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

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

(submitted by the evaluating Competent Authority)

TEKNOS BLUESTAIN PRIMERS

Product type 8

IPBC as included in the Union list of approved active substances

Case Number in R4BP: BC-PM043858-13

Evaluating Competent Authority: DK

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1 CONCLUSION

1.1 Summary of decisions and restrictions

TEKNOS BLUESTAIN PRIMERS is a wood preservative product family which consists of two meta-SPCs containing 0.294 – 0.30009 % (metaSPC1) or 0.588 – 0.6 % (metaSPC2) of 3-iodo-2-propynyl butyl carbamate (IPBC). The product family is to be used in use class 2 and 3. The application for product authorisation was submitted 12 October 2018.
After evaluation of the biocidal family it has been concluded that sufficient data has been provided to verify the outcomes and conclusions, and permit authorisation of the biocidal product family subject to the following conditions:

1.1.1 Usage area

User	Use area
Industrial	Wood preservative applied for preventative treatment by automated and manual spraying to prevent wood discolouring fungi. The product is intended to protect wood in use classes 2 and 3. Products within metaSPC1 contain 0.294 – 0.30009 % IPBC and are applied as both a base- and topcoat. Products within metaSPC2 contain 0.6 % IPBC and are applied only as a basecoat.
Professional	Wood preservative applied as a preventative treatment by manual spraying and brush, roller, pad to prevent wood discolouring fungi. The product is intended to protect wood in use classes 2 and 3. Products within metaSPC1 contain 0.294 % IPBC and are applied as both a base- and topcoat. Products within metaSPC2 contain 0.588 – 0.6 % IPBC and are applied only as a basecoat. The following conditions apply for Use Class 3 application: In-situ outdoor brush/roller and industrial application must be subject to risk mitigation measures, see section 1.1.6.

1.1.2 Conclusion for physical-chemical properties

For meta-SPC 1 (TEKNOCOMBI 2917-62), following specifications are applicable:
Homogeneous liquid, content IPBC: 0.3%, pH 8.21, density 1.20 g/ml, viscosity 79663 mPa.s to 2594 mPa.s at 40°C. Surface tension 24.0 mN/m test item is surface active.
Decrease of IPBC in HDPE can after 9 months -8.7% and after 12 months -13.2%.
Decrease of IPBC in metal can after 9 months -4.3% and after 12 months -14.1%.

For meta-SPC 2 (AQUAPRIMER 2907-63), following s specifications are applicable:
Homogeneous liquid, content IPBC: 0.6%, pH 8.10, density 1.23 g/ml, viscosity 10078 mPa.s to 923 mPa.s at 40°C. Surface tension 22.4 mN/m test item is surface active.
Decrease of IPBC in HDPE can after 9 months -9.9% and after 12 months -16.4%.
Decrease of IPBC in metal can after 9 months -6.0% and after 12 months -13.6%.

Although tested products from both meta-SPCs showed exceedance of the allowed max. residue in the pourability/rinsability test, safe disposal of the products is assured due to the label instructions. Moreover, products are only handled by professional users, therefore, label instructions are sufficient to make sure disposal is always done safely, i.e.

at the end of the treatment unused product and the packaging are disposed in accordance with local requirements.

The storage of the 2 products at 20°C ± 2°C both in a HDPE can as in a metal can show a significant decrease (decrease in IPBC content abow 10%)in IPBC content after 12 months storage. Based on the results of the storage stability studies, the products are granted a shelf-life of 9 months.

1.1.3 Conclusion for efficacy and label claims

The product family TEKNOS BLUESTAIN PRIMERS is approved for preventive use against wood discolouring fungi with the specified amount (MetaSPC 1: 250-400 g/m2, MetaSPC 2: 150-200 g/m2) for superficial application methods in use class 2 and 3 on wood material not susceptible to brown rot decay.
A non-biocidal topcoat is required when using products from metaSPC 2.

1.1.4 Conclusion for human health risk assessment

A safe use was identified for all application methods. Specifically,

1) A safe used was demonstrated when applying the biocidal product family by automated spraying while wearing chemical resistant gloves and coated coveralls as personal protective equipment,
2) A safe use was demonstrated when applying the biocidal product family by manual spraying while wearing chemical resistant gloves, impermeable coveralls and a filtering half mask
3) A safe use was demonstrated when applying the product by brushing/rolling without the use of personal protective equipment. Furthermore, a safe use was demonstrated for the non-professional user, when cutting/sanding and/or handling treated wood when dried as well as for the professional user.

A safe use was identified when laundering work clothes used for manual spraying (impermeable coveralls) after wearing the coveralls for five working days.

A risk was identified in the event that a toddler touches and mouths a piece of freshly treated wood. Including the sentence 'Keep children and pets away from treated wood during application and drying' in section 2.1.5.2 for risk mitigation measures (5.2 of the SPC) is considered to ensure that the situation is avoided.

No risk was identified for infants when chewing/mouthing a piece of treated dry wood as well as no risk was identified for infants when chronically exposed from contact to outdoor treated wood structures as well. Similarly, no risk was identified for all age groups when chronically exposed to residues available for inhalation.

The non-active substances formaldehyde (CAS 50-00-0), diproppylenglycol methyl ether (DPM) (CAS 34590-94-8), butyl diglycol (CAS 112-34-5) and bytyl diglycol/butyloxitol (CAS 111-76-2) were identified as substances of concern due to their EU applied OELs. A quantitative risk assessment for each substance for exposure to air concentration in the relevant scenarios was performed, and a safe level of exposure was identified. The non-active substances 2-methyl-2h-isothiazol-3-one (MIT) (CAS 2682-20-4) and 1,2-benzisothiazol-3(2h)-one (BIT) (CAS 2634-33-5) were identified as substances of concern due to their concentration leading products of both metaSPC1 and metaSPC2 to be labelled with the phrase EUH208. May cause an allergic reaction.

1.1.5 Endocrine disruption assessment

TEKNOS BLUESTAIN PRIMERS should not be considered to have endocrine-disrupting properties.
TEKNOS BLUESTAIN PRIMERS contain the active substance IPBC, which have not yet been evaluated for endocrine-disrupting properties according to the scientific criteria set out in the Regulation (EU) 2017/2100.
During the ED assessment of the non-active substances the rMS identified three substances for which it was not possible to conclude, based on the available information, whether they should be considered to have ED properties before the expiration of the legal deadline in the BPR (Articles 30(2) and 34(4)) and therefore the process will be concluded at the post-authorisation stage. These substances will be notified for an evaluation under REACH. Should this evaluation conclude that the substances have endocrine disruptive properties the authorisation holder is obliged to notify the reference Member State for TEKNOS BLUESTAIN PRIMERS, as a reassessment of the endocrine disruption potential of the biocidal family should be performed. For details on the identification and evaluation of the endocrine disruptive properties of the formulation, see the confidential annex of the PAR.

1.1.6 Conclusion for environmental risk assessment

An unacceptable risk for the soil compartment was identified for in-situ brushing by professionals. Therefore, the following RMM will be applied to the product:

"Cover the ground during application and collect any spillage."

The risk to soil during industrial storage was not assessed because the following RMM is applied to industrial uses:

"Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewr or water. Any losses of the product shall be collected for reuse or disposal."

For wood in service, none of the scenarios lead to an unaccepatable risk.

Three substances of concern relevant for the environmental compartment were identified and assessed.

It can be concluded that exposure to the environment during the application and service life phase of wood treated with products from the TEKNOS BLUESTAIN PRIMERS family is acceptable when the abovementioned RMMs are applied.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
TEKNOS BLUESTAIN PRIMERS	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Teknos A/S
	Address	Industrivej 19 DK-6580 Vamdrup Denmark
Authorisation number	DK-0027288-0000	
Date of the authorisation	20.10.2021	
Expiry date of the authorisation	20.10.2031	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Teknos A/S
Address of manufacturer	Industrivej 19 6580 Vamdrup Denmark
Location of manufacturing sites	Industrivej 19 6580 Vamdrup Denmark
Name of manufacturer	Teknos Oy
Address of manufacturer	Takkatie 3 FI-00371 Helsinki Finland
Location of manufacturing sites	Perämatkuntie 12 FI-05201 Rajamäki Finland

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

Active substance	3-iodo-2-propynylbutylcarbamate (IPBC)
Name of manufacturer	Troy Corporation
Address of manufacturer	8 Vreeland Road, 07932 Florham Park, New Jersey, United States
Location of manufacturing sites	One Avenue L07105 Newark, New Jersey, United States
Name of manufacturer	Troy Chemical Company BV
Address of manufacturer	Uiverlaan 12, E3145 XN Maassluis, Netherlands

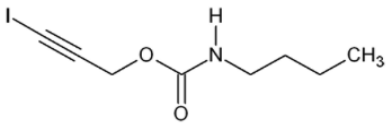
Location of manufacturing sites	Industriepark 23, 56593 Horhausen, Germany

2.1.2 Product (family) composition and formulation

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	IPBC, 3-iodo-2-propynyl butyl carbamate
IUPAC or EC name	3-iodo-2-propynyl butyl carbamate
EC number	259-627-5
CAS number	55406-53-6
Index number in Annex VI of CLP	616-212-00-7
Minimum purity / content	Purity: 98%; content (pure): min. 0.294% - max. 0.600%
Structural formula	

2.1.2.2 Candidate(s) for substitution

IPBC is not a candidate for substitution.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
IPBC	3-iodoprop-2-yn-1-yl butylcarbamate	Active substance	55406-53-6	259-627-5	0.294	0.600
BIT	1,2-benzisothiazolin-3-one	Non-active substance	2634-33-5	220-120-9	0.0227	0.0332
MIT	2-methyl-2h-isothiazol-3-one	Non-active substance	2682-20-4	220-239-6	0.0	0.0002
Formaldehyde	Formaldehyde	Non-active substance	50-00-0	200-001-8	0.0	0.0001

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
DPM	diproppylenglycol methyl ether	Non-active substance	34590-94-8	252-104-2	0.0	0.24
Butyl diglycol	2-(2-butoxyethoxy)ethanol	Non-active substance	112-34-5	203-961-6	0.0	5
Bytyl diglycol/butyloxitol	2-butoxyethanol	Non-active substance	111-76-2	203-905-0	0.0	0.45

2.1.2.4 Information on technical equivalence

Teknos A/S is supplied with IPBC by Troy Corporation from manufacturing site at One Avenue L, 07105 New Jersey, USA which was the reference source at active substance approval for IPBC in PT8. A letter of clarification is located within the Confidential Annex to this PAR as the manufacturing site address was not originally listed in the CAR for IPBC in PT8.

Teknos A/S is also supplied with IPBC by Troy Chemical Company BV from manufacturing site Industriepark 23, D-56593 Horhausen, Germany. An assessment of technical equivalence was finalized by Germany in 2019 and is located in R4BP-3 under case number BC-ME049519-34.

2.1.2.5 Information on the substance(s) of concern

1,2-benzisothiazolin-3-one (BIT) and 2-methyl-2h-isothiazol-3-one (MIT) (CAS 2682-20-4) are considered a substances of concern as their concentration in both metaSPC1 and metaSPC2 are at a concentration leading the products to be labelled with EUH208: "Contains 1,2-benzisothiazolin-3-one (BIT) and 2-methyl-2h-isothiazol-3-one (MIT). May cause an allergic reaction."

Formaldehyde (CAS 50-00-0), diproppylenglycol methyl ether (DPM) (CAS 34590-94-8), butyl diglycol (CAS 112-34-5) and bytyl diglycol/butyloxitol (CAS 111-76-2) have been assigned European OELs and a full quantitative risk evaluation has been performed in the relevant scenarios. Please refer to the Human Health Risk Assessment output tables in Annex 3.2 for exposure calculations and section 2.2.6.1 for the assessment.

2.1.2.6 Type of formulation

AL Any other liquid (ready-to-use liquid)

2.1.3 Hazard and precautionary statements

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

Classification	MetaSPC 1	MetaSPC 2
Hazard category	Aquatic Chronic 3	Aquatic Chronic 3

Hazard statement	H412: Harmful to aquatic life with long lasting effects.	H412: Harmful to aquatic life with long lasting effects.
Labelling		
Signal words		
Hazard statements		
Precautionary statements	P273: Avoid release to the environment. P501: Dispose of contents/container to …	P273: Avoid release to the environment. P501: Dispose of contents/container to …
Note	Products in metaSPC1 and metaSPC2 must be labelled with EUH208: Contains 3-iodo-2-propynyl-butyl-carbamate, 1,2-benzisothiazolin-3-one (BIT) and 2-methyl-2h-isothiazol-3-one (MIT). May cause an allergic reaction.	

2.1.4 Authorised use(s)

2.1.4.1 Use description

Uses for metaSPC 1

Table 1.1. Use # 1.1 – Industrial – Automated spraying

Product Type	PT8 wood preservative
Where relevant, an exact description of the authorised use	Application method in which the material is finely atomised in various types of automatic application/spraying equipment. The coating facilities will be equipped with automatic spray guns, rotation disks or rotation bells and the spraying process will typically take place in a closed chamber.
Target organism (including development stage)	Wood discolouring fungi
Field of use	Indoor Treated wood are used in: Use class 2 Use class 3
Application method(s)	Superficial application - automated spraying
Application rate(s) and frequency	250 – 400 g/m². This is achieved by 1-4 applications.
Category(ies) of users	Industrial user
Pack sizes and packaging material	20 ltr. metal can (inside coated tinplate) 120 ltr. HDPE drum (Plastic) 1000 ltr. HDPE IBC (Plastic)

2.1.4.2 Use-specific instructions for use

Please refer to section 5.1

2.1.4.3 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn. 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. Please refer to section 5.2 for additional general risk mitigation measures.

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

Please refer to section 5.3

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

Please refer to section 5.4

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

Please refer to section 5.5

Table 1.1. Use # 1.2 – Industrial – Professional - Manual spraying

Product Type	PT8 wood preservative
Where relevant, an exact description of the authorised use	Application method in which the material is finely atomised in various types of application/spraying equipment, e.g. a spray gun.
Target organism (including development stage)	Wood discolouring fungi
Field of use	Indoor Treated wood are used in: Use class 2 Use class 3
Application method(s)	Superficial application - manual spraying
Application rate(s) and frequency	250 – 400 g/m². This is achieved by 1-4 applications.
Category(ies) of users	Industrial user
Pack sizes and packaging	20 ltr. metal can (inside coated tinplate)

material	120 ltr. HDPE drum (Plastic) 1000 ltr. HDPE IBC (Plastic)

2.1.4.7 Use-specific instructions for use

Please refer to section 5.1

2.1.4.8 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Do not reuse gloves. Use new gloves at start of each work period or at least every 4 hours. A protective coverall (at least type 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information). Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information)'. Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewr or water. Any losses of the product shall be collected for reuse or disposal. Please refer to section 5.2 for additional general risk mitigation measures.

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

Please refer to section 5.3

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

Please refer to section 5.4

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

Please refer to section 5.5

Table 2. Use # 1.3 – Professional – Manual brush/roller/pad

Product Type	PT8 wood preservative
Where relevant, an exact description of the authorised use	Manual application with brush/roller or pad.
Target organism (including	Wood discolouring fungi

development stage)	
Field of use	Outdoor Use class 2 Use class 3
Application method(s)	Superficial application -brush/roller/pad treatment
Application rate(s) and frequency	250 – 400 g/m². This is achieved by 1-4 applications.
Category(ies) of users	Professional user
Pack sizes and packaging material	10 ltr. metal can (inside coated tinplate) 20 ltr. metal can (inside coated tinplate)

2.1.4.12 Use-specific instructions for use

Please refer to section 5.1

2.1.4.13 Use-specific risk mitigation measures

Cover the ground during application and collect any spillage. Please refer to section 5.2 for additional general risk mitigation measures.

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

Please refer to section 5.3

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

- Please refer to section 5.4

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

Please refer to section 5.5

Uses for metaSPC 2

Table 3. Use # 2.1 – Industrial – Automated spraying

Product Type	PT8 wood preservative
Where relevant, an exact description of the authorised use	Application method in which the material is finely atomised in various types of automatic application/spraying equipment. The coating facilities will be equipped with

	automatic spray guns, rotation disks or rotation bells and the spraying process will typically take place in a closed chamber.
Target organism (including development stage)	Wood discolouring fungi
Field of use	Indoor Treated wood are used in: Use class 2 Use class 3
Application method(s)	Superficial application - automated spraying
Application rate(s) and frequency	150 – 200 g/m². This is achieved by 1-2 applications.
Category(ies) of users	Industrial user
Pack sizes and packaging material	20 ltr. metal can (inside coated tinplate) 120 ltr. HDPE drum (Plastic) 1000 ltr. HDPE IBC (Plastic)

2.1.4.17 Use-specific instructions for use

Please refer to section 5.1

2.1.4.18 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn. 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. Please refer to section 5.2 for additional general risk mitigation measures.

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

Please refer to section 5.3

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

Please refer to section 5.4

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

Please refer to section 5.5

Table 3. Use # 2.2 – Industrial – Professional - Manual spraying

Product Type	PT8 wood preservative
Where relevant, an exact description of the authorised use	Application method in which the material is finely atomised in various types of application/spraying equipment, e.g. a spray gun.
Target organism (including development stage)	Wood discolouring fungi
Field of use	Indoor Treated wood are used in: Use class 2 Use class 3
Application method(s)	Superficial application - manual spraying
Application rate(s) and frequency	150 – 200 g/m². This is achieved by 1-2 applications.
Category(ies) of users	Industrial user
Pack sizes and packaging material	20 ltr. metal can (inside coated tinplate) 120 ltr. HDPE drum (Plastic) 1000 ltr. HDPE IBC (Plastic)

2.1.4.22 Use-specific instructions for use

Please refer to section 5.1

2.1.4.23 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Do not reuse gloves. Use new gloves at start of each work period or at least every 2 hours. The maximum application time per day and user may not exceed 4 hours. A protective coverall (at least type 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information). Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information)' Please refer to section 5.2 for additional general risk mitigation measures.

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

Please refer to section 5.4

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

Please refer to section 5.5

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

-

Table 4. Use # 2.3 – Professional – Manual brush/roller/pad

Product Type	PT8 wood preservative
Where relevant, an exact description of the authorised use	Manual application with brush/roller or pad.
Target organism (including development stage)	Wood discolouring fungi
Field of use	Outdoor Use class 2 Use class 3
Application method(s)	Superficial application -brush/roller/pad treatment
Application rate(s) and frequency	With topcoat: 150 – 200 g/m². This is achieved by 1-2 applications.
Category(ies) of users	Professional user
Pack sizes and packaging material	10 ltr. metal can (inside coated tinplate) 20 ltr. metal can (inside coated tinplate)

2.1.4.27 Use-specific instructions for use

Please refer to section 5.1

2.1.4.28 Use-specific risk mitigation measures

Cover the ground during application and collect any spillage. Please refer to section 5.2 for additional general risk mitigation measures.

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

Please refer to section 5.3

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

Please refer to section 5.4

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

Please refer to section 5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Aqueous opaque wood preservative designed for superficial application.

The product protects the wood surface and the treated area against wood discolouring fungi and satisfies the performance requirements in EN 599.1 for blue stain and for Use Class 2 and 3.1 when applied on wood that is minimum 'moderately to slightly durable to fungi' according to EN 350:2016: Durability Class DC3-4.

MetaSPC1: The total amount to be applied is 250 – 400 g/m². This is achieved by 1-4 applications. No topcoat is required.

MetaSPC2: The total amount to be applied is 150 – 200 g/m². This is achieved by 1-4 applications. A top coat must be applied to treated timber. The topcoat must not be a wood preservative or be treated with a film preservative. The topcoat has to be maintained.

Since actual absorption achieved depends on the wood species, the timber and surface quality, it may vary in practice and should be checked by appropriate means.

Drying times, determined at 20 °C and 50 % relative humidity:
Dry to handle: 2-3 hours
Dry to sand / recoat: 3-4 hours

The drying time can be reduced using special drying systems to force drying. The drying times are approximate and may vary according to wood quality, temperatures, humidity and ventilation.

Cleaning: The equipment is cleaned with water.

2.1.5.2 Risk mitigation measures

Keep children and pets away from treated wood during application and drying.
Do not use on wood which may come in direct contact with food feeding stuff and livestock animals.
The biocidal product shall not be used for treatment of wood which is intended for contact with food, feed or livestock.

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.
IF ON SKIN: Wash skin with soap and water. If symptoms occur call a POISON CENTRE or a doctor.
IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

2.1.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

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

Store in cool, dry place in well closed containers, below 20°C. Protect from direct sunlight. Shelf life: 9 months in original containers.

2.1.6 Other information

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2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Can/drum	10 L 20 L	Metal can (inside coated tinplate)	Metal cap	Prof.	Yes
Can/drum or IBC	20 L	Metal can (inside coated tinplate)	Metal cap	Industrial	Yes
Can/drum or IBC	120 L 1000 L	HDPE	Plastic (HDPE)	Industrial	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No additional data has been generated.

2.1.8.2 Access to documentation

Letters of access have been granted by Troy Chemical Company B.V. representing Troy Corporation for use of the BPD dossier covering product type 8 of IPBC (3-iodo-2-propynyl butyl carbamate - CAS no: 55406-53-6) for the evaluation of the products contained in TEKNOS BLUESTAIN PRIMER family. The LoAs are embedded in the IUCLID dossier.

2.2 Assessment of the biocidal product family

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

Table 1.2. Use # 1.1 – industrial preventive wood preservative for treatment against wood discouloring fungi (meta-SPC 1).

Product Type	PT8 wood preservative
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Wood discolouring fungi
Field of use	Indoor
Application method(s)	Superficial application - automated or manual spraying (industrial)
Application rate(s) and frequency	1-4 applications (this includes base coat and surface treatment)
Category(ies) of users	Industrial user
Pack sizes and packaging material	Please see the relevant section.

Table 2. Use # 1.2 – professional preventive wood preservative for treatment against wood discouloring fungi (meta-SPC 1).

Product Type	PT8 wood preservative
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Wood discolouring fungi
Field of use	Indoor/outdoor
Application method(s)	Superficial application -brush/roller/pad treatment (professional)
Application rate(s) and frequency	1-4 applications (this includes base coat and surface treatment)
Category(ies) of users	professional user (brushing)
Pack sizes and packaging material	Please see the relevant section.

Table 3. Use # 2.1 – industrial preventive wood preservative for treatment against wood discouloring fungi (meta-SPC 2).

Product Type	PT8 wood preservative

Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Wood discolouring fungi
Field of use	Indoor
Application method(s)	Superficial application - automated or manual spraying (industrial)
Application rate(s) and frequency	1-2 applications (this includes the base coat)
Category(ies) of users	Industrial user (spraying)
Pack sizes and packaging material	Please see the relevant section.

Table 4. Use # 2.2 – professional preventive wood preservative for treatment against wood discouloring fungi (meta-SPC 2).

Product Type	PT8 wood preservative
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Wood discolouring fungi
Field of use	Indoor/outdoor
Application method(s)	Superficial application -brush/roller/pad treatment (professional)
Application rate(s) and frequency	1-2 applications (this includes the base coat)
Category(ies) of users	professional user (brushing)
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	PA-U10-METDESCR	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	Homogeneous liquid	Study N° 24265, C. Cornet, 2018
Physical state at 20 °C and 101.3 kPa	PA-U10-METDESCR	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	Homogeneous liquid	Study N° 24428, C. Cornet, 2018
Colour at 20 °C and 101.3 kPa	PA-U10-METDESCR	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	Grey*	Study N° 24265, C. Cornet, 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Colour at 20 °C and 101.3 kPa	PA-U10-METDESCR	TEKNOCOMBI 2917-62 (meta-SPC 1) (meta-SPC 1): 2603810 (0.3% IPBC)	Grey*	Study N° 24428, C. Cornet, 2018
Odour at 20 °C and 101.3 kPa	PA-U10-METDESCR	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	chemical odour	Study N° 24265, C. Cornet, 2018
Odour at 20 °C and 101.3 kPa	PA-U10-METDESCR	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	chemical odour	Study N° 24428, C. Cornet, 2018
Acidity / alkalinity	CIPAC MT 75.3 (pH)	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	pH: 8.10 (20°C), acidity/alkalinity test not required since pH is >4 and <10	Study N° 24265, C. Cornet, 2018
Acidity / alkalinity	CIPAC MT 75.3 (pH)	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	pH: 8.21 (20°C), acidity/alkalinity test not required since pH is >4 and <10	Study N° 24428, C. Cornet, 2018
Relative density / bulk density	CIPAC MT 3.3.2 equivalent to EU Method A.3	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	Relative density 1.2262 (20°C) 1.2073 (40°C)	Study N° 24265, C. Cornet, 2018
Relative density / bulk density	CIPAC MT 3.3.2 equivalent to EU Method A.3	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	Relative density 1.1975 (20°C) 1.1790 (40°C)	Study N° 24428, C. Cornet, 2018
Storage stability test – **accelerated storage**	CIPAC MT 46.3.1	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	Initial: 0.5384 ± 0.0104 % w/w IPBC After 8 weeks (40°C) in HDPE container: 0.4070 ± 0.0367 % w/w IPBC Difference: -24 % **Physical state :** Liquid on the top. Non	Study N° 24265, C. Cornet, 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			homogeneous liquid. Homogeneous after gently stirring. Small modification of appearance <u>After 8 weeks (40°C) in metal can:</u> 0.4196 ± 0.0126 % w/w IPBC Difference: -22% **Physical state :** Liquid on the top and a soft sediment at the bottom. Non homogeneous liquid. Homogeneous after gently stirring. Modification of appearance after accelerated storage (analysis by MET/24562/A : GC-FID method)	
Storage stability test – **accelerated storage**	CIPAC MT 46.3.1	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	<u>Initial:</u> 0.2600 ± 0.0090 % w/w IPBC <u>After 8 weeks (40°C) in HDPE container</u>: 0.1909 ± 0.0154 % w/w IPBC Difference: -27% **Physical state :** <u>Liquid on the top.</u> Non homogeneous liquid.	Study N° 24428, C. Cornet, 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Homogeneous after gently stirring. Small modification of appearance <u>After 8 weeks (40°C) in metal can:</u> 0.1853 ± 0.0227 % w/w IPBC Difference:- 29% **Physical state :** Liquid on the top and soft sediment at the bottom. Non homogeneous liquid. Homogeneous after gently stirring. Modification of appearance after accelerated storage (analysis by MET/24562/B : GC-FID method)	
Storage stability test – **long term storage at ambient temperature**	MET/24562/A: GC-FID method	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	**<u>HDPE can IPBC content</u>** <u>Initial:</u> 0.5384 ± 0.0104 % w/w IPBC <u>After 6 months (20°C) in HDPE container:</u> 0.5132 ± 0.0028 % w/w IPBC Difference:-4.7% <u>After 9 months (20°C) in HDPE</u>	Study N° 24265, B. de Ryckel, 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			container: 0.4853 ± 0.0116 % w/w IPBC Difference:-9.9% **Physical state :** Liquid on the top and a light sediment at the bottom. Non homogeneous liquid. Homogeneous after gently stirring. Modification (faceseperation) of appearance after storage. No modification of appearance after gentle stirring After 12 months (20°C) in HDPE container: 0.4504 ± 0.0218 % w/w IPBC Difference: -16.4% Appearance: After 12 months: No modification of appearance after gentle stirring or no significant pack weight change. **pH** Initial: 8.10 After 6 months (20°C) in HDPE container: 7.87	
	CIPAC MT 75.3 CIPAC MT 148			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			After 9 months (20°C) in HDPE container: 7.81 After 12 months (20°C) in HDPE container: 7.75	
	PA-U10-METDESCR (visual method)		**Pourability – rinsability:** Initial: Pour residue: 5.75% Rinsed residue: 0.29%	
	MET/24562/A		After 6 months (20°C) in HDPE container: Pour residue: 6.16% Rinsed residue: 0.21%	
			After 9 months (20°C) in HDPE container: Pour residue: 6.38% Rinsed residue: 0.33%	
			After 12 months (20°C) in HDPE container: Pour residue: 5.85% Rinsed residue: 0.25%	
	CIPAC MT 75.3		**Metal can IPBC content** Initial: 0.5384 ± 0.0104 % w/w IPBC After 6 months	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	CIPAC MT 148 PA-U10-METDESCR (visual method)		(20°C) in metal can: 0.5276 ± 0.0089 % w/w w/w IPBC (-2.0%) After 9 months (20°C) in metal can: 0.5039 ± 0.0062 % w/w w/w IPBC Difference: -6.0% **Physical state** : Liquid on the top and a light sediment at the bottom. Non homogeneous liquid. Homogeneous after gentle stirring. After 12 months (20°C) in metal can: 0.4654 ± 0.0318 % w/w w/w IPBC Difference: -13.6% **Physical state** : Liquid on the top and a light sediment at the bottom. Non Homogeneous liquid. Homogeneous after gentle stirring. **pH:** Initial: 8.10 After 6 months (20°C) in metal can:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			7.98 After 9 months (20°C) in metal can: 7.87 After 12 months (20°C) in metal can: 7.83 **Pourability - rinsability:** Initial (20°C): Pour residue: 5.75% Rinsed residue: 0.29% After 6 months (20°C) in metal can: Pour residue: 5.91% Rinsed residue: 0.22% After 9 months (20°C) in metal can: Pour residue: 5.98% Rinsed residue: 0.25% After 12 months (20°C) in metal can: Pour residue: 6.29% Rinsed residue: 0.23% **Appearance:** After 9 months: No modification of appearance or significant pack weight change.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			After 12 months: No modification of appearance after gentle stirring or no significant pack weight change.	
Storage stability test – **long term storage at ambient temperature**	MET/24562/A CIPAC MT 75.3	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	**HDPE can IPBC content** Initial: 0.2600 ± 0.0090 % w/w IPBC After 6 months (20°C) in HDPE container: 0.2539 ± 0.0118 % w/w IPBC Difference: -2.4% After 9 months (20°C) in HDPE container: 0.2374 ± 0.0170 % w/w IPBC Difference: -8.7% **Physical state :** Weak gelly wet structure on the top but no sediment at the bottom. Non homogeneous liquid. Homogeneous after gentle shaking. After 12 months (20°C) in HDPE container: 0.2258 ± 0.0094 % w/w IPBC Difference: -13.2%	Study N° 24428, B. de Ryckel, 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	CIPAC MT 148		**Physical state :** Weak gelly wet structure on the top but no sediment at the bottom. Non homogeneous liquid. Homogeneous after gentle shaking. **pH** Initial: 8.21 After 6 months (20°C) in HDPE container: 8.15 After 9 months (20°C) in HDPE container: 8.10 After 12 months (20°C) in HDPE container: 8.09	
	PA-U10-METDESCR (visual method)		Appearance: After 12 months: No modification of appearance after gentle stirring or no significant pack weight change.	
	MET/24562/A		**Pourability – rinsability:** Initial: Pour residue: 14.40% Rinsed residue: 3.96% After 6 months (20°C) in HDPE	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			container: Pour residue: 13.93% Rinsed residue: 4.33% After 9 months (20°C) in HDPE container: Pour residue: 13.46% Rinsed residue: 4.70% After 12 months (20°C) in HDPE container: Pour residue: 14.26% Rinsed residue: 6.44%	
	CIPAC MT 75.3 CIPAC MT 148		**Metal can IPBC content** Initial: 0.2600 ± 0.0090 % w/w IPBC After 6 months (20°C) in metal can: 0.2570 ± 0.0082 % w/w w/w IPBC Difference: -1.1% After 9 months (20°C) in metal can: 0.2489 ± 0.0111 % w/w w/w IPBC Difference: -4.3% **Physical state** : Weak gelly wet structure on the top and a soft sediment at the bottom.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	PA-U10-METDESCR (visual method)		Non homogeneous liquid. Homogeneous after gentle shaking. <u>After 12 months (20°C) in metal can:</u> 0.2234 ± 0.0172 % w/w w/w IPBC Difference: -14.1% **Physical state** : Weak gelly wet structure on the top but no sediment at the bottom. Non homogeneous liquid. Homogeneous after gentle shaking. **pH:** Initial: 8.21 <u>After 6 months (20°C) in metal can:</u> <u>8.15</u> <u>After 9 months (20°C) in metal can:</u> <u>8.14</u> <u>After 12 months (20°C) in metal can:</u> <u>8.11</u> **Pourability - rinsability:** Initial (20°C): Pour residue:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			14.40% Rinsed residue: 3.96% <u>After 6 months (20°C) in metal can:</u> Pour residue: 14.03% Rinsed residue: 4.14% <u>After 9 months (20°C) in metal can:</u> Pour residue: 14.40% Rinsed residue: 3.66% <u>After 12 months (20°C) in metal can:</u> Pour residue: 12.11% Rinsed residue: 3.99% **Appearance:** After 9 months: No modification of appearance after gentle stirring or no significant pack weight change. After 12 months: No modification of appearance after gentle stirring or no significant pack weight change.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	Visually stable at low temperature	Study N° 24265, C. Cornet, 2018
Storage stability test – **low temperature**	CIPAC MT 39.3	TEKNOCOMBI 2917-62 (meta-	Visually stable at low temperature	Study N° 24428, C.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
stability test for liquids		SPC 1): 2603810 (0.3% IPBC)		Cornet, 2018
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	Labels mention "protect from direct sunlight"; the packaging is not transparent	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	Labels mention "protect from direct sunlight"; the packaging is not transparent	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	Labels mention "store in a cool, dry place, below 20°C"	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	Labels mention "store in a cool, dry place below 20°C"	-
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	PA-U10-METDESCR	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	No modification of appearance or significant pack weight change during 8 weeks at 40°C or after 9 months at 20°C.	Study N° 24265, C. Cornet, 2018 Study N° 24265, B. de Ryckel, 2018
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	PA-U10-METDESCR	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	No modification of appearance or significant pack weight change during 8 weeks at 40°C or after 9 months at 20°C.	Study N° 24428, C. Cornet, 2018 Study N° 24265, B. de Ryckel, 2018
Wettability	-	-	Test not required: products are liquid	-
Suspensibility, spontaneity and	-	-	Test not required:	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
dispersion stability			products are RTU	
Wet sieve analysis and dry sieve test	-	-	Test not required: products are RTU	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Test not required: products are RTU	-
Disintegration time	-	-	Test not required: products are liquid	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Test not required: The product is not sold together with a spraying device, applicable for solid and liquid products. The MMAD is not required as an input parameter for the human exposure assessment. The MMAD is not relevant to demonstrate efficacy.	-
Persistent foaming	-	-	Test not required: products are RTU	-
Flowability/Pourability/Dustability	CIPAC MT 148 (pourability)	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	Initial: Pour residue: 5.75 % Rinsed residue: 0.29 % After 9 months (20°C) in HDPE container: Pour residue: 6.38% Rinsed residue: 0.33% After 9 months (20°C) in metal can:	Study N° 24265, C. Cornet, 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Pour residue: 5.98% Rinsed residue: 0.25 Testing for flowability and dustability is not required for liquids.	
Flowability/Pourability/Dustability	CIPAC MT 148 (pourability)	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	Initial: Pour residue: 14.40% Rinsed residue: 3.96 % After 9 months (20°C) in HDPE container: Pour residue: 13.46% Rinsed residue: 4.70% After 9 months (20°C) in metal can: Pour residue: 14.40% Rinsed residue: 3.66% Testing for flowability and dustability is not required for liquids.	Study N° 24428, C. Cornet, 2018
Burning rate — smoke generators	-	-	Test not required: products are liquid	-
Burning completeness — smoke generators	-	-	Test not required: products are	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			liquid	
Composition of smoke — smoke generators	-	-	Test not required: products are liquid	-
Spraying pattern — aerosols	-	-	Test not required: products are liquid	-
Physical compatibility	-	-	Not applicable, product not to be mixed with other products	-
Chemical compatibility	-	-	Not applicable, product not to be mixed with other products	-
Degree of dissolution and dilution stability	-	-	Test not required: products are RTU	-
Surface tension	PA-U10-METTENS (equivalent to EEC A.5) Automatic Tensiometer 25°C±0.5°C	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	22.4 mN/m test item is surface active	Study N° 24265, C. Cornet, 2018
Surface tension	PA-U10-METTENS (equivalent to EEC A.5) Automatic Tensiometer 25°C±0.5°C	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	24.0 mN/m test item is surface active	Study N° 24428, C. Cornet, 2018
Viscosity	CIPAC MT 192	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	8158 mPa.s to 1444 mPa.s dependent on the shear rate applied to the sample @ 20°C 10078 mPa.s to 923 mPa.s dependent on the shear rate applied to the sample @ 40°C no Newtonian	Study N° 24265, C. Cornet, 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			flow behaviour	
Viscosity	CIPAC MT 192	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	79663 mPa.s to 2594 mPa.s dependent on the shear rate applied to the sample @ 20°C 72944 mPa.s to 1937 mPa.s dependent on the shear rate applied to the sample @ 40°C no Newtonian flow behaviour	Study N° 24428, C. Cornet, 2018

* other colours are possible within the meta SPC due to variations in pigment composition.

Conclusion on the physical, chemical and technical properties of the product
The 2 products that are used for testing represent the worst case regarding degradation of AS (lowest content of IPBC in meta-SPC, highest content of pigment) for each meta-SPC. For meta-SPC 1 (TEKNOCOMBI 2917-62), following specifications are applicable: Homogeneous liquid, content IPBC: 0.3%, pH 8.21, density 1.20 g/ml, viscosity 79663 mPa.s to 2594 mPa.s at 40°C. Surface tension 24.0 mN/m test item is surface active. For meta-SPC 2 (AQUAPRIMER 2907-63), following s specifications are applicable: Homogeneous liquid, content IPBC: 0.6%, pH 8.10, density 1.23 g/ml, viscosity 10078 mPa.s to 923 mPa.s at 40°C. Surface tension 22.4 mN/m test item is surface active. Although tested products from both meta-SPCs showed exceedance of the allowed max. residue in the pourability/rinsability test, safe disposal of the products is assured due to the label instructions. Moreover, products are only handled by professional users, therefore, label instructions are sufficient to make sure disposal is always done safely, i.e. at the end of the treatment unused product and the packaging are disposed in accordance with local requirements. As storage of the 2 products at 20°C ± 2°C both in a HDPE can as in a metal can show a significant decrease (decrease in IPBC content below 10%)in IPBC content after 12 months storage, a shelf-life of 9 months is proposed.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Desktop assessment	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	There is a C≡C in IPBC, but information sourced from ECHA submission of the active ingredient indicates that it does not have explosive properties. The rest of the co-formulants have been assessed and were found to be non-explosive. No elements of the screening procedure suggest that explosive properties may be exhibited by the substance.	Report N° GLP3016002649BR1V1/2017, S. Younis, 2017
Explosives	Desktop assessment	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	There is a C≡C in IPBC, but information sourced from ECHA submission of the active ingredient indicates that it does not have explosive properties. The rest of the co-formulants have been assessed and were found to be non-explosive No elements of the screening procedure suggest that explosive	Report N° GLP3016002649CR1V1/2017, S. Younis, 2017

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			properties may be exhibited by the substance.	
Flammable gases	-	-	not required: Products are liquid	-
Flammable aerosols	-	-	not required: Products are liquid	-
Oxidising gases	-	-	not required: Products are liquid	-
Gases under pressure	-	-	not required: Products are liquid	-
Flammable liquids	EEC A.9 Flash point in a closed cup	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	Flash point > 93°C The products are not flammable	Study N° 24265, C. Cornet, 2018
Flammable liquids	EEC A.9 Flash point in a closed cup	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	Flash point > 93°C The products are not flammable	Study N° 24428, C. Cornet, 2018
Flammable solids	-	-	not required: Products are liquid	-
Self-reactive substances and mixtures	-	-	Not required: the products do not contain any ingredients carrying chemical groups associated with explosive or self reactive properties	-
Pyrophoric liquids			Not required: the products are known to be stable at room temperature for prolonged periods of time	
Pyrophoric solids	-	-	not required: Products are liquid	-
Self-heating	-	-	Not required:	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
substances and mixtures			The product is liquid	
Substances and mixtures which in contact with water emit flammable gases	-	-	Not required: the products are stable aqueous solutions.	-
Oxidising liquids	Desktop assessment	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	The product meets all criteria for exemption from testing and has a structure not at all conducive with that required to exhibit oxidising tendencies	Report N° GLP3016002649BR1V1/2017, S. Younis, 2017
Oxidising liquids	Desktop assessment	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	The product meets all criteria for exemption from testing and has a structure not at all conducive with that required to exhibit oxidising tendencies	Report N° GLP3016002649CR1V1/2017, S. Younis, 2017
Oxidising solids	-	-	not required: Products are liquid	-
Organic peroxides	-	-	Not required: products do not contain an organic peroxide substance containing the bivalent -O-O- structure	-
Corrosive to metals	UN Test C. 1 28 days at 55 °C ± 1 °C	AQUAPRIMER 2907-63 (meta-SPC 2): 2603865 (0.6% IPBC)	Determination of the uniform corrosion showed, that the highest weight loss	Study no.: CSL-20-1429.01 M. Möller, 2021

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			observed over 28 days at 55 °C ± 1°C were: Steel speciment: 1.5 wt % Aluminium specimen: 0.5 wt %. Based on the highest observed weight losses, the test is considered negative with respect to uniform corrosion of the steel as well as aluminium specimen. The determination of the localized corrosion showed, that the highest intrusion depths observed over 28 days at 55 °C ± 1°C were: Steel specimen: 136.4 µm Aluminium specimen: 0 Based on the highest observed intrusion depths, the test is considered negative with respect to localized corrosion to steel as well as alminium.	
Auto-ignition temperatures of	EU Regulation	AQUAPRIMER 2907-63 (meta-	Auto-ignition temperature	Report N° GLP301600264

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
products (liquids and gases)	(EC) 440/2008, Annex Part A test A15	SPC 2): 2603865 (0.6% IPBC)	has been determined to be 535°C.	9BR1V1/2017, S. Younis, 2017
Auto-ignition temperatures of products (liquids and gases)	EU Regulation (EC) 440/2008, Annex Part A test A15	TEKNOCOMBI 2917-62 (meta-SPC 1): 2603810 (0.3% IPBC)	Auto-ignition temperature has been determined to be 497°C.	Report N° GLP301600264 9CR1V1/2017, S. Younis, 2017
Relative self-ignition temperature for solids	-	-	not required: Products are liquid	-
Dust explosion hazard	-	-	not required: Products are liquid	-

Conclusion on the physical hazards and respective characteristics of the product

The 2 products that are used for testing represent the worst case (lowest content of IPBC in meta-SPC, highest content of pigment) for each meta-SPC.

For meta-SPC 1 (TEKNOCOMBI 2917-62), following specifics are applicable:
No physical hazards identified.

For meta-SPC 2 (AQUAPRIMER 2907-63), following specifics are applicable:
No physical hazards identified.

The corrosive to metal test shows that there is no corrosion to metal

Other properties which were not tested are deemed not required based on physical state of the products and/or intrinsic properties of the ingredients.

The products in the TEKNOS BLUESTAIN PRIMERS family are not classified for physical hazards.

2.2.4 Methods for detection and identification

Active substance is dissolved/extracted from the sample with acetone. The solution is filtered and an aliquot is analysed by Gas Chromatography (GC) with flame ionisation detection (FID) using internal standard calibration.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IPBC (AQUAPRIMER 2907-63 (meta-SPC 2))	GC-FID (MET/24562/A)	0.3242 % w/w (n = 2) (50% of nominal concentration) 0.6670 % w/w (n = 2) (100% of nominal concentration) 0.9794 % w/w (n = 2) (150% of nominal concentration)	Range 194 – 876 µg/mL IPBC: r = 0.9996 [r^2=0.9998]. ratio IPBC / internal standard in range 194 - 876 µg/mL IPBC: r =0.9997 [r^2=0.9998]. The concentration of testsampels used for determination of as is 480 µg/ml. Hence the consentreation ±20 % is covered.	No interferences, There is chromatogram from sampel solution without active substance, were there is no signal at the IPBC signalrange	0.3242% IPBC (n=2) 0.6670% IPBC (n=2) 0.9794% IPBC (n=2) Mean (n= 6)	102.6% 101.2% 103.7% 102.5%	1.30% 0.77% 0.75% 1.33%	LOQ 0.3242 % w/w Repeatability mean: 0.5384% (RSD 1.83%)	Study N° 24562, C. Cornet, 2018
IPBC	GC-FID	0.1913 % w/w	Range 194 –	No	0.1913 %	98.38%	0.40%	LOQ 0.1913	Study N°

(TEKNOCOMBI 2917-62 (meta-SPC 1))	(MET/24562/B)	(n = 2) (50% of nominal concentration) 0.3428% w/w (n = 2) (100% of nominal concentration) 0.4631 % w/w (n = 2) (150% of nominal concentration)	876 µg/mL IPBC: r = 0.9996 [r^2=0.9998]. ratio IPBC / internal standard in range 194 - 876 µg/mL IPBC: r =0.9997 [r^2=0.9998]. The concentration of testsampels used for determination of as is 480 µg/ml. Hence the consentreation ±20 % is covered.	interferences There is chromatogram from sampel solution without active substance, were there is no signal at the IPBC signalrange	IPBC (n=2) 0.3428% IPBC (n=2) 0.4631 % w/w IPBC (n=2) Mean (n= 6)	100.4% 99.21% 99.34%	2.02% 0.49% 1.34%	% w/w Repeatability mean: 0.2600% (RSD 3.28%)	24562, C. Cornet, 2018

Analytical methods for monitoring the product in soil, water and air are covered by the methods as described in the Assessment Report of IPBC.

Analytical methods for monitoring in animal and human body fluids and tissues are not required.

Analytical methods for the determination of the active substance residues in food of plant and animal origin or feeding stuffs are only required if the biocidal product is intended to be used in a manner which may cause contact with food or feedstuffs. Since this is not the case for products from the TEKNOS BLUESTAIN PRIMERS family and exposure to food and feedstuff can be excluded when the product is applied according to the recommended uses, an analytical method for the determination in food or feeding stuffs is not required.

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IPBC	Assessment Report IPBC								

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IPBC	Assessment Report IPBC								

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IPBC	NA, IPBC is non-volatile (Assessment Report IPBC)								

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IPBC	Assessment Report IPBC								

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IPBC	NA, IPBC is not classified as toxic/very toxic.								

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
IPBC	NA, no contact with food or feedstuffs (IPBC Assessment Report)								

Conclusion on the methods for detection and identification of the product
The GC-FID method used for IPBC analysis in the products in meta-SPC 1 (TEKNOCOMBI 2917-62) and meta-SPC 2 (AQUAPRIMER 2907-63) is sufficiently validated in compliance with SANCO/3030/99.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The products in the TEKNOS BLUESTAIN PRIMERS family are intended for preventive preservation of wood and will cover the protection of the wood against wood discolouring fungi. The products are used for superficial treatments and will always be used in combination with timber made of such a wood quality that is by nature less prone to wood decay fungi. Timber to be treated are articles such as windows and doors, or other wooden surfaces and items which mainly consists of heartwood. Heartwood is known to be less prone to fungal attack over time, due to its lower water permeability and less hygroscopic properties compared to sapwood. Wood being treated with the products from the TEKNOS BLUESTAIN PRIMERS family will largely consist of heartwood categorized as minimum 'moderately to slightly durable to fungi' according to EN 350:2016: Durability Class DC3-4. Due to the intrinsic properties of the heartwood present in the timber, the biocidal action required from the products to provide protection against fungal attack can be limited and can be less broad than what is described according to the EN 599-1 and BPR Guidance Volume II Parts B+C (Version 3.0, 2018) for wood falling in use class 2 and 3. More precisely, the products from the TEKNOS BLUESTAIN PRIMERS family will only need to provide preventive protection against wood discouloring fungi/bluestain fungi. The system should be assessed as a whole, being: the use of the products by superficial treatment and the wood category/type will comprise protection against wood discolouring and decay fungi as prescribed by the EN 599-1.

All products in the family are ready-to-use formulations. The products contain active substance IPBC (3-iodo-2-propynyl butylcarbamate) in a concentration range of 0.3 to 0.6 % w/w. 2 meta-SPCs are present in the family: meta-SPC 1 (TEKNOCOMBI 2917-62) and meta-SPC 2 (AQUAPRIMER 2907-63). Products falling in meta SPC 1 contain IPBC technical concentrations of approx. 0.30% w/w, ranging between 0.294- 0.300 % w/w IPBC, and are special combination products that renders traditional primer-topcoat application unnecessary, the only treatment needed is sufficient layers of this product. Products falling in meta SPC 2 contain IPBC technical concentrations of approx. 0.60% w/w, ranging between 0.588- 0.600 % w/w IPBC, and will be used as primer, combined with an additional (non-biocidal) topcoat.

By using the products of the TEKNOS BLUESTAIN PRIMER family in combination with wood mainly consisting of heartwood (DC3-4), the entire system assures the treated wood can be assigned to following wood classes:

- Use class 2: Situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but where occasional, but not persistent, wetting can occur;

- Use class 3.1: Situation in which the wood or wood-based product is above ground and exposed to the weather (particularly rain): Wood and wood based products will not remain wet for long periods. Water will not accumulate.

This is in accordance with the agreement during WG IV – 2017. PT 8 products for which the uses are limited to protection against blue stain fungi is possible, as described in BPR Guidance- Volume II Parts B+C (Version 3.0, 2018) - footnote 28:

> *Products which only claim protection against blue stain can be authorized for uses where exemption of the requirement for efficacy against wood*

destroying fungi can be justified, e.g. for wood or wood products that by their nature are not susceptible to brown rot fungi. Pure anti-blue stain products may not be used together with product against wood destroying fungi to prevent double treatment of two fungicides.

Products in meta-SPC 1 are to be applied at a rate between 250 – 400 g/m^2, obtained by applying 1 to 4 coats. The products in this meta-SPC can be applied both as primer and topcoat. Below the claim matrix for products in meta-SPC 1 is provided.

Category	**Wording**	**Code**
User category	Industrial Professional	A.20 A.30
Wood category	Softwood	B.10
Wood product	Solid wood Reconstituted wood	C.10 C.11
Application aim and field of use	Preventive treatment / blue stain in service Use class 2 Use class 3 (3.1: wood and wood based products will not remain wet for long periods. Water will not accumulate)	D.30 E.20 E.31
Method of application and rate	Superficial application (label: 250 -400 g/m^2, by 1-4 coats); no top coat required Brush/roller/pad treatment Spray treatment	 F.10 F.11
Target organisms	Wood discolouring fungi: blue stain	G21.2

Products from meta SPC 1 are used in combination with wood mainly consisting of heartwood. The combination of product treatment and the wood category/type will assure the system is covering the claim matrix indicated below:

Category	**Wording**	**Code**
User category	Industrial Professional	A.20 A.30
Wood category	Softwood	B.10
Wood product	Solid wood Reconstituted wood	C.10 C.11
Application aim and field of use	Preventive treatment / blue stain in service Use class 2 Use class 3 (3.1: wood and wood based products will not remain wet for long periods. Water will not accumulate)	D.30 E.20 E.30 (E.31)
Method of application and	Superficial application (label: 250 -400 g/m^2, by 1-4 coats); no top coat required	

rate	Brush/roller/pad treatment Spray treatment	F.10 F.11
Target organisms	Wood decay fungi: brown rot fungi white rot fungi Wood discolouring fungi: blue stain	 G.10 G.11 G21.2

Products in meta-SPC 2 are to be applied at 150 – 200 g/m^2, obtained by applying 1 to 2 coats. The products in this meta-SPC are suitable for primer only. Wood treated with products from meta-SPC 2 will always undergo a subsequent treatment with a topcoat before the wood is exposed to weathering. The topcoat treatment will be an acrylic based topcoat. Below the claim matrix for products in meta-SPC 2 is provided.

Category	**Wording**	**Code**
User category	Industrial Professional	A.20 A.30
Wood category	Softwood	B.10
Wood product	Solid wood Reconstituted wood	C.10 C.11
Application aim and field of use	Preventive treatment / blue stain in service Use class 2 Use class 3 (3.1: wood and wood based products will not remain wet for long periods. Water will not accumulate)	D.30 E.20 E.30 (E.31)
Method of application and rate	Superficial application (label: 150-200 g/m^2, by 1-2 coats); a top coat must be applied for UC 3 wood: wood exposed to weathering: Brush/roller/pad treatment Spray treatment	 F.10 F.11
Target organisms	Wood discolouring fungi: blue stain	G21.2

Products from meta SPC 2 are used in combination with wood mainly consisting of heartwood. The combination of product treatment and the wood category/type will assure the system is covering the claim matrix indicated below:

Category	**Wording**	**Code**
User category	Industrial Professional	A.20 A.30
Wood category	Softwood	B.10
Wood product	Solid wood Reconstituted wood	C.10 C.11
Application aim and field of use	Preventive treatment / blue stain in service Use class 2	D.30 E.20

	Use class 3 (3.1: wood and wood based products will not remain wet for long periods. Water will not accumulate)	E.30 (E.31)
Method of application and rate	Superficial application (label: 150-200 g/m^2, by 1-2 coats); a top coat must be applied for UC 3 wood: wood exposed to weathering: Brush/roller/pad treatment Spray treatment	 F.10 F.11
Target organisms	Wood decay fungi: brown rot fungi white rot fungi Wood discolouring fungi: blue stain	 G.10 G.11 G21.2

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

Products of TEKNOS BLUESTAIN PRIMERS family are used for preventative treatment against wood discolouring fungi in heartwood.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The products prevents fungal species from attacking the treated wood. No unacceptable suffering is expected.

2.2.5.4 Mode of action, including time delay

IPBC is a carbamate fungicide. Carbamates disturb cell membrane permeability and fatty acids metabolism.

2.2.5.5 Efficacy data

For both meta-SPC's, the efficacy data has been performed on the products containing a maximum concentration of pigment (i.e. 2 % w/w), and the minimum amount of active substance IPBC in the meta-SPC. Other products from the same meta-SPC are covered by the tested product with max. amount of pigment in the meta-SPC, as described in EN-599-1 Annex A in A.2.2.e. The two tested products serve as a worst case for the entire meta-SPC and cover the range of concentrations within the meta-SPC.

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**

Fungicidal-bluestain protection	Preventive wood treatment UC 2/ UC 3.1 - softwood	TEKNOCOMBI 2917-62 (meta-SPC 1) Product code 2603810 (0.30 % w/w IPBC)	Aureobasidium pullulans and Sydowia pithyofilia (blue stain fungi)	EN152, no top coat (Type C)	<u>Primer:</u> 150 g/m^2(1 coat) 200 g/m^2(2 coats) 250 g/m^2(2 coats) <u>Primer + topcoat:</u> 150 g/m^2(1 coat) + 150 g/m^2(1 coat) 200 g/m^2(2 coats) + 200 g/m^2(2 coats) 250 g/m^2(2 coats) + 250 g/m^2(2 coats), duration 6 weeks, after 4 weeks QUV accelerated weathering	no individual rating ≥2 of blue stain, min. stain-free zone 1.0 mm, mean 2.5 mm at 250 g/m2 in 2 coats at 150 g/m2 (1 coat) + 150 g/m2 (1 coat) at 200 g/m2 (2 coats) + 200 g/m2 (2 coats) at 250 g/m2 (2 coats) + 250 g/m2 (2 coats)	Test report no 401/17/138 F/2-e, FCBA 08-02-2018

Fungicidal-bluestain protection	Preventive wood treatment UC 2 / UC 3.1 - softwood	AQUAPRIMER 2907-63 (META-SPC 2)Product code 2603865 (0.60 % w/w IPBC)	Aureobasidium pullulans and Sydowia pithyofilia (blue stain fungi)	EN152 with standard acrylic top coat (Type A)	150 g/m^2 – 1 coat + 216 g/m2 acrylic topcoat – 3 coats 200 g/m^2 – 2 coats + 216 g/m2 acrylic topcoat – 3 coats 250 g/m^2 – 2 coats + 216 g/m2 acrylic topcoat – 3 coats duration 6 weeks, after 4 weeks QUV accelerated weathering	no individual rating ≥2 of blue stain, min. stain-free zone 1.0 mm, mean 2.5 mm at 150 g/m^2 (1 coat) + 216 g/m2 acrylic topcoat (3 coats) at 200 g/m^2 (2 coats) + 216 g/m2 acrylic topcoat (3 coats) at 250 g/m^2 (2 coats) + 216 g/m2 acrylic topcoat (3 coats)	Test report no 401/17/138 F/1-e, FCBA, 08-02-2018

Conclusion on the efficacy of the product
The product family, TEKNOS BLUESTAIN PRIMERS may be approved for preventive use against wood discolouring fungi with the specified amount (Meta SPC 1: 250-400 g/m2,

Meta SPC 2: 150-200 g/m2) for superficial application methods in use class 2 and 3 on wood material not susceptible to brown rot decay.
A non-biocidal topcoat is required when using products from Meta SPC 2.

2.2.5.6 Occurrence of resistance and resistance management

The risk of resistance formation against carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee). This applies to the use of carbamate fungicides in agriculture, where yearly applications to the same fields are possible.
Based on the unspecific mode of action of IPBC, the risk of resistance formation during wood preservation is regarded to be low.

2.2.5.7 Known limitations

None

2.2.5.8 Evaluation of the label claims

Data for efficacy against blue stain fungi are available for worst case products in both meta-SPCs. EN152 tests have been performed on typical target organisms (*Sydowia pithyofilia* and *Aureobasidium pullulans)* with the worst case product of each meta-SPC.

The application rate used to support the wood discolouring fungi claim is based on the dose used in the EN152 study that leads to a minimum stain-free zone of 1.0 mm and mean stain-free zone of at least 2.5 mm.
The product from meta-SPC 1 has been tested, by applying the product both as primer and topcoat. The test shows that treatment with the product at a rate of 250-400 g/m2 by applying 1-4 coats is effective for protection of softwood against blue stain fungi.

The product from meta-SPC 2 has been tested in combination with use of a standard acrylic topcoat. The test shows that treatment with the product at a rate of 150-200 g/m2 by applying 1-2 coat is effective for protection of softwood against blue stain fungi, when an acrylic topcoat is used subsequently.

Wood being treated with the products from the TEKNOS BLUESTAIN PRIMERS family will largely consist of heartwood categorized as minimum 'moderately to slightly durable to fungi' according to EN 350:2016: Durability Class DC3-4. Timber being treated will typically be wood articles such as window frames or doors.
Due to the intrinsic properties of the heartwood present in the timber, the biocidal action required from the products to cover protection against fungal attack can be limited and can be less broad than what is described according to the EN 599-1 and BPR Guidance Volume II Parts B+C (Version 3.0, 2018) for wood falling in UC2 and 3. More precisely, the products from the TEKNOS BLUESTAIN PRIMERS family will only need to provide protection against wood discouloring fungi/bluestain fungi when the wood is of such durability that wood decay fungi will not need to be targeted by chemical substances. The system as a whole, being: the use of the products by superficial treatment and the wood category/type will provide protection against both wood discolouring and wood decay fungi as prescribed by the EN 599-1.

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

Products from TEKNOS BLUESTAIN PRIMER family are not to be used together with other biocidal products. For products in meta-SPC 2 (AQUAPRIMER 2907-63), a non-biocidal topcoat should be applied.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on human health

No toxicological studies are available for TEKNOS BLUESTAIN PRIMERS. The requirement for such studies can be waived, with reference to the Guidance on the Biocidal Products Regulation: Volume III Human Health, Part A (Information Requirements), on the basis that there is sufficient toxicological data on the active substance and non-active substances to allow classification of the products in TEKNOS BLUESTAIN PRIMERS according to Regulation (EC) No. 1272/2008 (CLP), and no synergistic effects between any of the components are expected.

DK CA submitted in June 2011 a classification proposal for IPBC to RAC for the purpose of a harmonised classification. RAC adopted its opinion 28 November 2012 by consensus for a harmonised classification of the following: Acute Tox. 3, H331; Acute Tox. 4, H302; Eye Dam. 1, H318; Skin Sens. 1, H317; STOT RE 1, H372 (larynx); Aquatic Acute 1, H400, M=10; Aquatic Chronic 1, H410, M= 1. The harmonised classification was entered in Annex VI to the CLP legislation through the ATP no. 6 update (enforced June 2014).

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Products in metaSPC 1 and 2 of TEKNOS BLUESTAIN PRIMERS do not cause skin irritation.
Justification for the value/conclusion	None of the non-active substances or the active substance in the mixture allow for classification for skin irritation of TEKNOS BLUESTAIN PRIMERS as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.1 "Skin corrosion or skin irritation"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Products in metaSPC 1 and 2 of TEKNOS BLUESTAIN PRIMERS do not cause eye irritation.
Justification for the	None of the non-active substances or the active substance in the

value/conclusion	mixtures allow for classification for eye irritation of metaSPC1 and metaSPC2* of TEKNOS BLUESTAIN PRIMERS as they are either not classified themselves for this endpoint or they are present in the products at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008. *) When viewing the actual concentration of one of the non-active substances in the applied-for products in metaSPC2, none of these concentrations would trigger the classification for eye irritation. However, the original maximum concentration range of metaSPC2 of this non-active substance would lead to classification of metaSPC2 as eye irritating. Therefore, the applicant was asked to lower the maximum concentration range of this non-active substance to match the products' level of hazard with the metaSPC's.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.2 "Eye irritation"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Products in metaSPC 1 and 2 of TEKNOS BLUESTAIN PRIMERS do not cause respiratory tract irritation.
Justification for the conclusion	None of the non-active substances or the active substance in the mixture allow for classification for respiratory tract irritation of TEKNOS BLUESTAIN PRIMERS as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Not a core data requirement.
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitization	
Value/conclusion	Products in metaSPC 1 and 2 of TEKNOS BLUESTAIN PRIMERS do not cause skin sensitisation, but should be labelled with EUH208: Contains 3-iodo-2-propynyl-butyl-carbamate (IPBC), 1,2-benzisothiazolin-3-one (BIT) and 2-methyl-2h-isothiazol-3-one (MIT).
Justification for the value/conclusion	None of the non-active substances or the active substance in the mixture trigger classification for skin sensitisation of TEKNOS BLUESTAIN PRIMERS as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008. The active substance IPBC and the co-formulants 1,2-benzisothiazolin-3-one (BIT) and 2-methyl-2h-isothiazol-3-one (MIT) are at concentrations in both metaSPC 1 and 2 leading to all products should be labelled with EUH208.
Classification of the product according to CLP and DSD	Not classified. Products contained in metaSPC1 and metaSPC2 should be labelled with EUH208: Contains 3-iodo-2-propynyl-butyl-carbamate (IPBC), 1,2-benzisothiazolin-3-one (BIT) and 2-methyl-2h-isothiazol-3-one (MIT).

Data waiving	
Information requirement	Annex III of BPR, point 8.3 "Skin sensitization"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitization	
Value/conclusion	Products in metaSPC 1 and 2 of TEKNOS BLUESTAIN PRIMERS do not cause respiratory sensitisation.
Justification for the value/conclusion	None of the non-active substances or the active substance in the mixture allow for classification for respiratory sensitisation of TEKNOS BLUESTAIN PRIMERS as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.4 "Respiratory sensitization" (ADS)
Justification	Currently no testing methods or test guidelines are available. Classification is therefore based on apparent evidence of potential respiratory sensitization attained from other sources submitted in the dossier.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Products in metaSPC 1 and 2 of TEKNOS BLUESTAIN PRIMERS are not acutely toxic via the oral route – ATE_{mix} > 2000 mg/kg bw.
Justification for the selected value	According to the calculation rules laid down in Reg. (EC) no. 1272/2008, the ATE_{mix} for products contained in TEKNOS BLUESTAIN PRIMERS f are > 2000 mg/kg bw.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.1 "Acute toxicity by oral route".
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Products in metaSPC 1 and 2 of TEKNOS BLUESTAIN PRIMERS are not not acutely toxic via inhalation. ATE_{mix} > 5 mg/L
Justification for the selected value	According to the calculation rules laid down in Reg. (EC) no. 1272/2008, the ATE_{mix} for for products contained in TEKNOS BLUESTAIN PRIMERS are > 5 mg/L
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.2 "Acute toxicity by inhalation"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Products in metaSPC 1 and 2 of TEKNOS BLUESTAIN PRIMERS are not acutely toxic via the dermal route.
Justification for the selected value	None of the non-active substances or the active substance are classified for acute dermal toxicity, and Products in metaSPC 1 and 2 of TEKNOS BLUESTAIN PRIMERS should therefore not be classified for acute dermal toxicity according to the rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information	Annex III of BPR, point 8.5.3 "Acute toxicity by dermal route"

requirement	
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	IPBC (3-iodo-2-propynyl butylcarbamate)
Value(s)*	50% for dilutions (products are ready to use solutions at 0.26 to 0.6 % w/w IPBC)
Justification for the selected value(s)	Default value for water-based dilution according to EFSA Guidance on dermal absorption[7]

Data waiving	
Information requirement	Dermal absorption of the active substance in products in meta-SPC 1 and 2 of TEKNOS BLUESTAIN PRIMERS
Justification	A dermal absorption value for IPBC used for the risk assessment is based on data available at the active substance Assessement Report for PT8 and by consultation of the EFSA Guidance on Dermal Absorption[1]. The data and info available are sufficient to derive the dermal absorption of the active substance IPBC in the product formulations in TEKNOS BLUESTAIN PRIMERS.

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

In addition to the active substance, the product may contain non-active substances (co-formulants) that are substances of concern (SoC). In order to identify relevant SoC, the Guidance on BPR Volume III Human Health, Annex A (2017) has been consulted. For the initial evaluation, please refer to the Confidential Annex to this PAR. Only the substances identified as substances of concern have been transferred to the non-confidential PAR and evaluated further here.

[1] EFSA (European Food Safety Authority), Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G, Ruffo F and Chiusolo A, 2017. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp.

1,2-benzisothiazolin-3-one (BIT) and 2-methyl-2h-isothiazol-3-one (MIT) (CAS 2682-20-4) are considered substances of concern as their concentrations in products in both metaSPC1 and metaSPC2 lead the products to be labelled with EUH208: Contains 1,2-benzisothiazolin-3-one (BIT) and 2-methyl-2h-isothiazol-3-one (MIT). May cause an allergic reaction.

Formaldehyde (CAS 50-00-0), diproppylenglycol methyl ether (DPM) (CAS 34590-94-8), butyl diglycol (CAS 112-34-5) and bytyl diglycol/butyloxitol (CAS 111-76-2) have been assigned European IOELVs and a full quantitative risk evaluation has been performed in the relevant scenarios according to Guidance on BPR Volume III Human Health, Annex A (2017). Only EU IOELVs have been used as reference values as agreed both at WG-II-HH-2019 and at the CG45 meeting where the final document CG-45-2021-20 was endorsed. Relevant scenarios are considered to be those involving the primary user in the work place, as the EU OELs have been assigned for this purpose. It is not considered relevant to calculate the exposure of the substances to the general public, as the reference values are not appropriate. Furthermore, the primary user in the workplace is assumed to act as a risk envelope for the general public (in situations where no PPE is worn) as they are exposed to the substances to a far greater extent than that of the general public. Please refer to the Human Health Risk Assessment Output tables in Annex 3.2 for details of this assessment. Considering the vapour pressures of the four substances of concern and taking into account HEEG Opinion no. 13, all of the substances should be considered available for inhalation, as their vapour pressure is above that of 10 mPa. They are however not considered volatile according to Guidance on BPR Volume III Human Health, page 44, table 2. It is therefore considered most appropriate to assess the inhalation exposure according to the exposure scenarios listed in HEAdhoc Recommendation no. 6 for non-volatile substances. The relevant scenarios are considered to be "automated spraying", "manual spraying", "brushing, rolling and pad" and "professional cutting and sanding".

Substance	CAS no.	Vapour pressure	EU OEL	STEL	Effect	Skin notation
Formaldehyde	50-00-0	4.7 *10^5 Pa	0.369 mg/m^3 0.3 ppm	0.763 mg/m^3 0.6 ppm	Local. Upper respiratory tract cancer	Yes Skin sens
Dipropylenglycol methyl ether	34590-94-8	60 Pa	308 mg/m^3 50 ppm	-	Systemic. CNS depression	Yes
Butyl diglycol	112-34-5	2.7 Pa	98 mg/m^3 20 ppm	246 mg/m^3 50 ppm	Systemic. Decrease in erythrocytes and haemoglobin conc.	Yes
Bytyl diglycol/butyloxitol	111-76-2	100 Pa	67.5 mg/m^3 10 ppm	101.2mg/m^3 15 ppm	Local. Lung inflammation	No

As can seen from the table above, formaldehyde has been assigned a skin notation. This is due to its sensitizing properties. Formaldehyde is also classified Skin sens; H317, and thus

this effect therefore already has been accounted for when determining the classification of TEKNOS BLUESTAIN PRIMERS.

Dipropylenglycol and butyl diglycol have been assigned skin notations as the dermal exposure could contribute substantially to the systemic effects that the OEL has been derived from. However, the EU OEL is not for use for dermal exposure. The ECHA registration dossiers for the two substances was therefore consulted, and the Derived No Effect Levels (DNEL's) for dipropylenglycol and butyl diglycol for worker hazard were set to 383 mg/kg bw/day and 83 mg/kg bw/day based on repeated dose dermal exposure. The relevant scenarios are considered to the same as for the inhalation exposure, those being "automated spraying", "manual spraying", "brushing, rolling and pad" and "professional cutting and sanding".

Please consult the output tables in section 3.2 for details of the exposure calculations.

Risk evaluation for substances of concern

Inhalation exposure

Formaldehyde

Task/ Scenario	Exposure mg/m3	EU OEL STEL mg/m3	Exposure/EU OEL STEL %	Exposure 8h TWA mg/m3	EU OEL 8h TWA mg/m3	Exposure 8h/EU OEL 8h TWA %	Acceptable Yes/no
1.2.1 Automated spraying	1.0×10^{-6}	0.763	0.00013	1.3×10^{-6}	0.369	0.00003	Yes
1.2.2 Manual spraying	7.6×10^{-6}	0.763	0.00996	7.6×10^{-6}	0.369	0.0206	Yes
2.2.2 Professional brushing	1.0×10^{-6}	0.763	0.00013	5.1×10^{-5}	0.369	0.00014	Yes
2.3.4 Professional cutting and sanding	3.4×10^{-3}	0.763	0.00004	2.5×10^{-7}	0.369	0.00007	Yes

Dipropylenglycol methyl ether

Task/ Scenario	Exposure mg/m3	EU OEL STEL mg/m3	Exposure/EU OEL STEL %	Exposure 8h TWA mg/m3	EU OEL 8h TWA mg/m3	Exposure 8h/EU OEL 8h TWA %	Acceptable Yes/no
1.2.1 Automated spraying	0.0024	-	-	0.0003	308.0	0.0001	Yes
1.2.2 Manual spraying	0.1824	-	-	0.1824	308.0	0.05922	Yes
2.2.2 Professional brushing	0.00243	-	-	0.00121	308.0	0.00039	Yes
2.3.4 Professional cutting and sanding	0.0008	-	-	0.0006	308.0	0.003	Yes

Butyl diglycol

Task/ Scenario	Exposure mg/m3	EU OEL STEL mg/m3	Exposure/EU OEL STEL %	Exposure 8h TWA mg/m3	EU OEL 8h TWA mg/m3	Exposure 8h/EU OEL 8h TWA %	Acceptable Yes/no
1.2.1 Automated spraying	0.05	246.0	0.04941	0.00625	98	0.00926	Yes
1.2.2 Manual spraying	3.8	246.0	3.75494	3.8	98.0	5.63	Yes
2.2.2 Professional brushing	0.05056	246.0	0.04996	0.02528	98.0	0.0258	Yes
2.3.4 Professional cutting and sanding	0.0168	246.0	0.007	0.0126	98.0	0.010	Yes

Bytyl diglycol/butyloxitol

Task/ Scenario	Exposure mg/m3	EU OEL STEL mg/m3	Exposure/EU OEL STEL %	Exposure 8h TWA mg/m3	EU OEL 8h TWA mg/m3	Exposure 8h/EU OEL 8h TWA %	Acceptable Yes/no
1.2.1 Automated spraying	0.0045	101.2	0.00445	0.00056	67.5	0.00083	Yes
1.2.2 Manual spraying	0.342	101.2	0.33794	0.342	67.5	0.50667	Yes
2.2.2 Professional brushing	0.00455	101.2	0.0045	0.00228	67.5	0.00337	Yes
2.3.4 Professional cutting and sanding	0.0015	101.2	0.001	0.0011	67.5	0.014	Yes

Dermal exposure

Dipropylenglycol methyl ether

Task/ Scenario	Tier	Exposure mg/kg bw/day	DNEL dermal exposure mg/kg bw/day	Exposure SoC/DNEL %	Acceptable Yes/no

1.2.1 Automated spraying	1/Gloves	0.488	283	0.2	Yes
1.2.2 Manual spraying	3/Impermeable coveralls, new gloves	9.50	283	3.4	Yes
2.2.2 Professional brushing	1/None	0.1	283	0.03	Yes
2.3.4 Professional cutting and sanding	1/None	0.01	283	0.004	Yes

Butyl diglycol

Task/ Scenario	**Tier**	**Exposure mg/kg bw/day**	**DNEL dermal exposure mg/kg bw/day**	**Exposure SoC/DNEL %**	**Acceptable Yes/no**
1.2.1 Automated spraying	1/Gloves	10.19	83	12.3	Yes
1.2.2 Manual spraying	3/Impermeable coveralls, new gloves	6.31	83	7.6	Yes
2.2.2 Professional brushing	1/None	2.05	83	2.5	Yes
2.3.4 Professional cutting and sanding	1/None	0.21	83	0.25	Yes

Conclusion
The exposure from the SoCs compared to the European applied OELs and dermal derived no effect levels is very low even without the use of personal protective equipment in most of the scenarios (manual spraying calculations included PPE). No risk of the effects exists following the exposure from the substances of concern in TEKNOS BLUESTAIN PRIMERS.

Available toxicological data relating to a mixture
No toxicological test data is available on the mixture.

Other

Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of the co-formulant(s), please refer to section 3.6.4 of the confidential annex to the PAR. In summary, no non-active substances are considered to have ED properties or to have indications of potential endocrine disrupting properties for which their presence in TEKNOS BLUESTAIN PRIMERS should be publically available in the SPC (as described in footnote 4 of *CA-March21-Doc4.4. –Cof with ED indications –names*).

2.2.6.2 Exposure assessment

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

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

The products in metaSPC 1 and metaSPC 2 are ready-to-use. The highest in-use concentration during the treatment is 0.6% IPBC (meta-SPC 2). This max. concentration of IPBC is taken into account as a worst case concentration during primary exposure, and covers all products in the TEKNOS BLUESTAIN PRIMERS. The highest retention rate of the product in treated wood is 200 g/m^2 of 0.6 % IPBC or 400 g/m^2 of 0.3 % IPBC, therefore, the max. retention rate of IPBC is 1.2 g/m^2. This value is also considered the worst case value for potential secondary exposure upon contact with treated wood.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
Industrial			
1.1.1	Mixing and loading	Chronic primary exposure. Fully-automated transfer/pumping of product for automated spraying.	Industrial users
1.2.1	Application Automated spraying	Chronic primary exposure. Automated enclosed spraying.	Industrial users
1.2.2	Application Spray application	Chronic primary exposure. Loading and stirring the RTU product and applying it to wood using spray equipment.	Industrial/professional users
1.3	Post-application Cleaning of spray equipment	Chronic primary exposure. Cleaning manual spray equipment after use.	Industrial/professional users
Professionals			
2.1	Mixing and loading	Chronic primary exposure. Manual transfer of product from pack sizes > 20 litres to painting pot.	Professionals
2.2	Application Brushing and rolling	Chronic primary exposure. Stirring RTU product and applying it to wood using a brush.	Professionals
2.3.1	Post-application Washing out of a brush	Chronic primary exposure. Cleaning brush after application.	Professionals
2.3.2	Post-application Sawing and sanding wood	Chronic secondary exposure. Sawing and sanding surface treated wood.	Professionals
Non-professionals			
3.1	Sawing and sanding wood	Acute secondary exposure. Sawing and sanding surface of treated wood .	Non-professionals
3.2	Handling treated wood once dry	Acute secondary exposure. Non-professional (adult) handling treated wood after application of the product.	Non-professionals
General public			
4.1	Laundering professional work clothes	Acute intermediary secondary exposure. Contaminated work clothing is handled prior to mechanical laundering.	Professionals, non-professionals, General public
4.2	Touching freshly treated wood	Acute secondary exposure, incidental. Toddler touching freshly treated wood with subsequent mouthing of fingers.	General public (toddler)

4.3	Chewing off-cut of treated wood	Acute secondary exposure. Infant chews wood cut-off, which has been treated with wood preservative.	General public (infant)
4.4	Playing on playground structure outdoors and mouthing	Chronic secondary exposure. Infant playing and mouthing weathered structure outdoors. Child playing on treated playground structure outdoors.	General public (infant, child)
4.5	Inhalation volatilised residues	Chronic secondary exposure. Inhalation of volatilised residues from treated wood indoors (restricted to windows, exterior doors and roof structures).	Industrial users, Professionals, non-professionals,, General public (infant, toddler, child, adult)

Industrial exposure

Scenario 1.1 Fully-automated transfer/pumping of product for automated spraying

Description of Scenario 1.1.
TEKNOS BLUESTAIN PRIMERS family is a ready-to-use (RTU) product family and does not require mixing. HEEG Opinion no. 1 *On the use of available data and models for the assessment of the exposure of* operators during the loading of products into vessels or systems in industrial scale provides models for assessing exposure related to loading of the product into industrial systems. Loading of TEKNOS BLUESTAIN PRIMERS family in industrial settings is expected to by fully-automated transfer/pumping. Exposure during fully-automated transfer/pumping is expected to be associated with negligible or only accidental exposure (see HEEG Opinion no. 1, under Comments, p. 8). Consequently, exposure during this task is not considered.

Scenario 1.2.1 Automated enclosed spraying

Description of Scenario 1.2.1

Spray/deluge systems consist of longitudinal or transversal boxes that apply a preservative to the wood on a continuously moving convey or belt. Wood enters the spraying box that applies the preservative to the surface of the wood. Spray boxes are relatively contained. Splashguards surround the spraying boxes to eliminate any droplets of spray from the rest of the mill area. Droplets are large enough to prevent the respiration of preservative solution. Due to its contained nature, operator exposure is expected to be low, and mainly constitutes handling freshly sprayed wood. Although there is no generic model available for automated spraying, the professional dipping model is considered as a good approximation in assessing exposure. Deluge process are operated on a batch basis, assuming as a worst case one batch per day, with a duration of 60 minutes per event.
The Dipping Model 1 is used to assess exposure of industrial users and includes dipping wooden articles, mixing/loading, handling wet articles and loading/unloading (based on values as reported in Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure).
The scenario described in Recommendation no. 6 indicates a value for exposure to hands inside gloves, therefore tier 1 considers the use of gloves.
In tier 2 a 90% protection factor can be used for wearing coated coveralls according to HEEG opinion 9 (TM I, 2010), as contact with wet preserved wood is the main challenge.

	Parameters	Value
Tier 1	Indicative dermal exposure, hands inside gloves [1]	25.7 mg/min
	Indicative dermal exposure, body [1]	178 mg/min
	Indicative inhalation exposure [1]	< 1 mg/m^3
	Clothing penetration	100%
	Duration [1]	60 min
	Number of treatments [1]	1/day
	Dermal absorption, IPBC	50 %
Tier 2	Coated coveralls protection [2]	90%

[1] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types p. 22 (version 3, 2017).

[2] HEEG opinion 9 - Default protection factors for protective clothing and gloves (TM I, 2010).

Exposure calculations are included in Annex 3.2

Scenario 1.2.2. Stirring the RTU product and applying it to wood using spray equipment

Description of Scenario 1.2.2

TEKNOS BLUESTAIN PRIMERS can be applied via a manual spray system. Generally, such an application is done in a ventilated workstation, to apply the preservative to a finished article such as window frames or doors. The manual spraying will be done in an industrial setting indoor, and the spraying model used for professional users outside industry will be equally applicable to the use envisaged for the products from TEKNOS BLUESTAIN PRIMERS family. The equipment used by industrial and professional users is the same, more precisely: a spray gun/powered spray device around 4- 7 bar pressure. Spraying Model 2 is used as reported in Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.

The duration of the task for products from meta-SPC 2:AQUAPRIMER 2907-63 is 4h or a half working day, as use of these products is always followed by a topcoat layer (which will be applied once the basecoat is dry/during the second half of the day).
For products from meta-SPC 1: TEKNOCOMBI 2917-62, the exposure duration can be up to 8h or a full working day, as these products do not need a topcoat. The duration of 4/8 hours is a worst case scenario for the industrial user which is considered to cover also the professional use of the product family.

The scenario and calculations assumes a task duration of 4hours for products from meta-SPC 2: AQUAPRIMER 2907-63 (0.6% IPBC).

Mixing, loading and application are included in the Spraying Model 2.

	Parameters	Value
Tier 1	Active substance conc.	0.6 w/w %
	Indicative dermal exposure, hands [1]	273 mg/min
	Indicative dermal exposure, body [1]	222 mg/min
	Indicative inhalation exposure [1]	76 mg/m^3
	Duration	4 h
	Dermal absorption, IPBC	50 %
Tier 2	Coated coveralls protection [3]	90 %
	Dermal exposure, hands inside gloves [2]	4.68 mg/min
Tier 2	Impermeable coveralls protection [3]	95%
	RPE-filtering half mask protection [4]	90 %

[1] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types , p21
[2] Biocides Human Health Exposure Methodology Guidance, p 339: New gloves reduce hand-in-glove exposure by a factor of 0.6.
[3] HEEG Opinion no. 9 – Default protection factors for clothing and gloves (TM I, 2010)
[4] Biocides Human Health Exposure Methodology Guidance, p. 154, table A: Filtered half mask used reduces inhalation exposure to 10%

Scenario 1.3 Cleaning manual spray equipment

Description of Scenario 1.

Post-application exposure after application of wood preservative with spray equipment can occur while cleaning the spray equipment. For water-based formulations, the spray equipment is cleaned with water. Cleaning is carried out in many different ways depending on the equipment and personal preferences. The most appropriate available input values for this task is considered to be those referred to in Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure from the Delgado et al., 2004 study[1]. The cleaning process is performed at the end of each working day and a maximum duration is expected to be 20 min. and is therefore considered to be relevant for long term exposure. Exposure from inhalation is not considered relevant.		
	Parameters	Value
Tier 1	IPBC	0.6 % w/w
	Body weight	60 kg
	Indicative dermal exposure, hands (90% percentiles) [2]	35.87 µL/min.
	Indicative dermal exposure, body [2]	19.28 µL/min.
	Potential inhalation exposure [2]	Negligible
	Number of cleanings [2]	1/day
	Event exposure duration [2]	20 min.
	Product density [3]	1.23 at 20°C
	Dermal absorption, IPBC	50 %
Tier 2	Coated coveralls protection [4]	90 %
	Gloves protection [4]	90 %

[1] Delgado P., Porcel J., Abril I., Torres N., Teran A., Zugasti A. (2004) Potential Dermal Exposure during the painting Process in Car Body Repair Shops. Annals of Occupational Hygiene (2004) 48 (3): 229-236

[2] HEAdhoc Recommendation no. 4 -Cleaning of spray equipment in antifouling use (PT21)

[3] Product density for metaSPC2 is 1.2262 at 20°C and product density for metaSPC is 1.1975 at 20°C. The density for metaSPC2 is therefore worst case.

[4] HEEG Opinion no. 9 – Default protection factors for clothing and gloves (TM I, 2010)

Exposure calculations are included in Annex 3.2

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg)**	**Estimated dermal uptake (mg)**	**Estimated oral uptake (mg)**	**Estimated total uptake (mg)**
1.1.1 Fully automated transfer	1/none	-	-	-	Negligible
1.2.1 Automated spraying	1/gloves	0.008	36.666		36.674
	2/gloves + coated coveralls	0.008	7.830		7.838

1.2.2 Manual spraying	1/gloves	2.280	356.400		358.680
	2/gloves + coated coveralls + RPE	0.228	21.600		21.828
	3/ new gloves + impermeable coveralls + RPE	0.228	11.398		11.626
1.3 Cleaning og spraying equipment	1	-	4.070		4.070
	2/gloves + coated coveralls	-	0.407		0.407
	3/gloves + impermeable coveralls	-	0.336		0.336

Combined scenarios

Summary table: combined systemic exposure from industrial uses						
Scenarios combined	**Tier**	**Estimated inhalation uptake (mg)**	**Estimated dermal uptake (mg)**	**Estimated oral uptake (mg)**	**Estimated total uptake (mg)**	**Estimated total dose (mg/kg bw)**
1.2.2+1.3 Manual spraying + cleaning of spray equipment	3+3	0.228	11.7	-	11.93	0.2

Professional exposure

Scenario 2.1 Loading of product into a painting pot

Description of Scenario 2.1

TEKNOS BLUESTAIN PRIMERS family is a ready-to-use product family and does not require mixing, however it can be assumed that wood preservative will be transferred from the containers to painting pots, therefore exposure during transfer of the product from a container to a painting pot should be considered. HEAdhoc Recommendation no. 6 provides models for assessing such exposure. Loading of TEKNOS BLUESTAIN PRIMERS family in relation to professional use may be performed via automated-, semi-automated and manual transfer/pumping and is expected to be a relatively brief activity[1]. Both a manual and semi-automated transfer has been considered, but only the values from the semi-automated transfer has been included in the exposure estimate as this yielded the highest degree of exposure. The RISKOFDERM *Potential Dermal Exposure Model* calculator was used to estimate semi-automated exposure to the product (process for assessment: Filling, mixing or loading; level of automation: Automated or semi-automated task) for the semi-automated pouring, and assuming negligible inhalation exposure. The model does not estimate body exposure. Assuming a daily exposure duration of 10 minutes and a product transfer rate of 10 L/min as a worst-case (giving a daily transfer of 100 L product), a hand exposure of 13 mg/min was calculated. For the manual pouring step, the Mixing and loading Model 4 for liquids, TNsG 2002 user guidance was applied. Please refer to the output tables in Annex 3.2 for the manual transfer exposure calculation.

	Parameter	**Value**
Tier 1	Dermal exposure, hands (90% percentiles) [2]	13 mg/min
	Indicative dermal exposure, body [2]	No exposure foreseen
	Indicative inhalation exposure [2]	Negligible; normal or good ventilation
	Exposure duration [2]	10 min
	Transfer rate of product [2]	10 L/min (as a worst case)
	Body weight, adult [3]	60 kg
	Dermal absorption, IPBC	50 %

[1] Please find in R4BP-3 under the case applicant's answer to request for additional information dated 30th of October on use of manual transfer

[2] RISKOFDERM Dermal Model Loading liquid, automated or semi-automated.

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

Exposure calculatinos are included in Annex 3.2

Scenario 2.2 Stirring the RTU product and applying it to wood using a brush

Description of Scenario 2.2

The professional user stirs and applies wood preservative to wood using a brush indoors or outdoors. The model "Professional brush treatment" based on Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenshaft, 2006 is used for estimation of dermal and inhalatory exposure as recommended in Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, no 23, p20 (version 3, 2017). Input values is further noted in the recommendation as application area 31.6 m^2 according to TNsG 2002 "Consumer product painting Model 3" with an exposure duration of 240 min. and a median work (application) rate at 7.6 min./m^3. The indicative values are normalized to 1 % active substance and refers to the exposure when brushing an area of 1 m^2 according to the abovementioned Summary Report. It can be derived that at product level, a value of 0.5417 mg/m^2 needs to be used to calculate exposure to hands, and 0.2382 mg/m^2 for exposure to the body. Similarly, an inhalation exposure of 0.0016 mg/m^2 can be used at product level.

	Parameters	Value
Tier 1	Indicative dermal exposure, hands [1]	0.5417 mg/m^2
	Indicative dermal exposure, body [1]	0.2382 mg/m^2
	Indicative inhalation exposure [1]	0.0016 mg/m^2
	Treated surface[1]	31.6m^2
	Duration [1]	240 min
	Body weight, adult [3]	60 kg
	Dermal absorption, IPBC	50 %

[1] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types (version 3, 2017).

[2] HEEG opinion 9 - Default protection factors for protective clothing and gloves (TM I, 2010).

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

Exposure calculatinos are included in Annex 3.2

Scenario 2.3.1. Cleaning brush after application

Description of Scenario 2.3.1

A post-application task which may lead to some degree of exposure is cleaning the brush used to apply the product. Brush cleaning by professionals can be expected to last for no more than 15 minutes and might result in some exposure to hands. A water-based formulation might be removed by washing the brush under a water stream, a process that would result in negligible dermal exposure. Thus, as discussed at WGIII2017, inclusion of a brush washing scenario may not be warranted for water-based products. However, in order to assess the contribution of an eventual brush-washing phase to exposure, exposure of professionals to the product is assessed using the *General Exposure Calculator for Washing out Of Brushes* of the annex to HEEG Opinion 11. It is considered a worst-case scenario as it is normally intended for non-water-based paints and does not involve cleaning under a stream of water.

Cleaning a brush used for water-based formulations may be done by repeated dipping and swaying it in a vessel containing clean water. In HEEG Opinion 11 (TM III, 2010), a large size brush with the dimensions 10 cm x 10 cm x 2 cm (200 mL) is used for calculation. The brush is assumed to be cleaned (dipped and swayed) three times, using fresh water on each occasion (step). The volume of water should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 mL, the required water volume would be at least 400 mL per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush. After each step the brush is assumed to be squeezed by hand to remove as much liquid as possible. It is assumed that with each step 50% of the solution in the brush is released and may potentially contaminate the hand. It is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which may absorb ~ 90% of the released liquid. Washing and squeezing may each be done a maximum of three times. During brush cleaning, professionals may retain gloves worn during brush application of the product (Tier 2 assessment). No exposure of areas of the body other than the hands is assumed to occur; and exposure via inhalation is considered negligible.

	Parameters[1]	Value
Tier 1	Volume of product on hands [1]	25 mL
	Volume of product removed by running water [1]	90%
	Number of treatments [1]	1/day
	Initial weight of the product on the brush	30.75 g
	Body weight, adult [3]	60 kg
	Dermal absorption, IPBC	50 %

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

Exposure calculatinos are included in Annex 3.2

Scenario 2.3.2 Sawing and sanding surface treated wood by a professional user

Description of Scenario 2.3.2

Cutting and sanding treated wood by professionals is considered a chronic exposure scenario as this is a daily activity. The highest end retention is the application rate of 200 g product/m^2 for the 0.6 % active substance concentration (the effective volume for prevention of wood discolouring fungal effects). Exposure data used in this scenario is derived from exposure studies conducted with amateurs without the use of gloves and presented in TNsG 2002 User Guidance -Version 1. Professionals are very likely to wear gloves, and the exposure is therefore considered an overestimation. The sanding scenario values from the abovementioned studies is further extrapolated from acute settings of one-hour duration to chronic settings for the professional user by assuming that exposure time is six hours.

The active substance is fixed in the outer 1cm layer of a treated wooden post (4 x 4 x 250 cm). The concentration of the active substances (AS) in the wood is calculated as follows:

Application rate product (g/m^2) x AS in product (%) x retention in wood (%) x layer thickness (cm)
The amount of active substances present in the treated wood will then be:
Volume wooden post (cm^3) x conc. AS in wood (mg/cm^3) / treated volume wooden post (cm^3)

Conc. AS. in wood
200 g/m^2 x 0.6% IPBC x 100 % x 1 cm =1.2 g/m^2 equal to 0.12 mg/cm^2

Con. A.s. in treated outer 1 cm
4000 cm^3 x 0.12 mg IPBC/cm^3 / 3008 cm^3 = 0.16 mg/cm^3

Dermal exposure is based on the surface area exposed (both hand palms), the percentage of this area that is affected by contamination and a transfer coefficient for painted wood using the following formula:
Conc. AS x exposed surface area (cm^2) x contaminated surface (%) x transfer efficiency (%)

To assess exposure by inhalation it is assumed that the concentration of wood dust would not exceed the occupational exposure limits for dust at the workplace. The Operator Exposure Limit (OEL) of the EU for respirable hardwood dust is used as worst-case. professional uses the task duration is six hours and a wood density of 0.40 g/cm^3 is assumed.

	Parameters	Value
Tier 1	Application rate product	200 g/m^2 (20.0 mg/cm^2)
	Layer thickness (product in wood) [1]	1 cm
	Volume wooden post [1]	4000 cm^3
	Exposed surface area (2 hand palms) [2]	410 cm^2
	Transfer efficiency from painted wood [3]	3%
	Wood dust in the air (OEL) [1]	5 mg/m^3
	Duration [4]	6 hours
	Density of wood dust [5]	0.40 g/cm^3

[1] TNsG, Part 3 (2002), p. 50
[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).

[3] Biocides Human Health Exposure Methodology Guidance, p. 171, table: Transfer coefficients –Disledgeable residues
[4] TNsG, Part 3 (2002), p. 37
[5] Technical Agreement for Biocides, 2017

Exposure calculatinos are included in Annex 3.2

Calculations for scenario 2.1, 2.2, 2.3.1 and 2.3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg)**	**Estimated dermal uptake (mg)**	**Estimated oral uptake (mg)**	**Estimated total uptake (mg)**
2.1 Semi-automated transfer	1/none	-	0.405	-	0.405
2.2 Brush application	1/none	0.03	7.393	-	7.424
2.3.1 Cleaning brush	1/none	-	0.466	-	0.466
2.3.2 Cutting and sanding wood	1/none	0.015	0.74		0.753

Combined scenarios

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg)**	**Estimated dermal uptake (mg)**	**Estimated oral uptake (mg)**	**Estimated total uptake (mg)**
2.1+2.2+2.3.1+2.3.2 All scenarios combined	0.045	9.002	-	9.047

Non-professional exposure

Scenario 3.1. Sawing and sanding surface-treated wood by the non-professional user

Description of Scenario 3.1

Cutting and sanding treated wood by the non-professional user (from the general public) is considered an acute exposure scenario as non-professionals are not likely to perform this task frequently. The highest end retention is the application rate of 200 g product/m^2 (the effective volume for prevention of wood discolouring fungal effects). This value is considered worst case for this scenario. Exposure data used in this scenario is derived from exposure studies conducted with amateurs without the use of gloves and presented in TNsG 2002 User Guidance -Version 1. Exposure duration is one hour. The active substances are fixed in the outer 1cm layer of a treated wooden post (4 x 4 x 250 cm). The concentration of the active substances (AS) in the wood is calculated as follows:

Application rate product (g/m^2) x AS in product (%) x retention in wood (%) x layer thickness (cm)

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

Dermal exposure is based on the surface area exposed (both hand palms), the percentage of this area that is affected by contamination and a transfer coefficient for rough-sawn wood, using the following formula:
Conc. AS x exposed surface area (cm^2) x contaminated surface (%) x transfer efficiency (%)

To assess exposure by inhalation it is assumed that the concentration of wood dust would not exceed the occupational exposure limits for dust at the workplace. The Operator Exposure Limit (OEL) of the EU for respirable hardwood dust is used as worst-case. For non-professional uses the task duration is one hour and a wood density of 0.40 g/cm^3 is assumed.

	Parameters	Value
Tier 1	Application rate product	200 g/m^2 (20.0 mg/cm^2)
	Layer thickness (product in wood) [1]	1 cm
	Volume wooden post [1]	4000 cm^3
	Exposed surface area (2 hand palms) [2]	410 cm^2
	Transfer efficiency from wood [3]	3%
	Wood dust in the air (OEL) [1]	5 mg/m^3
	Duration [1]	1 hour
	Density of wood dust [4]	0.40 g/cm^3

[1] TNsG, Part 3 (2002), p. 50
[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).
[3] Biocides Human Health Exposure Methodology Guidance, p. 171, table: Transfer coefficients –Disledgeable residues
[4] TNsG, Part 3 (2002), p. 37
[5] Technical Agreement for Biocides, 2017

Exposure calculatinos are included in Annex 3.2

Scenario 3.2. Handling of treated wood by the non-professional user

Description of Scenario 3.2		
Although the product is not intended for use by non-professionals it is possible that a non-professional may handle treated wood if purchasing treated wood items such as windows, doors etc. The wood-preservative is assumed to be completely dry at the time of handling/contact. The number of exposure (handling) cycles has been set to 3. Exposure via inhalation is considered negligible.		
	Parameters	Value
Tier 1	Concentration of IPBC on the wood surface [1]	0.12 mg/cm^2
	Application rate product	200 g/m^2
	Layer thickness (product in wood) [1]	1 cm
	Exposed surface area (palms of two hands) [2]	410 cm^2
	Body weight, adult [2]	60 kg
	Percent dislodgeable painted wood [3]	3%
	Dermal absorption, IPBC	50 %
	Handling cycles	3

[1] See scenario 2.3.4.
[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).
[3] Biocides Human Health Exposure Methodology Guidance, p. 171, table: Transfer coefficients –Disledgeable residues

Exposure calculatinos are included in Annex 3.2

Calculations for Scenario 3.1 and 3.2

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg)**	**Estimated dermal uptake (mg)**	**Estimated oral uptake (mg)**	**Estimated total uptake (mg)**
3.1 Cutting and sanding wood	1/none	0.003	0.740	-	0.741
3.2 Handling treated wood	1/none	-	2.21	-	2.21

Combined scenarios

Summary table: combined systemic exposure from non-professional uses

Scenarios combined (tier)	Tier	Estimated inhalation uptake (mg)	Estimated dermal uptake (mg)	Estimated oral uptake (mg)	Estimated total uptake (mg)	Estimated total dose (mg/kg bw)
3.1+3.2 Sanding and handling wood	1	0.003	2.952	-	2.955	0.0492

Exposure of the general public

Scenario 4.1. Laundering of work clothes

Description of Scenario 4.1		
Exposure to TEKNOS BLUESTAIN PRIMERS family may occur when laundering contaminated work clothing. Persons at risk are adults (professionals and the general public). The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. Laundering is assumed to occur mechanically. The only likely exposure is during handling of the contaminated clothing while preparing it for laundry. Exposure is restricted to the hands and is dependent on the area and concentration of dislodgeable residues on the surface of the clothing and the transfer coefficient to skin. It is assumed that the clothing to be washed is a coverall worn by a professional, that the coverall is washed after one working week (corresponding to five working days), and that the total residue accumulated during this time is equivalent to 5-times the daily contamination associated with application by brushing following the exposure scenario 2.2. The contamination of the coveralls is based on the type from which the tiers in the aforementioned scenario show safe use. The mixing and loading step contamination of clothes is considered negligible and is not included. The sum transfer area is determined by estimating how many times the coverall is touched by the hands while preparing it for laundering. It is assumed that this happens three times, twice with the palms of both hands and once with the total hands surface, the sum transfer area is 1640 cm^2. As a worst-case assumption, 20% of the residues in the touched area is transferred to the skin (transfer coefficient).		
	Parameter	**Value**
Tier 1	Clothing contamination from manual spraying [1]	303.7 mg a.s./day (impermeable coveralls)
	Days before washing	5 days
	Percentage dislodgeable (transfer coefficient) [2]	20%
	Surface of medium impermeable coverall [3]	22700 cm^2
	Sum transfer area [4]	1640 cm^2

[1] Clothing contamination equals the highest potential body exposure (scenario 1.2.2.) minus the amount that penetrates through the clothing (5 % tier 3) and is expressed as mg a.s./day.

[2] Biocides Human Health Exposure Methodology 2015, p. 17 -Table: *Transfer coefficients – Dislodgeable residues,* dried fluid cotton, knitwear, plastic dry hand
[3] CAR Propiconazole (FI CA, 2007).
[4] HEAdhoc Recommendation no. 14 - Default human factors values for use in exposure assessment for biocidal products -Based on a surface area of both palms of 410 cm2 and total surface of both hands of 820 cm^2

Exposure calculatinos are included in Annex 3.2

Scenario 4.2. Toddler touching freshly treated wood

Description of Scenario 4.2		
Although it is expected that organizational measures are in place when professionals apply wood preservatives, it is possible that a toddler or child may come into contact with wood preservative being applied by professionals, e.g. when applying wood preservatives to public fences etc. Contact with freshly-treated surfaces is assumed to be of short duration, as parents/guardians will remove the product from the toddler's or child's hands as soon as the incident is observed. This scenario is therefore only included in exposure evaluation for consideration of a worst-case scenario. Harmonised input values are given in HEAdhoc Recommendation no. 5. It is assumed that 100% of the palms of both hands is exposed. The transfer coefficient (from freshly treated wood to hands) is set to 50%. All of the material on the palms of both hands is considered available for mouthing; the amount ingested is set to 10%, constituting the area of two fingers. The toddler is used as a risk envelope for all relevant child groups; the scenario is not considered relevant for infants.		
	Parameter	**Value**
Tier 1	Concentration of a.s. on the wood surface [1]	0.12 mg/cm^2
	Toddler hand surface (palm)[2]	115.2 cm^2
	Hand area contaminated[3]	100 %
	Transfer coefficient, wet paint [3]	50 %
	Transferable fraction to mouth [3]	10 %
	Body weight, toddler [2]	10 kg
	Dermal absorption, IPBC	50%
	Oral absorption, IPBC	100 %

[1] See scenario 2.3.4.
[2] HEAdhoc Recommendation no. 14- Default human factors values for use in exposure assessment for biocidal products.
[3] HEAdhoc Recommendation no. 5 - Non-professional use of antifouling paints: exposure assessment for a toddler.

Exposure calculatinos are included in Annex 3.2

Scenario 4.3. Infant chewing off-cut of treated wood

Description of Scenario 4.3

Secondary exposure can occur if an infant chews a piece of treated wood. This scenario is considered an acute scenario. In accordance with scenario 2.3.4 and 3.1 for sanding of treated wood, it is assumed that the active substances are bound to the outer 1 cm of the wood and that this part is accessible for infants chewing. It is assumed that an infant chews a 4x4x1cm piece of wood chip and in doing so releases 10% of the active substances according to TNsG User guidance, version 1, 2002. The TnsG further regards the scenario unrealistic for children as opposed to infants, as they are unlikely to chew treated wood. Dermal exposure is not considered.		
	Parameters	Value
Tier 1	Application rate product	200 g/m^2
	Volume off-cut from treated wood [1]	16 cm^3
	Conc. active substances in treated wood *see scenario 2.3.4 for details on calculations*	0.16 mg/cm^2 IPBC
	Extraction substance from wood by chewing [1]	10%
	Oral absorption, IPBC	100 %
	Body weight, infant [2]	8 kg

[1] TNsG, Part 3 (2002).
[3] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).

Exposure calculatinos are included in Annex 3.2
Exposure calculatinos are included in Annex 3.2

Scenario 4.4. Playing on playground structure and mouthing

Description of Scenario 4.4		
Chronic exposure to infants and toddlers can occur from playing on and mouthing weathered playing structures. Likewise, chronic exposure can occur for children playing on weathered structures. The exposure settings are based on TNsG 2002 User guidance – Version 1 and TNsG 2002, part III and implements that during play on timber structures, infants, toddlers, and children are exposed dermally and orally (via hand-to-mouth transfer route). Dermal exposure is based on the hand surface area exposed, the percentage of this area that is affected by contamination and a transfer coefficient for painted wood, using the following formula: *Conc. AS x exposed surface area (cm^2) x contaminated surface (%) x transfer efficiency (%)* For oral exposure 50% hand-to-mouth transfer is assumed (external dermal exposure = external oral exposure). Only infant exposure has been calculated and is considered to act as a risk envelope for the other age populations.		
	Parameters	Value
Tier 1	Application rate product	200 g/m^2

	Conc. active substances on treated surface [1] *see scenario 2.3.4 for details on calculations*	0.16 mg/cm^2 IPBC
	Infant hand surface (palms) [2]	98.4 cm^2
	Hand area contaminated [3]	40 %
	Transfer efficiency from wood [4]	2%

[1] TNsG User Guidance version 1 (2002)
[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)
[3] HEAdhoc Recommendation no. 5, Non-professional use of antifouling paints: exposure assessment for a toddler, 40 % transfer coefficient for hand to dry paint.
[4] Biocides Human Health Exposure Methodology Guidance, p. 171, table: Transfer coefficients –Disledgeable residues

Scenario 4.5. Inhalation of volatilised residues

Description of Scenario 5
Long-term exposure to volatilised residues can be neglected if the following Tier 1 screening tool is ≤ 1 (HEEG Opinion 13; endorsed TM IV, 2011, amended TM III, 2013): $0.328 \times {}^{molecular\ weight \times vapour\ pressure} / _{AEL\ long\text{-}term} \leq 1$ Since this is not the case for IPBC (value of >2 is obtained), further assessment with regards to long-term inhalation exposure to volatilised residues is considered. Henry's law can be used to approximate the partitioning of substances between the liquid phase and the atmosphere: $C_{air}/C_{liquid} = kH/RT$ (see parameters in table below), or: $C_{air} = kH/RT * C_{liquid}$ Systemic inhalatory exposure of adults is calculated by correcting the concentration in air for the daily respiratory rate and adult body weight. Chronic exposure to wood preservatives may arise from the interior surfaces of exterior window frames and and exterior doors (including their frames) treated with a wood preservative. As a worst case, inhalation exposure was taken as 100% of the saturated vapour pressure/concentration (SVC) according to HEEG opinion 13[1]. SVC = (vp (Pa) x mw (g/mol)) / (8.31 (gas constant, J/mol.K) x T (K)) The calculation is highly conservative and is designed as a screening tool for identifying a risk. Preserved window frames or joists are required to be coated and hence the wood preservative is sealed and cannot evaporate. Furthermore the vapour pressure of IPBC is in general considered to be low (<0.5 kPa). The tier 2 exposure calculations were performed in ConsExpo based on default input values obtained from ConsExpo factsheets as well as information on the composition of the product familiy. For details on the exposure calculations please refer to Appendix 3.2.

	Parameters	Value

Tier 1	Saturated vapour concentration, IPBC		
	Molecular weight [1]		281.1 (g/mol)
	Vapour pressure [1]		4.5 x 10^{-3} Pa at 25°C
	Henry's law constant (H) [2]		6.45 x 10^{-3} Pa*m^3/mol
	Ideal gas constant (R) [2]		8.315 J/K mol
	Temperature (T) [2]		298 K (25°C)
	Concentration in liquid		0.60%
	Adult	Body weight [3]	60 kg
		Inhalation rate	16 m^3/day
	Child	Body weight	23.9 kg
		Inhalation rate	12 m^3/day
	Toddler	Body weight	10 kg
		Inhalation rate	8 m^3/day
	Infant	Body weight	8 kg
		Inhalation rate	5.4 m^3/day
Tier 2	Cons-Expo		
	Model [4]		Exposure to vapour - evaporation
	Room size [5]		20 m^3
	Ventilation rate [5]		0.6/h
	Molecular weight matrix [6]		45
	Exposure duration [4]		Set to 1 day
	Emission duration [4]		Set to 1 day
	Mass transfer [4]		Langmuir
	Release area		4 m^2
	Product amount		4 m^2 x application rate 200 g/m^2

[1] Assessment Report IPBC (2008)
[2] HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocide active substance
[3] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)
[4] ConsExpo model documentation https://www.rivm.nl/bibliotheek/rapporten/2017-0197.pdf#page=35
[5] ConsExpo General Fact sheets, https://www.rivm.nl/bibliotheek/rapporten/090013003.pdf
[6] ConsExpo Paint Product Fact Sheets, https://www.rivm.nl/bibliotheek/rapporten/320104008.pdf
[7] Release area is an estimation of worst case painted surfaces following the intended uses. TEKNOS BLUESTAIN PRIMERS family is subject to iónly be used for wood structures outside, aside from the use on outside doors and windows. 4 m^2 seems reasonable.

Calculations for Scenario 4.1, 4.2, 4.3, 4.4 and 4.5

Summary table: systemic exposure from non-professional uses						
Exposure scenario	**Tier/PPE**		**Estimated inhalation uptake (mg)**	**Estimated dermal uptake (mg)**	**Estimated oral uptake (mg)**	**Estimated total uptake (mg)**
4.1 Laundry Manual spraying	Adult/Impermeable coveralls 1		Negligible	10.97	Not relevant	10.97
4.2 Toddler touching and mouthing freshly treated wood	Toddler		Negligible	3.456	0.691	4.15
4.3 Infant chewing on wood cut off	Infant		Negligible	Negligible	0.192	0.19
4.4 Infant playing and mouthing on weathered play structures	Infant		Negligible	0.071	0.071	0.142
4.5 Inhalation of volatilised residues	Adult	1	8.17	Not relevant	Not relevant	8.17
		2	0.078	Not relevant	Not relevant	0.078
	Child	1	6.13	Not relevant	Not relevant	6.13
		2	0.01	Not relevant	Not relevant	0.01
	Toddler	1	4.09	Not relevant	Not relevant	4.09
		2	0.0039	Not relevant	Not relevant	0.0039
	Infant	1	2.76	Not relevant	Not relevant	2.76
		2	0.0026	Not relevant	Not relevant	0.0026

Combined scenarios

Summary table: combined systemic exposure for general public					
Scenarios combined	**Estimated inhalation uptake** (mg)	**Estimated dermal uptake** (mg)	**Estimated oral uptake** (mg)	**Estimated total uptake** (mg)	**Estimated total uptake** (mg/kg bw/d)
4.4+4.5 Infant playing and mouthing + inhalation long-term	0.00265	0.071	0.071	0.144	0.018

Monitoring data

No information on surveys or studies with the actual biocidal product or with a comparable product was submitted.

Dietary exposure

Exposure to food, drinking water or livestock can be excluded when the product is applied according to the recommended uses. Additionally the RMM's 'Do not use on wood that will come in direct contact with food or animal feed' and 'The biocidal product shall not be used for treatment of wood which is intended for contact with food, feed or livestock' should be applied to exclude contact with food and feedstuff.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Cosmetics	Preservative	Daily-recommended dose in Europe 150 µg/d (with an upper short term limit of 1000 µg/d) [1]

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

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Impregnated wood must not come in contact with food or feedstuffs. The RMM's 'Do not use on wood that will come in direct contact with food or animal feed' and 'The biocidal product shall not be used for treatment of wood which is intended for contact with food, feed or livestock' should be applied.

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

Impregnated wood must not come in contact with food or feedstuffs. The RMM's 'Do not use on wood that will come in direct contact with food or animal feed' and 'The biocidal product shall not be used for treatment of wood which is intended for contact with food, feed or livestock' should be applied.

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

TEKNOS BLUESTAIN PRIMER family is not intended for non-professional use. The RMM 'Do not use on wood that will come in direct contact with food or animal feed' and 'The biocidal product shall not be used for treatment of wood which is intended for contact with food, feed or livestock' should ensure that treated wood is not for use for direct contact to food.

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

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

Aggregated exposure

There is insufficient data available on exposure to the active substance other than originiating from the treated wood to conduct an assessment of aggregated exposure.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw)**
1.1.1 Fully automated transfer	Industrial users	1/none	-
1.2.1 Automated spraying	Industrial users	1/gloves	0.611
		2/gloves + coated coveralls	0.131
1.2.2 Manual spraying	Industrial/professional users	1/gloves	5.978
		2/gloves + coated coveralls + RPE	0.364
		3/new gloves + impermeable coveralls + RPE	0.194
1.3 Cleaning spraying equipment	Industrial/professional users	1/gloves	0.068
		2/gloves + coated coveralls	0.007
		3/gloves + impermeable coveralls	0.006
2.1 Semi-automatic transfer	Professionals	1/none	0.007
2.2 Brush application	Professionals	1/none	0.124
2.3.1 Cleaning brush	Professionals	1/none	0.008

2.3.2 Cutting and sanding wood	Professionals	1/none	0.013
3.1 Cutting and sanding wood	Non-professionals	1/none	0.012
3.2 Handling treated wood	Non-professionals	1/none	0.037
4.1 Laundry Manual spraying	Professionals, non-professionals, General public	1/Impermeable coveralls	0.183
4.2 Toddler touching and mouthing freshly treated wood	General public, toddler	1/none	0.415
4.3 Infant chewing on wood cut off	General public, infant	1/none	0.024
4.4 Infant playing and mouthing on weathered play structures	General public, infant	1/none	0.018
4.5 Inhalation of volatilised residues	General public, adult	1/SVC	0.136
		2/ConsExpo	0.0001
	General public, child	1/SVC	0.256
		2/ConsExpo	0.00025
	General public, toddler	1/SVC	0.409
		2/ConsExpo	0.0004
	General public, infant	1/SVC	0.344
		2/ConsExpo	0.00033

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value (AEL)
AELshort-term	90-day gavage rat	NOAEL : 35 mg/kg/d	100	No correction – oral abs. close to 100%	0.35 mg/kg/d
AELlong-term	2-years rat study	NOAEL : 20 mg/kg/d	100	No correction – oral abs. close to 100%	0.20 mg/kg/d

[1] IPBC Assessment Report PT8 (DK)

Maximum residue limits or equivalent
Impregnated wood must not come in contact with food or feedstuffs, no MRL is therefore defined.

Specific reference value for groundwater
No specific reference value for groundwater was established. Therefore, the European standard value of 0.1 µg/L for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC) applies.

Risk for industrial users

Systemic effects

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)
1.1.1 Fully automated transfer	1/none	20	0.2	-	-	Yes
1.2.1 Automated spraying	1/gloves	20	0.2	0.611	305.6	**No**
	2/gloves + coated coveralls	20	0.2	0.131	65.3	Yes
1.2.2 Manual spraying	1/gloves	20	0.2	5.978	2989.0	**No**
	2/gloves + coated coveralls + RPE	20	0.2	0.364	181.9	**No**
	3/new gloves + impermeable coveralls + RPE	20	0.2	0.194	96.9	Yes
1.3 Cleaning spraying equipment	1/gloves	20	0.2	0.068	33.9	Yes
	2/gloves + coated coveralls	20	0.2	0.007	3.4	Yes

	3/gloves + impermeable coveralls	20	0.2	0.006	2.8	Yes

Combined scenarios

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)
1.2.2+1.3 Manual spraying and cleaning equipment	3+3/gloves+ impermeable coveralls	20	0.2	0.199	99.4	Yes

Local effects

No metaSPCs are classified for local effects. No risk assessment is warranted.

Conclusion

A safe used was demonstrated when applying the biocidal product family by automated spraying when wearing chemical resistant gloves and coated coveralls as personal protective equipment. Including the RMMs 'Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)' and 'A protective coverall (at least type 6, EN 13034) shall be worn' in the SPC is considered to ensure a safe use when applying the product family by automated spraying.

A safe use was demonstrated when applying the biocidal product family by manual spraying when wearing chemical resistant gloves, impermeable coveralls and a half filtering mask providing a reduction in inhaled particles by a factor 10. A safe use was demonstrated when wearing chemical resistant gloves and impermeable coveralls during cleaning of the spray equipment. The RMMs 'Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)', 'A protective coverall (at least type 4, EN 14605) shall be worn' and 'Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information)' in the SPC is considered to ensure a safe use when applying the product family by manual spraying.

Risk for professional users

Systemic effects

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)
2.1 Semi-	1/none	20	0.2	0.007	3.4	Yes

automatic transfer						
2.2 Brush application	1/none	20	0.2	0.124	61.9	Yes
2.3.1 Cleaning brush	1/none	20	0.2	0.008	3.9	Yes
2.3.2 Cutting and sanding wood	1/none	20	0.2	0.013	6.3	Yes

Combined scenarios

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)
All professional scenarios combined	1/none	20	0.2	0.151	75.4	Yes

Local effects

No metaSPCs are classified for local effects. No risk assessment is warranted.

Conclusion

A safe use was demonstrated when applying the product by brushing/rolling without the use of personal protective equipment. A safe use was also demonstrated when applying the product family by manual spraying (assessed in scenario 1.2.2 in section for industrial users)

Risk for non-professional users

Systemic effects

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)
3.1 Cutting and sanding wood	1/none	35	0.35	0.012	3.5	Yes
3.2 Handling treated wood	1/none	35	0.35	0.037	10.5	Yes

Combined scenarios

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)
3.1+3.2 Cutting/sanding and handling treated wood	1/none	35	0.35	0.0492	14.1	Yes

Local effects
No metaSPCs are classified for local effects. No risk assessment is warranted.

Conclusion
A safe use was demonstrated for the non-professional user, when cutting/sanding and/or handling treated wood when dried.

Risk for the general public

Systemic effects

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)
4.1 Laundry manual spraying	1	35	0.35	0.182	52.2	Yes
4.2 Toddler touching and mouthing freshly treated wood	1/toddler	35	0.35	0.415	118.5	**No**
4.3 Infant chewing on wood cut off	1/infant	35	0.35	0.024	6.9	Yes
4.4 Infant playing and mouthing on weathered play structures	1/infant	20	0.2	0.018	8.9	Yes
4.5 Inhalation of volatilised residues	1/adult	20	0.2	0.136	68.1	Yes
	1/adult	20	0.2	0.0001	0.07	Yes
	1/child	20	0.2	0.256	128.2	**No**
	1/child	20	0.2	0.00025	0.12	Yes
	1/toddler	20	0.2	0.409	204.3	**No**
	1/toddler	20	0.2	0.0004	0.2	Yes
	1/infant	20	0.2	0.344	172.4	**No**
	1/infant	20	0.2	0.00033	0.17	Yes

Combined scenarios

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)
4.4+4.5 Infant playing/mouthing +inhalation of volatilised residues	1+2/none	20	0.2	0.018	9.0	Yes

Local effects
No metaSPCs are classified for local effects. No risk assessment is warranted.

Conclusion
A safe use was identified when laundering work clothes used for manual spraying (impermeable coveralls) after using wearing the coveralls for five working days.

A risk was identified in the event that a toddler touches and mouths a piece of freshly treated wood. Including the sentence 'Keep children and pets away from treated wood during application and drying' in the general section for risk mitigation measures is considered to ensure that the situation is avoided.

No risk was identified for infants when chewing/mouthing a piece of treated dry wood as well as no risk was identified for infants when chronically exposed from contact to outdoor treated wood structures as well. Similarly, no risk was identified for all age groups when chronically exposed to residues available for inhalation.

Risk for consumers via residues in food
Impregnated wood must not come in contact with food or feedstuffs, residue in food is not applicable. Including the sentences 'Do not use on wood which may come in direct contact with food feeding stuff and livestock animals' and 'The biocidal product shall not be used for treatment of wood which is intended for contact with food, feed or livestock' is considered to ensure that consumers are not exposed to residues in food.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product
The substances of concern in TEKNOS BLUESTAIN PRIMERS and the active substance IPBC are not subject to a combined systemic risk assessment, as the effects triggered by the substances of concern are local and/or not additive to those of IPBC.

2.2.7 Risk assessment for animal health

Methodology for exposure to companion animals is not available. Safe use for human exposure has been demonstrated and is considered to cover exposure from treated articles to companion animals. the sentence 'Keep children and pets away from treated wood during application and drying' in the general section for risk mitigation measures is considered to ensure that animals are not expososed while applying the products of the biocidal product family.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The products from TEKNOS BLUESTAIN PRIMERS family contains 1 active substance, IPBC. The PNEC values for IPBC were taken from the Assessment Report for active substance IPBC in PT8 products.

$PNEC_{water}$: 0.0005 mg/L
$PNEC_{STP}$: 0.44 mg/L

$PNEC_{soil}$: 0.005 mg/kg wet soil

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

IPBC degrades to PBC and iodine species within 4 hours. PBC was identified as a relevant metabolite of IPBC in water, sediment and soil, because it was found in degradation studies at above the limit value of 10%. Due to a relative short half-life of PBC (DT50 of 31.2; 31.4 and 9.5 days at 12°C in water, sediment and soil, respectively) PBC can be regarded as a transient metabolite. In addition, the ecotoxicity of PBC is a factor of 300 – 1000 lower for fish, invertebrates and algae compared to IPBC. For completeness, this compound is taken up in the risk assessment.

In addition, iodine can be transformed to 100% iodate (IO3-) and 100% iodide (I-) in aquatic environments. Iodide formation or occurrence in soils is less likely. At TMII-2012 it was therefore agreed that only 14% of iodine is transformed into iodide for the soil compartment, for iodate, 100% transformation is taken into account.
At WG-V-2016 is was agreed that PEC/PNEC ratios above 1 can be accepted as long as the corresponding PEC values is within the natural background concentration (TAB entry ENV 8). Therefore, the PECs for iodine, iodide and iodate have been compared to typical background levels for each environmental compartment rather than to PNECs. According to the AR for Iodine, this is justified as "*the PNEC values may be regarded as truly worst case and not realistic as indicators of the toxicity of iodine in the form it is present in the environment.*" (AR for Iodine in PT 1, 3, 4 and 22, p. 43).

The PNEC values for PBC were taken from the Assessment Report for IPBC- PT13 (2015):

$PNEC_{water}$: 0.0413 mg/L
$PNEC_{STP}$: 0.44 mg/L (worst case same as IPBC)
$PNEC_{soil}$: 0.149 mg/kg wet soil

For iodine, iodide and iodate, background concentrations found in environment were taken as (taken from the AR for iodine in PT 1, 3, 4 and 22):

Water: 0.5- 20 µg/L
Soil: 0.4 -18 mg/kg wwt (0.5-20 mg/kg dwt)
Sediment: 6 mg/kg wwt
Groundwater: 1-70 µg/L

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

No new data available. The classification of the products of the BPF was based on the classification of the active substance.

Further Ecotoxicological studies

No data available.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
No data available.

Supervised trials to assess risks to non-target organisms under field conditions
No data available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
No data available.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)
No data available.

Foreseeable routes of entry into the environment on the basis of the use envisaged
No additional data available, reference is made to the section 'fate and distribution in exposed environment compartments' in section 2.2.8.2.

Further studies on fate and behaviour in the environment (ADS)
No data available.

Leaching behaviour (ADS)
3 Semi-field leaching tests according to NT Build 509 are available for the TEKNOS BLUESTAIN PRIMERS family: For TEKNOCOMBI 2917-62 (meta-SPC 1) the representative formulation (formula code 2603810) was tested after application of 2 coats, without any topcoat. For AQUAPRIMER 2907-63 (meta-SPC 2) the representative formulation (formula code 2603865) was tested with and without acrylic topcoat in 2 separate tests.

The results from the leaching studies were used to derive leaching rates for exposure from wood in service during the initial and longterm assessment periods. The derived leaching rates can be found in the table below. Please refer to annex 3.2.2.1 for the detailed calculations.

Leaching rates applied for the risk assessment of Teknos Bluestain Primers BPF	
Time:	**IPBC/PBC (mg/m2/day)**
Time 1a = 30 days	1.20
Time 1b = 365 days	1.53E-01
Time 2a = 5 years	3.75E-02
Time 2b = 15 years	1.41E-02

Testing for distribution and dissipation in soil (ADS)

No data available.

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

No data available.

Testing for distribution and dissipation in air (ADS)

No data available.

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

No data available.

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

Not relevant, no large scale formation of dust.

Assessment of substance(s) of concern

Please refer to section 3.6.3 of the Confidential Annex of the PAR for the assessment of substances of concern.

2.2.8.2 Exposure assessment

General information

Assessed PT	*PT 8*
Assessed scenarios	*Product application:* *Scenario 1a: industrial process: automated spraying* *Scenario 1b: brushing: in-situ* *Scenario 2: treated wood in service: house* *Scenario 3: treated wood in service: noise barrier* *Scenario 4: treated wood in service: bridge over pond*
ESD(s) used	*Emission Scenario Document for Product Type 8: Revised Emission Scenario Document for Wood Preservatives ENV/JM/MONO(2013)21*
Approach	*Average consumption*
Distribution in the	*Calculated based on BPR Guidance (2017) Volume VI part*

environment	*B+C.*
Groundwater simulation	Leaching to groundwater was simulated with the model FOCUS PEARL 4.4.4. according to the recommendations given in appendix 4 to the ESD for PT8. Details of the calculations can be found in annex 3.2.2.
Confidential Annexes	-
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: Yes
Remarks	

Storage of treated wood at industrial site is not considered significant, as the wood to be treated is mainly window frames and doors. Joineries in which the preservation treatment is applied on wooden articles that have been made to shape such as windows, doors and door frames, generally do not have an open storage area. These treated commodities/articles are immediately processed (e.g. painted) and are not stored after wood preservation treatment. Therefore, leaching during storage at industrial site is not considered relevant. Nontheless, the following RMM will be applied to industrial uses: "Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewr or water. Any losses of the product shall be collected for reuse or disposal".

Emission estimation

Scenario 1a: industrial process: automated spraying

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *industrial process, automated spraying*			
Application rate of biocidal product	200	g/m²	Max. application rate for products containing 0.6% IPBC (equal to application rate products at 0.3% used at max. 400 g/m^2)
Concentration of active substance in the product	0.6	%	
Area of wood treated per day	20000	m^2.d^{-1}	Large plant
Fraction released to facility drain	0.03	-	Based on water solubility >100 mg/L

Fraction released to air	0.01	-	Based on vapour pressure at 20°C between 0.005 and 0.005 Pa

Calculations for Scenario 1a (Large plant)

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Air	4.80E-02	Local emission rate to air - quantity locally emitted per day to air
Facility drain	7.20E-01	Local emission rate to facility drain - quantity of a substance locally emitted per day to the facility drain

Scenario 1b: professional in-situ brushing

Exposure to the environment during in-situ application of wood is covered by in-situ brushing of a house for the soil compartment. Although direct application above water is not envisaged, the exposure to adjacent water for in-situ brushing is also taken into account for the products from the TEKNOS BLUESTAIN PRIMERS family. The in-situ brushing a bridge over pond scenario is taken for direct exposure to the water compartment.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *in-situ treatment brushing house/bridge over pond*			
Application rate of biocidal product	200	g/m²	Max. application rate for products containing 0.6% IPBC (equal to application rate products at 0.3% used at max. 400 g/m²)
Concentration of active substance in the product	0.6	%	
Fraction product losses released to soil or water compartment by professional user	0.03	-	

Calculations for Scenario 1b

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
soil	4.50E-03	Local emission rate to soil
water	3.60E-04	Local emission rate to water

Scenario 2: treated wood in service: house

Depending on the application treatment, the default service life of treated wood can differ. For the products in the TEKNOS BLUESTAIN PRIMERS family, the service life for spraying is taken into account. Although brushing is also a potential application method, the service life of this method will not be taken as reference as the application via brushing is only relevant for small scale applications, i.e. for touch up of small areas of the windows or doors and no large scale application areas.

For a treated surfaces above the ground, a wooden house is taken as worst case sceanario, covering other surfaces such as windows and doors. The receiving compartment is the soil.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: treated wood in service: house			
Time 1a Time 1b Time 2a Time 2b	30 365 1825 5475	d	service life for spraying application method
Q*leach, time 1a	35.87	mg.m^{-2}	Worst case leaching value derived from NT Build 509
Q*leach, time 1b	55.73		
Q*leach, time 2a	68.52		
Q*leach, time 2b	77.26		

Calculations for Scenario 2

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Soil-time 1a	1.49E-04	Average daily emission of substance due to leaching during time 1a

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Soil-time 1b	1.91E-05	Average daily emission of substance due to leaching during time 1b
Soil-time 2a	4.69E-06	Average daily emission of substance due to leaching during time 2a
Soil-time 2b	1.76E-06	Average daily emission of substance due to leaching during time 2b

Scenario 3: treated wood in service: noise barrier

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Please refer to input values for scenario 2.			

Calculations for Scenario 3

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP-time 1a	2.51E-03	Average daily emission of substance due to leaching during time 1a
STP-time 1b	3.21E-04	Average daily emission of substance due to leaching during time 1b
STP-time 2a	7.88E-05	Average daily emission of substance due to leaching during time 2a
STP-time 2b	2.96E-05	Local daily emission rate to the STP following leaching from treated wood time 2b

Scenario 4: treated wood in service: bridge over pond

Input parameters for calculating the local emission

Input	Value	Unit	Remarks
Please refer to input values for scenario 2.			

Calculations for Scenario 4

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
water-time 1a	1.20E-05	Average daily emission due to leaching time 1a
water-time 1b	1.53E-06	Average daily emission due to leaching time 1b
water-time 2a	3.75E-07	Average daily emission due to leaching time 2a
water-time 2b	1.41E-07	Average daily emission due to leaching time 2b

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh - water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1a – industrial spraying	yes	yes	n.r.	n.r.	yes	no	yes	yes	/
Scenario 1b – in situ brushing	yes	yes	n.r.	n.r.	no	no	yes	yes	
Scenario 2 - house	no	no	n.r.	n.r.	no	no	yes	yes	/
Scenario 3 - noise barrier	yes	yes	n.r.	n.r.	yes	no	yes	yes	/
Scenario 4- bridge	yes	yes	n.r.	n.r.	no	no	no	no	/

n.r.: not relevant

Data below were taken from the Assessment Report from IPBC for product type 8.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks

Molecular weight	281.1	g/mol	
Melting point	66	°C	
Boiling point	/	°C	No boiling point, decomposes
Vapour pressure (at 25° C)	0.00343	Pa	
Water solubility (at 20°C)	168	mg/l	At pH 7
Log Octanol/water partition coefficient	2.81	Log 10	
Organic carbon/water partition coefficient (Koc)	113.25	l/kg	
Henry's Law Constant (at 25° C)	0.00338	Pa/m3/mol	
Biodegradability	Not readily biodegradable		
DT_{50} for biodegradation in surface water	0.129	d (at 12ºC)	
DT_{50} for degradation in soil	0.196	d (at 12ºC)	

For metabolites PBC and iodine,iodide, iodiate, the following values are taken:

Input parameters (only set values)* for calculating the fate and distribution in the environment						
Input	**PBC**	**iodine**	**iodide**	**iodate**	**Unit**	**Remarks**
Molecular weight	155.2	253.81	126.9	174.9	g/mol	
Melting point	-	-	-	-	°C	
Boiling point	-	-	-	-	°C	
Vapour pressure (at 25° C)	18.8	1.00E-06	1.00E-06	1.00E-06	Pa	min. default
Water solubility (at 20°C)	2860	1.00E+05	1.00E+05	1.00E+05	mg/l	max. default
Log Octanol/water partition coefficient	1.64	-	2.49	2.49	Log 10	
Organic carbon/water partition coefficient (Koc)	198.1	290	290	290	l/kg	IPBC PT13 CAR 2015
Henry's Law Constant (at 25° C)	1.02	N/A	N/A	N/A	Pa/m3/mol	calculated
Biodegradability	-	Not applicable, inorganic substance	Not applicable, inorganic substance	Not applicable, inorganic substance		
DT_{50} for biodegradation in surface water	31.2	-	-	-	d (at 12ºC)	
DT_{50} for degradation in	9.5	-	-	-	d (at 12ºC)	

soil						
Solids-water partitioning coefficient of suspended matter	19.8	220	220	220	L/kg	PT 1,3,4,22 Iodine CAR (2013)
Solids-water partitioning coefficient of soil	-	5.8	5.8	5.8	L/kg	PT 1,3,4,22 Iodine CAR (2013)
Suspended matter-water partitioning coefficient	5.85	55.9	55.9	55.9	m3/m3	
Soil-water partitioning coefficient	6.14	8.9	8.9	8.9	m3/m3	

*Valuese are deducted from the IPBC PT6 CAR (September 2013)

Calculated fate and distribution in the STP			
Compartment	Percentage [%]		Remarks
	PBC*	Iodide, Iodate**	
Air	1.901	0	*Calculated by Simple Treat 4.0 **CAR for iodine, 2013
Water	95.61	80	
Sludge	2.489	20	
Degraded in STP	0	0	

Distribution in the STP is calculated for PBC as IPBC is completely degraded within 4 hours in the STP (CAR for IPBC in PT13). For iodine only 80% of the emission is discharged to the surface water, since 20% of the influent concentration is adsorbed to the sewage sludge (CAR for iodine, 2013).

Calculated PEC values

IPBC

Summary table on calculated PEC values for IPBC							
	Timepoint	**PEC_{STP}**	**PEC_{water}**	**PEC_{water}***	**PEC_{soil}**	**PEC_{soil}***	**$PEC_{groundw}$****
		[mg/L]	[mg/l]	[mg/l]	[mg/kgwwt]	[mg/kgwwt]	[µg/L]
Scenario 1a (aut. Spraying)	Time 0	3.60E-02	n.a.		RMM		
Scenario 1b (in-situ brushing)	Time 0	n.a.	3.60E-04	n.a.	2.04E-01	n.a.	**96.22**
Scenario 2 (House)	Time 1a	n.a.	n.a.	n.a.	2.03E-01	1.91E-03	**9.03E-01**
	Time 1b	n.a.	n.a.	n.a.	3.15E-01	2.44E-04	**1.15E-01**
	Time 2a	n.a.	n.a.	n.a.	3.88E-01	6.00E-05	2.84E-02
	Time 2b	n.a.	n.a.	n.a.	4.37E-01	2.25E-05	1.07E-02
Scenario 3 (Noise barrier)	Time 1a	1.26E-03	please refer to PBC		Covered by House scenario		
	Time 1b	1.60E-04					
	Time 2a	3.94E-05					
	Time 2b	1.48E-05					
Scenario 4 (Bridge over pond)	Time 1a	n.a.	3.59E-04	2.20E-06	n.a.	n.a.	n.a.
	Time 1b	n.a.	5.57E-04	2.81E-07	n.a.	n.a.	n.a.
	Time 2a	n.a.	6.85E-04	6.92E-08	n.a.	n.a.	n.a.
	Time 2b	n.a.	7.73E-04	2.60E-08	n.a.	n.a.	n.a.

*Removal processes considered
**Tier 1 calculated as porewater concentration

PBC

Summary table on calculated PEC values for PBC						
	Timepoint	**PEC_{STP}**	**PEC_{water}**	**PEC_{water}***	**PEC_{soil}***	**$PEC_{groundw}$****
		[mg/L]	[mg/l]	[mg/l]	[mg/kg wwt]	[µg/L]
Scenario 1a (aut. Spraying)	Time 0	1.90E-02	1.90E-03	n.a.	RMM	
Scenario 1b (in-situ brushing)	Time 0	n.a.	n.a.	n.a.	n.a.	n.a.
Scenario 2 (House)	Time 1a	n.a.	n.a.	n.a.	4.54E-02	**12.6**
	Time 1b	n.a.	n.a.	n.a.	6.53E-03	**1.81**

	Time 2a	n.a.	n.a.	n.a.	1.61E-03	**4.45E-01**
	Time 2b	n.a.	n.a.	n.a.	6.04E-04	**1.67E-01**
Scenario 3 (Noise barrier)	Time 1a	6.62E-04	6.62E-05	n.a.	Covered by House scenario	
	Time 1b	8.46E-05	8.46E-06	n.a.		
	Time 2a	2.08E-05	2.08E-06	n.a.		
	Time 2b	7.82E-06	7.82E-07	n.a.		
Scenario 4 (Bridge over pond)	Time 1a	n.a.	n.a.	2.43E-04	n.a.	n.a.
	Time 1b	n.a.	n.a.	3.73E-05	n.a.	n.a.
	Time 2a	n.a.	n.a.	9.17E-06	n.a.	n.a.
	Time 2b	n.a.	n.a.	3.44E-06	n.a.	n.a.

*Removal processes considered
**Tier 1 calculated as porewater concentration

Iodine, Iodide and Iodate

For the iodine metabolites, only worst case scenarios has been calculated. Worst case scenarios for the iodine species are:
PECstp: Noise barrier, time 1a.
PECwater: Bridge over pond, time 2b.
PECsoil: House scenario, time 2b. Only emission during service life was assessed.
PECgw: House scenario, time 2b. Only emission during service life was assessed.

Summary table on calculated PEC values for Iodine species				
	PEC_{STP} (µg/L)	**PEC_{water}** (µg/L)	**PEC_{soil}** (mg/kg wwt)	**PEC_{GW}*** (µg/L)
Iodine (I2)	0.453	0.620	0.197	**37.7**
Iodide (I-)	0.453	0.620	0.028	**5.3**
Iodate (IO3-)	0.625	0.854	0.272	**51.9**

*Tier 1 calculated as porewater concentration.

Considering a PNECstp=2.9 mg/L for iodine (AR for Iodine in PT1,3,4,22) compared to a PNECstp=0.44mg/L for IPBC and considering a molar fraction for the transformation of IPBC to iodine equal to 0.451, the risk assessment for IPBC is covering the risk of iodine in the STP. Therefore the PECstp values for the iodine species are not used in the risk assessment, but only shown for completeness.Details of the PEC calculations for the iodine species can be found in annex 3.2.2.2.

PEC values for groundwater

Concentrations in groundwater was assessed using the model FOCUS PEARL 4.4.4. for the metabolites PBC, iodide and iodate (IPBC was conisdered not relevant due to the rapid degradation in soil). Please refer to annex 3.2.2.3 for further details on the calculations.

Summary table on calculated PECgw values using FOCUS PEARL 4.4.4.			
Scenario	**PBC**	**Iodide**	**Iodate**
	[µg/l]	[µg/l]	[µg/l]
CHATEAUDUN	>0.0001	0.216111	2.595846
HAMBURG	>0.0001	0.186108	2.531751
JOKIOINEN	>0.0001	0.007877	0.551961
KREMSMUENSTER	>0.0001	0.157264	2.025263
OKEHAMPTON	>0.0001	0.186617	2.024443
PIACENZA	>0.0001	0.289885	3.126411
PORTO	>0.0001	0.129609	1.278609
SEVILLA	>0.0001	0.284468	3.387451
THIVA	>0.0001	0.353402	3.729142

Primary and secondary poisoning

Primary poisoning

Not applicable

Secondary poisoning

As described in the CAR of IPBC, the log Kow for this compound is less than 3, therefore secondary poisoning potential is considered to be low. The same accounts for metabolites.

2.2.8.3 Risk characterisation

Atmosphere

Air will not be an environmental compartment of concern for IPBC or its metabolites (PBC,iodine/iodide/iodate) due to the low vapour pressure of these compounds. It should also be noted that the calculated $T_{1/2}$ of IPBC in air is only about 15 hours and the compound is therefore not considered persistent in air. A low $T_{1/2}$ for metabolites also excludes persistence for these compounds.

Conclusion: No risk identified for the air compartment

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values (IPBC)		
	Timepoint	**PEC/PNEC$_{STP}$**
Scenario 1a (aut. Spraying)	time 0	8.18E-01
Scenario 3 (Noise barrier)	Time 1a	2.85E-03
	Time 1b	3.64E-04
	Time 2a	8.96E-05
	Time 2b	3.37E-05

Conclusion: No risk identified for micro-organisms in the Sewage Treatement Plant during industrial treatment of wood, nor during service life of noise barrier. It should be noted that release during application will generally be avoided, as release of wood preservatives from the treating installation or where the treated timber is stored into a surface water drain or drain connected to a Sewage Treatment Plant (STP) is not permitted. Any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process.
The risk for STP compartment is only driven by the parent compound IPBC.

Aquatic compartment

Summary table on calculated PEC/PNEC values for IPBC		
	Timepoint	**PEC/PNEC$_{water}$***
Scenario 1b (in-situ brushing)	Time 0	-
Scenario 4 (bridge over pond)**	Time 1a	4.41E-03
	Time 1b	5.63E-04
	Time 2a	1.38E-04
	Time 2b	5.20E-05

*Removal processes taken into account
**In-service+application (scenario 1b)

Summary table on calculated PEC/PNEC values for PBC			
	Timepoint	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{water}$***
Scenario 1a (aut. spraying)	Time 0	0.46	-
Scenario 3 (Noise barrier)	Time 1a	1.51E-03	-
	Time 1b	1.92E-04	-
	Time 2a	4.73E-05	-
	Time 2b	1.78E-05	-
Scenario 4 (bridge over pond)**	Time 1a	-	5.88E-03
	Time 1b	-	9.04E-04
	Time 2a	-	2.22E-04
	Time 2b	-	8.34E-05

*Removal processes taken into account
** in-service+application (scenario 1b)

Conclusion:

The risk level for indirect exposure to the water compartment during application is acceptable, both for industrial and professional treatment. In addition, as stated in the risk characterisation for STP compartment, the release via STP will generally be avoided from treatment installations with wood preservatives.

Direct exposure to the water compartement during the service life of the bridge over pond leads to acceptable exposure levels of IPBC and PBC when removal processes are considered.

For indirect exposure due to leaching from the noise barrier, no risk is identified for PBC, even when no removal processes are considered.

It should be noted that the risk levels for IPBC and PBC for sediment compartment are not reported here, as the calculation method to derive PECs is equal to the method used to derive the PNEC for comparison (i.e. EPM). Therefore, the risk for sediment dwelling organisms will be considered equal to the risk of the water compartment.

For iodide and iodate levels, the PECs all remain within the background levels found naturally in the environment.

Terrestrial compartment

Summary table on calculated PEC/PNEC values for IPBC		
	Timepoint	**PEC/PNEC$_{soil}$**
scenario 1b (in-situ brushing)	Time 0	**40.8**
Scenario 2 (House)	Time 1a	1.65E-01*
	Time 1b	5.62E-02*
	Time 2a	1.38E-02*
	Time 2b	5.20E-03*

*Removal processes taken into account

Summary table on calculated PEC/PNEC values for PBC			
	Timepoint	**PEC/PNEC$_{soil}$**	**PEC/PNEC$_{soil}$***
Scenario 2 (House)	Time 1a	n.a.	3.05E-01
	Time 1b	n.a.	4.38E-02
	Time 2a	n.a.	1.08E-02
	Time 2b	n.a.	4.05E-03

*Removal processes taken into account

Conclusion:

A risk to soil was identified for in-situ brushing (scenario 1b). To avoid unacceptable release to soil during in-situ application, the ground must be covered and any spillage should be collected.

Taking into account removal processes, the PEC/PNEC value can be reduced to an acceptable level and no unsafe exposure is found for the soil compartment. PBC shows acceptable levels when removal processes are considered.

Natural concentrations in soil for iodine compounds are between 0.4 and 18 mg/kg wwt. The PECs calculated all remain below the natural background level.

Groundwater

As a first tier, PECs for groundwater were calculated as concentrations in porewater. The threshold level for IPBC and PBC of 0.1 µg/L was exceeded for the house scenario, hence a tier 2 groundwater assessment using FOCUS PEARL 4.4.4. was performed for PBC. IPBC was considered covered by the assessment for PBC due to the rapid degradation of IPBC in the soil compartment.

In tier 2, the calculated concentrations of PBC at one metre depth was far below the trigger value of 0.1 µg/L, hence no unacceptable risk is considered for the groundwater from the use of the products of the Teknos Bluestain Primers BPF.

The estimated (tier 2) PEC_{GW} for iodide and iodate were in the range of 7.88E-03 – 3.53E-1 µg/L and 5.52E-1 – 3.73 µg/L, respectively. In compliance with the approach provided in the PT6 IPBC CAR, a groundwater assessment for iodide and iodate is performed by considering the natural background concentration of iodine of 1 – 70 µg/L with extremes up to 400 µg/L. This corresponds to a background concentration of 1.38 –96.6 µg/L with extremes up to 552 µg/L for iodate by considering the molecular weight correction factor of 1.38. The background concentration for iodide is identical to the iodine background concentrations since the molecular weight correction factor between iodine and iodide is 1. The calculated concentrations of iodide and iodate in the leachate are within the background concentration in all nine considered scenarios.

Conclusion

Exceedence of the permissable concentrations in groundwater is not expected following use of the Teknos Bluestain Primers BPF.

Primary and secondary poisoning

Primary poisoning

Not relevant, products of the BPF are not solid formulations, nor available for direct uptake.

Secondary poisoning

Not relevant, log Kow of IPBC is below 3. The same accounts for metabolites.

Mixture toxicity

Not relevant as the product family contains only one active substance and no substances of concern.

Aggregated exposure (combined for relevant emmission sources)

Not relevant.

Overall conclusion on the risk assessment for the environment of the product
The products in the TEKNOS BLUESTAIN PRIMERS family are applied by spraying (manual or automated) in industrial environment or by in-situ brushing application by professional users. An unacceptable risk for the soil compartment was identified for in-situ brushing by professionals. Therefore, the following RMM will be applied to the product: "**Cover the ground during application and collect any spillage.**" The risk to soil during industrial storage was not assessed because the following RMM is applied to industrial uses: "**Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewr or water. Any losses of the product shall be collected for reuse or disposal.**" For wood in service, none of the scenarios lead to an unaccepatable risk. It can be concluded that exposure to the environment during the application and service life phase of wood treated with products from the TEKNOS BLUESTAIN PRIMERS family is acceptable when the abovementioned RMMs are applied.

2.2.9 Measures to protect man, animals and the environment

See section 11 of IUCLID dossier.

2.2.10 Assessment of a combination of biocidal products

The biocidal products in the family TEKNOS BLUESTAIN PRIMERS are not intended for combined use with other biocidal products.

2.2.11 Comparative assessment

Biocidal products in the family TEKNOS BLUESTAIN PRIMERS are not subject to comparative assessment, as the active substance in the products is not a candidate for substitution.

3 ANNEXES

3.1 List of studies for the biocidal product (family)

List_of_studies_TE

3.2 Output tables from exposure assessment tools

3.2.1 Human health exposure

HHRA.xlsx

Scenario 1.2.2 Automated spraying				
	IPBC	**IPBC**	**Dipropylenglycol**	**Butyl diglycol**
Active substance % (w/w) Tier	0,60% 1	0,60% 2	0,24% 1	5,00% 1
Potential body exposure				
Indicative value mg/min	178	178	178	178
Duration min	60	60	60	60
Potential dermal deposit mg	10680	10680	10680	10680
Clothing type	None	Coated coveralls	None	None
Clothing penetration %	100%	10%	100%	100%
Actual dermal deposit [product] mg	10680	1068	10680	10680
Hand exposure				
Indicative value mg/min (In gloves, actual)	25,7	25,7	25,7	25,7

Duration min	60	60	60	60
Hand deposit mg	1542	1542	1542	1542
Mitigation by gloves	Not applicable	Not applicable	Not applicable	Not applicable
Actual hand deposit [product] mg	1542	1542	1542	1542
Total dermal exposure				
Total dermal deposit [product] mg	12222	2610	12222	12222
Active substance mg	73,33	15,66	29,33	611,10
Dermal absorption %	50%	50%	100%	100%
Systemic exposure via dermal route mg	36,6660	7,8300	29,3328	611,1000
Exposure by inhalation				
Indicative value mg/m³	1	1		
Duration	60	60		
Inhalation rate m³/h	1,25	1,25		
Mitigation by RPE (PF)	1	1		
Inhaled [product] mg	1,25	1,25		
Systemic exposure via inhalation route mg	0,008	0,008		
Systemic exposure				
Total systemic exposure a.s. mg	36,6735	7,8375	29,3328	611,1000
Body weight kg	60	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	0,61123	0,13063	0,48888	10,18500
AEL mg kg^{-1} day^{-1}	0,2	0,2	283	83
% AEL	**305,6%**	**65,3%**	**0,2%**	**12,3%**

Scenario 1.2.2 Manual spraying

	IPBC			Dipropylenglycol	Butyl
Active substance % (w/w)	0,60%	0,60%	0,60%	0,24%	5
Tier	1	2	3	3	
Potential body exposure					
Indicative value mg/min	222	222	222	222	
Duration min	240	240	240	480	
Potential dermal deposit mg	53280	53280	53280	106560	10
Clothing type	None	Coated coveralls	Impermeable coveralls	None	Impe co
Clothing penetration %	100%	10%	5%	100%	
Actual dermal deposit [product] mg	53280	5328	2664	106560	5
Active substance mg	319,68	31,968	15,984	255,744	2
Hand exposure					
Indicative value mg/min	273	7,8	4,68	273	4
Duration min	240	240	240	480	
Hand deposit mg	65520	1872	1123,2	131040	2
Mitigation by gloves	None	Gloves	New gloves	None	New
Actual hand deposit [product] mg	65520	1872	1123,2	131040	2
Total dermal exposure					
Total dermal deposit [product] mg	118800	7200	3787,2	237600	7
Active substance mg	712,80	43,20	22,72	570,24	3
Dermal absorption %	50%	50%	50%	100%	1

Systemic exposure via dermal route mg	356,4000	21,6000	11,3616	570,2400	37
Exposure by inhalation					
Indicative value mg/m³	76	76	76	[redacted]	
Duration	240	240	240		
Inhalation rate m³/h	1,25	1,25	1,25		
Mitigation by RPE (RF)	1,00	0,10	0,10		
Inhaled [product] mg	380,00	38,00	38,00		
Systemic exposure via inhalation route mg	2,280	0,228	0,228		
Systemic exposure					
Total systemic exposure a.s. mg	358,6800	21,8280	11,5896	570,2400	37
Body weight kg	60	60	60	60	
Systemic exposure mg kg^{-1} day^{-1}	5,97800	0,36380	0,19316	9,50400	6,
AEL mg kg^{-1} day^{-1}	0,2	0,2	0,2	283	
% AEL	**2989,0%**	**181,9%**	**96,6%**	**3,4%**	**7**

1.3 Cleaning spray equipment

	IPBC		
Tier	1	2	3
Concentration of active substance %	0,60%	0,60%	0,60%
Event exposure duration	20,00	20,00	20,00
Product density g/mL	1,23	1,23	1,23
Hand exposure			
Indicative value µL/min	35,87	35,87	35,87
Penetration through gloves 1/1	100%	10%	10%
Actual dermal deposit product mg	882,40	88,24	88,24
Actual dermal deposit a.s.mg	5,2944	0,5294	0,5294
Body exposure			
Indicative value µL/min	19,28	19,28	19,28
Clothing type	None	Coated coveralls	Impermeable coveralls
Penetration through clothing %	100%	10%	5%
Actual dermal deposit product mg	474,29	47,43	23,71
Actual dermal deposit a.s.mg	2,8457	0,2846	0,1423
Total dermal exposure mg	8,1401	0,8140	0,6717
Dermal absorption %	50,00%	50,00%	50,00%
Systemic exposure via dermal route mg	4,0701	0,4070	0,3359
Systemic exposure			
Total systemic exposure mg	4,0701	0,4070	0,3359
Body weight kg	60,00	60,00	60,00
Total systemic exposure mg/kg w/day	0,067835	0,006783	0,005598
AEL mh/kg bw/day	0,2	0,2	0,2
% AEL	**33,92%**	**3,39%**	**2,80%**

Scenario 2.1 Maunal loading of product into manual dipping tank or painting pot

	IPBC

Active substance concentration % w/w	0,60%	0,60%
Tier	1	2
Number of loadings per day	1	1
Dermal exposure		
Hands, 1 loading mL b.p.	0,5	0,5
Density b.p. mg/mL	1	1
Hands, loading mg b.p.	0,5	0,5
Penetration through gloves %	100%	10%
Hand dermal deposit as a.s. mg	0,003	0,0003
Systemic exposure		
B Dermal absorption **%**	50%	50%
Total systemic exposure mg	0,0015	0,0002
Body weight kg	60	60
Total systemic exposure mg/kg bw/day	0,000025	0,0000025
AEL mg/kg bw/day	0,2	0,2
% AEL	**0,01%**	**0,00%**

Scenario 2.1.2 Semi-automatic loading of product into manual dipping tank or painting pot		
	A.S.	
Active substance concentration % w/w	0,60%	0,60%
Tier	1	2
Duration of activity min	10	10
Dermal exposure		
Hands, rate (90% percentile) mg/min	13,5	13,5
Hands, loading (90% percentile) mg	135	135
Penetration through gloves %	100%	10%
Hand dermal deposit as a.s. mg	0,81	0,081
B Dermal absorption **%**	50%	50%
Total systemic exposure mg	0,4050	0,0405
Systemic exposure		
Body weight kg	60	60
Total systemic exposure mg/kg bw/day	0,00675	0,000675
AEL mg/kg bw/day	0,2	0,2
% AEL	**3,38%**	**0,34%**

Scenario 2.2 Brushing				
	IPBC		**Dipropylenglycol**	**Butyl diglycol**
Tier	1	2	1	1

Active substance %	0,6%	0,6%	0,2%	5,0%
Potential hand exposure				
Indicative value mg a.s./m²	0,5417	0,5417	0,5417	0,5417
Indicative value, corrected mg a.s./m²	0,3250	0,3250	0,1300	2,7085
Duration min	240	240	240	240
Application area m²	31,6	31,6	31,6	31,6
Potential hand deposit mg a.s.	10,3	10,3	4,1	85,6
Penetration through gloves %	100	10	100	100
Actual hand deposit mg a.s.	10,3	1,0	4,1	85,6
Potential body exposure				
Indicative value mg a.s./m²	0,2382	0,2382	0,2382	0,2382
Indicative value, corrected mg a.s./m²	0,1429	0,1429	0,0572	1,1910
Duration min	240	240	240	240
Application area m²	31,6	31,6	31,6	31,6
Potential dermal deposit mg	4,5	4,5	1,8	37,6
Clothing type	None	Coated coveralls	None	None
Clothing penetration* %	100%	10%	100%	100%
Actual dermal deposit mg a.s.	4,5	0,5	1,8	37,6
Total dermal exposure				
Total dermal deposit [a.s.] mg	14,787	1,479	5,915	123,224
Dermal penetration rate %	50	50	100	100
Systemic exposure via dermal route mg	7,393	0,739	5,915	123,224
Exposure by inhalation				
Indicative value mg a.s./m²	0,0016	0,0016		
Indicative value, corrected mg a.s./m²	0,0010	0,0010		
Duration min	240	240		
Application area m²	31,6	31,6		
Systemic exposure via inhalation route mg	0,03	0,03		
Systemic exposure				
Total systemic exposure mg	7,42	0,77	5,91	123,22
Body weight kg	60	60	60	60
Total systemic exposure mg/kg bw/day	0,12373	0,01283	0,09858	2,05374
$AEL_{long-term}$	0,2	0,2	283	83
% $AEL_{long-term}$	**61,86%**	**6,41%**	**0,03%**	**2,47%**

Scenario 2.3.1 Washing of brush			
Activity and Parameters	**Tier 1 No gloves**	**Tier 2 Gloves**	**Units**
	A.S.		
Volume of brush	200	200	**ml**
Volume of paint remaining on brush after painting ($^1/_8$ of 200 ml = 25 ml)	25	25	ml
Density of paint	1,23	1,23	**g/ml**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	30,75	30,75	g
Concentration of a.s. in paint	0,60	0,60	**% w/w**
A. Weight of a.s. on brush after painting	184,5000	184,5000	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	18,4500	18,4500	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	166,0500	166,0500	mg

C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	9,2250	9,2250	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of C)	0,9225	0,9225	mg
Penetration of a.s. through gloves	100	10	**%**
Weight of a.s. on hand	0,92250	0,09225	mg
Dermal absorption of a.s.	50,00	50,00	**%**
Weight of a.s. entering the body	0,46125	0,04613	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	9,2250	9,2250	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	0,9225	0,9225	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	8,3025	8,3025	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0,4613	0,4613	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of F)	0,0461	0,0461	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	0,04613	0,00461	mg
Dermal absorption of a.s.	9,00	9,00	%
Weight of a.s. entering the body	0,00415	0,00042	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (**E** – **F**)	0,4613	0,4613	mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	0,0461	0,0461	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	0,4151	0,4151	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	0,0231	0,0231	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of I)	0,0023	0,0023	mg
Penetration of **a.s.** through gloves	100	10	%
Weight of a.s. on hand	0,00231	0,00023	mg
Dermal absorption of a.s.	9,00	9,00	%
Weight of a.s. entering the body	0,00021	0,00002	mg
Total weight of a.s. entering the body *(to 4 decimal places)*	0,4656	0,0466	mg
Body weight	60	60	kg
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE *(to 4 decimal places)*	0,0078	0,0008	mg a.s./kg bw
AEL	0,2	0,2	
%AEL longterm	**3,88%**	**0,39%**	

Scenario 2.3.4- Sanding treated wood professionals			
	IPBC	**Dipropylenglycol**	**Butyl diglycol**
Concentration of a.s. (% w/w)	0,60%	0,24%	5,00%
Density (g/cm³)	1,23	1,23	1,23
Concentration in wood			
Application rate [product] (g/m²)	200	200	200
Application rate [a.s.] (mg/cm²)	0,12	0,05	1,00

Area of wood to be sanded surface area (cm^2) (4 x 4cm x 250cm + 2 x 4cm x 4cm)	4032	4032	4032
Volume of outer layer (cm^3) (4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm)	3008	3008	3008
Amount in wood [a.s] (mg)	483,8	193,5	4032,0
Exposure by inhalation			
Concentration of in wood dust a.s (mg/cm^3)	0,16	[redacted]	
Wood dust concentration in air (mg/m^3)	5		
Exposure duration (h)	6		
Inhalation rate (m^3/h)	1,25		
Retention of a.s. in wood	100%		
Density of wood (g/cm^3)	0,40		
Amount dust inhaled in 6 hours (cm^3)	0,09		
Systemic exposure via inhalation mg	0,0151		
Dermal exposure			
A Concentration on the wood surface (mg/cm^2)	0,12	0,05	1,00
B Transfer coefficient (%)	3%	3%	3%
C Surface of palm of hand (cm^2)	410	410	410
D Dermal absorption (%)	50%	100%	100%
Systemic exposure via dermal route mg	0,74	0,59	12,30
Total systemic exposure			
Total systemic exposure mg	0,7531	0,5904	12,3000
Body weight kg	60	60	60
Total systemic exposure a.s. (mg kg^{-1} day^{-1})	0,01255	0,00994	0,20709
AEL (mg kg^{-1} day^{-1})	0,20	283,00	83,00
% AEL	**6,28%**	**0,0035%**	**0,25%**

Scenario 3.1- Sanding treated wood non-professionals

	IPBC	Formaldehyd	Dipropylenglycol methyl ether	Butyl diglycol	Bytyl doglycol/butyloxitol
Concentration of a.s. (% w/w)	0,60%	0,00%	0,24%	5,00%	0,45%
Density (g/cm³)	1,0023	1,0023	1,0023	1,0023	1,0023
Concentration in wood					
Application rate product (g/m²)	200	200	200	200	200
Application rate a.s./SoC (mg/cm²)	0,12	0,00	0,05	1,00	0,09
Area of wood to be sanded surface area (cm²) (4 x 4cm x 250cm + 2 x 4cm x 4cm)	4032	4032	4032	4032	4032
Volume of outer layer (cm³) (4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm)	3008	3008	3008	3008	3008
Amount in wood a.s/SoC(mg)	483,8	0,1	193,5	4032,0	362,9
Exposure by inhalation					
Concentration in wood dust a.s (mg/cm³)	0,16	0,00	0,06	1,34	0,12
Wood dust concentration in air (mg/m³)	5	5	5	5	5
Exposure duration (h)	1	1	1	1	1
Inhalation rate (m³/h)	1,25	1,25	1,25	1,25	1,25
Retention of a.s. in wood	100%	100%	100%	100%	100%
Density of wood (g/cm³)	0,40	0,40	0,40	0,40	0,40
Amount dust inhaled in 1 hour (cm³)	0,02	0,02	0,02	0,02	0,02
Systemic exposure via inhalation mg	0,0025	0,0000	0,0010	0,0209	0,0019
Dermal exposure					
A Concentration on the wood surface (mg/cm²)	0,12	0,00	0,05	1,00	0,09
B Transfer coefficient (%)	3%	3%	3%	3%	3%
C Surface of palm of hand (cm²)	410	410	410	410	410
D Dermal absorption (%)	50%	50%	50%	50%	50%
Systemic exposure via	0,74	0,00	0,30	6,15	0,55

dermal route mg					
Total systemic exposure					
Total systemic exposure mg	0,7405	0,0001	0,2962		
Body weight kg	**60**	**60**	**60**	**60**	**60**
Total systemic exposure a.s. (mg kg^{-1} day^{-1})	0,01234	0,00000	0,00494	0,10285	0,00926
AEL (mg kg^{-1} day^{-1})	0,35	0,35	0,35	0,35	0,35
% AEL	**3,53%**	**0,00%**	**1,41%**	**29,39%**	**2,64%**

3.2.2 Annex to the environmental exposure calculations

3.2.2.1 Leaching calculations

Semi-field leaching studies (according to NT Build 509) was performed for two products of the BPF, namely Teknocombi 2917-62 (0.3 % IPBC) and Aquaprimer 2907-63 (0.6 % IPBC) with and without topcoat. The topcoat did not contain any preservative. A summary of the test reports is included in the IUCLID dossier under Point 10.3. Retention was approx. 200 g/m² (mean retention: 203.1) and 400 g/m² (mean retention: 404.8) for Aquaprimer 2907-63 and Teknocombi 2917-62, respectively. A study period of 879 days with a total rainfall amount of 1444 mm within this period was assessed (equivalent to 753 normalised days).

Summary of the results for Aquaprimer 2907-63 (without topcoat) can be found below:

Test duration [days]	**Cumulated precipitation [mm]**	**Cumulated loss of IPBC/PBC [mg/m2]**		
		Aquaprimer 2907-63 (no topcoat)	Aquaprimer 2907-63 (with topcoat)	Teknocombi 2917-62
28	53.9	25.34	15.88	15.16
68	88.2	49.91	32.93	29.46
242	274.6	52.24	38.96	32.29
295	358.6	52.54	39.85	32.69
524	706.1	57.18	44.03	36.35
627	962.4	57.76	45.48	37.00
699	1179.5	58.63	46.68	37.64
879	1444.5	61.39	48.47	39.11

Leaching rates used for the risk assessment
The cumulative quantities leached was plotted versus the time. For fitting the experimental Cumulative leached amount(t)=f(t) curve a first order decay model was employed:

Cumulative leached amount(t) = a * ln (t) + b

All datapoints were used for the fitting. The trend lines with the corresponding regression equations and coefficients of variation can be found in Figure 3.1(Aquaprimer with and without topcoat) and Figure 3.2 (Teknocombi) below.

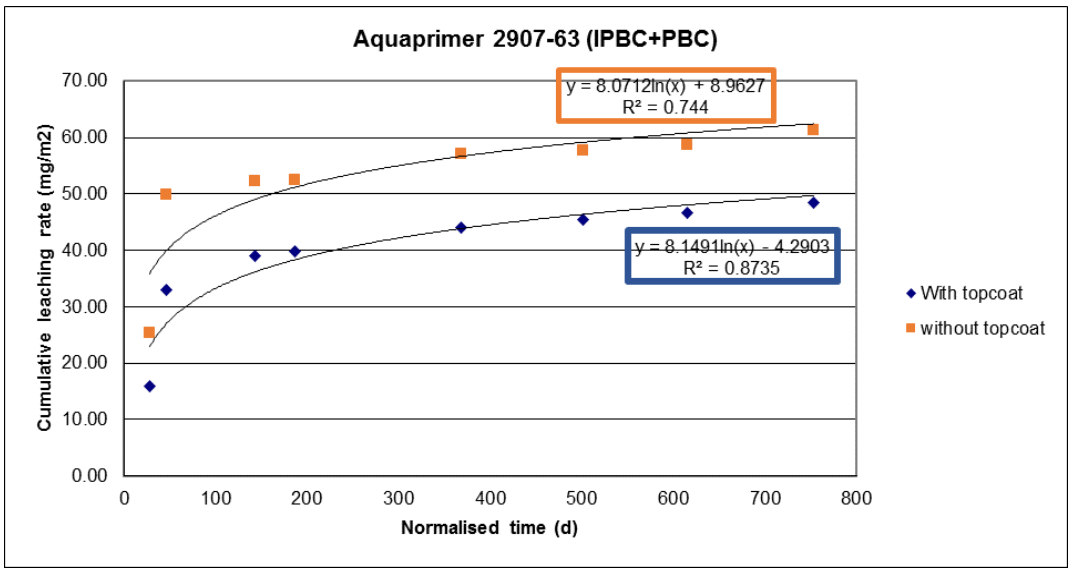

Figure 3.1: Fitted cumulative leaching rate of IPBC/PBC versus normalised time for Aquaprimer 2907-63 with and without topcoat.

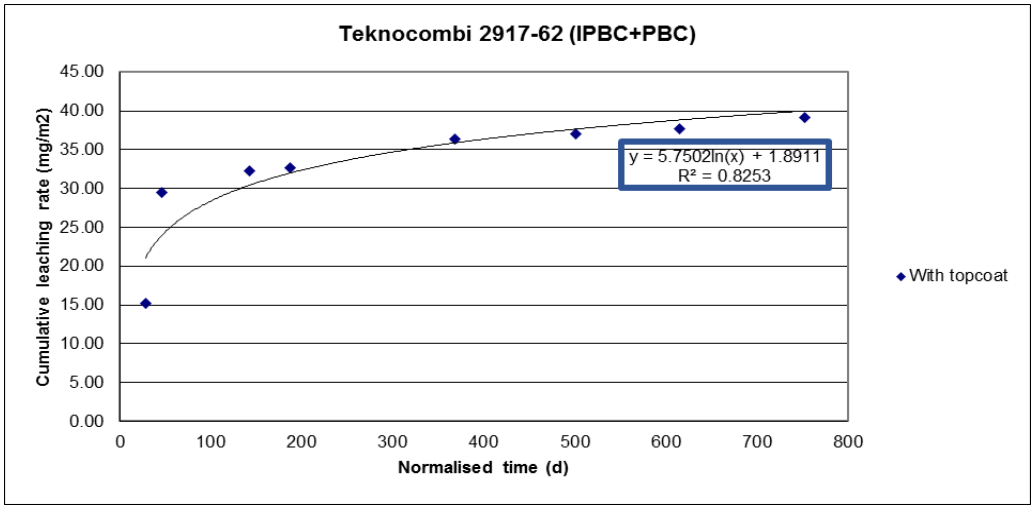

Figure 3.2: Fitted cumulative leaching rate of IPBC/PBC versus normalised time for Teknocombi 2917-62.

Derivation of leaching rates:

For all assessment times (30d, 365d, 5y and 15y) the leaching rate for the emission calculations are based on the derived equations from Figure 3.1 and Figure 3.2.

Example calculations:

Aquaprimer 2907-63 without topcoat (5 years): **0.038 mg/m$_2$/d**
(8.0712*ln(1825)+8.9627)/1825

Aquaprimer 2907-63 with topcoat (5 years): **0.062 mg/m$_2$/d**
((8.0712*ln(1825)+8.9627)/1825)*2

Teknocombi 2917-62 (5 years): **0.025 mg/m$_2$/d**
(5.7502*ln(1825)+1.8911)/1825

Subsequently, all leaching rates was corrected for the measured retention rate in the leaching studies.

As concluded in the Summary Conclusions of the 2nd Leaching Workshop on wood preservatives (please see TAB 2.1, entry ENV 104), when studies for the same product with and without topcoat are available, the leaching rates from the study without topcoat should be used for Time 2, if the calculated leaching rates from the study with topcoat using an appropriate AF exceeds those from the study without topcoat.
As a consequence, the leaching rates for Aquaprimer 2907-63 without topcoat has been used as a worst case for all assessment times covering all products of the BPF.

3.2.2.2 Environmental risk assessment for the iodine species

PEC calculations
The PEC calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Vol IV, Part B). For the iodine risk assessment only the worst case scenarios (highest IPBC output values) for each relevant compartment has been taken into consideration.
In the evaluation of iodine released from IPBC, it is chosen to consider 100% formation of both iodide and iodate. This proposed assessment is however worst case as it is expected that much less than 100% of the different iodine species will be present. For calculation of soil concentrations it is assumed that the total iodine concentration in soil is transformed into 14% iodide and 100% iodate (CAR for IPBC, PT6 (2013) and agreed to use for PT 8 products at TM II, 2012).

The molar fraction of iodine (I2) is 0.451 (2 moles of IPBC to form one mole of I2). Further it is assumed that all iodine is transformed either to iodide or iodate. As one mole of iodine (I2) forms two moles of iodide (I-) the molar fraction between iodine and iodide is 1, whereas for iodate (IO3-) the molar fraction is 1.38.

PEC for sewage treatment plant
In the CAR for IPBC, the influent concentration of IPBC is considered to be relevant in order to assess predicted environmental concentrations in sewage treatment plants. For further modelling surface water concentrations it is assumed, that the whole IPBC in the STP is transformed into PBC and iodine species. Hence, the STP risk assessment is based on IPBC influent concentration with no removal/degradation or translocation processes.

A risk assessment for soils being target for iodine species emission via sewage sludge is not considered to be necessary as the house scenario is considered worst case with respect to the soil compartment.

The PEC_{STP}-value for iodine is calculated based on the PEC_{STP} values for IPBC. For iodine only 80% of the emission is discharged to the surface water, since 20% of the influent concentration is adsorbed to the sewage sludge (CAR for iodine, 2013). Therefore, the PEC_{STP}-value for iodine is calculated according the following formulas:

$PEC_{STP,iodine}$ = PEC_{STP} for IPBC * 0.451 * 80%

For the worst case ($PEC_{STP,IPBC}$ = 1.26 µg/L) ”noise barrier, 30 days” this results in a $PEC_{STP,iodine}$ of 0.453 µg/L.

PEC Surface water
For the iodine risk assessment the “bridge over pond” scenario has been chosen as a worst case since it represents an intake into a static water body. Iodine as an inorganic compound is not biodegradable so it was assumed, that the whole IPBC emissions might

accumulate during the service life. For IPBC this results in a concentration of 1.37 µg/L after 15 years. Mol weight transformation results in 0.62 µg/L iodine.

PEC Sediment
In the CAR (2008) for IPBC the reported PNEC for the sediment was derived using the equilibrium method. So the risk of the sediment compartment is the same as that assessed for surface water. Therefore, the calculation of $PEC_{sediment}$ values is not considered necessary.

PEC Soil
With reference to the iodine risk assessment for soil, the same procedure as for surface water has been followed, taking the house scenario and a service life of 15 years. IPBC emissions are assumed to accumulate over 15 years, and this yields an IPBC concentration of 0.437 mg/kg wet weight soil. Mol weight corrected this result in 0.197 mg/kg (wwt) iodine. The total iodine content in soil is transformed to iodide (14 %) and to iodate (100%).

PEC for air
Exposure to air is not considered as it is assumed that iodine speciate into non-volatile iodide and iodate in the different compartments.

PEC for groundwater
As a first tier, PECs for groundwater was calculated as concentrations in porewater. The estimated concentrations of iodine, iodide and iodate exceeded the general drinking water limit of 0.1µg/L, but was within the background concentrations of iodine in groundwater. Hence, this exceedance is considered acceptable.

Second tier estimations of PECgw for the iodine species was performed with FOCUS-PEARL 4.4.4. The calculations were undertaken for an IPBC release of 68.52 mg/m^2 treated wood over a period of 5 years corresponding to the results from the house scenario. The following transformation rates were used: IPBC is transformed 100% to iodine and the total iodine content in soil is transformed to iodide (14 %) and to iodate (100%).
The maximum calculated concentrations of iodide/iodate in the leachate at one metre soil depth were found for the Thiva scenario (0.3534 µg iodide/L and 3.729 µg iodate/L) (80th percentile).
The concentration in one metre soil depths is considered to represent a worst case environmental concentration in groundwater. The calculated concentrations of iodide and iodate in the leachate are within the background concentration and it can be concluded that the direct release of IPBC to soil can be considered safe with respect to leaching to groundwater and contamination of drinking water (cf. the assessment report for IPBC, PT 13).

3.2.2.3 Groundwater assessment

A FOCUS-PEARL-4.4.4 groundwater modelling was performed for PBC and the iodine species iodide and iodate. The inputs for the simulation are as shown in the table below.

Parameters	**Unit**	**PBC**	**Iodide**	**Iodate**	**Remark**
Physio-chemical properties					
Molecular weight	g/mol	155.2	126.904	174.903	
Water solubility	mg/l	2860	1E+05	1E+05	
Reference temp.	°C	25	25	25	
Vapour pressure	Pa	18.8	1E-06	1E-06	
Reference temp.	°C	25	25	25	
Degradation parameters					

DT50	d	9.5	1000	1000	
Reference temp.	°C	12	20	20	
Sorption parameters					
Koc	ml/g	198.1	290	290	
Kom	ml/g	114.85	168.2	168.2	
Exponent of Freunlich isotherm	-	0.9	0.9	0.9	
Management related substance parameters					
Crops	-	Grass			
Dosages	kg/ha	7.56E-4	8.65E-5	8.52E-4	Derived from the table below.
Incorporation depth	cm	0	0	0	

For the simulation, leaching from a painted house was considered. The scenario with a service life of 5 years showed the highest leaching per day, and was therefore chosen as a worst case. The dosages were calculated for the metabolites from the molar ratios between them and IPBC, and it was further assumed in the modelling, that IPBC is transformed to 100 % PBC and Iodine in the soil compartment, and Iodine is transformed to 100 % Iodate and 14 % Iodide.

Calculation of the application rate [kg.ha-1] of IPBC for the PEARL simulation

Parameter	IPBC	Unit	Remarks
Inputs			
Cumulative leaching of AS TIME 2a	68.52	mg/m2	derived from leaching test
Service life TIME 4	15	years	according to ESD for PT8
Number of house pr ha	16	ha	
Area of house	125	m2	
Fweatherside	0,5	-	
Number of events pr year	10	-	
Output			
Leaching per year	1,37E-05	kg/m2/year	cumulative leaching*1E-06/Time 2a
Total amount leached per year per ha	2.741E-02	kg/ha/year	leaching per year * nr. of houses * Area of house
Total amout leached pr year pr ha * Fweatherside	1.37E-02	kg/ha/year	
10-jan	1.37E-03	kg/ha	total amout leached out pr year and hectare, considering Fweatherside, and the number of events pr year.
15-feb	1.37E-03		
24-mar	1.37E-03		
29-apr	1.37E-03		
05-jun	1.37E-03		
11-jul	1.37E-03		
17-aug	1.37E-03		
22-sep	1.37E-03		
29-okt	1.37E-03		
01-dec	1.37E-03		

3.3 New information on the active substance

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3.4 Residue behaviour

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3.5 Summaries of the efficacy studies (B.5.10.1-xx)

See IUCLID section 6

3.6 Confidential annex

3.7 Other