products, which determines the focus of the comparative assessment.

Table 145: Intended use(s)

Product type(s)	Wood protection (PT 8)
Where relevant, an exact description of the authorised use	This product can only be used for the control of wood destroying fungi, wood discolouring fungi and wood boring insects
Target organism (including, where relevant) development stage)	wood destroying fungi; wood discolouring fungi; wood boring insects
Field(s) of use	For the protection of wood in use class 2 and 3
Application method(s)	Superficial treatment: brushing Manual dipping, automated dipping, automated spraying
Category(ies) of users	Non-professional; professional, industrial

The products within the BPF Primer TIP are solvent-based liquids and ready-to-use.

They are effective against wood destroying fungi, wood discolouring fungi and wood boring insects.

The active substance tebuconazole inhibits in the ergosterol biosynthesis of fungi, thus prohibiting formation of cell walls.
The active substance IPBC is a carbamate fungicide. The target sites of carbamates in fungi are cell membrane permeability and fatty acids, which leads to disruption of basic cell functions.
As an insecticide when formulated as a wood preservative, permethrin is an axonic poison, binding to voltage-gated sodium channels in nerves. By binding to these channels, the substance group of pyrethroids prevent the channels from closing which cause prolonged sodium channel activation. The nervous system is irreversibly damaged leading to death.

3.10.5 Mapping of existing alternatives to the relevant BP in Germany

Identified eligible alternative BPs[23]

According to the information available in R4BP (on 06.06.2019), there are about 3096 active authorisations under product type 8 (wood protection) including mutual recognitions and same product authorisations.

These are based on 41 active substances: Clothianidin, cypermethrin, propiconazole, tebuconazole, IPBC, permethrin, basic copper carbonate, DDACarbonate, boric acid, fenoxycarb, fenpropimorph, thiacloprid, OIT, thiabendazole, ADBAC/BKC (C12-16), DCOIT, chlorfenapyr, bifenthrin, disodium tetraborate decahydrate, disodium tetraborate pentahydrate, ATMAC/TMAC, copper (II) oxide, copper hydroxide, creosote, Cu-HDO, cyproconazole, tolylfluanid, DDAC, disodium octaborate tetrahydrate, disodium tetraborate, etofenprox, granulated copper, hydrogen cyanide, K-HDO, dichlofluanid, penflufen, bardap 26, potassium sorbate, sulfuryl fluoride, dazomet and, thiamethoxam.

No PT 8 products containing the following 21 active substances are authorised in Germany yet: clothianidin, DDACarbonate, OIT, thiabendazole, DCOIT, chlorfenapyr, disodium tetraborate pentahydrate, ATMAC/TMAC, Copper (II) oxide, copper hydroxide, Cu-HDO, cyproconazole, tolylfluanid, DDAC, disodium octaborate tetrahydrate, etofenprox, dichlofluanid, penflufen, bardap 26, potassium sorbate, thiamethoxam.

Propiconazole, boric acid, fenpropimorph, thiacloprid, bifenthrin, disodium tetraborate decahydrate, creosote, disodium tetraborate, are themselves candidates for substitution.

Products based on sulfuryl fluoride and hydrogen cyanide are fumigation products with all their intrinsic hazards. Therefore, all the fumigation products are not considered as eligible alternative products and are therefore not included in this comparative assessment.

Since permethrin and cypermethrin act as insecticides only, products solely containing these actives cannot be alternatives for the products under assessment containing the fungicide tebuconazole and are therefore not included in this comparative assessment.

[23] In accordance with the Technical Guidance Note on comparative assessment of biocidal products (CA-May-15-Doc-4.3a-final) the biocidal products of the BPF were only compared to the alternative biocidal products authorised in Germany as the R4BP3 is not yet populated with searchable SPCs and no search tool has been provided by ECHA yet.

The basic copper carbonate or granulated copper containing products authorised in Germany contain tebuconazole as well and accordingly cannot be alternatives for the tebuconazole containing products under assessment.

The only fenoxycarb containing product and the ADBAC/BKC (C12-16) containing products authorised in Germany contain boric acid (which is a candidate for substitution itself) as well and accordingly cannot be an alternative for the tebuconazole containing products under assessment.

The only K-HDO containing product authorised in Germany is not authorised for use in use class 3.
The only dazomet containing product authorised in Germany is authorised only for use in use class 4.

Accordingly, the only remaining alternatives for the protection of wood against fungi in Germany are IPBC containing products.
Table 146 lists the mode of action of the remaining active substances and the risk of resistance development.

Table 146: Mode of action and risk of resistance development for PT 8 (Wood protection)

Active Substance	Mode of action	Resistance reported
Tebuconazol	Tebuconazole inhibits in the ergosterol biosynthesis of fungi, thus prohibiting formation of cell walls.	No
IPBC	IPBC is a carbamate fungicide. The target sites of carbamates in fungi are cell membrane permeability and fatty acids, which leads to disruption of basic cell functions.	No

The products under assessment do not contain only the actives tebuconazole and IPBC against fungi but also the active permethrin against insects.
Therefore, products containing only the active substance IPBC cannot be considered as an alternative to the products under assement since they would lack the insecticidal activity.
Therefore, no alternative products are available on the German market that can be used for the comparative assessment.

Identified eligible non-chemical alternatives

In Germany, there are no preventive non-chemical alternatives against wood destroying fungi, wood discolouring fungi and wood boring insects available. In order to protect the wood from insects and fungi, Germany recommends carrying out the woodwork in accordance with DIN 68800.

Conclusion

The German CA concludes that there are currently no alternatives in order to replace the tebuconazol containing products of the BPF Primer TIP because the IPBC containing products, which could be an alternative regarding the fungicidal activity, would lack the insecticidal activity and no non-chemical alternatives are available.

Addendum after COMMISSION IMPLEMENTING DECISION (EU) 2022/835: According to the information provided by ECHA nowadays (after COM taking its decision in accordance with Article 36 BPR) no longer the active substance Tebuconazole but the Permethrin fulfils the substitution criteria. However, as the combination of insecticidal and fungicidal activity within a single biocidal product is based on the combination of the fungicidal active substances (Tebuconazol and IPBC) and the insecticidal active substance permethrin there are currently no alternatives in order to replace the products of the BPF Primer TIP. Accordingly, the conclusion of the comparative assessment does not change.

For the comparative assessment Tebuconazol and Permethrin were taken into account. Currently, there are no alternatives in order to replace the products of the BPF Primer TIP. This is because possible alternatives feature only fungicidal or insecticidal activity while the products of the BPF under authorisation include the fungicidal active substances (Tebuconazol and IPBC) and the insecticidal active substance permethrin.

The comparative assessment is finalised at this stage. The products of the BPF Primer TIP are authorised for a period not exceeding 5 years in accordance with Article 23 (6) BPR.

4 Annexes

4.1 List of studies for the biocidal product family

Table 147

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1.	Accelerated and low temperature Storage Stability of JJT 6310	Erstling, K	2014	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
2	3.1.1.	Accelerated and low temperature Storage Stability of JJT 6310	Erstling, K	2014	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
3	3.1.2.	Accelerated and low temperature Storage Stability of JJT 6310	Erstling, K	2014	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
4	3.1.3.	Accelerated and low temperature Storage Stability of JJT 6310	Erstling, K	2014	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
5	3.2.	Determination of pH Value in 5 biocide formulations	Schloesser, H.-G.	2014	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
6	3.2.	Determination of pH Value in 5 biocide formulations	Schloesser, H.-G.	2015	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
7	3.3.	Determination of Safety-Relevant Data of JJT6310 (solvent-based formulation containing IPBC, Tebuconazole and Permethrin)	Keldenich, H.-P.	2014a	LANXESS Deutschland GmbH, 50569 Köln, Germany
8	3.3.	Determination of the flashpoint and density for [trade name]	Buca, M.	2016	PPG Architectural Coatings EMEA, Wrocław, Poland
9	3.4.1.1.	Accelerated and low temperature Storage Stability of JJT 6310	Erstling, K	2014	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
10	3.4.1.2.	Long Term Storage Stability of JJT 6310	Erstling, K.	2016	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
11	3.4.1.3.	Accelerated and low temperature Storage Stability of JJT 6310	Erstling, K	2014	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
12	3.4.1.1. / 2	Accelerated temperature Storage Stability of JJT 6310	Erstling, K	2016	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
13	3.4.2.2.	Accelerated and low temperature Storage Stability of JJT 6310	Erstling, K	2014	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
14	3.4.2.3.	Long Term Storage Stability of JJT 6310	Erstling, K.	2016	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany
15	3.4.2.1.	Accelerated and low temperature Storage Stability of JJT 6310	Erstling, K	2014	Lanxess Deutschland GmbH, D-51369 Leverkusen, Germany

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
16	3.8.	Determination of Safety-Relevant Data of JJT6310 (solvent-based formulation containing IPBC, Tebuconazole and Permethrin)	Keldenich, H.-P.	2014a	LANXESS Deutschland GmbH, 50569 Köln, Germany
17	4.13.	Determination of Safety-Relevant Data of JJT6310 (solvent-based formulation containing IPBC, Tebuconazole and Permethrin)	Keldenich, H.-P.	2014a	LANXESS Deutschland GmbH, 50569 Köln, Germany
18	4.16.	Determination of Safety-Relevant Data of JJT6310 (solvent-based formulation containing IPBC, Tebuconazole and Permethrin)	Keldenich, H.-P.	2014a	LANXESS Deutschland GmbH, 50569 Köln, Germany
19	4.6.	Determination of Safety-Relevant Data of JJT6310 (solvent-based formulation containing IPBC, Tebuconazole and Permethrin)	Keldenich, H.-P.	2014a	LANXESS Deutschland GmbH, 50569 Köln, Germany
20	4.6.	Determination of the flashpoint and density for [trade name]	Buca, M.	2016	PPG Architectural Coatings EMEA, Wrocław, Poland
21	4.1.	Determination of Safety-Relevant Data of JJT6310 (solvent-based formulation containing IPBC, Tebuconazole and Permethrin)	Keldenich, H.-P.	2014a	LANXESS Deutschland GmbH, 50569 Köln, Germany
22	4.17.1.	Determination of Safety-Relevant Data of JJT6310 (solvent-based formulation containing IPBC, Tebuconazole and Permethrin)	Keldenich, H.-P.	2014a	LANXESS Deutschland GmbH, 50569 Köln, Germany
23	5.1.	Determination of IPBC, PBC, tebuconazole, propiconazole and permethrin in BPR formulations (modified 2017-07-13)	Erstling K.	2015	LANXESS Deutschland GmbH, 50569 Köln, Germany

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
24		Determination of IPBC, PBC, tebuconazole, propiconazole and permethrin in BPR formulation for XXX[24]	Erstling, K.	2013	LANXESS Deutschland GmbH, 50569 Köln, Germany
25	5.2.2.	OSHA Method ORG-48 (PV2139)	"Shulsky, M.L.		
26	5.2.2.	NIOSH Method 1550	Grote, A.A.	1994	
27	6.6.	Preventol Primer TIP Product Information	Anonymous	2015	
28	6.7./1	Biological testing of JJT 6311 in accordance with ÖNORM EN 152 after 26 weeks field exposure (natural weathering)	Pfabigan, N. & Gründlinger, R.	2014	
29	6.7./1	Laboratory method for determining the protective effectiveness of a preservative treatment against blue stain according to EN 152 (2011) after 4 weeks artificial weathering	Schumacher, P. & Fennert, E.-M. & Doblinski, M.	2013	
30	6.7./2	Test Report. EN 113 Testing.	Morsing, E. & Klamer, M.	2013	
31	6.7./2	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with leaching procedure according to EN 84 (1997)	Schumacher, P. & Fennert, E.-M. & Doblinski, M.	2013	
32	6.7./3	Test Report. EN 113 Testing.	Morsing, E. & Klamer, M.	2014	
33	6.7./3	Determination of the protective effectiveness against wood destroying basidiomycetes	Schumacher, P. & Fennert, E.-M. & Doblinski, M.	2013	

[24] See full title of the method in chapter **Fehler! Verweisquelle konnte nicht gefunden werden.** (page 254) in the confidential annex.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
		according to EN 113 (1996) in combination with leaching procedure according to EN 84 (1997)			
34	6.7./4	Determination of preventive action against Hylotrupes bajulus (Linnaeus) - Part 1: Larvicidal effect according to EN 46-1:2009	Arancon, J.	2013	
35	6.7./4	Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46 - 1(2009) after evaporative ageing procedure according to EN 73 (1988)	Schumacher, P. & Fennert, E.-M. & Doblinski, M.	2013	
36	6.7./5	Determination of preventive action against Hylotrupes bajulus (Linnaeus) - Part 1: Larvicidal effect according to EN 46-1:2009	Arancon, J.	2013	
37	6.7./5	Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46 - 1(2009) after leaching procedure according to EN 84 (1997)	Schumacher, P. & Fennert, E.-M. & Doblinski, M.	2013	
38	6.7./6	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with evaporative ageing procedure according to EN 73 (1988)	Schumacher, P. & Fennert, E.-M.	2014	
39	6.7./7	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with evaporative ageing procedure according to EN 73 (1988)	Schumacher, P. & Fennert, E.-M.	2014	

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
40	8.6.	The In Vitro Percutaneous Absorption of Radiolabelled Tebuconazole in Two Formulations Through Human Skin	Craig, S.	2015	Lanxess Deutschland GmbH, Köln, Germany
41	8.6./2	[14C]-Permethrin: In Vitro Dermal Penetration Study	Webbley, K.	2015	Lanxess Deutschland GmbH, Köln, Germany
42	8.6.	In vitro percutaneous absorption of IPBC, from solvent-based and water-based formulations, through human skin	Maas, W.J.M.	2015	Lanxess Deutschland GmbH, Köln, Germany
43	10.3.	NT BUILD 509 "Leaching of active ingredients from preservative-treated timber- Semifield testing" First year Primer TIP	Wegner, R.	2013	LANXESS Deutschland GmbH, 50569 Köln, Germany
44	10.3./2	NT BUILD 509 "Leaching of active ingredients from preservative-treated timber- Semifield testing" Second year Primer TIP	Wegner, R.	2014	LANXESS Deutschland GmbH, 50569 Köln, Germany
45	11.4.1.	Preventol Primer TIP Product Information	Anonymous	2015	
46	11.7.	Preventol Primer TIP Product Information	Anonymous	2015	
47	12.7.	Preventol Primer TIP Product Information	Anonymous	2015	

4.1.1.1 Access to data from active substance approval

The applicant was participated in the procedure of all the active substance approval procedures. Please, refer to the corresponding Assessment Report for a reference list.

4.2 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.2.1 Safety for professional users

Calculations for exposure assessments

Adobe Acrobat PDFXML Document

ConsExpo reports.txt

4.2.2 Safety for non-professional users and the general public

Calculations for the general public scenario 2

Meta-SPC 1, 2, 3

The systemic dermal exposure is calculated as follows:				
Activity and Parameters	**IPBC No gloves**	**Permethrin No gloves**	**Tebuconazol**	**Units**
Volume of brush	**200**	**200**	**200**	**ml**
Volume of paint remaining on brush after painting ($^1/_8$ of 200 ml = 25 ml)	25	25	25	ml
Density of paint	**0,804**	**0,804**	**0,804**	**g/ml**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	20,25	20,25	20,25	g
Concentration of a.s. in paint	**0,5**	**0,06**	**0,2**	**% w/w**
A. Weight of a.s. on brush after painting	103,2750	12,1500	42,5250	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	10,0500	1,2060	4,0200	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	90,4500	10,8540	36,1800	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	5,0250	0,6030	2,0100	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of C)	0,5025	0,0603	0,2010	mg
Penetration of a.s. through gloves	**100**	**100**	**100**	**%**
Weight of a.s. on hand	0,50250	0,06030	0,20100	mg
Dermal absorption of a.s.	**54,00**	**10,00**	**37,00**	**%**
Weight of a.s. entering the body	0,27135	0,00603	0,07437	mg

D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	5,0250	0,6030	2,0100	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	0,5025	0,0603	0,2010	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	4,5225	0,5427	1,8090	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0,2513	0,0302	0,1005	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of F)	0,0251	0,0030	0,0101	mg
Penetration of a.s. through gloves	100	100	100	%
Weight of a.s. on hand	0,02513	0,00302	0,01005	mg
Dermal absorption of a.s.	54,00	10,00	37,00	%
Weight of a.s. entering the body	0,01357	0,00030	0,00372	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (**E** – **F**)	0,2513	0,0302	0,1005	mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	0,0251	0,0030	0,0101	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	0,2261	0,0271	0,0905	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	0,0126	0,0015	0,0050	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of I)	0,0013	0,0002	0,0005	mg
Penetration of **a.s.** through gloves	100	100	100	%
Weight of a.s. on hand	0,00126	0,00015	0,00050	mg
Dermal absorption of a.s.	54,00	10,00	37,00	%
Weight of a.s. entering the body	0,00068	0,00002	0,00019	mg
Total weight of a.s. entering the body *(to 4 decimal places)*	**0,2856**	**0,0063**	**0,0783**	**mg**
Body weight	**60**	**60**	**60**	**kg**
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE *(to 4 decimal places)*	**0,00476**	**0,00011**	**0,00130**	**mg a.s./kg bw**

ConsExpo 4.1 report for the general public Scenario 10, Tier 2 (IPBC only)

Meta-SPC 1, 2, 3 (Primer)

Product

Primer TIP

Compound

Compound name :	IPBC	
CAS number :	55406-53-6	
molecular weight	281	g/mol
vapour pressure	0,0045	Pascal
KOW	2,81	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	0,5	%
exposure duration	24	hour
room volume	20	m3
ventilation rate	0,6	1/hr
applied amount	724	gram
release area	4	m2
application duration	30	minute
mol weight matrix	150	g/mol
mass transfer rate	2,23E3	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	8	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,00139	mg/m3
inhalation mean concentration on day of exposure:	0,00139	mg/m3
inhalation air concentration year average :	0,00139	mg/m3/day
inhalation acute (internal) dose :	0,00111	mg/kg
inhalation chronic (internal) dose :	0,00111	mg/kg/day

Integrated (point estimates)

total external dose:	0,00111	mg/kg
total acute dose (internal):	0,00111	mg/kg
total chronic dose (internal):	0,00114	mg/kg/day

4.2.3 Output tables from environmental exposure assessment tools

The following evaluation of leaching studies belongs only to the exemplary BP JJT6310, which represents the BPs of Meta-SPC 1, 2, 3.

Table 148: Leaching values (mean values of three test set-ups) for tebuconazole, IPBC and permethrin from the semi-field study

Exposure period (days)	Cumulated Precipitation (mm)	Tebuconazole		IPBC (sum IPBC+PBC)		Permethrin	
		Concentration in leachate		Concentration in leachate		Concentration in leachate	
		mg/m² wood	% of applied	mg/m² wood	% of applied	mg /m² wood	% of applied
30-09-2013/14-10-2013 (14 days)	18	0.16	0.06	0.23	0.04	2.00×10^{-4}	<0.01
14-10-2013/28-10-2013 (14 days)	39	0.36	0.14	0.56	0.09	1.00×10^{-4}	<0.01
28-10-2013/07-11-2013 (10 days)	59	0.37	0.14	0.43	0.07	3.00×10^{-4}	<0.01
07-11-2013/09-12-2013 (32 days)	124	3.48	1.35	3.59	0.56	6.00×10^{-4}	<0.01
09-12-2013/26-03-2014 (107 days)	239	2.51	0.97	1.73	0.27	<LOQ	<0.01
26-03-2014/06-08-2014 (133 days)	479	0.99	0.39	0.25	0.04	<LOQ	<0.01
06-08-2014/30-09-2014 (55 days)	543	0.03	0.01	0.01	<0.01	<LOQ	<0.01
30-09-2014/29-01-2015 (121 days)	754	1.55	0.60	3.34	0.52	2.50×10^{-3}	<0.01
29-01-2015/27-07-2015 (179 days)	994	0.48	0.18	0.39	0.06	2.50×10^{-4}	<0.01
27-07-2015/30-09-2015 (65 days)	1096	0.13	0.05	0.07	0.01	4.00×10^{-5}	<0.01

Limits of quantification of active substances:
Tebuconazole: 1 µg/L; IPBC/PBC: 2 µg/L; Permethrin: 0.5 µg/L (first year), 0.01 µg/L (second year)

Leaching rates used for the risk assessment (Meta-SPC 1, 2, 3)

For determination of the leaching rates used for the risk assessment, the experimental leaching rate was normalized to a yearly precipitation of 700 mm as recommended in the revised ESD for PT8 (OECD, 2013). The normalized FLUX is presented in Table 149:

Table 149: FLUX values (mg/m²/d) for tebuconazole, IPBC and permethrin normalized to a precipitation of 700 mm / year.

Cumulative sampling time (d)	Cumulative precipitation (mm)	Cumulative normalized precipitation (mm)	Cumulative normalized sampling time (d)	Normalized FLUX Tebuconazole (mg/m²/d)	Normalized FLUX IPBC (sum IPBC+PBC) (mg/m²/d)	Normalized FLUX permethrin (mg/m²/d)
14	18	27	9.4	0.02	0.02	2.60×10^{-4}
28	39	54	20	0.03	0.05	1.30×10^{-4}
38	59	73	31	0.04	0.04	3.90×10^{-4}
70	124	134	65	0.10	0.11	7.79×10^{-4}
177	239	339	125	0.04	0.03	<LOQ
310	479	595	250	7.91×10^{-3}	2.00×10^{-3}	<LOQ
365	543	700	283	8.99×10^{-4}	3.00×10^{-4}	<LOQ
486	754	932	393	0.01	0.03	3.25×10^{-3}
665	994	1275	518	3.84×10^{-3}	3.12×10^{-3}	3.25×10^{-4}
730	1096	1400	571	2.44×10^{-3}	1.32×10^{-3}	5.19×10^{-5}

The leaching study was conducted over 2 years. The experimental data of each active substances were fitted by a polynomial regression of second order:

$$Log_{10}FLUX(t) = a + b \cdot Log_{10}(t) + c \cdot Log_{10}(t)^2$$

The trend lines with the corresponding regression equations and coefficients of variation for Tebuconazole and IPBC/PBC are shown in the following figures:

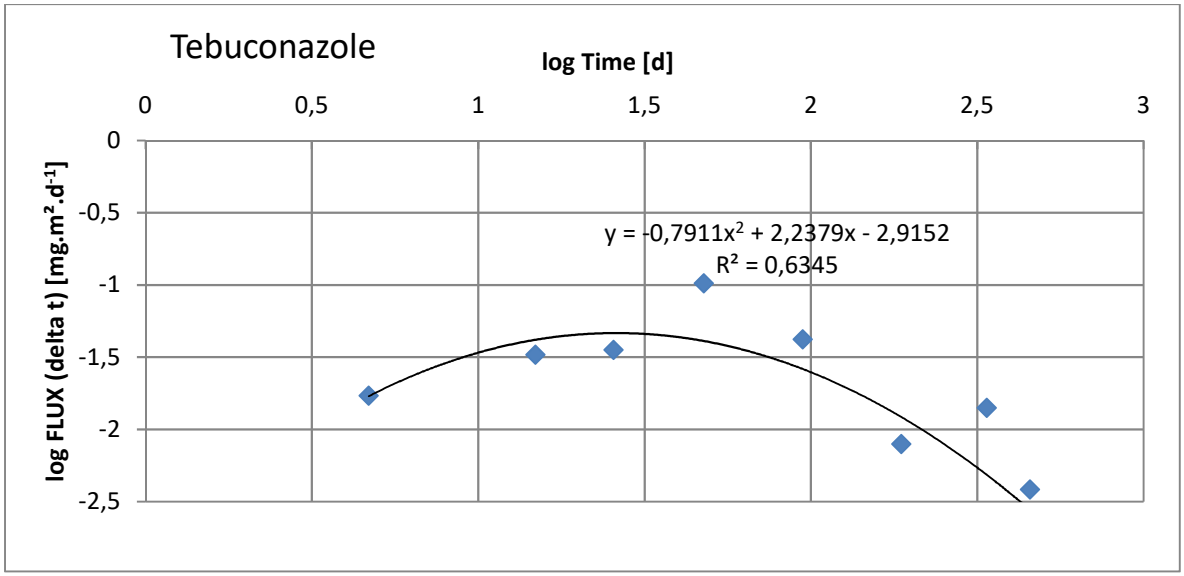


Figure 2

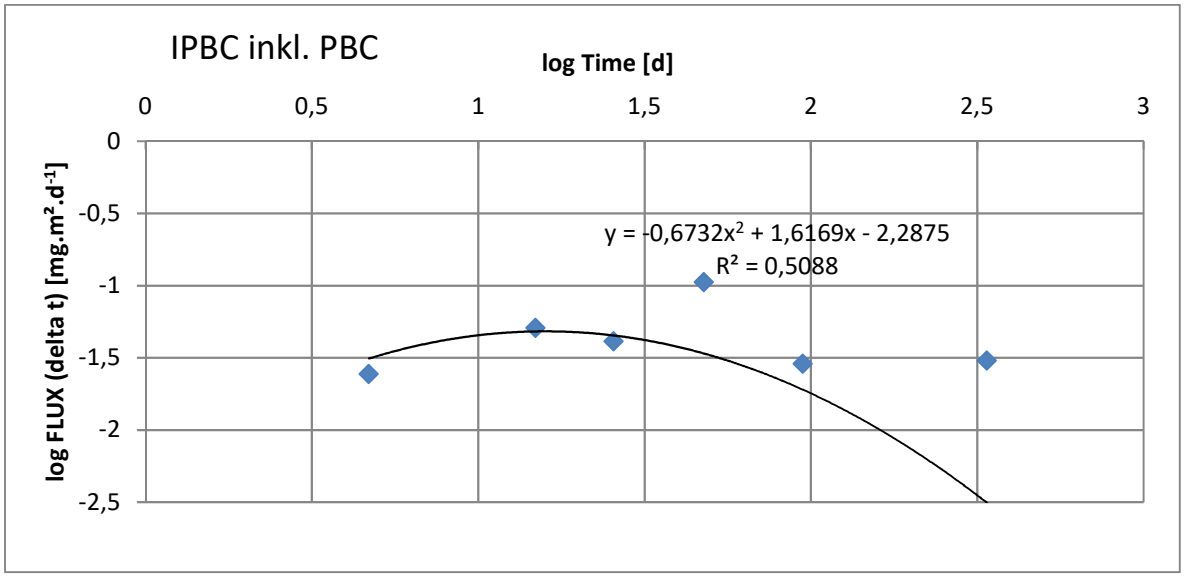


Figure 3

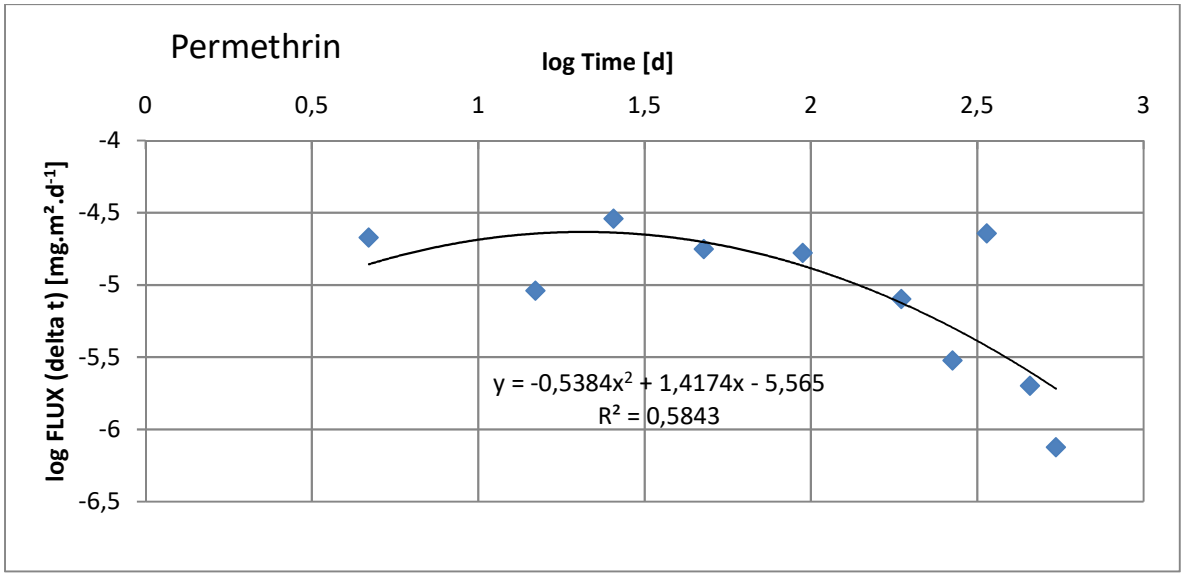


Figure 4

For the a.s. tebuconazole, IPBC and permethrin the fitted curves are not appropriate for further evaluation indicated by a $R^2 \leq 0.65$. The curves cannot be used for calculation of fluxrates.

For tebuconazole and IPBC the approach in Appendix 2 point 519 of the ESD for PT 8 (OECD, 2013) is proposed instead:

The cumulative quantities leached out [Qc(t)], normalized to 700 mm precipitation, were plotted in a diagram (see below). All points are fitted with one logarithmic curve.
This curve is used to derive Time 1 leach rates. The long term leaching rates $Q_{leach,\ 5\ years}$ and $Q_{leach,\ 15\ years}$ are calculated by extrapolation.

For tebuconazole the following rates are derived:
30 days: (2.704 x Ln(30) – 7.0171) / (30) days = 0.073 mg/m²/d
5 years: (2.704 x Ln(1825) – 7.0171) / (1825) days = 0.007 mg/m²/d
15 years: (2.704 x Ln(5475) – 7.0171) / (5475) days = 0.003 mg/m²/d

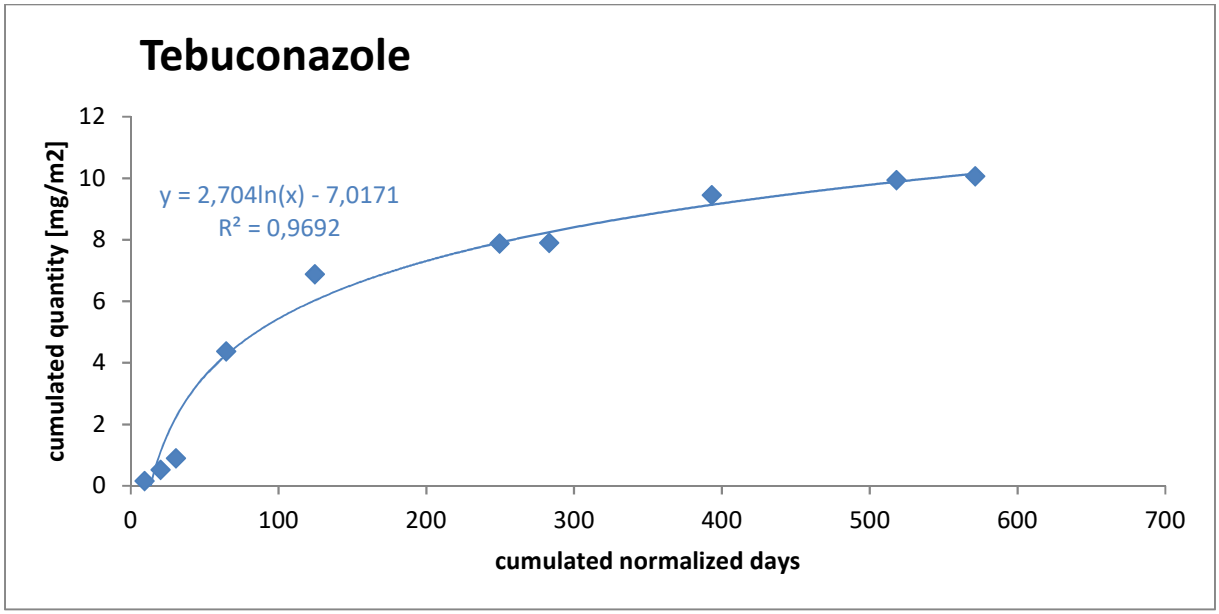
For IPBC the following rates are derived:
30 days: (2.6742 x Ln(30) – 6.834) / (30) days = 0.075 mg/m²/d
5 years: (2.6742 x Ln(1825) – 6.834) / (1825) days = 0.007 mg/m²/d
15 years: (2.6742 x Ln(30) – 6.834) / (30) days = 0.003 mg/m²/d

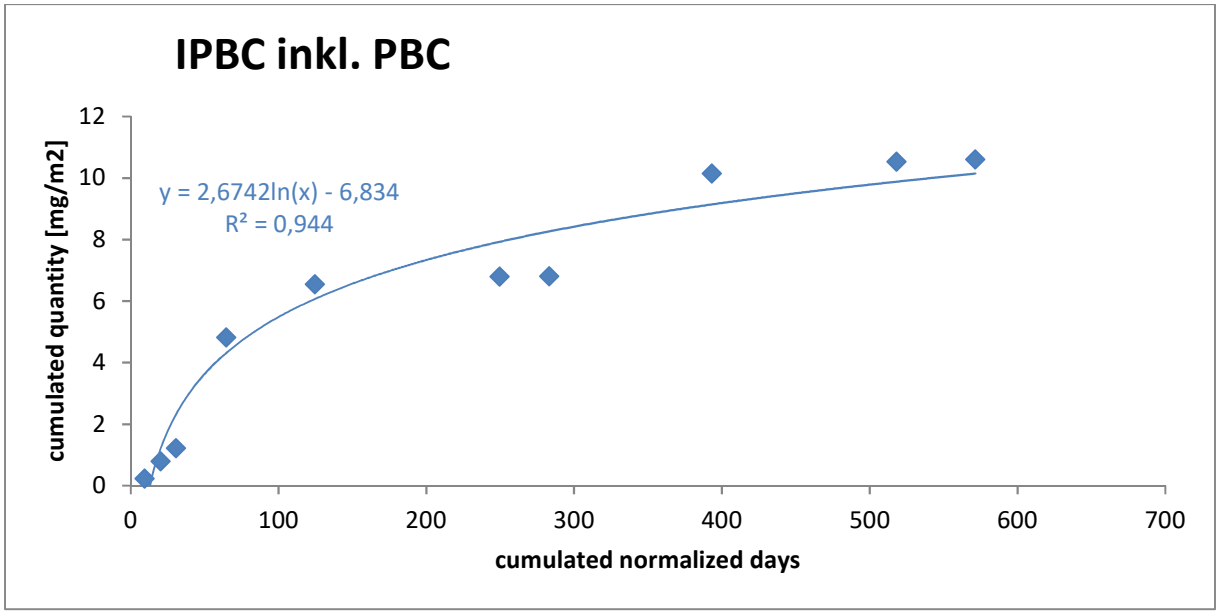
For permethrin the fitting with a logarithmic curve did not represent the data points well and resulted in an underestimation of leaching at the last three data points of the study. Hence, an underestimation of

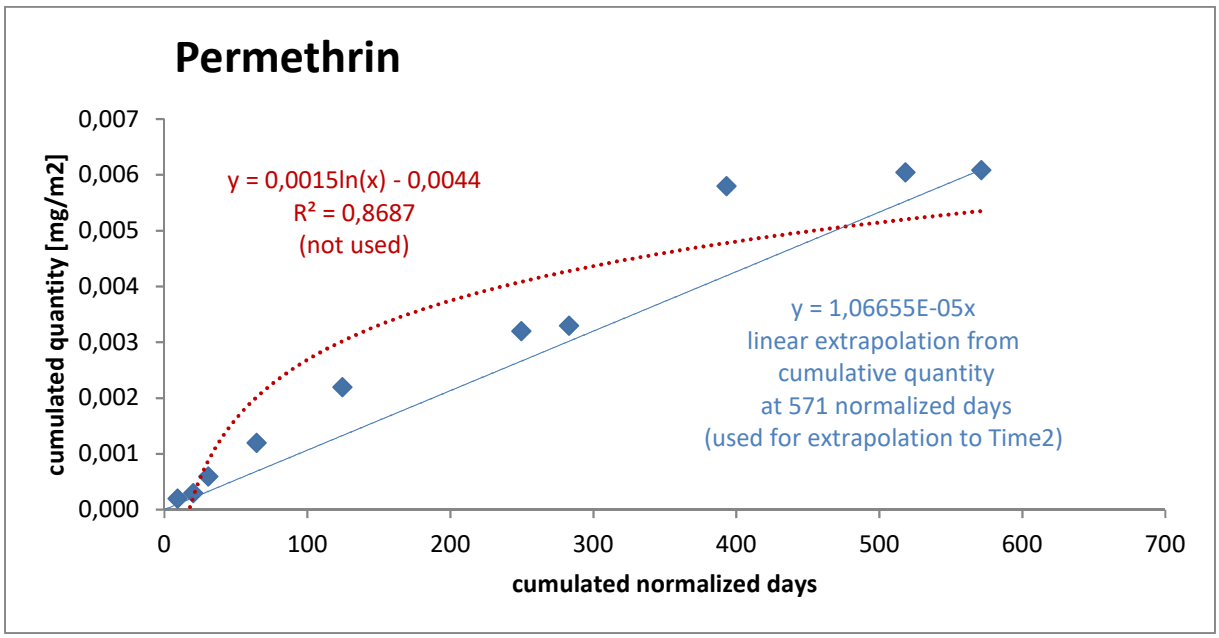
leaching in the extrapolation to time 2 is likely. Therefore, leaching rates were calculated by using mean values, which is the more conservative approach. For time 1 (30 days) leaching rates were derived by dividing the cumulative quantity at the 3rd sampling point by the number of normalized days at the 3rd sampling point (31 days). For the extrapolation to time 2 (5 years or 15 years) leaching rates were derived by dividing the cumulative quantity at the last sampling point by the number of normalized days at the last sampling point (571 days).

For permethrin the following rates are derived:
30 days: 0.0006 / 31 days = 0.00002 mg/m²/d
5 years: 0.00609 / 571 days = 0.0000107 mg/m²/d
15 years: 0.00609 / 571 days = 0.0000107 mg/m²/d

The cumulative plots of the three active substances and the trend lines used for the derivation of the leaching rates are shown in the following graphs:







The maximum retention applied for during product authorization is 160 mL/m2 for softwood and 225 mL/m2 for hardwood. Therefore, for environmental risk assessment of the products used for hardwood a correction factor of 1.406 has to be applied during calculation of leaching rates.