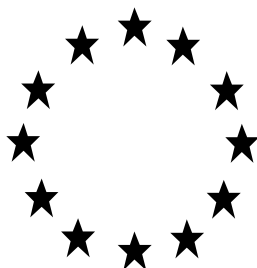


Regulation (EU) No 528/2012 concerning
the making available on the market
and use of biocidal products

**PRODUCT ASSESSMENT REPORT
OF A BIOCIDAL PRODUCT (FAMILY)
FOR NATIONAL AUTHORISATION
APPLICATIONS**

(submitted by the evaluating Competent Authority)



Koralan GL 220 Biocidal Product Family

Product type PT 8

IPBC as included in the Union list
of approved active substances

Case Number in R4BP: BC-NW024274-16

Evaluating Competent Authority: Poland

Date: 13.06.2019
(Updated 22.01.2020)

Note to the reader:

This PAR, the Confidential Annex, and the SPC have been updated since the first authorisation of Koralan GL 220 Biocidal Product Family following agreements made in the course of discussions with the following concerned Member States during their respective NA-MRS procedures: CH, NL, FI, DK, and ES.

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1 CONCLUSION

In opinion of the Polish CA authorization of Koralan GL 220 Biocidal Product Family can be granted according to art. 19(1) of BPR 528/2012.

Products within Koralan GL 220 Biocidal Product Family are wood preservatives (PT8) containing 0.95% of 3-Iodo-2-propynyl butyl carbamate, (IPBC, CAS: 55406-53-6) as the active substance and are dedicated to:

- industrial users by automated spraying, automated dipping, manual dipping and flow coating (deluging);
- professionals by manual dipping, brushing and rolling;
- non-professional users by brushing and rolling.

Based on the efficacy reports, which were submitted, the products are suitable for preventive treatment against bluestain fungi and mould in service in use class 2 and 3. The application rate is 120-140 ml/m² of wood surface if the products are used with top coat and 160-180 ml/m² if they are used without top coat.

The biocidal product family consist ready to use water-based formulations with confirmed long term stability up to 2 years in HDPE and tin plate can packaging. Physicochemical properties of evaluated products are considered to be acceptable. Acceptable analytical methods have been also submitted.

The intended use of Koralan GL 220 Biocidal Product Family would not pose unacceptable risk to human health or environment if used according to the instruction for use and risk mitigation measures as proposed by PL CA to be put on the labels. Use-specific instructions for use and use-specific risk mitigation measures are summarized in tables with authorised uses in section 2.1.4.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier ¹	Country (if relevant)
Koralan GL 220 Biocidal Product Family	National authorization: Poland
	Mutual Recognition: Austria Czech Republic Germany

Biocidal product within BPF	Trade names of products within BPF
1	Koralan Imprägnier-Grund farblos
2	Koralan GL 220 farblos
3	Koralan GL 220 Silbergrau
4	Koralan GL 220 Eiche
5	Koralan GL 220 Lärche
6	Koralan GL 220 Teak
7	Koralan GL 220 Schiefergrau
8	Koralan GL 220 Nussbaum
9	Koralan GL 220 Tabakbraun
10	Koralan GL 220 Kastanie
11	Koralan GL 220 Palisander
12	Koralan GL 220 Color
13	Koralan GL 220 Kiefer
14	Koralan GL 220 Hellgrau
15	Koralan GL 220 Weiß
16	Koralan Imprägnier-Grund Weiß
17	Koralan GL 220 Bangkirai
18	Koralan GL 220 Mittelgrau

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	Kurt Obermeier GmbH & Co. KG
	Address	Berghäuser Straße 70, D-57319 Bad Berleburg, Germany
Authorisation number	PL/2019/0395/BPF	
Date of the authorisation	13.06.2019	

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

Expiry date of the authorisation	10 years from the date of authorisation
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2.1.1.3 Manufacturer of the products of the family

Name of manufacturer	Kurt Obermeier GmbH & Co. KG
Address of manufacturer	Berghäuser Straße 70, D-57319 Bad Berleburg, Germany
Location of manufacturing sites	Berghäuser Straße 70, D-57319 Bad Berleburg, Germany

2.1.1.4 Manufacturer of the active substance

Active substance	3-iodo-2-propynylbutylcarbamate (IPBC)
Name of manufacturer	Troy Chemical Company BV
Address of manufacturer	Uiverlaan 12E 3145 XN Maassluis The Netherlands
Location of manufacturing sites	1. One Avenue L, 07105 Newark, New Jersey, United States 2. Industriepark 23, 56593 Horhausen, Germany

2.1.2 Product (family) composition and formulation

The full composition of the product according to Annex III Title 1 is provided in the confidential annex.

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

Yes
No

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	IPBC
IUPAC or EC name	3-Iodo-2-propynylbutylcarbamate
EC number	259-627-5
CAS number	55406-53-6
Index number in Annex VI of CLP	616-212-00-7
Minimum purity/content	≥98% w/w
Structural formula	$\text{I}-\text{C}\equiv\text{C}-\text{CH}_2-\text{O}-\overset{\text{O}}{\parallel}{\text{C}}-\text{NH}-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_3$

2.1.2.2 Candidate(s) for substitution and ED properties

The active substance 3-iodo-2-propynylbutylcarbamate (IPBC) is not a candidate for substitution.

In addition there is no evidence that the active substance or other ingredients present in products within Koralan GL 220 BPF have ED properties based on the assessment provided below. The active substance and other ingredients have been evaluated for their ED properties based on whether there has already been a decision made within the EU programs conducted in order to identify endocrine disruptors (EDs). None of the substances have been identified in searches of the following databases:

- Substance identified as ED under the BPR:
<https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d>
- Substance identified as ED under the PPPR:
https://ec.europa.eu/food/sites/food/files/pesticides_ppp_app-proc_cfs_database-201501.xlsx
- ECHA Candidate List of substances of very high concern for Authorisation:
<https://echa.europa.eu/candidate-list-table>
- ECHA's Endocrine disruptor assessment list
<https://echa.europa.eu/ed-assessment>
- EU Community rolling action plan (CoRAP)
<https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>

- EU Priority list
 - BKH report
 - BHK-RPS report
 - WRc-NSF Final Report
- http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm#priority_list

In addition to the EU programs, other databases (listed below) have been searched and none of them identified any of the substances present in the products within Koralan GL 220 BPF with ED properties.

- UN List of Identified Endocrine Disrupting Chemicals
https://www.chemsafetypro.com/Topics/Restriction/UN_list_identified_endocrine_disrupting_chemicals_EDCs.html
- EPA Endocrine Disruptor Screening Program
<https://www.epa.gov/endocrine-disruption/>
- USEPA EDSP21
<https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-21st-century?>
- USEPA ToxCast Dashboard
<https://actor.epa.gov/dashboard/>
- Japan Strategic Programs on Environmental Endocrine Disruptors '98 (SPEED '98)
<https://www.env.go.jp/en/chemi/ed/speed98/sp98t3.html>

The eCA PL considers the results of the searches to be sufficient to conclude that there is no evidence that the active and non-active substances present in the biocidal product family have ED properties.

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-Iodo-2-propynyl butylcarbamate	Active substance	55406-53-6	259-627-5	0.95	0.95

The complete composition of the product is provided in the confidential annex.

2.1.2.4 Information on technical equivalence

IPBC used in Koralan GL 220 Biocidal Product Family is supplied by Troy Chemical Company BV, who makes IPBC produced by Troy Chemical Company available on the market. Troy is a member of the European Union IPBC Task Force who is the participant for IPBC. The IPBC of Troy is defined as reference source. Consequently information on technical equivalence is not required.

2.1.2.5 Information on the substance(s) of concern

The products of the Koralan GL 220 Biocidal Product Family contain 0.000%-0.499% of 2-buthoxythanol as a substance of concern.

2.1.2.6 Type of formulation

Any other liquid (AL)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Chronic 3
Hazard statement	H412: Harmful to aquatic life with long lasting effects.
Labelling	
Signal words	No signal word
Hazard statements	H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P273: Avoid release to the environment. P501: Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.
GHS pictograms	No GHS pictogram
Note	EUH208: Contains 3-iodo-2-propynyl butylcarbamate, 5-chloro-2-methyl-2H-isothiazol-3-one, mixt. with 2-methyl-2H-isothiazol-3-one and 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Automated spraying by industrial users

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Automated spraying
Application rate(s) and frequency	with top coat: 120-140 ml/m ² without top coat: 160-180 ml/m ² The application rate depends on the wood surface (e.g. sawn surface or planed surface).
Category(ies) of users	Industrial users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L]

IBC (intermediate bulk container), Plastic: HDPE, 600/1000 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin plate, 0.375/0.75/1/2.0/2.5/5/10/20 [L]

2.1.4.1.1 Use-specific instructions for use

Regarding the contact time the user has to carry out a test treatment.

The wood is initially dry after approx. 1-2 hours at 23 °C and 50% relative humidity. High humidity and low temperatures delay drying. If needed, the next layer of wood preservative or a top coat can be subsequently applied after 2 hours (at 23 °C and 50% relative humidity).

Spray only in a closed spraying chamber to avoid any aerosols.

Use closed connecting lines to transfer the product to the spraying chamber.

Transfer the timber after treatment by fork lift to a storage area where it is placed to dry.

2.1.4.1.2 Use-specific risk mitigation measures

Use gloves (material to be specified by the authorisation holder within the product information) and protective coverall (coated coverall, at least type 6, EN 13034) during the handling of the treated timber and maintenance of the machinery.

The product may only be used with an automated onward transport of the freshly treated wood with automated stacking or into a drier so as to avoid manual contact with the freshly treated wood.

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

Freshly treated timber shall be stored after the treatment under a shelter or on impermeable hard standing, or both both, to prevent direct losses to soil, sewer or water and any losses must be collected for reuse or disposal.

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

2.1.4.2 Use description

Table 2. Use # 2 – Automated dipping by industrial users

Product Type	PT8
Where relevant, an exact description of	not relevant

the authorised use	
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Automated dipping
Application rate(s) and frequency	with top coat: 120-140 ml/m ² without top coat: 160-180 ml/m ² The application rate depends on the wood surface (e.g. sawn surface or planed surface).
Category(ies) of users	Industrial users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L] IBC (intermediate bulk container), Plastic: HDPE, 600/1000 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin plate , 0.375/0.75/1/2.0/2.5/5/10/20 [L]

2.1.4.2.1 Use-specific instructions for use

Regarding the contact time the user has to carry out a test treatment.
The wood is initially dry after approx. 1-2 hours at 23 °C and 50% relative humidity. High humidity and low temperatures delay drying. If needed, the next layer of wood preservative or a top coat can be subsequently applied after 2 hours (at 23 °C and 50% relative humidity).
Use closed connecting lines to transfer the product to the dipping tank.
Avoid any manual handling of the treated wood.
Use a fork lift to lower the wood into the dipping tank.
Use in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to the draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until the treated articles are surface dry. The untreated wood may only be lowered by a separate lifting unit into the dipping tank.
Transfer the timber after treatment by fork lift to a storage area where it is placed to dry.

2.1.4.2.2 Use-specific risk mitigation measures

Use gloves (material to be specified by the authorisation holder within the product information) and protective coverall (coated coverall, at least type 6, EN 13034) during the handling of the treated timber and maintenance of the equipment.
Application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
Freshly treated timber shall be stored after the treatment under a shelter or on impermeable hard standing, or both both, to prevent direct losses to soil, sewer or water and any losses must be collected for reuse or disposal.

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

2.1.4.3 Use description

Table 3. Use # 3 – Manual dipping by industrial users

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Manual dipping
Application rate(s) and frequency	with top coat: 120-140 ml/m ² without top coat: 160-180 ml/m ² The application rate depends on the wood surface (e.g. sawn surface or planed surface).
Category(ies) of users	Industrial users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L] IBC (intermediate bulk container), Plastic: HDPE, 600/1000 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin plate, 0.375/0.75/1/2.0/2.5/5/10/20 [L]

2.1.4.3.1 Use-specific instructions for use

Regarding the contact time the user has to carry out a test treatment. The wood is initially dry after approx. 1-2 hours at 23 °C and 50% relative humidity. High humidity and low temperatures delay drying. If needed, the next layer of wood preservative or a top coat can be subsequently applied after 2 hours (at 23 °C and 50% relative humidity).

Decanting (loading phase) has to be done by using a dosing pump.

Lift and place the wooden article into the dipping tank.

Use a post to push the wooden article under the wood preservative in the dipping tank and/or use a broom to brush the wood preservative onto the wooden article (the article has to be still in the dipping tank as the preservative is brushed on the wood).

After lifting the wooden article from the dipping tank stack the article to dry.

2.1.4.3.2 Use-specific risk mitigation measures

Use gloves (material to be specified by the authorisation holder within the product information) and protective coverall (coated coverall, at least type 6, EN 13034) during the handling of the treated timber and maintenance of the equipment.

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

Freshly treated timber shall be stored after the treatment under a shelter or on impermeable hard standing, or both both, to prevent direct losses to soil, sewer or water and any losses must be collected for reuse or disposal.

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

2.1.4.4 Use description

Table 4. Use # 4 – Manual dipping by professionals

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Manual dipping
Application rate(s) and frequency	with top coat: 120-140 ml/m ² without top coat: 160-180 ml/m ² The application rate depends on the wood surface (e.g. sawn surface or planed surface).
Category(ies) of users	Professional users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L] IBC (intermediate bulk container), Plastic: HDPE, 600/1000 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin plate, 0.375/0.75/1/2.0/2.5/5/10/20 [L]

2.1.4.4.1 Use-specific instructions for use

Regarding the contact time the user has to carry out a test treatment. The wood is initially dry after approx. 1-2 hours at 23 °C and 50% relative humidity. High humidity and low temperatures delay drying. If needed, the next layer of wood preservative or a top coat can be subsequently applied after 2 hours (at 23 °C and 50% relative humidity).

Decanting (loading phase) has to be done by using a dosing pump.

Lift and place the wooden article into the dipping tank.

Use a post to push the wooden article under the wood preservative in the dipping tank and/or use a broom to brush the wood preservative onto the wooden article (the article has to be still in the dipping tank as the preservative is brushed on the wood).

After lifting the wooden article from the dipping tank stack the article to dry.

2.1.4.4.2 Use-specific risk mitigation measures

Use gloves (material to be specified by the authorisation holder within the product information) and protective coverall (coated coverall, at least type 6, EN 13034) during the handling of the treated timber and maintenance of the equipment.

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

Freshly treated timber shall be stored after the treatment under a shelter or on impermeable hard standing, or both both, to prevent direct losses to soil, sewer or water and any losses must be collected for reuse or disposal.

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

2.1.4.5 Use description

Table 5. Use # 5 – Flow coating (deluging) by industrial users

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.

Application method(s)	Flow coating (deluging)
Application rate(s) and frequency	with top coat: 120-140 ml/m ² without top coat: 160-180 ml/m ² The application rate depends on the wood surface (e.g. sawn surface or planed surface).
Category(ies) of users	Industrial users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L] IBC (intermediate bulk container), Plastic: HDPE, 600/1000 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin plate, 0.375/0.75/1/2.0/2.5/5/10/20 [L]

2.1.4.5.1 Use-specific instructions for use

Regarding the contact time the user has to carry out a test treatment. The wood is initially dry after approx. 1-2 hours at 23 °C and 50% relative humidity. High humidity and low temperatures delay drying. If needed, the next layer of wood preservative or a top coat can be subsequently applied after 2 hours (at 23 °C and 50% relative humidity).

Use closed connecting lines to transfer the product.

Pass the timber through an enclosed tunnel in which the preservative is applied. After the flooding process conduct treated timber through a drying channel, where the wooden articles will be dried with a warm air stream.

2.1.4.5.2 Use-specific risk mitigation measures

During the handling of the treated timber and maintenance of machinery, gloves (material to be specified by the authorisation holder within the product information) and protective coverall (coated coverall, at least type 6, EN 13034) are to be used.

The product may only be used with an automated onward transport of the freshly treated wood with automated stacking or into a drier so as to avoid manual contact with the freshly treated wood.

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

Freshly treated timber shall be stored after the treatment under a shelter or on impermeable hard standing, or both both, to prevent direct losses to soil, sewer or water and any losses must be collected for reuse or disposal.

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

2.1.4.6 Use description

Table 6. Use # 6 – Brushing/roller by professionals

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Brushing/rolling
Application rate(s) and frequency	with top coat: 120-140 ml/m ² For use with top coat 1 L of product is sufficient to treat 7-8 m ² of wood. without top coat: 160-180 ml/m ² For use without top coat 1 L of product is sufficient to treat 5-6 m ² of wood.
Category(ies) of users	Professional users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin plate, 0.375/0.75/1/2.0/2.5/5/10/20 [L]

2.1.4.6.1 Use-specific instructions for use

The wood is initially dry after approx. 1-2 hours at 23 °C and 50% relative humidity. High humidity and low temperatures delay drying. If needed, the next layer of wood preservative or a top coat can be subsequently applied after 2 hours (at 23 °C and 50% relative humidity).

Decanting (loading phase) has to be done by using a dosing pump.

After application, clean the brush with water.

2.1.4.6.2 Use-specific risk mitigation measures

Wear protective gloves (material to be specified by the authorisation holder within the product information) during application and handling of treated wood.

Cover the ground with impermeable sheet during application and whilst surfaces are drying and collect any spillage.

Do not apply over/near bodies of surface water.

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

2.1.4.7 Use description

Table 7. Use # 7 – Brushing/roller by non-professionals

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Brushing/rolling
Application rate(s) and frequency	with top coat: 120-140 ml/m ² For use with top coat 1 L of product is sufficient to treat 7-8 m ² of wood. without top coat: 160-180 ml/m ² For use without top coat 1 L of product is sufficient to treat 5-6 m ² of wood.
Category(ies) of users	Non-professional users
Pack sizes and packaging material	Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5 [L] Can, Bucket, Metal: Tin plate, 0.375/0.75/1/2.0/2.5/5 [L]

2.1.4.7.1 Use-specific instructions for use

The wood is initially dry after approx. 1-2 hours at 23 °C and 50% relative humidity. High humidity and low temperatures delay drying. If needed, the next layer of wood preservative or a top coat can be subsequently applied after 2 hours (at 23 °C and 50% relative humidity).

After application, clean the brush with water.

2.1.4.7.2 Use-specific risk mitigation measures

Keep children away during treatment.

Cover the ground with impermeable sheet during application and whilst surfaces are

drying and collect any spillage.

Do not apply over/near bodies of surface water.

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

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

See general directions for use (section 2.1.5).

2.1.5 General directions for use

2.1.5.1 Instructions for use

The product may not be used together with products against wood destroying fungi. Product is intended for wood or wood products that by their nature are not susceptible to wood destroying (brown rot) fungi.

The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting. Not for indoor application (except windows and exterior doors).

Stir well before use.

Wood surface must be clean and dry.

Do not dilute (product is RTU).

If a topcoat is applied, it should not have a biocidal function and it should be regularly maintained.

See respective use-specific instructions for use provided above.

2.1.5.2 Risk mitigation measures

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

Wash hands and exposed skin before meals and after use.

Do not contaminate foodstuffs, eating utensils or food contact surfaces.

See respective use-specific risk mitigation measures provided above.

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

Description of first aid measures

General information: Change contaminated, saturated clothing. When in doubt or if symptoms are observed, get medical advice. Never give anything by mouth to an unconscious person or a person with cramps.

Following inhalation: Remove casualty to fresh air and keep warm and at rest. Provide fresh air.

In case of skin contact: After contact with skin, wash immediately with plenty of water and soap. In case of skin reactions, consult a physician.

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Remove contact lenses if easily accessible and keep rinsing. In case of eye irritation consult an ophthalmologist.

After ingestion: Do NOT induce vomiting. Rinse mouth thoroughly with water.

Self-protection of the first aider: First aider: Pay attention to self-protection!

Information to physician: Treatment: Treat symptomatically.

Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

Indication of any immediate medical attention and special treatment needed:
None

Protective measures: Use only in well-ventilated areas. Do not breathe gas/fumes/vapour/spray.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: Take the precautions customary when handling chemicals. Use personal protection equipment.

Environmental precautions: Do not allow to enter into surface water or drains. Do not contaminate ground, waterbodies or watercourses with chemicals or used container.

Prevent spread over a wide area (e.g. by containment or oil barriers).

Methods and material for containment and cleaning up: Take up mechanically. Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid - or universal binding agents). Collect in closed and suitable containers for disposal.

Stability and reactivity:

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under recommended conditions of storage, use and temperature.

Possibility of hazardous reactions: No dangerous reactions known.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Waste disposal according to Directive 2008/98/EC, covering waste and dangerous waste. Consult the appropriate local waste disposal expert about waste disposal.

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Handle all contaminated materials, packaging, waste water (e.g. from cleaning the brush) and spillage in the same way as the product itself.

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

24 months shelf-life

Keep/store only in the original, closed container in dry and well-ventilated conditions. Protect from frost and sunlight. Keep/store below 30°C. Protect containers against damage.

The product must be kept away from food, drink and animal feedstuffs.

2.1.6 Other information

Application codes

Categories	Matrix wording	Code for product
User category	Non-professional/general public	A.10
	Industrial	A.20
	Professional	A.30
Wood category	Softwood and Hardwood	B.10 ; B.20
Wood product	Solid wood/Reconstituted solid wood/Panels/Plywood panels/OSB panels/Particles panels/Fibers panels	C.10/C11/C20/ C21/C22/C23/C24
Application aim	Preventive treatment/Blue stain in service	D. 30
Field of use	Use classes 2 and 3	E.20, E.30
Method of application and rate	Superficial application/brush/roller	F.10
	Superficial application/spray treatment	F.11
	Superficial application/flow coat	F.12
	Superficial application/dipping treatment	F.14
Target organisms	Wood discolouring fungi	G.21.2

Mould fungi	G.22
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2.1.7 Packaging of the biocidal products within BPF

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, Bucket	0.375/0.75/1/2.0/2.5/5/10/20 [L]	Tin	Tin	Industrial and Professional	yes
	0.375/0.75/1/2.0/2.5/5 [L]			Non-professional	
Can, Bucket	0.375/0.75/1/2.0/2.5/5/10/20 [L]	HDPE	HDPE	Industrial and Professional	yes
	0.375/0.75/1/2.0/2.5/5 [L]			Non-professional	
Drum	10/20/60/120/200 [L]	HDPE	HDPE	Industrial and Professional	yes
IBC	600/1000 [L]	HDPE	HDPE	Industrial	yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please find a reference list attached to the Annex.

2.1.8.2 Access to documentation

The Letter of access for the active substance dossier will be sent to the national authorities directly by the data owner. A copy of the Letter of access is attached in Section 13 of the IUCLID dossier.

2.2 Assessment of the biocidal product (family)

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

Table 4. Use # 1 – Automated spraying by industrials

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Automated spraying
Application rate(s) and frequency	with top coat: 120-140 ml/m ² without top coat: 160-180 ml/m ² The application rate is applied in 1 application.
Category(ies) of users	Industrial users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L] IBC (intermediate bulk container), Plastic: HDPE, 600/1000 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin, 0.375/0.75/1/2.0/2.5/5/10/20 [L]

Table 5. Use # 2 – Automated dipping by industrials

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Automated dipping
Application rate(s) and frequency	with top coat: 120-140 ml/m ² without top coat: 160-180 ml/m ² The application rate is applied in 1 application.
Category(ies) of users	Industrial users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L] IBC (intermediate bulk container), Plastic: HDPE, 600/1000 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin, 0.375/0.75/1/2.0/2.5/5/10/20 [L]

Table 6. Use # 3 – Manual dipping by industrials and professionals

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Manual dipping
Application rate(s) and frequency	with top coat: 120-140 ml/m ² without top coat: 160-180 ml/m ² The application rate is applied in 1 application.
Category(ies) of users	Industrial and professional users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L] IBC (intermediate bulk container), Plastic: HDPE, 600/1000 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin, 0.375/0.75/1/2.0/2.5/5/10/20 [L]

Table 7. Use # 4 – Flow coating (deluging) by industrials

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Flow coating (deluging)
Application rate(s) and frequency	with top coat: 120-140 ml/m ² without top coat: 160-180 ml/m ² The application rate is applied in 1 application.
Category(ies) of users	Industrial users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L] IBC (intermediate bulk container), Plastic: HDPE, 600/1000 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin, 0.375/0.75/1/2.0/2.5/5/10/20 [L]

Table 8. Use # 5 – Brushing/roller by professionals

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant

Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Brushing/rolling
Application rate(s) and frequency	with top coat: 120-140 ml/m ² The application rate is applied in 1 application. without top coat: 160-180 ml/m ² The application rate is applied in 2-3 applications. Application of the next coat after a waiting time of at least 2 hours (in normal ambient conditions).
Category(ies) of users	Professional users
Pack sizes and packaging material	Drum, Plastic: HDPE, 10/20/60/120/200 [L] Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5/10/20 [L] Can, Bucket, Metal: Tin, 0.375/0.75/1/2.0/2.5/5/10/20 [L]

Table 9. Use # 6 – Brushing/roller by non-professionals

Product Type	PT8
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against wood discolouring fungi such as blue stain and mould.
Field of use	Preventive wood preservation in use class 2 and 3.
Application method(s)	Brushing/rolling
Application rate(s) and frequency	with top coat: 120-140 ml/m ² The application rate is applied in 1 application. without top coat: 160-180 ml/m ² The application rate is applied in 2-3 applications. Application of the next coat after a waiting time of at least 2 hours (in normal ambient conditions).
Category(ies) of users	Non-professional users
Pack sizes and packaging material	Can, Bucket, Plastic: HDPE, 0.375/0.75/1/2.0/2.5/5 [L] Can, Bucket, Metal: Tin, 0.375/0.75/1/2.0/2.5/5 [L]

2.2.2 Physical, chemical and technical properties

In December 2017 the applicant reported that the composition of Koralan GL 220 Biocidal Product Family was changed. The in-can preservative Acticide MBS has been replaced by Mergal 723K. The stability of the product remains unchanged by the exchange of the in-can preservative. This has been shown with an accelerated stability study for 8 weeks at 40 C° and a long term stability study for 24 months at ambient temperature. The other properties of the product are not influenced by the modification because of the very small amount of 0.2% of the formulation which has been changed. The accelerated storage stability test Rose, A. (2017), No. HPLC-17-092B-KN GL and the long term storage at ambient temperature Rose, A. (2018), Study No. : HPLC-17-45-A_KN_GL were made with Koralan GL 220 Kastanie containing Mergal 723K.

Property	Guideline and Method	Test item	Results	Reference
Physical state at 20°C and 101.3 kPa	Visual check	Koralan GL 220 Kastanie Batch no.: BA 291015	Physical state: Suspension	Rose, A. (2018), Study No. : HPLC-17- 45-A_KN_GL
Colour at 20°C and 101.3 kPa			Colour: Dark brown	
Odour at 20°C and 101.3 kPa			Odor: not determined	
Physical state at 20°C and 101.3 kPa	Visual and olfactory check	All products	Physical state: liquid	Hellkamp, S. (2016), No. UB10570
Colour at 20°C and 101.3 kPa			Colour: Please see the study report	
Odour at 20°C and 101.3 kPa			Odor: light	
Acidity/alkalinity	CIPAC MT 75.3	Koralan GL 220 Kastanie Batch no.: BA 291015	pH (undiluted): 7.5 pH (1% dilution in water): 8.2	Rose, A. (2018), Study No. : HPLC-17- 45-A_KN_GL
Relative density/bulk density	EC A.3 (DIN 51757)	Koralan GL 220 Kastanie BTS sample number: 120687	D ²⁰ _{4 liquid} = 1.032	Heitkamp, D. (2016), No. 2015/01303
Storage stability test – accelerated storage	CIPAC MT 46.3	Koralan GL 220 Kastanie Batch no.: BA 17059-1	Results accelerated storage 8 weeks at 40°C (during the storage the measured temperature was 40.0°C ± 0.5 °C): <u>Plastic bottles (PE):</u> Appearance Initial Dark brown, Suspension with little sediment (before shaking),	Rose, A. (2017), No. HPLC-17- 092B-KN GL

Property	Guideline and Method	Test item	Results	Reference
			<p>Homogeneous suspension (after shaking), 8 weeks No change.</p> <p>IPBC content Initial 0.961% 8 weeks 0.901%</p> <p><u>Tin plate cans:</u> Appearance Initial Dark brown, Suspension with little sediment (before shaking), Homogeneous suspension (after shaking), 8 weeks No change.</p> <p>IPBC content Initial 0.961% 8 weeks 0.915%</p>	
Storage stability test – long term storage at ambient temperature	GIFAP No. 17	Koralan GL 220 Kastanie Batch no.: BA 291015	<p><u>Results after 6, 12 and 24 months, storage at ambient temperature (23°C ± 0.5 °C) in plastic bottles (PE).</u></p> <p>Appearance Initial Dark brown, Suspension with little sediment (before shaking), Homogeneous suspension (after shaking), 6m No change. No weight loss. 12m No change. No weight loss. 24m No change. No weight loss.</p>	Rose, A. (2018), Study No. : HPLC-17-45-A_KN_GL

Property	Guideline and Method	Test item	Results	Reference
			Packaging Initial No corrosion, leakage or other interaction. 6m no change 12m no change 24m no change IPBC content Initial 0.933% 6m 0.930% 12m 0.921% 24 m 0.924% pH _{100%} Initial 7.5 6m 7.4 12m 7.5 24m 7.5 pH _{1%} Initial 8.1 6m 8.0 12m 8.1 24m 8.2 <u>Results after 6, 12 and 24 months, storage at ambient temperature (23°C ± 0.5 °C) in tin plate cans.</u> Appearance Initial Dark brown, Suspension with little sediment (before shaking), Homogeneous suspension (after shaking), 6m No change. No weight loss. 12m No change. No weight loss. 24m No change. No weight loss. Packaging	

Property	Guideline and Method	Test item	Results	Reference
			Initial No corrosion, leakage or other interaction. 6m no change 12m no change 24m no change IPBC content Initial 0.933% 6m 0.937% 12m 0.928% 24 m 0.931% pH _{100%} Initial 7.5 6m 7.5 12m 7.4 24m 7.5 pH _{1%} Initial 8.1 6m 8.3 12m 8.0 24m 8.1	
Storage stability test – low temperature stability test for liquids	The products are not recommended to be stored below 0°C (see statement on label: "Protect from frost").			
Effects on content of the active substance and technical characteristics of the biocidal product - light	The products are not recommended to be stored under the influence of light (see statement on label: "Protect from sunlight").			
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	Temperature: The products are not recommended to be stored above 30°C (see statement on label: "Do not store > 30 °C") Humidity: The products are stored in sealed packaging. In addition, the formulations are water-based, therefore humidity is not expected to influence content of active substance during storage.			
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	GIFAP No. 17	Koralan GL 220 Kastanie Batch no.: BA 291015	Results of long term storage at ambient temperature (during the storage the measured temperature was 23.0°C ± 0.5 °C): <u>Plastic bottle (PE):</u> Initial	Rose, A. (2018), Study No. : HPLC-17-45-A_KN_GL

Property	Guideline and Method	Test item	Results	Reference
			No weight loss. No corrosion, leakage or other interaction. 6m no change 12m no change 24m no change <u>Tin plate can:</u> Initial No weight loss. No corrosion, leakage or other interaction. 6m no change 12m no change 24m no change	
Wettability	The products of this biocidal product family are water based ready-to-use products. Thus, testing of wettability is not applicable.			
Suspensibility, spontaneity and dispersion stability	The products of the biocidal product family are water based ready-to-use products. Thus, testing of suspensibility, spontaneity and dispersion stability is not applicable.			
Wet sieve analysis and dry sieve test	The products of the biocidal product family are water based ready-to-use products. Thus, wet sieve analysis and dry sieve test is not applicable.			
Emulsifiability, re-emulsifiability and emulsion stability	The products of the biocidal product family are water based ready-to-use products. Thus, testing of emulsifiability, re-emulsifiability and emulsion stability is not applicable.			
Disintegration time	The products of the biocidal product family are water based ready-to use-products. Thus, testing of disintegration time is not applicable.			
Particle size distribution, content of dust/fines, attrition, friability	The products of the biocidal product family are used for automated spraying in closed systems, so that no aerosols can occur. Thus, the determination of particle size distribution, content of dust/fines, attrition, friability is not necessary.			
Persistent foaming	The products of the biocidal product family are water based ready-to-use products. Since the products are not applied in water for use, determination of persistent foam is not applicable.			
Flowability/Pourability/Dustability	The products of the biocidal product family are water based ready-to-use products. Thus, testing of Flowability/Pourability/Dustability is not applicable.			
Burning rate — smoke generators	The products of the biocidal product family are water based ready-to-use products. Thus, testing of burning rate is not applicable.			
Burning completeness — smoke generators	The products of the biocidal product family are water based ready-to-use products. Thus, testing of burning completeness is not applicable.			
Composition of smoke — smoke generators	The products of the biocidal product family are water based ready-to-use products. Thus, testing of composition of smoke is not applicable.			
Spraying pattern — aerosols	The products of the biocidal product family are water based ready-to-use products. Only automated spraying under closed conditions is intended. Thus, testing of spraying pattern is not applicable.			

Property	Guideline and Method	Test item	Results	Reference
Other technical characteristics	The products of the biocidal product family are water based ready-to-use products. Testing of other technical characteristics is not applicable.			
Physical compatibility	Not applicable. None of the products of this biocidal product family are recommended to be used in combination with other products.			
Chemical compatibility	Not applicable. None of the products of this biocidal product family are recommended to be used in combination with other products.			
Degree of dissolution and dilution stability	Not applicable. The products of the biocidal product family are water based ready-to-use products.			
Surface tension	OECD Guideline No 115, DIN EN 14370	Koralan GL 220 Kastanie BTS sample number: 120687	The surface tension of original test substance (undiluted) was determined as $\sigma = 37.38$ mN/m at 20 °C.	Heitkamp, D. (2016), No. 2015/01303
Viscosity	Test according to DIN 53019	Koralan GL 220 Kastanie Batch no.: 270214	The Dynamic Viscosity at 20°C is 0.0024 Pa*s. The Dynamic Viscosity at 40°C is 0.0016 Pa*s. The Kinematic Viscosity at 20°C is 2.4 mm ² /s. The Kinematic Viscosity at 40°C is 1.6 mm ² /s.	Rose, A. (2016), No. 01/16/PC

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

Koralan GL 220 Kastanie, belonging to the Koralan GL 220 Biocidal Product Family Biocidal Product Family, has been tested for the relevant parameters characterising their physical, chemical and technical properties. Long term storage studies at ambient temperature after 24 month are successfully demonstrating the stability of the product and the packaging. The data obtained for PE packaging can be extrapolated for HDPE packaging.

The formulations of the biocidal product family display variability in content and nature of pigments, defoamer and surfactant. However, these differences are not expected to significantly influence the storage stability, the pH value, the reactivity towards container material, the relative density, the surface tension, the viscosity of the formulations. Therefore all products of the biocidal product family are covered by the data generated for the product Koralan GL 220 Kastanie.

Appropriate risk mitigating measure will be stated on label (please see 2.1.5.5).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Test item	Results	Reference
Explosives	Expert statement	Koralan GL 220 Kastanie	'Koralan GL 220 Kastanie' is not explosive.	Heitkamp, D. (2016), No. 2015/01303

Property	Guideline and Method	Test item	Results	Reference
Flammable gases	Not applicable. All products of this biocidal product family are water based liquids.			
Flammable aerosols	Not applicable. All products of this biocidal product family are water based liquids, which are not to be applied in form of aerosols.			
Oxidising gases	Not applicable. All products of this biocidal product family are water based liquids.			
Gases under pressure	Not applicable. All products of this biocidal product family are water based liquids.			
Flammable liquids	DIN EN ISO 2719 (Procedure A)	Koralan GL 220 Kastanie	'Koralan GL 220 Kastanie' exhibited no flash point up to the boiling point 'Koralan GL 220 Kastanie' is not a flammable liquid.	Heitkamp, D. (2016), No. 2015/01303
Flammable solids	Not applicable. All products of this biocidal product family are water based liquids.			
Self-reactive substances and mixtures	Due to water content and known experience none of the formulations of the biocidal product family is self-reactive.			
Pyrophoric liquids	Due to water content and known experience none of the formulations of the biocidal product family has pyrophoric properties.			
Pyrophoric solids	Not applicable. All products of this biocidal product family are water based liquids.			
Self-heating substances and mixtures	Due to water content and known experience none of the formulations of the biocidal product family is known to be self-heating.			
Substances and mixtures which in contact with water emit flammable gases	Not applicable. All products of this biocidal product family are water based liquids.			
Oxidising liquids	Expert statement	Koralan GL 220 Kastanie	'Koralan GL 220 Kastanie' has no oxidizing properties. 'Koralan GL 220 Kastanie' is according to Regulation (EC) No. 1272/2008 (CLP-Regulation) not an oxidizing liquid.	Heitkamp, D. (2016), No. 2015/01303
Oxidising solids	Not applicable. All products of this biocidal product family are water based liquids.			

Property	Guideline and Method	Test item	Results	Reference
Organic peroxides	Not applicable, no organic peroxides contained in any of the products of the biocidal product family.			
Corrosive to metals	Not applicable, the formulations of the biocidal product family do not contain components that are classified to be corrosive to metals.			
Auto-ignition temperatures of products (liquids and gases)	EC Test Procedure A.15, DIN 51794	Koralan GL 220 Kastanie	'Koralan GL 220 Kastanie' has an auto-ignition temperature of 470°C when tested.	Heitkamp, D. (2016), No. 2015/01303
Relative self-ignition temperature for solids	Not applicable. All products of this biocidal product family are water based liquids.			
Dust explosion hazard	Not applicable. All products of this biocidal product family are water based liquids.			

Conclusion on the physical hazards and respective characteristics of the product

Koralan GL 220 Kastanie, belonging to the Koralan GL 220 Biocidal Product Family, is a water-based ready-to-use product. Its physical hazards and respective characteristics can be derived based on its formulation type (i.e. water-based liquid) and the intrinsic properties of the individual components.

The tests on flammability and auto-ignition temperatures of liquids as well as the expert statements on explosive and oxidising properties did not reveal any physico-chemical hazards related to Koralan GL 220 Kastanie.

The formulations of the biocidal product family display variability in content and nature of pigments, defoamer and surfactant. However, these differences are not expected to lead to auto-ignition, imply flammable properties, oxidising properties or lead to explosive and therefore all products of the family are covered by the data generated for the product "Koralan GL 220 Kastanie".

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range/Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RS D		
Koralan GL 220 Kastanie (active substance)	HPLC-UV	n=6	R ² =0.9999	No interferences from matrix were detected.	99.7% - 100.1%	99.93%	1.33%	Not required; method for determination	Rose, A. (2018), No. HPLC-17-45-A_KN_GL

e: IPBC 0,95%)								g active substance content in formulated product	
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The formulations of the biocidal product family display variability in content and nature of pigments, defoamer and surfactant. However, these differences are not expected to significantly influence the results of the analytical method. Therefore the products of the biocidal product family are covered by the analytical method generated for the product "Koralan GL 220 Kastanie".

Analytical methods for monitoring

Analytical methods for soil

For the determination of IPBC in soil an analytical method is available and described in the assessment report of IPBC (Denmark, February 2008).

Analytical methods for air

A analytical method for the determination of IPBC in air is not necessary since IPBC is not volatile and spray applications only involve non-respirable particles.

Analytical methods for water

For the determination of IPBC in water an analytical method is available and described in the assessment report of IPBC (Denmark, February 2008).

Analytical methods for animal and human body fluids and tissues

For the active substance IPBC an analytical method in animal and human body fluids is described in the IPBC assessment reports PT 6 (September 2013) and PT 13 (January 2015).

Analytical methods for monitoring of active substances and residues in food and feeding stuff

No data required. Proposed use is for wood preservation. No use related to food or feeding stuffs foreseen.

Conclusion on the methods for detection and identification of the product

The analytical method provided is sufficient to determine the content of the active substance IPBC in the products of the Koralan GL 220 Biocidal Product Family with respect to specificity, linearity, precision and recovery.

Analytical methods for monitoring of the active substance in soil and water as well as in animal and human body fluids and tissues are described in the respective assessment reports.

An analytical method for monitoring in air is not deemed necessary, since IPBC is not volatile and spray applications only involve non-respirable particles.

Likewise, analytical methods for monitoring of the active substance or residues in food and feeding stuffs are not necessary, since no corresponding use is foreseen.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The products of the Koralan GL 220 Biocidal Product Family are ready to use water based products based on the active substance IPBC. They are used for superficial treatments of wood against wood discolouring fungi (blue stain) and mould. The fields of use are use classes 2 and 3. The products are to be applied by industrials, professionals and non-professionals.

Application codes

Categories	Matrix wording	Code for product
User category	Non-professional/general public	A.10
	Industrial	A.20
	Professional	A.30
Wood category	Softwood and Hardwood	B.10; B.20
Wood product	Solid wood/Reconstituted solid wood/Panels/Plywood panels/OSB panels/Particles panels/Fibers panels	C.10/C11/C20/C21/C22/C23/C24
Application aim	Preventive treatment/Blue stain in service	D. 30
Field of use	Use classes 2 and 3	E.20, E.30
Method of application and rate	Superficial application/brush/roller	F.10
	Superficial application/spray treatment	F.11
	Superficial application/flow coat	F.12
	Superficial application/dipping treatment	F.14
Target organisms	Wood discolouring fungi	G.21.2
	Mould fungi	G.22

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

The products of the Koralan GL220 BPD are wood preservatives with a protective effectiveness against wood discolouring fungi (blue stain) and mould.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The products of the Koralan GL 220 Biocidal Product Family have documented preventive effects on wood discolouring fungi (blue stain) and mould in use class 2 and 3.

2.2.5.4 Mode of action, including time delay

IPBC has a carbamate structure. The target sites of carbamates in fungi are cell membrane permeability and fatty acids.

2.2.5.5 Efficacy data

To support the claims for product family Koralan GL 220 Biocidal Product Family, the applicant has submitted two tests to prove the preventive efficacy against blue stain and one test to prove the efficacy against mould fungi.

To prove the fungicide action for surface treatment (blue stain) after 6 months of outdoor weathering, for use classes 2 and 3, the tests n° 32/14/9755/01-02 has been submitted. The applicant has tested the formulation named Koralan Bläueschutzgrundierung, containing 0.95% of IPBC. As proposed in the EN 599-1 (2009), the test follows EN 152-1 norm on *Aureobasidium pullulans* and *Sydowia polyspora*. The application method is brushing procedure (with top coat). The result shows that the product is effective in rate: 120-140 ml/m² (mean 130 ml/m²).

To prove the fungicide action for surface treatment (blue stain), after 6 months of outdoor weathering, for use classes 2 and 3, the tests n° 32/17/10056/01 has been submitted. The applicant has tested the formulation named Koralan Bläueschutzgrundierung, containing 0.95% of IPBC. As proposed in the EN 599-1 (2009), the test follows EN 152-1 norm on *Aureobasidium pullulans* and *Sydowia polyspora*. The application method is brushing procedure (without top coat). The result shows that the product is effective in rate: 160-180 ml/m² (mean 168.4 ml/m²).

Applicant has not submitted suitable laboratory data demonstrating efficacy after ageing test accordance with EN 73, but tests after 6 months of outdoor weathering has been submitted. According to TNsG it is possible to submitted test after a natural or artificial weathering cycle as given in EN 152.

According to EN 152 Scots pine sapwood (*Pinus sylvestris* Linnaeus) is obligatory for every test. Scots pine sapwood is the most susceptible species for blue stain. Therefore the submitted study covers the efficacy against all wood species and no further testing is required.

To prove the fungicide action against mould for surface treatment as additional study, the tests n° 32/17/10056/30 has been submitted. The applicant has tested the formulation named Koralan Bläueschutzgrundierung, containing 0.95% of IPBC. As proposed in the DIN EN 15457 (2014) laboratory method for testing the efficacy of film preservatives in a coating against fungi on paints and varnishes on *Aureobasidium pullulans*, *Alternaria alternate*, *Cladosporium cladosporioides* and *Aspergillus niger*. The result shows that the product is effective in rate: 140-160 ml/m² (mean value 151.1 ml/m²).

According to TNsG blue stain causes blue to black permanent colour of variable intensity and depth mainly in the sapwood, depending on the wood species. This does not result in appreciable alteration of the mechanical properties but can increase the permeability of the wood and thereby makes it more susceptible to fungal degradation. Moulds being evident as spots of various colours on the surface of moist wood. They do not significantly alter the mechanical properties of the wood but have a special significance for wood in service if discoloration is undesirable or unacceptable.

As the protection objective of the products of the biocidal product family is not protection against degradation, but protection against discoloration (optical problem), efficacy against wood destroying fungi is not required.

The products of the biocidal product family may not be used together with products against wood destroying fungi.

DIN EN 15457 is a laboratory study for testing the efficacy of film preservatives in coatings but is considered as additional proof for the efficacy against mould as another type of would discoloring fungi and no CEN standard is available to cover mould.

Justification of Biocidal Family ranges:

The efficacy testing has been made with Koralan Bläueschutzgrundierung Kastanie, a product from the biocidal product family. The tested product is a ready-to-use product.

Within the biocidal product family the products vary mainly with regard to the content of coloring ingredients. The coloring ingredients will not penetrate into the timber during the treatment but will remain on the surface of the wood. The distribution of the active substances is not influenced by the coloring ingredients because no absorption processes from the active substances on the coloring ingredients is observed. After filtration the remaining colourless product contains unchanged contents of active substances. Therefore no influence by coloring ingredients on the efficacy is expected for the various products of the biocidal product family.

Some ingredients within Koralan GL 220 Biocidal Product Family are preserved with IPBC (maximum concentration in products of Koralan GL 220 Biocidal Product Family could be 0.01%). The function of IPBC in these ingredients is in-can preservation, therefore these amounts do not contribute to the function of the active ingredient IPBC in PT 8. It is not justified to sum up the active substance (IPBC) content in the product with the theoretical IPBC content based on the in-can preservative content of some co-formulants (pigments) for the following reason: The function of IPBC in the co-formulants (pigments) is to preserve those co-formulants during storage until they are used in production of another product. Therefore it can be expected that IPBC is consumed during that time and the concentration of IPBC as preservative is significantly reduced until the co-formulants are used in the production process for wood preservatives.

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/concentration s applied/exposure time	Test results: effects	Reference
Fungicide (bluestain fungi)	Use Class 2,3	Koralan Bläueschutz-grundierung (Farbton Kastanie)	<i>Aureobasidium pullulans</i> (de Bary) Arnaud <i>Sydowia polyspora</i> (Bref. & Travel) E. Müller	EN 152-1 after 6 month outdoor weathering	Superficial treatment (brushing) /with top coat Application rate: 120-140 ml/m ² (mean 130 ml/m ²) Exposure time: 6 weeks	Visual evaluation 6 x 0 (no blue stain) Zone width free of blue stain: 1,6 mm	Schumacher, P.; Fennert, E.-M. 2015 Test report 32/14/9755/01-02
Fungicide (bluestain fungi)	Use Class 2,3	Koralan Bläueschutz-grundierung (BA 13135-63; Kastanie)	<i>Aureobasidium pullulans</i> (de Bary) Arnaud <i>Sydowia polyspora</i> (Bref. & Travel) E. Müller	EN 152-1 after 6 month outdoor weathering	Superficial treatment (brushing) /without top coat Application rate: 160-180 ml/m ² (mean 168.4 ml/m ²) Exposure time: 6 weeks	Visual evaluation 3 x 0 (no blue stain) 3 x 1 (insignificantly blue-stained) Zone width free of blue stain: 1,6 mm	Schumacher, P.; Fennert, E.-M. 2018a Test report 32/17/10056/01
Fungicide (mould)		Koralan Bläueschutz-grundierung (BA 13135-63; Kastanie) Biozidfreie Matrix von Koralan Bläueschutzgr undierung	<i>Aureobasidium pullulans</i> P268 <i>Alternaria alternate</i> DSM 62010 <i>Cladosporium cladosporioides</i> DSM 62121	DIN EN 15457 (2014)	Superficial treatment (brushing) /without top coat Application rate (Koralan Bläueschutz-grundierung): 140-160 ml/m ² (mean value 151.1 ml/m ²)	Growth of mould-visual evaluation: 2 specimen were rated with 0 (no mycelium on the surface), 1 specimen was rated with 2, (over 10% up	Schumacher, P.; Fennert, E.-M. 2018b Test report 32/17/10056/30

			<i>Aspergillus niger</i> DSM 12634		Application rate (biozidfreie Matrix Koralan Bläueschutz- grundierung): 140-160 ml/m ² (mean value 145.6 ml/m ²) Exposure time: 21 days	to 30% growth on the surface of the test blocks)	
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Conclusion on the efficacy of the product

The efficacy data shows, that the products of the Koralan GL 220 Biocidal Product Family have protective effectiveness against wood discolouring fungi (blue stain) and mould:

Application rate with topcoat: 120-140 ml/m².

Application rate without topcoat: 160-180 ml/m².

2.2.5.6 Occurrence of resistance and resistance management

There are no reported cases of development of resistance involving the use of IPBC in wood preservation.

The resistance formation due to the use of wood preservatives constitutes an even smaller problem related to the use of fungicides in agriculture. The number of treatments of a wood preservative to a wooden structure is generally low (in many cases only one application is made per lifetime of timber structures) resulting in a low selection pressure.

2.2.5.7 Known limitations

None

2.2.5.8 Evaluation of the label claims

Wood preservative against blue stain and mould (Anti-blue stain primer). The efficacy data provided in Section 6.7 of the IUCLID dossier shows that the products of the Koralan GL 220 Biocidal Product Family have a protective effectiveness against blue stain and mould.

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

The products of the Koralan GL 220 Biocidal Product Family are not intended to be authorised for use with other biocidal product(s).

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.1 "Skin corrosion or skin irritation"
IUCLID data point	Section 8.1, Skin irritation/corrosion
Justification	<p>Studies on potential skin corrosive or skin irritating properties of the individual products pertaining to the biocidal product family (BPF) are not required.</p> <p>According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.1 "Skin corrosion or skin irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."</p> <p>For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.</p> <p>The RTU products of the BPF contain components which are classified with respect to local effects on the skin. However, most of these ingredients are not relevant because each of them is present in concentrations of less than 1% in the mixture (according to 3.2.3.3.1 of the CLP Regulation (EC) No 1272/2008). The concentration of one ingredient is 1.4% at maximum but this ingredient is classified as Skin Irrit. 2, so that the mixture has not be classified. For specification of these components and the calculations of their concentrations in the respective products please refer to the confidential annex.</p> <p>Therefore, according to the CLP principles, the individual products</p>

	of the BPF, and thus the BPF itself, do not need to be classified with respect to local effects on the skin.
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Eye irritation

Conclusion used in Risk Assessment – Eye irritation

Value/conclusion	Not causing severe damage or eye irritation
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving

Information requirement	Annex III of BPR, point 8.2 "Eye irritation"
IUCLID data point	Section 8.2, Eye irritation
Justification	<p>Studies on potential eye damaging or eye irritating properties of the individual products pertaining to the biocidal product family (BPF) are not required.</p> <p>According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.2 "Eye irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."</p> <p>For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.</p> <p>The RTU products of the BPF contain IPBC and further components which are classified with respect to local effects on the eye. However, these ingredients are not relevant because each of them is present in concentrations of less than 1% in the mixture (according to 3.3.3.3.1 of the CLP Regulation (EC) No 1272/2008). For specification of these components and the calculations of their concentrations in the respective products please refer to the confidential annex.</p> <p>Therefore, according to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to local effects on the eye.</p>

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components, the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	There are no testing requirements for respiratory irritation under the BPR.
IUCLID data point	Section 8.7.1, other endpoints.
Justification	<p>Studies on potential respiratory tract irritation properties of the individual products pertaining to the biocidal product family (BPF) are not required.</p> <p>There are no testing requirements for respiratory irritation under the BPR (see point "Respiratory irritation" under chapter II, point 8.2 "Eye irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014).</p> <p>However, Annex I, chapter 3.8.3.4.5 of Regulation (EC) No 1272/2008 (CLP) allows for extrapolation of the toxicity of a mixture that contains substances classified with respect to specific target organ toxicity after single exposure category 3 (STOT SE, Cat. 3; H335) based on valid data on all components in the mixtures classified with STOT SE, Cat. 3; H335.</p> <p>For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.</p> <p>None of the components in the products within the BPF are classified with respect to respiratory tract irritation.</p> <p>Therefore, according to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to respiratory tract irritation.</p>

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitizing to skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.3 "Skin sensitization"
IUCLID data point	Section 8.3, Skin sensitisation
Justification	<p>Studies on potential skin sensitization properties of the individual products pertaining to the biocidal product family (BPF) are not required.</p> <p>According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.3 "Skin sensitization" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."</p> <p>For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.</p> <p>The products contain components which are classified with respect to skin sensitization. IPBC, MIT (2-methyl-2H-isothiazol-3-one), CIT/MIT (5-chloro-2-methyl-2H-isothiazol-3-one, mixt. with 2-methyl-2H-isothiazol-3-one), BIT (1,2-benzisothiazol-3(2H)-one) and OIT are considered to be the most relevant components.</p> <p>The maximum concentrations of IPBC, MIT, CIT/MIT, BIT and OIT in the individual products are <1%, <0.00015%, <0.0015%, <0.05% and <0.05%, respectively.</p> <p>According to Table 3.4.5 of the CLP Regulation (EC) No 1272/2008, the generic concentration limit of a component of a mixture classified as skin sensitizer that triggers the classification of the mixture is $\geq 1\%$. The concentration limit for elicitation (Table 3.4.6 of the CLP Regulation (EC) No 1272/2008) is $\geq 0.1\%$. This concentration limit for</p>

	<p>elicitation is used for the application of the special labelling requirement EUH208 – “Contains (name of sensitizing substance). May produce an allergic reaction.”</p> <p>For IPBC the generic concentration limit for the classification as skin sensitizer is applicable. The maximum content of IPBC is <1% but > 0.1%, therefore EUH208 is required.</p> <p>For MIT, CIT/MIT, BIT and OIT, specific concentration limits (SCLs) are available.</p> <p>MIT: 0.0015%</p> <p>CIT/MIT (3:1): 0.0015%</p> <p>BIT: 0.05%</p> <p>OIT: 0.05%</p> <p>According to Table 3.4.6 (Note 1), for sensitizing substances with specific concentration limit lower than 0.1 %, the concentration limit for elicitation should be set at one tenth of the specific concentration limit.</p> <p>As the maximum concentrations of IPBC, CMIT/MIT and BIT in the products is below the respective concentration limits for the classification with skin sensitization but above the respective concentration limits for elicitation, the products of the BPF do not need to be classified with respect to skin sensitization but the labels of all products shall bear the statement: EUH208 – “Contains 3-iodo-2-propynyl butylcarbamate, 5-chloro-2-methyl-2H-isothiazol-3-one, mixt. with 2-methyl-2H-isothiazol-3-one and 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.”</p> <p>For detailed justification please refer to confidential annex.</p>
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Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing to respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.4 “Respiratory sensitization” (ADS)
IUCLID data point	Section 8.4, Respiratory sensitisation
Justification	Studies on potential respiratory sensitization properties of the individual products pertaining to the biocidal product family (BPF) are not required.

	<p>According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.4 "Respiratory sensitization" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.</p> <p>None of the components in the products within the BPF are classified with respect to respiratory sensitization.</p> <p>According to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to respiratory sensitization.</p>
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Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.1 "Acute toxicity by oral route".
IUCLID data point	Section 8.5.1, Acute toxicity: oral
Justification	Studies on the potential acute oral toxicity of the individual products pertaining to the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the

mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."

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

According to chapter 3.1.3.6 "Classification of mixtures based on ingredients of the mixture (Additivity formula)" of the CLP Regulation, the ATE of the mixture (ATE_{mix}) is determined by calculation from the ATE values for all relevant ingredients according to the following formula and using the LD50/LC50-values of the respective components for Oral, Dermal or Inhalation Toxicity:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

where:

C_i = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATE_i = Acute Toxicity Estimate of ingredient i.

IPBC and one further component are classified with Acute Tox. 4; H302 and the LD50 values are 300-500 mg/kg bw and 500 mg/kg bw, respectively. The maximum concentrations of IPBC and the other component in the products are 0.95% and 1%, respectively. For specification of this component and the calculations of its concentrations in the respective products please refer to the confidential annex.

According to CLP Regulation, section 3.1.3.3., page 124, "(d) when only range data (or acute toxicity hazard category information) are available for components in a mixture, they may be converted to point estimates in accordance with Table 3.1.2 when calculating the classification of the new mixture using the formulas in sections 3.1.3.6.1 and 3.1.3.6.2.3". In table 3.1.2, the converted acute toxicity point estimated is 500 for the experimentally obtained acute toxicity range values of $300 < LD50 \leq 2000$ mg/kg bw.

The potential acute oral toxicity of the products is calculated as follows:

$$ATE_{mix} = 100 / ((0.95/500) + (1/500)) = 100 / 0.0039 = 25641 \text{ mg/kg bw.}$$

According to Tab.3.1.2 of the CLP Regulation (EC) No 1272/2008, the

	calculated ATE of the mixture for acute oral toxicity is > 2000 mg/kg bw. Thus, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to acute oral toxicity.
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Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.2 "Acute toxicity by inhalation"
IUCLID data point	Section 8.5.2, Acute toxicity: inhalation
Justification	<p>Studies on the potential acute inhalation toxicity of the individual products pertaining to the biocidal product family (BPF) are not required.</p> <p>According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."</p> <p>For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.</p> <p>According to chapter 3.1.3.6 "Classification of mixtures based on ingredients of the mixture (Additivity formula)" of the CLP Regulation, the ATE of the mixture (ATE_{mix}) is determined by calculation from the ATE values for all relevant ingredients according to the following formula and using the LD50/LC50-values as provided for in section 11 ("Toxicological Information") of the SDS of the respective components</p>

	<p>for Oral, Dermal or Inhalation Toxicity:</p> $\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$ <p>where: C_i = concentration of ingredient i (% w/w or % v/v) i = the individual ingredient from 1 to n n = the number of ingredients ATE_i = Acute Toxicity Estimate of ingredient i.</p> <p>IPBC is classified with Acute Tox. 3; H331, while one further component is classified with Acute Tox. 4; H332. The LC50 values for IPBC and the other component are 0.67 mg/L (as provided in the MSDS) and 1.5 mg/L (converted acute toxicity point estimate) for dust/mist. The maximum concentrations of IPBC and the other component in the products are 0.95% and 1%, respectively. For specification of this component and the calculations of its concentrations in the respective products please refer to the confidential annex.</p> <p>The potential acute inhalation toxicity of the products is calculated as follows:</p> $ATE_{mix} = 100 / ((0.95/0.67) + (1/1.5)) = 100/2.08 = 48.1 \text{ mg/L}$ <p>According to Tab.3.1.2 of the CLP Regulation (EC) No 1272/2008, the calculated ATE of the mixture for acute inhalation toxicity is > 5 mg/L for dust/mist. Thus, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to acute inhalation toxicity.</p>
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Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.3 "Acute toxicity by dermal route"
IUCLID data point	Section 8.5.3, Acute toxicity: dermal
Justification	Studies on the potential acute dermal toxicity of the individual products pertaining to the biocidal product family (BPF) are not

	<p>required.</p> <p>According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."</p> <p>For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.</p> <p>None of the raw material used for the biocidal product family is classified with respect to dermal toxicity. Thus, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to acute dermal toxicity.</p>
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Acute toxicity of product combinations

Data waiving	
Information requirement	Annex III of BPR, point 8.5.4 "Acute toxicity of product combinations"
IUCLID data point	Section 8.5.4, Acute toxicity: product combinations
Justification	Since the RTU products of the BPF are not intended to be authorized for use with other products, an assessment of the potential acute toxicity of product combinations is not required.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	IPBC
Value(s)*	50% (for 0.96% IPBC) ² 1.6% (for dried solutions)
Justification for the selected value(s)	Read-across to similar tested mixtures. ²

² Value used by the read-across to the dermal absorption study evaluated in the context of the active substances dossier on IPBC (see respective CARs Annex I Doc IIIB 6.4., for PT8). However, during trilateral discussions it appeared that such approach is not justified since the formulation of the biocidal products within Koralan BPF is different than evaluated in CAR for IPBC (water-based products vs. solvent based reference product).

For above reasons it was finally decided that in the absence of information on dermal absorption for products within Koralan BPF the default value of 50 % for diluted water-based formulations as proposed in the EFSA GD on Dermal Absorption (2017) should be used on decision making on the HH risk.

** please include the concentration range(s) the values are applicable for, if relevant*

Data waiving	
Information requirement	Annex III of BPR, point 8.6 "Dermal absorption"
IUCLID data point	Section 8.6, Dermal absorption
Justification	<p>No studies on the dermal absorption of the RTU products pertaining to the BPF were performed.</p> <p>According to chapter III, section 8.6 "Information on dermal absorption" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), dermal absorption can be estimated by extrapolation of experimental data obtained with a similar formulation.</p> <p>In the Draf PAR dermal absorption has been assessed by read-across to the dermal absorption study evaluated in the context of the active substances dossier on IPBC (see respective CARs Annex I Doc IIIB 6.4., for PT8). Despite above during trilateral discussions it appeared that such approach is not justified since the formulation of the biocidal products within Koralan BPF is different than evaluated in CAR for IPBC (water-based products vs. solvent based reference product).</p> <p>For above reasons it was finally decided that in the absence of information on dermal absorption for products within Koralan BPF the default value of 50 % for diluted water-based formulations as proposed in the EFSA GD on Dermal Absorption (2017) should be used on decision making on the HH risk.</p> <p>However as this change had no impact on the conclusion on risk no further changes in the Final PAR has been made.</p>

Available toxicological data relating to Other endpoints

Specific target organ toxicity – repeated exposure

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not toxic after repeated exposure.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Long-term repeated dose toxicity studies are required for active substances but not for biocidal products under the BPR.
IUCLID data point	Section 8.7.1, other endpoints – Specific target organ toxicity – repeated exposure
Justification	Studies on potential specific target organ toxicity of the individual products pertaining to the biocidal product family (BPF) are not

	<p>required.</p> <p>Long-term repeated dose toxicity studies are required for active substances but not for biocidal products under the BPR.</p> <p>However, according to chapter 3.9.3 "Classification criteria for mixtures" of the CLP Regulation (EC) No 1272/2008, "mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures shall be classified for specific target organ toxicity following repeated exposure."</p> <p>For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required.</p> <p>IPBC is classified with STOT RE 1; H372 (larynx). The maximum concentration of IPBC in the products is 0.95%.</p> <p>According to Table 3.9.4 of the CLP Regulation (EC) No 1272/2008, the generic concentration limit of ingredients of a mixture classified as a specific target organ toxicant Category 1 that trigger classification of the mixture as a specific target organ toxicant Category 2 is $\geq 1.0\%$ but $< 10\%$.</p> <p>As the maximum concentration of 0.96% of IPBC in the products is below the concentration limit of 1%, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to specific target organ toxicity after repeated exposure.</p>
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Toxicological assessment of Koralan GL 220 Biocidal Product Family has been done for 0.95% content of IPBC. However, the maximum content of IPBC in the some of Koralan GL 220 Biocidal Product Family products is 0.96% due to content of the 10% pigment containing 0.0999% of IPBC. As the maximum concentration of 0.96% of IPBC in the products is below the concentration limit of 1%, it can be concluded that addition of the pigment containing IPBC does not have impact on classification triggered by IPBC.

Other endpoints

No other toxicological effects (e.g. CMR; STOT SE) are anticipated from the biocidal products pertaining to the BPF.

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

According to the note for discussion on substances of concern (SoC), CA-Nov14-Doc.5.11, the biocidal products pertaining to the BPF contain 2-Buthoxythanol as a substance of concern (SoC) -.

Available toxicological data relating to a mixture that a substance(s) of concern is a component of

Other

Food and feedingstuffs studies

Feeding and metabolism studies in livestock animals are not required as the biocidal products pertaining to the BPF are not intended for applications where contact with feedingstuffs may arise. Consequently, the transfer of potential residues of the biocidal products to food of animal origin *via* feedingstuffs is not relevant.

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

Not relevant, since residues in food due to the use of the biocidal products as wood preservative do not occur.

Other test(s) related to the exposure to humans

Other tests related to the exposure of humans are not required for the biocidal products pertaining to the BPF. The exposure of humans in all relevant exposure scenarios has been assessed with accepted exposure models (according to "Biocides Human Health Exposure Methodology") and considering most recent recommendations of HEEG. The results of the human exposure and risk assessments for the intended use scenarios are provided in the respective chapters of the PAR.

As the biocidal products pertaining to the BPF are not intended to be applied directly or around livestock, residue studies are not needed.

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	Yes	No	Yes	Yes	n.a.
Dermal	Yes	Yes	Yes	No	Yes	Yes	n.a.
Oral	No	No	No	No	No	Yes	n.a.

n.a.: not applicable

Explanatory note:

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

As a first step, primary exposure assessments are performed for all individual scenarios (work tasks) which are relevant for wood preservatives – PT8 (see table "list of scenarios" below) considering the concentration of 0.96% IPBC (for more details, please refer to "general considerations" provided on the next page).

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

- **Use # 1: Automated spraying by industrials**
- **Use # 2: Automated dipping by industrials**
- **Use # 3: Manual dipping by industrials and professionals**
- **Use # 4: Flow coating (deluging) by industrials**
- **Use # 5: Brushing/roller by professionals**
- **Use # 6: Brushing/roller by non-professionals**

Furthermore, secondary exposure of professionals and the general public is assessed considering the highest effective retention of 180 mL/m² in wood (please see table on the next page).

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

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

Secondary exposure in the residential environment may result from amateur applications. These exposures include dermal contact with contaminated surfaces or handling contaminated objects. Skin contact and oral contact with treated wood objects or hand-to-mouth contact is related to infants, toddlers and children playing. Children, toddlers and infants are assumed to be a group at risk and some secondary exposure scenarios are related to them. Secondary exposure can occur soon after the application of the product or as a single event (acute phase), or thereafter during the long term and may be continuous (chronic phase).

According to the information refMS received from the Applicant, known nanomaterials in the forms of traditional powdered pigments, natural powdered fillers, powdered synthetic amorphous silica and/or liquid/powdered polymers (used as dispersion aids or defoamers) are used for production of colorants used in the BPF. These nanomaterials during production are either dispersed (pigments, silica or fillers) or dissolved (polymers) within the liquid medium to form the colorant (pigment dispersion).

The above mentioned nanomaterials are bound within the pigment dispersion at all times and are not functionally intended to be extracted or released under normal or reasonably foreseeable conditions of use.

Therefore, according to the Applicant's interpretation of the criteria, in particular the wording relating to 'unbound state', the colorants do not fall under the definition of a nanomaterial according to Article 3 paragraph 1 (z) of BPR.

PL CA agrees with this argumentation, therefore risk assessment mentioned in Article 19(1)(f) of BPF doesn't need to be carried out.

General considerations:

The biocidal products within the BPF are ready-to-use (RTU) water-based formulations containing IPBC at a concentration of 0.96% (see Table below).

The RTU products are used by industrials (use #1-4), by professionals (use # 3 and 5) and non-professionals (use # 6).

Use #	Concentration	Effective retention in wood
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	(a.s.)	
1: Automated spraying by industrials	0.96% IPBC	120-140 mL/m ² for the use with top coat 160 -180 mL/m ² for the use without top coat Note: The highest effective retention of 180 mL/m² in wood is used for the calculation of the secondary exposure scenarios.
2: Automated dipping by industrials		
3: Manual dipping by industrials and professionals		
4: Flow coating (deluging) by industrials		
5: Brushing/roller by professionals		
6: Brushing/roller by non-professionals		

The dermal absorption values used for risk assessment of the RTU products containing IPBC are provided in the following table. For more details, please refer to chapter 2.2.6.1 "Information on dermal absorption".

Substance	Dermal absorption value
IPBC	50% for the concentration of 0.96% ³ 1.6% for dried solutions

The protection factors for personal protective equipment (PPE) used for the exposure assessments are defaults from the HEEG opinion 2010 "Default protection factors for protective clothing and gloves".

These general considerations apply to all scenarios (work tasks) provided in the following "List of scenarios". Consequently, these considerations are not repeated in the descriptions of the individual scenarios.

³ See section related to the *Information on dermal absorption*

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)
1. Primary exposure by industrials			
1.1.	Mixing/loading of RTU products by industrials	The water-based RTU products are delivered in IBC or by tanker. Any transfer of the RTU products is done automated by connecting lines.	Industrials
1.2.1.	Application - Automated spraying by industrials	During automated spraying, the operator's exposure is negligible, as it is an automated process and the operator's position is away from the spraying area of the wood. The operator exposure arises from handling the treated wood.	Industrials
1.2.2.	Application - Automated dipping by industrials	For automated dipping, an operator using a fork-lift truck lowers the wood into the dipping tank or transfers the wood to a bathing tray. Automated dipping is an automated process. After the treatment, the wood is lifted out by the fork-lift truck. The wood is then transferred by the fork-lift truck to a storage area where it is placed to dry. 4 cycles per day are considered. The operator exposure arises from handling the treated wood.	Industrials
1.2.3.	Application - Manual dipping by industrials and professionals	During manual dipping, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts manually the wooden article from the dipping tank and stacks the article to dry. Manual dipping is undertaken during a very short time during the day.	Industrials and professionals

1.2.4.	Application - Flow coating (deluging) by industrials	During flow coating, timber is passed through an enclosed tunnel in which the preservative is applied. The device is open at both sides, i.e. front and back side. Timber enters through the front side and the treated timber comes out dripping wet through the back side. After the flooding process treated timber is conducted through a drying channel, where the wooden articles are dried with a warm air stream. The wood preservative is applied in one cycle (60 min). Operator exposure should be low during this process and be predominantly due to residues from handling freshly treated timber.	Industrials
1.3.	Post-application - System maintenance by industrials	The post-application phase includes disposal. For maintenance of treatment vessels and dipping tanks, test and clean greasing door seals, collecting fallen timber as well as clearing sludge is considered. For maintenance of flow coating systems, the cleaning of spray nozzles is considered. According to TNSG user guidance version 1 (p.44 & 48), Handling model 1" (and the "Dipping model 1") described in TNSG Part 2, p 160 (and 167) includes application and postapplication exposures.	Industrials
2. Primary exposure by professionals			
2.1.	Mixing and Loading of RTU by professionals	Not applicable for the RTU product which is applied direct from can.	No exposure
2.2.	Application – Brushing and rolling by professionals	The activities of the professional users are stirring the RTU product and applying it to wood using a brush.	Professionals
2.3.	Post-application – Washing out of a brush by professionals	After the application, the brush is washed out.	Professionals
3. Primary exposure by non-professionals			
3.1.	Mixing and Loading of RTU by non-professionals	Not applicable for the RTU product which is applied direct from can.	No exposure
3.2.	Application – Brushing and rolling by non-professionals	The activities of the non-professional users are stirring the RTU product and applying it to wood using a brush.	Non-professionals
3.3.	Post-application – Washing out of a brush by non-professionals	After the application, the brush is washed out.	Non-professionals

4. Secondary exposure by professionals and general public			
4.1.1.	Sawing and sanding treated wood by professionals	Cutting and sanding treated wood by professional worker (chronic exposure).	Professionals
4.1.2.	Sawing and sanding treated wood by general public	Cutting and sanding treated wood by general public (acute exposure).	General public (adult)
4.2.	Chewing wood off-cut	Infant picks up and chews wood off-cut, which has been treated with wood preservative (acute exposure).	General public (infant)
4.3.	Playing on playground structure outdoors and mouthing	Infant playing on and mouthing weathered structure (chronic exposure). Child playing on treated playground structure outdoors (chronic exposure).	General public (infant and child)
4.4.	Inhalation of volatilized residues	Chronic exposure to wood preservatives may arise via residues volatilised from treated wood indoors (restricted to windows, exterior doors and roof structures).	General public (infant and child, adult)

Industrial exposure

Scenario [1.1. Mixing/loading of RTU products by industrials]

Description of Scenario [1.1. Mixing/loading of RTU products by industrials]

The water-based RTU products are delivered in IBC or by tanker. Any transfer of the RTU products is done automated by connecting lines.

According to HEEG 2013, "where the wood preservative fluid is delivered by tanker and is transferred from the tanker into the dip tank using connecting hosing then, it could be assumed, providing the operator wears suitable PPE, exposure of the operator's skin is minimal and does not need to be quantified."

The inhalation exposure is considered to be less than during the individual applications phases and, thus, to be covered by them.

Calculations for Scenario [1.1. Mixing/loading of RTU products by industrials]

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

Scenario [1.2.1. Application -Automated spraying by industrials]**Description of Scenario [1.2.1. Application -Automated spraying by industrials]**

During automated spraying, the operator's exposure is negligible, as it is an automated process and the operator's position is away from the spraying area of the wood. The operator might be exposed after the spraying process by contact with the treated timber. Considering that automated spraying is fully enclosed and minimal spray mist is released, it is assumed that exposure of operators by this application method will be equivalent to automated dipping.

4 cycles (60 min per cycle) per day are considered according to Biocides Human Health Exposure Methodology (October 2015) – PT8 "Professional automated dipping/immersion of wood articles".

According to the HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4.

The model used is Handling model 1 water-based (TNSG 2002 User Guidance – Version 1 and 2 and HEEG opinions 8 and 18 - 2009/2013) for dermal and inhalation exposure estimation.

	Parameters	Value
Tier 1	IPBC	0.96%
	Dermal absorption	50%
	Body weight	60 kg
	Inhalation rate (short - and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m ³ /h (0.021 m ³ /min)
	Exposure duration	4 cycles (dermal exposure) 240 min (inhalation exposure)
	Indicative values for water-based products from Handling model 1	Hands: 1080 mg/cycle (inside gloves) Body: 8570 mg/cycle Inhalation: 1.9 mg/m ³
Tier 2	Gloves	The Handling model 1 provides an indicative value for hand exposure inside gloves.
	Impermeable coverall	90% protection

Calculations for Scenario [1.2.1. Application -Automated spraying by industrials]

In the following, the results of the calculations are provided for scenario 1.2.1. for RTU products containing **0.96% IPBC**.

Summary table: estimated exposure [mg/kg bw/day] from industrial uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1.2.1.]	Tier 2/ Gloves Impermeable coverall	1.53E-03	0.155	-	0.1565

The calculation sheets are provided in Appendix 1.

Scenario [1.2.2. Application -Automated dipping by industrials]

Description of Scenario [1.2.2. Application -Automated dipping by industrials]		
<p>For automated dipping, an operator using a fork-lift truck lowers the wood into the dipping tank or transfers the wood to a bathing tray. Automated dipping is an automated process. After the treatment, the wood is lifted out by the fork-lift truck. The wood is then transferred by the fork-lift truck to a storage area where it is placed to dry. The operator exposure arises from handling the treated wood. 4 cycles (60 min per cycle) per day are considered according to Biocides Human Health Exposure Methodology (October 2015) – PT8 “Professional automated dipping/immersion of wood articles”.</p> <p>According to the HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4.</p> <p>The model used is Handling model 1 water-based (TNsG 2002 User Guidance – Version 1 and 2 and HEEG opinions 8 and 18 - 2009/2013) for dermal and inhalation exposure estimation.</p>		
	Parameters	Value
Tier 1	IPBC	0.96%
	Dermal absorption	50%
	Body weight	60 kg
	Inhalation rate (short - and long-term; acc. to HEEG opinion “Default human factor values for use in exposure assessments for biocidal products”, 2013)	1.25 m ³ /h (0.021 m ³ /min)

	Exposure duration	4 cycles (dermal exposure) 240 min (inhalation exposure)
	Indicative values for water-based products from Handling model 1	Hands: 1080 mg/cycle (inside gloves) Body: 8570 mg/cycle Inhalation: 1.9 mg/m ³
Tier 2	Gloves	The Handling model 1 provides an indicative value for hand exposure inside gloves.
	Impermeable coverall	90% protection

Calculations for Scenario [1.2.2. Application - Automated dipping by industrials]

In the following, the results of the calculations are provided for scenario 1.2.2. for RTU products containing **0.96% IPBC**.

Summary table: estimated exposure [mg/kg bw/day] from industrial uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1.2.2.]	Tier 2/ Gloves Impermeable coverall	1.53E-03	0.155	-	0.1565

The calculation sheets are provided in Appendix 2.

Scenario [1.2.3. Application -Manual dipping by industrials and professionals]

Description of Scenario [1.2.3. Application -Manual dipping by industrials and professionals]		
<p>During manual dipping, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts manually the wooden article from the dipping tank and stacks the article to dry. Manual dipping is undertaken during a very short time during the day.</p> <p>A duration time of 30 min is considered according to Biocides Human Health Exposure Methodology (October 2015) – PT8 “Professional manual dipping of wood articles”.</p> <p>The model used is Dipping model 1 water-based (TNSG 2002 User Guidance – Version 1 and 2 and HEEG opinions 8 - 2009) for dermal and inhalation exposure estimation.</p>		
	Parameters	Value
Tier 1	IPBC	0.96%

	Dermal absorption	50%
	Body weight	60 kg
	Inhalation rate (short - and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m ³ /h (0.021 m ³ /min)
	Exposure duration	30 min
	Indicative values for Dipping model 1	Hands: 25.7 mg/min (inside gloves) Body: 178 mg/min Inhalation: 1 mg/m ³
	Tier 2	Gloves
	Impermeable coverall	90% protection

Calculations for Scenario [1.2.3. Application -Manual dipping by industrials and professionals]

In the following, the results of the calculations are provided for scenario 1.2.3. for RTU products containing **0.96% IPBC**.

Summary table: estimated exposure [mg/kg bw/day] from industrial uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1.2.3.]	Tier 2/ Gloves Impermeable coverall	1.01E-04	0.104	-	0.1041

The calculation sheets are provided in Appendix 3.

Scenario [1.2.4. Application -Flow coating (deluging) by industrials]

Description of Scenario [1.2.4. Application -Flow coating (deluging) by industrials]

During flow coating, timber is passed through an enclosed tunnel in which the preservative is applied. The device is open at both sides, i.e. front and back side. Timber enters through the front side and the treated timber comes out dripping wet through the back side. After the flooding process treated timber is conducted through a drying channel, where the wooden articles are dried with a warm air stream. The wood preservative is applied in one cycle (60 min). Operator exposure should be low during this process and be predominantly due to residues from handling freshly treated wood.

Instead of Dipping model 1 recommended in Biocides Human Health Exposure Methodology (October 2015) – PT8 “Professional deluging”, the Handling model 1 water-based (TNsG 2002 User Guidance – Version 1, 2 and HEEG opinions 8 and 18 - 2009/2013) is used for the assessment of the exposure. This is justifiable since the operator exposure arises from handling the treated timber rather than manual dipping of wood⁴.

	Parameters	Value
Tier 1	IPBC	0.96%
	Dermal absorption	50%
	Body weight	60 kg
	Inhalation rate (short - and long-term; acc. to HEEG opinion “Default human factor values for use in exposure assessments for biocidal products”, 2013)	1.25 m ³ /h (0.021 m ³ /min)
	Exposure duration	1 cycle (dermal exposure) 60 min (inhalation exposure)
	Indicative values for water-based products from Handling model 1	Hands: 1080 mg/cycle (inside gloves) Body: 8570 mg/cycle Inhalation: 1.9 mg/m ³
Tier 2	Gloves	The Handling model 1 provides an indicative value for hand exposure inside gloves.
	Impermeable coverall	90% protection

Calculations for Scenario [1.2.4. Application -Flow coating (deluging) by industrials]

In the following, the results of the calculations are provided for scenario 1.2.4. for RTU products containing **0.96% IPBC**.

⁴ During trilateral discussion it was finally agreed that the “Handling Model 1” is not agreed within Headhoc to assess the flow coating (deluging) or automated spraying process and thus the exposure assessment performed in accordance with Biocides Human Health Exposure Methodology and Dipping Model 1 should be used instead. Since the later methodology results in the exceedance of the AEL when taking into account the dermal absorption of 50%, the following RMM should be for automated spraying and flow coating (deluging) applied:

“The product may only be used with an automated onward transport of the freshly treated wood with automated stacking or into a drier so as to avoid manual contact with the freshly treated wood.”

Summary table: estimated exposure [mg/kg bw/day] from industrial uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1.2.4.]	Tier 2 / Gloves Impermeable coverall	1.53E-03	0.155		0.1565

The calculation sheets are provided in Appendix 4.

Scenario [1.3. Post-application -System maintenance by industrials]

Description of Scenario [1.3. Post-application - System maintenance by industrials]		
<p>The post-application phase includes disposal. For maintenance of treatment vessels and dipping tanks, test and clean greasing door seals, collecting fallen timber as well as clearing sludge is considered. For maintenance of flow coating systems, the cleaning of spray nozzles is considered.</p> <p>According to TNSG user guidance version 1 (p.44 & 48), Handling model 1" (and the "Dipping model 1") described in TNSG Part 2, p 160 (and 167) includes application and postapplication exposures. Therefore, further calculations are not presented.</p>		
	Parameters	Value
Tier 1		
Tier 2		

Calculations for Scenario [1.3. Post-application - System maintenance by industrials]

In the following, the results of the calculations are provided for scenario 1.3. for RTU products containing **0.96% IPBC**.

Summary table: estimated exposure [mg/kg bw/day] from industrial uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake

Scenario [1.3.]	Tier 2/ Gloves Impermeable coverall	n.a.	n.a.	n.a.	n.a.
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The calculation sheets are provided in Appendix 5.

Combined scenarios

Not applicable

Professional exposure

Scenario [2.1. Mixing and Loading of RTU by professionals]

Description of Scenario [2.1. Mixing and Loading of RTU by professionals]

Not applicable for the RTU product which is applied direct from can.

Scenario [2.2. Application – Brushing and rolling by professionals]

Description of Scenario [2.2. Application – Brushing and rolling by professionals]

The activities of the professional users are stirring the RTU product containing 0.96% IPBC and applying it 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 Wissenschaft, 2006) according to Biocides Human Health Exposure Methodology (October 2015) – PT8 is used for the dermal and inhalation exposure estimation.

The following assumptions are considered in the used model:

- Exposure duration: 240 min
- Application area: 31.6 m²
The application area is calculated using the median work rate of 7.6 min/m² (acc. to TNsG 2002 "Consumer product painting Model 3" and the exposure duration of 240 min. Calculation: 1/7.6 min/m² * 240 min = 31.6 m²)
- The indicative values are normalized to 1% active substance and are referring to the exposure when brushing an area of 1 m² (acc. to Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenschaft, 2006).

	Parameters	Value
Tier 1	IPBC	0.96%
	Dermal absorption	50%
	Body weight	60 kg
	Inhalation rate (short - and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m ³ /h (0.021 m ³ /min)
	Exposure duration	240 min

	Application area	31.6 m ²
	Indicative values	Hands: 0.5417 mg/m ² Body: 0.2382 mg/m ² Inhalation (non-volatile compounds): 0.0016 mg/m ²
Tier 2	PPE (gloves)	90% protection

Calculations for Scenario [2.2. Application – Brushing and rolling by professionals]

In the following, the results of the calculations are provided for scenario 2.2.3. for the RTU product containing **0.96% IPBC**.

Summary table: estimated exposure [mg/kg bw/day] from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2.2.]	Tier1/ None	8.01E-04	1.95E-01	-	1.958E-01
Scenario [2.2.]	Tier2/ gloves	8.01E-04	7.70E-02	-	7.78E-02

The calculation sheets are provided in Appendix 6.

Scenario [2.3. Post-application – Washing out of a brush by professionals]

Description of Scenario [2.3. Post-application – Washing out of a brush by professionals]		
After the application of the wood preservative, the brush is washed out.		
The model "Exposure model primary exposure scenario - washing out of a brush which has been used to apply a paint" (HEEG opinion 11 – 2010) is used for dermal exposure estimation. According to this model, inhalation exposure is considered to be negligible.		
	Parameters	Value
Tier 1	IPBC	0.96%
	Dermal absorption	50%
	Body weight	60 kg
	No PPE	0% protection

Calculations for Scenario [2.3. Post-application – Washing out of a brush by professionals]

In the following, the results of the calculations are provided for scenario 2.3. for the RTU product containing **0.96% IPBC**.

Summary table: estimated exposure [mg/kg bw/day] from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2.3.]	Tier1/ None	considered to be negligible	1.06E-02	-	1.06E-02

The calculation sheets are provided in Appendix 7.

Combined scenarios

Explanatory note:

The exposure calculated for the individual work tasks are combined (added up) for the following intended use:

- Use # 5: Brushing/roller by professionals

Summary table: combined systemic exposure from professional uses					
Scenarios combined	Tier/PPE	Concentration of IPBC	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Brushing/ roller by professionals Scenarios [2.1.; 2.2.; 2.3.]	Tier 1/ No PPE	0.96%	8.01E-04	2.056E-1	2.064E-1
Scenarios [2.1.; 2.2 Tier 2/ Gloves; 2.3.]		0.96%	8.01E-04	7.70E-02	7.78E-02

Secondary exposure by professionals**Scenario [4.1.1. Sawing and sanding treated wood by professionals]****Description of Scenario [4.1.1. Sawing and sanding treated wood by professionals]**

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

The application rate of 180 mL product/m² of the water-based product (taking into account the concentration of 0.96% IPBC) is considered the highest-end-retention.

According to TNsG 2002 User Guidance - Version 1, the model exposure data used in these calculations are derived from exposure studies on amateurs where no gloves were worn. Therefore, the following calculated dermal exposure levels for professionals are an overestimate, as professionals would usually wear gloves. Furthermore, the acute sanding scenario is extrapolated to the chronic situation by assuming that the exposure time is 8 hours per day.

During sawing/sanding of treated wood, dermal and inhalation exposure of workers is considered. Exposure towards dust containing IPBC is considered to be associated with systemic exposure since the inhaled dust is assumed to be taken up both orally and via the inhalation route.

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

	Parameters	Value
Tier 1	Application rate	180 mL/m ²
	IPBC	0.96%
	Dermal absorption	1.6% (for dried solutions)
	Body weight	60 kg
	Inhalation rate (short - and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m ³ /h (0.021 m ³ /min)
	Hand area (palms of both hands) (adult) (acc. to HEEG 2013)	410 cm ²
	Assuming that 20% of hand area will be contaminated (adult).	82 cm ²
	Transfer coefficient (acc. to TNsG 2007 for dried fluids on rough sawn wood)	2%
	Exposure duration	8 h

	Generated dust/m ³ of sanded treated wood. U.K. WEL of 5 mg/m ³ wood dust (8-hour time-weighted average)	5 mg/m ³
	Density of wood (Mota version 6, 2013)	0.4 g/cm ³

Calculations for Scenario [4.1.1. Sawing and sanding treated wood by professionals]

In the following, the results of the calculations are provided for scenario 4.1.1. considering the concentration of **0.96% IPBC (highest application rate of the product of 180 mL/m²)**

Summary table: estimated exposure [mg/kg bw/day] from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [4.1.1.]	Tier 1/ No PPE	5.05E-04	1.02E-04	-	6.07E-04

The calculation sheet is provided in Appendix 8.

Scenario [3.1. Mixing and Loading of RTU by non-professionals]

Description of Scenario [3.1. Mixing and Loading of RTU by non-professionals]

Not applicable for the RTU product which is applied direct from can.

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

Description of Scenario [3.2. Application – Brushing and rolling by non - professionals]

The activities of the non-professional users are stirring the RTU product containing 0.96% IPBC and applying it to wood using a brush.

The TNsG 2002 “Consumer painting model 3” (equivalent to TNsG 2007 “2. Brushing sheds and fences, outdoor”) according to Biocides Human Health Exposure Methodology, chapter 6.2, p. 216 (version 1, October 2015) is used for dermal and inhalation exposure estimation. The exposure duration is 150 min (acc. to TNsG 2002 User Guidance – Version 1, p. 51 for non-professionals.).

	Parameters	Value
Tier 1	IPBC	0.96%
	Dermal absorption	50%
	Body weight	60 kg
	Inhalation rate (short - and long-term; acc. to HEEG opinion “Default human factor values for use in exposure assessments for biocidal products”, 2013)	1.25 m ³ /h (0.021 m ³ /min)

	Exposure duration	150 min
	Indicative values from Consumer painting model 3	Hand: 5.91 mg/min Body: 16.9 mg/min Inhalation: 1.63 mg/m ³

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

In the following, the results of the calculations are provided for scenario 3.2. for the RTU product containing **0.96% IPBC**.

Summary table: systemic exposure [mg/kg bw/day] from non-professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [3.2.]	Tier 1/ No PPE	2.60E-04	2.74E-01	-	2.742E-01

The calculation sheet is provided in Appendix 9.

Scenario [3.3. Post-application – Washing out of a brush by non-professionals]

Description of Scenario [3.3. Post-application – Washing out of a brush by non-professionals]		
After the application of the wood preservative, the brush is washed out.		
The model "Exposure model primary exposure scenario - washing out of a brush which has been used to apply a paint" (HEEG opinion 11 – 2010) is used for dermal exposure estimation. According to this model, inhalation exposure is considered to be negligible.		
	Parameters	Value
Tier 1	IPBC	0.96%
	Dermal absorption	50%
	Body weight	60 kg
	No PPE	0% protection

Calculations for Scenario [3.3. Post-application – Washing out of a brush by non-professionals]

In the following, the results of the calculations are provided for scenario 3.3. for the RTU product containing **0.96% IPBC**.

Summary table: systemic exposure [mg/kg bw/day] from non-professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [3.3.]	Tier 1/ No PPE	considered to be negligible	1.06E-02	-	1.06E-02

The calculation sheets are provided in Appendix 10.

Combined scenarios

Explanatory note:

The exposure calculated for the individual work tasks are combined (added up) for the following intended use:

- Use # 6: Brushing/roller by non-professionals

Summary table: combined systemic exposure from non-professional uses					
Scenarios combined	Tier/PPE	Concentration of IPBC	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Brushing/ roller by non-professionals Scenarios [3.1.; 3.2.; 3.3.]	Tier 1/ No PPE	0.96%	2.6E-04	2.85E-01	2.85E-01

Exposure of the general public

Scenario [4.1.2. Sawing and sanding treated wood by general public]

Description of Scenario [4.1.2. Sawing and sanding treated wood by general public]		
Cutting and sanding treated wood by general public (adults) is considered an <u>acute exposure</u> scenario.		
The application rate of 180 mL product/m ² of the water-based products (taking into account the concentration of 0.96% IPBC) is considered the highest-end-retention.		
For the acute situation, exposure duration of 1 h is assumed. The model exposure data used in these calculations are derived from exposure studies on amateurs where no gloves were worn.		
During sawing/sanding of treated wood, dermal and inhalation exposure of adults is considered. Exposure towards dust containing IPBC is considered to be associated with systemic exposure since the inhaled dust is assumed to be taken up both orally and via the inhalation route.		
This secondary exposure scenario is based on TNsG 2002 User guidance - Version 1 and TNsG 2002, part III.		
	Parameters	Value
Tier 1	Application rate	180 mL/m ²
	IPBC	0.96%
	Dermal absorption	1.6% (for dried solutions)
	Body weight	60 kg

	Inhalation rate (short - and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m ³ /h (0.021 m ³ /min)
	Hand area (palms of both hands) (adult) (acc. to HEEG 2013)	410 cm ²
	Assuming that 20% of hand area will be contaminated (adult).	82 cm ²
	Transfer coefficient (acc. to TNsG 2007 for dried fluids on rough sawn wood)	2%
	Exposure duration	1 h
	Generated dust/m ³ of sanded treated wood. U.K. WEL of 5 mg/m ³ wood dust (8-hour time-weighted average)	5 mg/m ³
	Density of wood (Mota version 6, 2013)	0.4 g/cm ³

Calculations for Scenario [4.1.2. Sawing and sanding treated wood by general public]

In the following, the results of the calculations are provided for scenario 4.1.2. considering the highest in-use concentration of **0.96% IPBC (highest application rate of the product of 180 mL/m²)**.

Summary table: systemic exposure [mg/kg bw/day] of the general public					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [4.1.2.]	Tier 1/ No PPE	7.77E-05	1.02E-04	-	1.80E-04

The calculation sheet is provided in Appendix 11.

Scenario [4.2. Chewing wood off-cut]**Description of Scenario [4.2. Chewing wood off-cut]**

Infant picks up and chews wood off-cut, which has been treated with wood preservative. This scenario is considered an acute exposure scenario.

The application rate of 180 mL product/m² of the water-based products (taking into account the concentration of 0.96% IPBC) is considered the highest-end-retention.

For infants who are chewing wood it is assumed that the active substance in the treated timber is located in the outer 1 cm layer. It is assumed that the infant is chewing a 4 cm × 4 cm × 1 cm = 16 cm³ chip and in doing so extracts 10% of the active substance.

For children this scenario is not relevant according to TNSG 2002. This scenario is regarded as unrealistic for children, as opposed to infants, because children are highly unlikely to chew treated wood in any significant amounts.

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

	Parameters	Value
Tier 1	Application rate	180 mL/m ²
	IPBC	0.96%
	Dermal absorption	1.6% (for dried solutions)
	Body weight of infant (acc. to HEEG opinion 17 (2013))	8 kg
	Oral uptake by extraction of a.s. from the wood (acc. to User Guidance (2002))	10%
	Volume of the piece of wood	16 cm ³

Calculations for Scenario [4.2. Chewing wood off-cut]

In the following, the results of the calculations are provided for scenario 4.2. considering the concentration of **0.96% IPBC (highest application rate of the product of 180 mL/m²)**.

Summary table: systemic exposure [mg/kg bw/day] of the general public					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [4.2.]	Tier 1/No PPE	-	-	4.66E-02	4.66E-02

The calculation sheet is provided in Appendix 12.

*Scenario [4.3. Playing on playground structure outdoors and mouthing]***Description of Scenario [4.3. Playing on playground structure outdoors and mouthing]**

Infant playing on and mouthing weathered structure. Child playing on treated playground structure outdoors.

These scenarios are considered chronic exposure scenarios.

The application rate of 180 mL product/m² of the water-based products (taking into account the concentrations of 0.96% IPBC) is considered the highest-end-retention.

In this scenario, during playing on timber structure (infants and children), dermal as well as oral (through hand-to-mouth transfer) exposure is considered.

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

	Parameters	Value
Tier 1	Application rate	180 mL/m ²
	IPBC	0.96%
	Dermal absorption	1.6% (for dried solutions)
	Body weight of infant (acc. to HEEG opinion 17 (2013))	8 kg
	Body weight of child (acc. to HEEG opinion 17 (2013))	23.9 kg
	Area of hands - both palms and backs of both hands (infant) (acc. to HEEG opinion 17 (2013))	196.8 cm ²
	Area of hands - both palms and backs of both hands (child) (acc. to HEEG opinion 17 (2013))	427.8 cm ²
	Contamination of hands – it is assumed that 20% of hand area will be contaminated.	20%
	Dislodgeable fraction (acc. to TNsG 2007 for dried objects on wood)	2%
	Oral uptake after licking of hands (infant/child) (ConsExpo) (50% of the potential dermal exposure)	50%

Calculations for Scenario [4.3. Playing on playground structure outdoors and mouthing]

In the following, the results of the calculations are provided for scenario 4.3. considering the highest in-use concentration of **0.96% IPBC (highest application rate of the product of 180 mL/m²)**.

Summary table: systemic exposure [mg/kg bw/day] of the general public					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [4.3.] - infant	Tier 1/No PPE	-	3.62E-04	1.13E-02	1.17E-02
Scenario [4.3.] - child	Tier 1/No PPE	-	2.64E-04	8.24E-03	8.50E-03

The calculation sheet is provided in Appendix 13.

Scenario [4.4. Inhalation of volatilized residues]

Description of Scenario [4.4. Inhalation of volatilized residues]		
<p><u>Chronic exposure</u> to wood preservatives may arise via residues volatilised from treated wood indoors.</p> <p>The scenario has been calculated although the indoor use of the product is restricted to exterior doors, windows and roof structures.</p> <p>IPBC has a vapour pressure of 4.5×10^{-3} Pa (at 25°C). Although, inhalation from treated dried wood is considered to be very low, exposure by volatilised residues indoors was calculated ConsExpo.</p>		
	Parameters	Value
Tier 1	Vapour pressure of IPBC	4.5×10^{-3} Pa
	MW of IPBC	281.1 g/mol
	Unspecified room	20 m ³
	Inhalation rate of infant	5.4 m ³ /24 h
	Inhalation rate of child	12 m ³ /24 h
	Inhalation rate of adult	16 m ³ /24 h
	Body weight of infant	8 kg
	Body weight of child	23.9 kg
	Body weight of adult	60 kg

Calculations for Scenario [4.4. Inhalation of volatilized residues]

In the following, the results of the calculations are provided for scenario 4.4. for **IPBC**.

Summary table: systemic exposure [mg/kg bw/day] of the general public					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [4.4.] - infant	Tier 1/No PPE	2.09E-04	-	-	2.09E-04
Scenario [4.4.] - child	Tier 1/No PPE	1.56E-04	-	-	1.56E-04
Scenario [4.4.] - adult	Tier 1/No PPE	8.27E-05	=	=	8.27E-05

Monitoring data

Concerning human exposure, no monitoring data are available.

Dietary exposure

Not required since the RTU products pertaining to the BPF are not used in a manner which may cause direct contact with food and feed.

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

Production/formulation of the biocidal product

The production/formulation of the biocidal product is done in accordance with local and national occupational health and safety regulations.

The production is done in a closed system. The raw materials are fed sequentially, using automatic dosing equipment, into a closed stainless steel vessel equipped with a mixer and air extraction to prevent emission into the working environment. For working steps, for which exposure of workers cannot be excluded, such as connecting lines or quality control, the workers use adequate PPE. The workers are trained professionals.

From the vessels the finished product is filled into the packaging for transport. The filling process is done with air exhaust in place. Thus, exposure of industrial workers is minimal.

Environmental exposure

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

Disposal of the biocidal product

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

Aggregated exposure

Aggregated exposure is not relevant.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group	Tier/PPE	Estimated total uptake (mg/kg bw/d) of <u>IPBC</u>
1.1.	Not applicable		
1.2.1.	industrials	Tier 2/ Gloves Impermeable coverall	0.1565
1.2.2.	industrials	Tier 2/ Gloves Impermeable coverall	0.1565
1.2.3.	Industrials and professionals	Tier 2/ Gloves Impermeable coverall	0.1041
1.2.4.	industrials	Tier 2/ Gloves Impermeable coverall	0.1565
1.3.	industrials	Tier 2/ Gloves Impermeable coverall	n.a.
2.1.	Exposure during mixing and loading of the RTU product is not applicable which is applied direct from can.		
2.2.	professionals	Tier1/ None	1.958E-01
2.2	professionals	Tier2/ Gloves	7.78E-02
2.3.	professionals	Tier1/ None	1.06E-02
3.1.	Exposure during mixing and loading of the RTU product is not applicable which is applied direct from can.		
3.2.	non-professionals	Tier1/ None	2.74E-01
3.3.	non-professionals	Tier1/ None	1.06E-02
4.1.1. – secondary chronic exposure	professionals	Tier1/ None	6.07E-04
4.1.2. – secondary acute exposure	general public – adult	Tier1/ None	1.80E-04
4.2. – secondary acute exposure	general public – infant	Tier1/ None	4.66E-02

4.3. – secondary chronic exposure	general public - infant	Tier1/ None	1.17E-02
	general public - child	Tier1/ None	8.50E-03
4.4. – secondary chronic exposure	general public - infant	Tier1/ None	2.09E-04
	general public - child	Tier1/ None	1.56E-04
	general public - adult	Tier1/ None	8.27E-05

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation for **IPBC**

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

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

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

n.r.: not relevant

Maximum residue limits or equivalent

Not relevant

Risk for industrial users

General remark:

The results reflect industrial applications using RTU products containing 0.96% IPBC.

Systemic effects

In the following table, the results are provided for **IPBC**.

Task/ Scenario	Tier / PPE	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Mixing/loading of RTU products by industrials / [1.1.]	Tier 2/ suitable PPE	Providing the operator wears suitable PPE, exposure is considered to be minimal				yes
Application – Automated spraying by industrials / [1.2.1.]	Tier 2/ Gloves Impermeable coverall	20	0.2	0.1565	78.26	yes
Application - Automated dipping by industrials / [1.2.2.]	Tier 2/ Gloves Impermeable coverall	20	0.2	0.1565	78.26	yes
Application - Manual dipping by industrials and professionals / [1.2.3.]	Tier 2/ Gloves Impermeable coverall	20	0.2	0.1041	52.02	yes
Application - Flow coating (deluging) by industrials / [1.2.4.]	Tier 2/ Gloves Impermeable coverall	20	0.2	0.1565	78.26	yes
Post-application -System maintenance by industrials / [1.3.]	Tier 2/ Gloves Impermeable coverall	20	0.2	n.a.	n.a.	n.a.

Combined scenarios

Not applicable

Local effects

Not relevant

Conclusion

The water-based RTU products containing IPBC are used undiluted by industrials for wood preservation by automated spraying (use # 1), automated dipping (use # 2), manual dipping (use # 3; also used by professionals) and flow coating (use # 4).

Workers in industrial premises are trained professionals. Appropriate PPE (protective gloves, protective clothing, footwear, eye protection and face protection) may be used for exposure control.

Using the RTU products containing 0.96% IPBC, the following risk characterisation is given:

Tier 2: Exposure considering PPE (Tier 2: gloves (90% protection) and impermeable coverall (90% protection) during automated spraying or automated dipping by industrials results in 78.26% of the respective AEL for IPBC.

Tier 2: Exposure considering PPE (Tier 2: gloves (90% protection) and impermeable coverall (90% protection) during manual dipping by industrials and professionals results in 52.02 % of the respective AEL for IPBC.

Tier 2: Exposure considering PPE (Tier 2: gloves (90% protection) and impermeable coverall (90% protection) during flow coating (deluging) by industrials results in 78% of the respective AEL for IPBC.

In conclusion, the risk during the individual intended uses (use # 1-4) is acceptable for the RTU products of the BPF, if protective clothing and gloves are used during the individual working tasks.

In addition in case of automated spraying and flow coating (deluging method) the following RMM should be applied: The product may only be used with an automated onward transport of the freshly treated wood with automated stacking or into a drier so as to avoid manual contact with the freshly treated wood.

Risk for professional users

General remark:

The results reflect the concentration of 0.96% of IPBC and the highest application rate of 180 ml/m² of the RTU products to be applied by professional users.

Systemic effects

In the following table, the results are provided for **IPBC**.

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Mixing and Loading of RTU by professionals/ [2.1.]	Tier 1	Not applicable for the RTU product which is applied direct from can.				yes
Application – Brushing and rolling by professionals / [2.2.]	Tier 1	20	0.2	1.958E-01	97.90	yes
Post-application – Washing out of a brush by professionals/ [2.3.]	Tier 1	20	0.2	1.06E-02	5.31	yes
Sawing and	Tier 1	20	0.2	6.07E-04	0.30	yes

sanding treated wood by professionals/ [4.1.1.]						
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Combined scenarios

In the following table, the results are provided for **IPBC**.

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Brushing/ roller by professionals Scenarios [2.1.; 2.2.; 2.3.]	Tier 1	20	0.2	2.064E-01	103.2	no
Scenarios [2.1.; 2.2 Tier 2/ Gloves; 2.3.]	Tier2	20	0.2	7.78E-02	38.90	yes

Local effects

Not relevant

Conclusion

The water-based RTU products containing IPBC are used by professionals for wood preservation by brushing and rolling (use # 5).

In addition, the secondary exposure to professional workers during sawing and sanding of treated wood is considered.

Using the RTU products containing 0.96% IPBC and considering the highest application rate of 180 ml/m², the following risk characterisation is given:

Tier 1: Exposure without considering PPE during brushing and rolling by professionals results in 97.90% of the respective AEL for IPBC.

Tier 1: Secondary exposure without considering PPE during sawing and sanding of treated wood by professionals results in 0.30% of the respective AEL for IPBC.

A combined exposure and risk assessment of primary exposure (brushing/roller) and secondary exposure (sawing and sanding treated wood) is not considered to be relevant, since the workers cannot be expected to apply wood preservative and sawing treated wood at the same time on one working day.

In conclusion,

The risk during brushing/rolling (use # 5) and during sawing/sanding treated wood by professionals is acceptable for the RTU products pertaining to the BPF without considering PPE.

Professional users are expected to follow a minimum of instructions. Appropriate PPE (protective clothing, footwear, eye protection and face protection) may be used for exposure control. Due to the unacceptable risk during brushing/rolling (use # 5) and cleaning of brush (103.2%), professional user should wear protective gloves.

Risk for non-professional users

General remark:

The results reflect the concentration of 0.96% of IPBC and the highest application rate of 180 ml/m² of the RTU products to be applied by non-professional users.

Systemic effects

In the following table, the results are provided for **IPBC**.

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Mixing and Loading of RTU by non-professionals/[3.1.]	Tier 1	Not applicable for the RTU product which is applied direct from can.				yes
Application – Brushing and rolling by non - professionals/[3.2.]	Tier 1	35	0.35	2.74E-01	78.28	yes
Post-application – Washing out of a brush by non-professionals/[3.3.]	Tier 1	35	0.35	1.06E-02	3.02	yes

Combined scenarios

In the following table, the results are provided for **IPBC**.

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Brushing/ roller by non- professionals Scenarios [3.1.; 3.2.; 3.3.]	Tier 1	35	0.35	2.85E-01	81.40	yes

Local effects

Not relevant

Conclusion

The water-based RTU products containing IPBC are used by non-professionals for wood preservation by brushing and rolling (use # 6).

Using the RTU products containing 0.96% IPBC and considering the highest application rate of 180 ml/m², the following risk characterisation is given:

Tier 1: Exposure without considering PPE during brushing and rolling by non-professionals results in 78.28% of the respective AEL for IPBC.

In conclusion, the risk during brushing/rolling (use # 6) by non-professionals is acceptable without considering PPE.

Risk for the general public

General remark:

The results reflect the concentration of 0.96% of IPBC and the highest application rate of 180 ml/m² of the RTU products.

Systemic effects

In the following table, the results are provided for **IPBC**.

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Sawing and sanding treated wood by general public /[4.1.2.] – acute scenario	Tier 1	35	0.35	Adult: 1.80E-04	0.05	yes
Chewing wood off-cut /[4.2.] – acute scenario	Tier 1	35	0.35	Infant: 4.66E-02	13.31	yes
Playing on playground structure outdoors and mouthing /[4.3.] – chronic scenario	Tier 1	20	0.2	Infant: 1.17E-02 Child: 8.50E-03	5.85 4.25	yes
Inhalation of volatilized residues /[4.4.] – chronic scenario	Tier 1	20	0.2	Infant: 2.09E-04 Child: 1.56E-04 Adult: 8.27E-05	0.10 0.08 0.04	yes

Combined scenarios

Not relevant

Local effects

Not relevant

Conclusion

The water-based RTU products containing IPBC are used by industrials, professionals and non-professionals for wood preservation (use # 1-6).

The general public can be secondarily exposed via the oral, dermal and inhalation routes. The results of the exposure estimation by oral and dermal routes are all below 14% of the respective AELs for IPBC.

Exposure by volatilised residues indoors was calculated using ConsExpo. The use of Koralan GL 220 Biocidal Product Family products indoors is restricted to treatment of roof structures or treatment of exterior doors or windows. The results of the exposure estimation by inhalation route is below 1% of the respective AELs for IPBC.

Due to the low value of inhalation exposure, a combined assessment is not considered to be relevant for secondary exposure.

To protect children against contact with product on wet wood the following RMm has been added: Keep children away during treatment.

Reference values and Risk Characterisation for SoC 2-butoxyethanol

Quantitative assessment of inhalative exposure towards the SoC 2-Buroxyethanol in Koralan GL 220 BPF:

Use	Indicative value for inhalative exposure	Inhalative exposure Product with 0,5 % SoC	Occupational exposure limit (OEL) for 2-Butoxyethanol	% OEL
Automated spraying (industrial) Handling model 1 solvent based ¹	0.6 mg/m ³	0.003 mg/m ³	49 mg/m ³	0.006 %
Automated dipping (industrial) Handling model 1 solvent based ¹	0.6 mg/m ³	0.003 mg/m ³	49 mg/m ³	0.006 %
Manual dipping (industrial) Dipping model 1 ¹	1.0 mg/m ²	0.005 mg/m ³	49 mg/m ³	0.01 %
Flow coating (industrial) Handling model 1 solvent based ¹	0.6 mg/m ³	0.003 mg/m ³	49 mg/m ³	0.006 %
Brushing outdoor Consumer painting model 3, TNsG 2002	1.63 mg/m ³	0.008 mg/m ³	49 mg/m ³	0.02 %

Considering the results in the table above the risk caused by the SoC 2-Buthoxythanol is negligible.

Risk for consumers via residues in food

Not relevant. The treated wood is not intended for the manufacture of articles coming into contact with food or drinking water.

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

Not relevant

2.2.7 Risk assessment for animal health

Not relevant. The treated wood is not intended for the manufacture of articles coming into contact with livestock, feed and drinking water.

2.2.8 Risk assessment for the environment

Authorisation is requested for Koralan GL 220 Biocidal Product Family in PT 8. All biocidal products within the BPF are ready-to-use (RTU) water-based formulations containing 0.95% of IPBC as the active substance in PT 8. In addition some formulations within BPF contain IPBC as the in-can-preserved. For that reason the worst-case 0.96% of IPBC has been considered in the environmental exposure and risk assessment.

According to the Applicant's submission and the efficacy studies the products are intended to be used in UC 2 and 3 in the highest application rate of 180 ml/m² by:

- automated spraying, automated dipping, manual dipping and flow coating (by the industrial users);
- brushing/rolling (by the professionals and non-professionals).

The products have not been tested for toxicity on aquatic and terrestrial organisms. In addition Applicant did not provide any new data on the active substance (IPBC).

Apart from IPBC products within Koralan GL 220 Biocidal Product Family contain several substances being potentially of environmental concern:

- several in-can preservatives are used to preserve some ingredients within the BPF:
 - **CMIT/MIT** (CAS: 55965-84-9) according to harmonised CLP is very toxic to aquatic life (H400 with M=100) and very toxic to aquatic life with long lasting effects (H410 with M=100). Since the concentration of CMIT/MIT is very low (for further details please refer to the confidential annex) this substance does not affect the classification of any product with the BPF.
 - **MIT** (CAS: 2682-20-4) according to harmonised CLP is very toxic to aquatic life (H400 with M=10) and very toxic to aquatic life with long lasting effects (H410 with M=1). Despite above the concentration of MIT is too low (for further details please refer to the confidential annex) to affect the classification of the products within BPF.
 - **BIT** (CAS: 2634-33-5) according to harmonised CLP it is very toxic to aquatic life (H400 with M=1) and very toxic to aquatic life with long lasting effects H410 with M=10). Since the concentration of BIT is very low (for further details please refer to the confidential annex) this substance does not affect the classification of the whole product.
 - **OIT** (CAS: 26530-20-1) according to harmonised CLP is also very toxic to aquatic life (H400 with M=100) and very toxic to aquatic life with long lasting effects H410 with M=1000). Concentration of this substance is also not enough (for further details please refer to the confidential annex) to affect the classification of the assessed products.
 - **Bronopol** (CAS: 52-51-7) according to harmonised CLP is very toxic to aquatic life (H400 with M=10) and very toxic to aquatic life with long lasting effects H410 with M=10). Since the concentration of bronopol is low

(for further details please refer to the confidential annex) this substance does not affect the classification of the Koralan BPF products.

- **IPBC as the in-can preservative:** some ingredients within Koralan GL 220 Biocidal Product Family are preserved with IPBC (for further details please refer to the confidential annex). The function of IPBC in these ingredients is in-can preservation, therefore these amounts do not contribute to the function of the active ingredient IPBC in PT 8.
- other substances having environmental classification: apart from above there are the other substances which according to the provided SDS are classified as follows:
 - **Amines, coco alkyl, ethoxylated 1-4.5 moles ethoxylated** (CAS: 61791-14-8) and **Alcohols, C12-14-secondary, ethoxylated** (EC: 935-058-4) are very toxic to aquatic life (H400 with M =1)
 - **Alcohols, C12-14-secondary** (CAS: 126950-60-5) is very toxic to aquatic life (H400 with M =1) and very toxic to aquatic life with long lasting effects H410 with M=1)
 - Nevertheless concentration of these three substances is also too low to affect classification of any product with the assessed BPF (for further details please refer to the confidential annex).

Although no substance beside IPBC affects the classification of products within Koralan GL 220 Biocidal Product Family the other aspects should be taken into consideration as well.

According to „*Transitional Guidance on mixture toxicity assessment for biocidal products for the environment*“ (2014) and “Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C)” (October, 2017) independent of classification limits the active substances from the other PTs are relevant for the mixture assessment.

As already mentioned wood preservatives within Koralan GL 220 Biocidal Product Family contain active substances from other PTs: CMIT/MIT, MIT, OIT, BIT and bronopol.

Since for the latest two active substances there is no harmonised LoEP their assessment on the basis of CLP is sufficient. In a contrast, assessment for CMIT/MIT, MIT and OIT should be subjected for the further screening.

Based on the available list of endpoints for IPBC, CMIT/MIT, MIT and OIT Toxic Units have been calculated (for further details please refer to the Annex Confidential to the Applicant). Then it could be clearly concluded that IPBC is the only driver of the ecotoxicity for all products within Koralan GL 220 Biocidal Product Family.

2.2.8.1 Effects assessment on the environment

Since the active substance is the only substance in the evaluated products of the environmental concern the effects assessment is based on the data presented. Since the active substance is the only substance in the evaluated products of environmental concern the effects assessment is based on the data presented for IPBC and its degradations product - PBC (as stated in AR for PT8 (2008), PT6 (2013), PT13 (2015) and iodine (as stated in the AR for PT 1, 3, 4, 22 (December 2013)).⁵

Summary table on PNEC values			
Compartment	IPBC	PBC	iodine/iodate/iodide
STP	0.44 mg · L ⁻¹		Please refer to the Annex

⁵ Since Applicant has not provided the LoA to iodine as the active substance the data are presented in the annex Confidential to the Applicant. In a contrast background concentrations for iodine has been provided by the Applicant on the basis of literature data.

surface water	0.0005 mg · L ⁻¹	0.0413 mg · L ⁻¹	Confidential to Applicant
Sediment	covered by surface water		
Soil	0.0044 mg · kg wwt ⁻¹	0.149 mg · kg wwt ⁻¹	

In addition there is another relevant metabolite of IPBC – iodine. Since this substance is an essential dietary trace element present in the environment its background concentration must be taken into account in the environmental assessment. Relevant data for iodine are presented in the table below according to literature data deduced from the PT 1, 3, 4, 22 iodine AR (December 2013).

Summary table on iodine background concentration in the environment	
Compartment	Value
Freshwater (river and lake)	0.0005 – 0.020 mg · L ⁻¹
Soil	typical: 0.5 - 20 mg · kg dwt ⁻¹ (0.44 – 17.7 mg · kg wwt ⁻¹) extremes: up to 98 mg · kg ⁻¹ global mean: 5 mg · kg ⁻¹
Groundwater	mean concentration: 1 µg · L ⁻¹ range: 1-70 µg · L ⁻¹ (with extremes up to 400 µg · L ⁻¹)

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

Further Ecotoxicological studies

Further ecotoxicological studies are not required. As explained in point 2.3.8 data for the active substance and its degradation products is sufficient.

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

No studies were performed or available on the ecotoxicology of the products of the Koralan GL 220 Biocidal Product Family.

For all components of the products of the Koralan GL 220 Biocidal Product Family, valid data are available through state-of-the-art safety data sheets. The decisive component of the products for the classification of environmental hazards and environmental exposure is the active substance IPBC.

For the performance of the environmental exposure and risk assessment only data on the active substance IPBC and its metabolites is required. The available data are sufficient to perform the exposure and risk assessments.

Further studies are therefore not required.

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

According to the Vol. IV part A higher tier field studies may be required if a habitat such as a water body, wetland, forest or field is treated. This is not the intended use for PT8 products.

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

Not relevant for PT8 products. The products are not applied in form of a bait or granule.

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

Not relevant for PT8 products.

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

Biocidal products within Koralan GL 220 Biocidal Product Family are ready to use water-based wood preservatives. They contain IPBC at 0.95% w/w as the active substances in PT 8.

In addition some formulations within BPF contain IPBC as the in-can-preservative. For that reason the worst-case 0.96% of IPBC has been considered in the environmental exposure and risk assessment.

Products within the BPF are used for wood indoors and outdoors in UC 2 and 3, by:

- automated spraying (industrial users),
- automated dipping (industrial users),
- manual dipping (industrial and professional users),
- flow coating (industrial users),
- brushing or roller (professionals and non-professionals).

Independent on the method of application products within BPF are to be applied in a rate of 120-180 ml/m². The highest application rate of 180 ml/m² has been used in the environmental risk assessment.

According to the OECD ESD no. 2 (2013): "Revised Emission Scenario Document for Wood Preservatives" (PT 8) the following routes of entry into environmental compartment are relevant for the Koralan GL 220 Biocidal Product Family:

- **for industrial application (by automated spraying, automated/manual dipping and flow coating) and storage of the treated wood (independent on UC):**

Emissions to environment can occur during the treatment process including post-treatment conditioning as well as during storage of treated wood prior to shipment to the STP and then to the surface water (in case of application) or to soil and surface water (during the storage period).

- **for professional/non-professional *in-situ* indoor application (UC 2):**

Emissions to environment are not relevant.

- **for professional/non-professional *in-situ* outdoor application (UC3):**

Emission of wood preservative can occur due to spills and drips to the soil (and then groundwater) or to the surface water (incl. sediment).

- **for treated wood in UC2 during service life:**

The potential emissions from treated wood to the outer environment are considered negligible.

- **for treated wood in UC3 during service life:**

Depending on the considered scenario (noise barrier, house and bridge over pond) emissions may occur due to leaching from the treated wood to: the soil and STP (and then to surface water, sediment, soil and groundwater), the soil (and then to groundwater) or to the surface water (incl. sediment).

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

According to the Volume IV Part A further studies may be required for "products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance." However, as already explained in point 2.2.8 the available data on the active substance – IPBC and its metabolites are sufficient for the environmental exposure assessment. Additional data on fate and behaviour in the environment are not required.

Leaching behaviour (ADS)

One semi-field leaching study was submitted for Koralan GL 220 Biocidal Product Family (please refer to IUCLID-Section 10.3 "leaching behaviour"; study by Wegner, 2015). The study was designed according to the NT Build 509 method and was conducted for 366 days.

The product used in the study - Koralan GL 220 Biocidal Product Family – contained 0.95% of IPBC and was representative for all products within evaluated BPF.

Pine sapwood was treated with Koralan GL 220 Biocidal Product Family by brush (2 times), with the average retention of 137.4 g b.p./ m² (equivalent to 1.30 g IPBC/ m²).

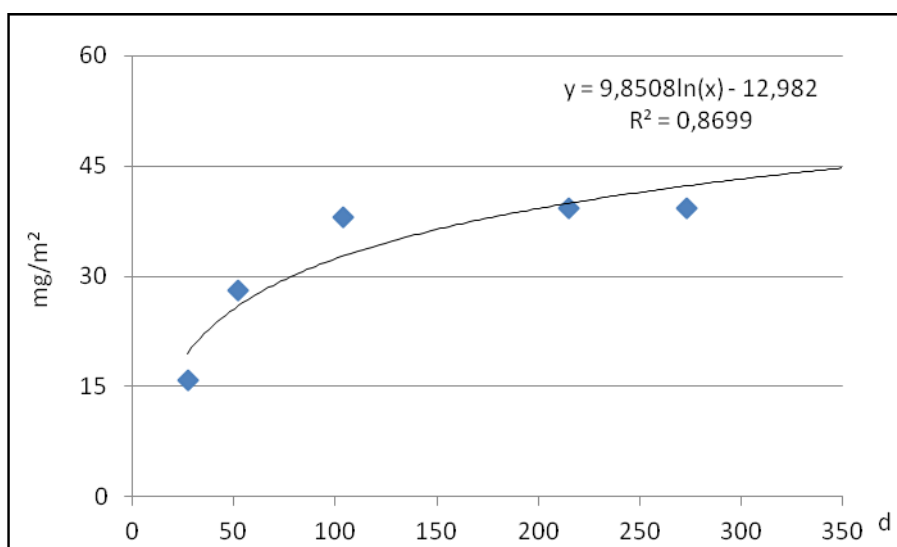
Leaching rates used for the exposure/risk assessment

The experimental leaching rates were normalised to the average annual precipitation of 700 mm (please refer to the table presented below) and then were plotted against time by using the first order decay model (please refer to the figure presented below):

$$Q_c(t) = a \cdot \ln(x) + b$$

Cummulative sampling time (d)	Cummulative precipitation (mm)	Cummulative normalised sampling time (d)	Cummulative quantity of IPBC* leached over the certain time (mg/m²)
39	52	27	15.92
67	100	52	28.05
141	199	104	37.97
266	412	215	39.19
366	524	273	39.31

* including PBC



Finally, the extrapolated leaching rates were corrected for discrepancies between the dosage of IPBC considered in the leaching study ($137.4 \text{ g b.p./m}^2 \cdot 0.0095 \text{ IPBC} = 1.30 \text{ g IPBC/m}^2$) and dosage of IPBC in the BPF products under evaluation study ($185.8 \text{ g b.p./m}^2 \cdot 0.0096^6 \text{ IPBC} = 1.78 \text{ g IPBC/m}^2$).

The result are presented in the table below:

Time	Application method	Cummulative quantity of IPBC leached over certain time
Time 1 (30 days)	all	27.48 (mg/m²)
Time 2 (1825 days)	brush/roller	81.65 (mg/m²)
Time 2 (5475 days)	automated spraying dipping/flow coating	96.14 (mg/m²)

It was determined from the derived leaching rates that the amount of IPBC leached in the study did not exceed the amount of the a.s. applied.

Testing for distribution and dissipation in soil (ADS)

According to the BPR Guidance Volume IV Part A further studies may be required "if there are indications that other components in the product influence distribution and degradation characteristics".

The environmental exposure and risk assessments, which are based on the data set of the active substance, do not require the performance of further studies. The PEC/PNEC values for the respective compartments are below 1, or the risk may be mitigated by the adequate measures.

⁶ Considering 0.95% of IPBC as the active substance in PT 8 and 0.01% of IPBC being the in-can preservative of some b.p. within Koralan GL 220 Biocidal Product Family.

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

The environmental exposure and risk assessments, which are based on the data set of the active substance, do not require the performance of further studies. The PEC/PNEC values for the respective compartments are below 1, or the risk may be mitigated by the adequate measures.

Testing for distribution and dissipation in air (ADS)

Due to the low vapour pressures of IPBC (4.5×10^{-3} Pa at 25°C) the emission to air is negligible and consequently not relevant.

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)

The products within BPF Koralan GL220 are not intended to be used for an *in-situ* spray application. An overspray study is therefore not required.

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)

The products within BPF Koralan GL220 are not foreseen for an *in-situ* spray application. Data on overspray behaviour are therefore not required.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 8
Assessed scenarios	<p>Scenarios for industrial application in UC 2-3: Scenario 1: Automated spraying Scenario 2: Dipping (also valid for flow coating)</p> <p>Scenarios for storage of industrially treated wood in UC 2-3: Scenario 3: Automated spraying Scenario 4: Dipping (also valid for flow coating)</p> <p>Scenarios for <i>in-situ</i> application in UC 3: Scenario 5: House scenario (brushing and rolling by professionals and non-professionals) Scenario 6: Bridge over pond scenario (brushing and rolling by professionals and non-professionals)</p> <p>Scenarios relevant for service life of treated wood in UC 3: Scenario 7: House Scenario 8: Bridge over pond Scenario 9: Noise barrier</p>
ESD(s) used	Emission Scenario Document for Product Type 8: OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2; Revised Emission

	Scenario Document for Wood Preservatives (27 September 2013); ENV/JM/MONO(2013)21
Approach	Scenario 1-9: Average consumption
Distribution in the environment	Calculated based on ECHA-Guidance (2017) BPR, Vol. IV, ENV – Part B+C
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation: No Use: Yes (scenario 1, 2, 5, 6) Storage of treated article: Yes (scenario 3, 4) Service life of the treated articles: Yes (scenario 7, 8, 9)
Remarks	-

Emission estimation

Input parameters for calculating the local emission for all scenarios			
Input	Value	Unit	Remarks
Scenario 1, 2, 5, 6: Application			
Application rate of biocidal products	180	ml/m ²	S (please refer to chapter 2.1.4)
	185.8 ⁷	g/m ²	
	7432 ⁸	g/m ³	
Concentration of IPBC in the products	0.96 ⁹	% [w/w]	S

Fate and distribution in exposed environmental compartments

The fate and distribution in exposed environmental compartments are covered by the active substance data on IPBC (incl. its degradation products) and the leaching study provided for Koralan GL 220 Biocidal Product Family.

Identification of relevant receiving compartments based on the exposure pathway						
Scenario	STP	Surface water	Sediment	Air	Soil	Ground-water
Industrial application by automated spraying and dipping	++	+	+	(+)	-	-
Storage of wood treated industrially	-	++	+	(+)	++	+
<i>In-situ</i> application in UC 3	House	-	-	-	++	+
	Bridge over pond	-	++	+	-	-

⁷ Assuming that density of the products with the BPF is 1.032 g/cm³

⁸ Calculated on the basis of the factor of 40.

⁹ Worst-case for BPF assuming 0.95% of IPBC as the a.s. in PT 8 and 0.01% as in-can preservative.

Service life of treated wood in UC3	House	-	-	-	-	++	+
	Bridge over pond	-	++	+	-	-	-
	Noise barrier	++	+	+	-	++ /+	+

++ direct emission

+ indirect emission

(+) not relevant based on IPBC and its degradation products properties, for further details please refer to description given below

IPBC is stable to hydrolysis and photolysis. Air is out of an environmental concern for this active substance because of the low vapour pressure ($2.36 \div 4.5E-03$ Pa at 25°C) and the short half-life in this compartment ($DT_{50} = 15$ hr).

IPBC has a medium to high mobility potential. Based on a log Pow value of 2.8 it can be also concluded that its bioaccumulation potential is low.

IPBC is not readily biodegradable but it undergoes rapid primary biodegradation in the STP, surface water and soil.

In scenarios with emission via STP it should be assumed that as a result of rapid (within 4 hours) and total degradation of IPBC in the STP its presence in the effluent should not be expected. In those cases only PECs STP (as the Cinfluent) are relevant for the parent compound - IPBC while the exposure assessment for the aquatic and terrestrial compartment should be focused on the degradation products (PBC and iodine).

In scenarios with direct emission to soil and surface water biodegradation half-life of 4.7 and 3.1 hour at 12°C, respectively should be for IPBC assumed. In addition it should be noted that as PNEC sediment for IPBC given in the AR (PT8) is calculated using the EPM, the exposure/risk assessment for the sediment will be covered sufficiently by the assessment for the surface water.

PBC is a major metabolite of IPBC formed in the STP, water and soil. Due to a relative short half-life (12°C) of 9.5 days in soil and 31.2 days in water PBC can be regarded as a transient metabolite nevertheless it must be considered the environmental assessment.

Iodine species are major metabolites of IPBC released in the STP, surface water and soil. In a contrast to IPBC and PBC iodine species do not undergo degradation. Exposure to air for iodine species is considered to be low, as these compounds are assumed not to be volatile.

Input parameters (only set values) for calculating the fate and distribution in the environment for IPBC		
Input	Unit	IPBC
Molecular weight	g/mol	281.1
Vapour pressure (at 25°C)	Pa	$2.36 \div 4.5E-03$
Water solubility (at 20°C pH = 7)	mg/L	168
Log Kow(at 25°C)	-	2.81
Henry law constant (at 25°C)	Pa/m ³ /mol	$3.38 \div 6.45E-03$
Organic carbon/water partition coefficient (Koc)	L/kg	113.5
Biodegradability	-	Not readily IPBC is primary biodegradable

Input parameters (only set values) for calculating the fate and distribution in the environment for IPBC		
Input	Unit	IPBC (within 2 hours)
Hydrolysis	-	Stable
Photolysis	-	Stable
DT ₅₀ for degradation in soil	d (at 12°C)	0.196
DT ₅₀ for biodegradation in surface water	d (at 12°C)	0.129
DT ₅₀ for degradation in air	hr	15

* values are deduced from the IPBC PT13 AR (2015)

** values are deduced from the iodine AR PT 1, 3, 4, 22 (2013).

** for degradation products only values used in the assessment are presented

Fate and distribution in the STP*		
Compartment	Percentage [%]	
	PBC	Iodine species
Air	0.935	Please refer to the Annex Confidential to Applicant
Water	96.7	
Sludge	2.41	
Degraded in STP	0	

* In the STP IPBC is completely degraded within 4 hours into PBC and iodine species. For that reason parameters for degradation products of IPBC are presented only.

Local emissions to environmental compartments

Emission to relevant environmental compartments has been calculated on the basis of ESD for PT 8 (2013). For further details please refer to Annex 15 - 23.

Calculated PEC values for IPBC

Summary table on calculated PEC values for IPBC				
Scenario	PEC _{STP} ¹⁰	PEC _{water}	PEC _{soil}	PEC _{GW}
	[mg/L]	[mg/L]	[mg/kg _{wwt}]	[µg/l]
Scenario 1a: Automated spraying - small plants	5.35E-02	Not relevant for IPBC ¹¹		
Scenario 1b: Automated spraying - large plants	5.35E-01			
Scenario 2:	1.07E-01			

¹⁰ According to the Assessment Report for IPBC (2015) the influent concentration is relevant for the assessment of PEC_{STP} of IPBC. Further emissions to surface water are estimated from PBC concentrations in the STP effluent.

¹¹ IPBC is degraded in the STP (thus only PBC and iodine species will be present in the effluent and in the other compartments exposed further)

Summary table on calculated PEC values for IPBC					
Scenario	PEC _{STP} ¹⁰	PEC _{water}	PEC _{soil}	PEC _{GW}	
	[mg/L]	[mg/L]	[mg/ kg _{wwt}]	[µg/l]	
Dipping					
Scenario 3a Automated spraying - small plants storage of treated wood Time 1	-	1.54E-05	1.67E-03	Please refer to the results of PEARL modelling presented at the end of chapter 2.2.8.2	
Scenario 3a Automated spraying - small plants storage of treated wood Time 2	-	1.54E-05	1.67E-03		
Scenario 3b Automated spraying - large plants storage of treated wood Time 1	-	1.54E-04	1.67E-03		
Scenario 3b Automated spraying - large plants storage of treated wood Time 2	-	1.54E-04	1.67E-03		
Scenario 4 Dipping storage of treated wood Time 1	-	1.36E-04	1.67E-03		
Scenario 4 Dipping storage of treated wood Time 2	-	1.36E-04	1.67E-03		
Scenario 5a: House scenario - brushing/rolling by professionals	-	-	3.03E-01		
Scenario 5b: House scenario - brushing/rolling by non-professionals	-	-	5.04E-01		
Scenario 6a: Bridge scenario - brushing/rolling by professionals	-	5.35E-04	-		-
Scenario 6b: Bridge scenario - brushing/rolling by non-professionals	-	8.92E-04	-		-
Scenario 7a:	-	-	1.46E-03	Please	

Summary table on calculated PEC values for IPBC				
Scenario	PEC _{STP} ¹⁰	PEC _{water}	PEC _{soil}	PEC _{GW}
	[mg/L]	[mg/L]	[mg/ kg _{wwt}]	[µg/l]
House scenario – service life of wood treated by brush with degradation Time 1				refer to the results of PEARL modelling presented at the end of chapter 2.2.8.2
Scenario 7a: House scenario – service life of wood treated by brush with degradation Time 2	-	-	7.15E-05	
Scenario 7b: House scenario – service life of wood treated industrially with degradation Time 1	-	-	1.46E-03	
Scenario 7b: House scenario – service life of wood treated industrially with degradation Time 2	-	-	2.81E-05	
Scenario 8a: Bridge scenario – service life of wood treated by brush with degradation Time 1	-	1.70E-06	-	-
Scenario 8a: Bridge scenario – service life of wood treated by brush with degradation Time 2	-	8.34E-08	-	-
Scenario 8b: Bridge scenario – service life of wood treated industrially with degradation Time 1	-	1.70E-06	-	-
Scenario 8b: Bridge scenario – service life of wood treated industrially with degradation Time 2	-	3.27E-08	-	-
Scenario 9 – release via STP				
Scenario 9a: Noise barrier scenario – service life of wood treated by brush Time 1	9.62E-04	Not relevant for IPBC ¹²		
Scenario 9a:	4.70E-05			

¹² IPBC is degraded in the STP (thus only PBC and iodine species will be present in the effluent and in the other compartments exposed further)

Summary table on calculated PEC values for IPBC				
Scenario	PEC _{STP} ¹⁰	PEC _{water}	PEC _{soil}	PEC _{GW}
	[mg/L]	[mg/L]	[mg/kg _{wwt}]	[µg/l]
Noise barrier scenario –service life of wood treated by brush Time 2				
Scenario 9b: Noise barrier scenario – service life of wood treated by dipping Time 1	9.62E-04			
Scenario 9b: Noise barrier scenario – service life of wood treated by dipping Time 2	1.84E-05			
Scenario 9 – emission to soil (calculations with degradation)				
Scenario 9a: Noise barrier scenario – service life of wood treated by brush Time 1	-	-	5.48E-04	Please refer to the results of PEARL modelling presented at the end of chapter 2.2.8.2
Scenario 9a: Noise barrier scenario – service life of wood treated by brush Time 2	-	-	2.68E-05	
Scenario 9b: Noise barrier scenario – service life of wood treated by dipping Time 1	-	-	5.48E-04	
Scenario 9b: Noise barrier scenario – service life of wood treated by dipping Time 2	-	-	2.68E-05	

PEC calculations for PBC:

PBC is a major metabolite of IPBC formed in the STP, water and soil. To simplify the assessment for biocidal products within Koralan GL 220 Biocidal Product Family PEC values for PBC are presented for the worst – case scenarios only:

STP, surface water and soil - scenarios with emission via STP

As stated previously, according to AR for IPBC **in all scenarios with emission via STP** (scenario 1, 2 and 9) it should be assumed that as a result of rapid (within 4 hours) and total degradation of IPBC in the STP its presence in the effluent should not be expected. In that cases the exposure for the surface water should be focused on PBC. According to AR for IPBC 100% of transformation of 1 moles of IPBC into 1 mole of PBC is assumed resulting in the conversion factor of 0.552.

The calculations for PBC were performed as follows:

$$PEC_{STP\ PBC} = C_{influent\ IPBC} \cdot F_{STP,\ water\ PBC} \cdot CONV\ factor$$

$$PEC_{water\ PBC} = PEC_{STP,\ water\ PBC} / (DILUTION \cdot (1 + K_{susp\ PBC} \cdot SUSP_{water}))$$

where:

$$C_{\text{influent IPBC}} = 5.35\text{E-}01 \text{ [mg/L]}$$

$$F_{\text{STP, water PBC}} = 0.967 \text{ [-]}$$

$$\text{CONV factor} = 0.552 \text{ [-]}$$

$$\text{DILUTION} = 10 \text{ [-]}$$

$$K_{\text{susp PBC}} = 19.8 \text{ [L/kg]}$$

$$\text{SUSPwater} = 15 \text{ [mg/L]}$$

$$E_{\text{local water PBC}} = E_{\text{local water IPBC}} \cdot \text{CONV factor}$$

$$C_{\text{sludge}} = (F_{\text{STP, sludge PBC}} \cdot E_{\text{local water PBC}} \cdot 10^6) / \text{SLUDGERATE} \text{ [mg} \cdot \text{kg}^{-1}]$$

$$C_{\text{sludge soil 1}}(0) = (C_{\text{sludge}} \cdot \text{APPL}_{\text{sludge}}) / (\text{DEPTH}_{\text{soil}} \cdot \text{RHO}_{\text{soil}})$$

$$\text{PEC}_{\text{initial soil 10}}(0) = \text{PEC}_{\text{soil}} = C_{\text{sludge soil 10}}(0) = C_{\text{sludge soil 1}}(0) \cdot (1 + \sum_{n=1}^9 \text{Facc}^n)$$

$$\text{PEC}_{\text{soil}} = (\text{PEC}_{\text{initial soil 10}}(0) \cdot (1 - e^{-kt})) / (k \cdot t)$$

where:

$$E_{\text{local water IPBC}} = 1.07 \text{ [kg/d]}$$

$$\text{CONV factor} = 0.552 \text{ [-]}$$

$$F_{\text{STP, sludge PBC}} = 0.0241 \text{ [-]}$$

$$\text{SLUDGERATE} = 710 \text{ [kg/d]}$$

$$\text{APPL}_{\text{sludge}} = 0.5 \text{ [kg}_{\text{dwt}} / \text{m}^2 / \text{yr}]$$

$$\text{DEPTH}_{\text{soil}} = 0.2 \text{ [m]}$$

$$\text{RHO}_{\text{soil}} = 1700 \text{ [kg/m}^3\text{]}$$

$$k = 0.0729 \text{ [/d]}$$

$$t = 30 \text{ [d]}$$

Calculated PECs for PBC is presented in the table below on the basis of the worst-case scenario (Scenario 1b: Automated spraying - large plants):

Summary table on calculated PEC values for PBC in the worst-case scenario with release <i>via</i> STP			
Scenario	PEC_{STP}	PEC_{water}	PEC_{soil}
	[mg/L]	[mg/L]	[mg/kg _{wwt}]
Scenario 1b: Automated spraying - large plants	2.86E-01	2.86E-02	1.20E-02

Surface water - scenarios with direct emission to water

PEC_{water} for PBC has been calculated on the basis of Bridge over pond scenario during service life of industrially treated wood after the longer time period (Scenario 8b Time 2). This scenario represents the worst-case approach for the direct emission to surface water, when no degradation of IPBC is taken into account (please refer to Appendix 22).

For that purpose the following assumption has been considered:

$$\text{PEC}_{\text{water PBC}} = \text{PEC}_{\text{water IPBC without degradation}} \cdot \text{CONV factor}$$

where:

$$\text{PEC}_{\text{water IPBC without degradation}} = 9.61\text{E-}04 \text{ [mg/L]}$$

$$\text{CONV factor} = 0.552 \text{ [-]}$$

Summary table on calculated PEC_{water} values for PBC in the worst-case scenario with direct release to surface water	
Scenario	PEC_{water}
	[mg/L]
Scenario 8b: Bridge scenario – service life of wood treated by industrially Time 2	5.30E-04 ¹³

Soil - scenarios with direct emission to soil

PEC_{soil} for PBC has been calculated on the basis of the House scenario during service life of industrially treated wood after the longer time period (Scenario 7b Time 2). This scenario represents the worst-case approach for the direct emission to soil, when no degradation of IPBC is taken into account (please refer to Appendix 21).

The following assumption has been considered:

$$\text{PEC}_{\text{soil PBC}} = \text{PEC}_{\text{soil IPBC without degradation}} \cdot \text{CONV factor}$$

where:

$$\text{PEC}_{\text{soil IPBC without degradation}} = 5.44\text{E-}01 \text{ [mg/kg}_{\text{wwt}}\text{]}$$

$$\text{CONV factor} = 0.552 \text{ [-]}$$

In addition Tier 2 for PBC has been assessed, considering DT₅₀ of this degradation product in soil as follows:

$$\text{E}_{\text{soil,leach,Time 2 PBC}} = \text{E}_{\text{soil,leach,Time 2 IPBC}} \cdot \text{CONV factor}$$

$$\text{C}_{\text{local soil Time2, PBC}} = \text{E}_{\text{soil,leach,Time 2 IPBC}} / (\text{V}_{\text{soil}} \cdot \text{RHO}_{\text{soil}} \cdot k) - [\text{E}_{\text{soil,leach,Time x}} / (\text{V}_{\text{soil}} \cdot \text{RHO}_{\text{soil}} \cdot k)] \cdot e^{-\text{time,x} \cdot k}$$

where:

$$\text{E}_{\text{soil,leach,Time 2 IPBC}} = 5.44\text{E-}01 \text{ [kg/d]}$$

$$\text{CONV factor} = 0.552 \text{ [-]}$$

$$k \text{ for PBC} = 0.0729 \text{ [/d]}$$

Summary table on calculated PEC_{soil} values for PBC in the worst-case scenario with direct release to soil		
Scenario		PEC_{soil}
		[mg/kg _{wwt}]
Scenario 7b: House scenario – service life of wood treated by industrially Time 2	Tier 1 (with no degradation of PBC)	3.00E-01
	Tier 2 (with degradation of PBC)	7.51E-04

Groundwater

Please refer to the results of PEARL modelling presented at the end of chapter 2.2.8.2.

¹³ The value is overestimated for PBC since it does not take into account the degradation in soil (acc. to AR for IPBC k_{water} for PBC = 0.022 in 12°C). Despite above, as the presented value results in an acceptable risk no further calculations (including DT₅₀) has been performed.

PEC calculations for iodine species:

Please refer to the Annex Confidential to Applicant.¹⁴

PEARL modelling for IPBC, PBC and iodine species

In case of scenarios with emission via STP assessment for groundwater could be relevant for PBC and iodine species only as the IPBC is expected to be totally and quickly degraded in the STP. Again, to simplify the assessment only the worst-case scenarios have been described below.

In CAR for IPBC (PT 6, 2013) PEARL modelling has been performed for the worst-case scenario (with Elocal of 0.572 kg of IPBC/d) and it has been concluded that acceptable concentration of PBC in the groundwater in all scenarios has been achieved. In case of iodine species (iodate and iodide, which are the dominant iodine species in soil) the concentration has been identified at the background level in almost all scenarios with one exception – Thiva scenario.

In case of calculations performed for Koralan GL 220 Biocidal Product Family the highest Elocal of 1.07 kg IPBC/d (in Scenario 1b – Automated spraying in big plants) is higher than this considered in CAR and thus would result in the worse-results. Nevertheless for this scenario already a RMM is proposed (please refer to conclusion on risk) thus groundwater assessment is for it out of concern.

The second worst-case scenario for Koralan GL 220 Biocidal Product Family (Scenario 2 – Application by diipping) results in Elocal of 0.214 kg IPBC/d and is sufficiently covered by the assessment provided in CAR. It should be also noted that since the difference between Elocal of IPBC in Scenario 2 is about 2.67 lower than these considered CAR even the Thiva scenario would result in acceptable concentration of iodine species in the groundwater.

In case of scenarios with direct emission to soil

For the purpose of PEARL modelling IPBC release from treated wood over a period of 5 years from 35 houses /ha have been taken into account in CAR for IPBC (PT 6, 2013) with the application rate of 0.00458 kg IPBC/ha. The performed assessment allowed to conclude that predicted concentration of all substances of concern (IPBC, PBC and iodine species) is within the acceptable level.

Taking into account the results of leaching studies for Koralan GL 220 Biocidal Product Family for the time period of 5 years, density of 16 houses per hectare (as currently allowed according to TAB) and the 10 applications per year the following application rate of IPBC could be used in PEARL model:

$$81.65 \text{ mg/m}^2 \cdot 16 \text{ houses/ha} \cdot 125 \text{ m}^2/\text{house} = 1.63\text{E-}01 \text{ kg IPBC/ha (over 5 years)}$$

$$0.1633 \text{ kg IPBC/ha/1825d} = 8.95\text{E-}05 \text{ kg IPBC/ha/d}$$

$$8.95\text{E-}05 \text{ kg IPBC/ha/d} \cdot 365\text{d}/10 \text{ applications} = \mathbf{0.00327 \text{ kg IPBC/ha}}$$
 (to be input into PEARL model)

¹⁴ Since Applicant has not provided the LoA to iodine as the active substance the data are presented in the annex Confidential to the Applicant.

Since the above application rate is lower than those obtained in CAR it can be concluded without further assessment that use of the products within Koralan GL 220 Biocidal Product Family will not pose unacceptable risk for the groundwater.

Primary and secondary poisoning

Primary poisoning

The products within BPF are RTU wood preservatives applied by automated spraying, dipping and rolling or brushing. For that reason direct uptake of these products is unlikely.

Secondary poisoning

According to the BPR Guidance Vol IV part A a log Kow ≥ 3 gives an indication for a bioaccumulation potential and a secondary poisoning assessment needs to be performed. IPBC has a log Kow < 3 . A secondary poisoning assessment is therefore not required.

2.2.8.3 Risk characterization

Atmosphere

Conclusion: Due to the low vapour pressures of IPBC (4.5×10^{-3} Pa at 25°C), PBC and iodine the emission to air seems to be negligible and consequently not relevant. Therefore, the air compartment is not considered for the active substance and its degradation products in the environmental risk assessment.

Sewage treatment plant (STP), surface water and soil and groundwater (assessment for IPBC):

Summary table on calculated PEC/PNEC values for IPBC				
Scenario	STP	Surface water	Soil	Groundwater
Scenario 1a: Automated spraying - small plants	1.22E-01	not relevant for IPBC ¹⁵		
Scenario 1b: Automated spraying - large plants	1.22			
Scenario 2: Dipping	2.43E-01			
Scenario 3a Automated spraying - small plants storage of treated wood Time 1	-	3.07E-02	3.80E-01	Please refer to the overall conclusions from PEARL modelling presented at the end of chapter 2.2.8.3
Scenario 3a Automated spraying - small plants storage of treated wood Time 2	-	3.07E-02	3.80E-01	

¹⁵ IPBC is degraded in the STP (thus only PBC is present in the effluent and further exposed compartments).

Summary table on calculated PEC/PNEC values for IPBC				
Scenario	STP	Surface water	Soil	Groundwater
Scenario 3b Automated spraying - large plants storage of treated wood Time 1	-	3.07E-01	3.80E-01	
Scenario 3b Automated spraying - large plants storage of treated wood Time 2	-	3.07E-01	3.80E-01	
Scenario 4 Dipping storage of treated wood Time 1	-	2.72E-01	3.80E-01	
Scenario 4 Dipping storage of treated wood Time 2	-	2.72E-01	3.80E-01	
Scenario 5a: House scenario - brushing/rolling by professionals	-	-	68.8	
Scenario 5b: House scenario - brushing/rolling by non-professionals	-	-	114.6	
Scenario 6a: Bridge scenario - brushing/rolling by professionals	-	1.07	-	-
Scenario 6b: Bridge scenario - brushing/rolling by non-professionals	-	1.78	-	-
Scenario 7a: House scenario – service life of wood treated by brush with degradation Time 1	-	-	3.33E-01	Please refer to the overall conclusions from PEARL modelling presented at the end of chapter 2.2.8.3
Scenario 7a: House scenario – service life of wood treated by brush with degradation Time 2	-	-	1.62E-02	
Scenario 7b: House scenario – service life of wood treated industrially with degradation Time 1	-	-	3.33E-01	

Summary table on calculated PEC/PNEC values for IPBC				
Scenario	STP	Surface water	Soil	Groundwater
Scenario 7b: House scenario – service life of wood treated industrially with degradation Time 2	-	-	6.38E-03	
Scenario 8a: Bridge scenario – service life of wood treated by brush with degradation Time 1	-	3.39E-03	-	-
Scenario 8a: Bridge scenario – service life of wood treated by brush with degradation Time 2	-	1.67E-04	-	-
Scenario 8b: Bridge scenario – service life of wood treated industrially with degradation Time 1	-	3.39E-03	-	-
Scenario 8b: Bridge scenario – service life of wood treated industrially with degradation Time 2	-	6.54E-05	-	-
Scenario 9 – release via STP				
Scenario 9a: Noise barrier scenario – service life of wood treated by brush Time 1	2.19E-03	Not relevant for IPBC ¹⁴		
Scenario 9a: Noise barrier scenario – service life of wood treated by brush Time 2	1.07E-04			
Scenario 9b: Noise barrier scenario – service life of wood treated by dipping Time 1	2.19E-03			
Scenario 9b: Noise barrier scenario – service life of wood treated by dipping Time 2	4.19E-05			
Scenario 9 –direct emission to soil (calculations with degradation)				
Scenario 9a: Noise barrier scenario – service life of wood treated by brush Time 1	-	-	1.25E-01	Please refer to the overall conclusions from PEARL
Scenario 9a: Noise barrier scenario – service life of	-	-	6.08E-03	

Summary table on calculated PEC/PNEC values for IPBC				
Scenario	STP	Surface water	Soil	Groundwater
wood treated by brush Time 2				modelling presented at the end of chapter 2.2.8.3
Scenario 9b: Noise barrier scenario – service life of wood treated by dipping Time 1	-	-	1.25E-01	
Scenario 9b: Noise barrier scenario – service life of wood treated by dipping Time 2	-	-	2.39E-03	

PEC/PNEC values for PBC

STP PEC/PNEC ratio for PBC	
Scenario	
Emission via STP to surface water on the basis of the worst-case Scenario 1b: Automated spraying - big plants	6.49E-01

Surface water PEC/PNEC ratio for PBC	
Scenario	
Emission via STP to surface water on the basis of the worst-case Scenario 1b: Automated spraying - big plants	6.91E-01
Direct emission to surface water on the basis of the worst-case Scenario 8b: Bridge scenario – service life of wood treated industrially Time 2	1.28E-02

Soil PEC/PNEC ratio for PBC	
Scenario	
Emission via STP to soil on the basis of the worst-case Scenario 1b: Automated spraying - big plants	8.03E-02
Direct emission to soil on the basis of the worst-case Scenario 7b: House scenario – service life of wood treated industrially with degradation of PBC Time 2	5.04E-03

Groundwater:

Please refer to the overall conclusions from PEARL modelling presented at the end of chapter 2.2.8.3

PEC/PNEC values for iodine

Please refer to the Annex Confidential to Applicant.¹⁶

Overall conclusions:

Air:

Due to properties of IPBC, PBC and iodine species air compartment is out of environmental concern.

STP:

The PEC/PNEC values for IPBC, PBC and iodine are below the trigger value with 1 exception - application by automated spraying in big plants, where the PEC/PNEC for IPBC is 1.22. For above reason for application by automated spraying the standard risk mitigation measure should be proposed:

Presented conclusion is in line with revised ESD for PT 8, where it is stated that release of wood preservatives from treatment installations to the drain connected to an STP is not permitted in EU countries, and that calculations for industrial application are performed for the sake of completeness only.

Assuming all above the following RMM is proposed for all industrial uses of products within Koralan BPF:

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

Surface water:

The PEC/PNEC values for IPBC in almost all scenarios are within acceptable risk, with exception of *in-situ* application of wooden preservative by both professional and non-professional. For that reason the following RMM is mandatory for the biocidal products within the Koralan GL 220 Biocidal Product Family Biocidal Product Family, if they are used by the roller/brush:

Do not apply near bodies of surface water or in the area of water protection zones.

For all relevant scenarios degradation products - PBC and iodine species - pose no unacceptable risk to surface water. All PEC/PNEC values for PBC are below 1 and in case of iodine species are below 1 or within the background concentration.

Sediment:

Risk assessment for surface water covers the risk for the sediment.

Soil:

In most of scenarios IPBC poses no unacceptable risk. The one exception is *in-situ* application of wood preservatives by professional and non-professional users. Consequently, biocidal products within the Koralan GL 220 Biocidal Product Family intended to be used by the roller/brush should be labelled as follows:

Cover the ground during application and whilst surfaces are drying and collect any spillage.

¹⁶ Since Applicant has not provided the LoA to iodine as the active substance the data are presented in the annex Confidential to the Applicant.

PBC poses no unacceptable risk to soil. In a contrast in the worst-case scenarios with direct and indirect emission to soil, PEC/PNEC ratios for iodine and iodate are above 1. Nevertheless, it may be accepted, because the calculated PECs are within the background concentration.

Groundwater

As described at the end of chapter 2.2.8.2 use of biocidal products within Koralan GL 220 Biocidal Product Family would not result in unacceptable risk for IPBC, PBC and iodine species to groundwater.

Primary and secondary poisoning

Primary poisoning

The products within BPF are RTU wood preservatives. A direct uptake of these products is unlikely.

Secondary poisoning

According to the BPR Guidance Vol IV part A a log Kow ≥ 3 gives an indication for a bioaccumulation potential and in such cases a secondary poisoning assessment needs to be performed. IPBC has a log Kow < 3 . A secondary poisoning assessment is therefore not required.

Other relevant

Additionally, in line with the Implementing Directive of IPBC (2008) the following RMM is proposed for wood treated by automated spraying, manual/automated dipping and flow-coating:

Freshly treated timber shall be stored after the treatment under a shelter or on impermeable hard standing, or both both, to prevent direct losses to soil, sewer or water and any losses must be collected for reuse or disposal.

Mixture toxicity

According to the performed assessment mixture toxicity and risk assessment is not relevant for the products within Koralan GL 220 Biocidal Product Family.

Aggregated exposure (combined for relevant emission sources)

Not relevant for the products within Koralan GL 220 Biocidal Product Family.

Overall conclusion on the risk assessment for the environment of the BPF

The results of the environmental risk assessment show that there is no unacceptable risk for the environment for the products of the Koralan GL 220 Biocidal Product Family with exception of the risk identified during the industrial application by automated spraying and *in-situ* application by the roller/brush.

For that reason and according to the ESD for PT 8 and Implementing Directive of IPBC (2008), when:

- products within the BPF are applied by the automated spraying, manual/automated dipping and flow-coating the following standard risk mitigation measures has to be considered:
 - **Application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).**
 - **Freshly treated timber shall be stored after the treatment under a shelter or on impermeable hard standing, or both both, to prevent direct losses to soil, sewer or water and any losses must be collected for reuse or disposal.**
- the products are applied by the roller/brush the following RMMs have be applied:
 - **Cover the ground with impermeable sheet during application and whilst surfaces are drying and collect any spillage (independent of the user category).**
 - **Do not apply over/near bodies of surface water (independent of the user category).**

2.2.9 Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage of active substance/biocidal product, shelf-life of biocidal product

Requirements for storage rooms and vessels
Keep/Store only in original container.

Hints on joint storage
Storage class (TRGS 510) : 12

Further information on storage conditions
Protect containers against damage. Protect against : Frost

Recommended methods and precautions concerning handling and transport

Precautions for safe handling
Avoid contact with skin and eyes.

Protective measures
Use only in well-ventilated areas. Do not breathe gas/fumes/vapour/spray.

Personal protection equipment
Eye/face protection: Eye glasses with side protection

Skin protection

Hand protection: The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

Suitable material : Butyl caoutchouc (butyl rubber) NBR (Nitrile rubber)

Breakthrough time (maximum wearing time) : 480 minutes. Check leak tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Thickness of the glove material: 0.4 mm

Respiratory protection

Usually no personal respirative protection necessary.

General health and safety measures

Avoid contact with skin, eyes and clothes. Remove contaminated, saturated clothing. Wash hands before breaks and after work. Keep away from food, drink and animal feeding stuffs.

Transport information

UN number

No dangerous goods in sense of this transport regulation.

UN proper shipping name

No dangerous goods in sense of this transport regulation.

Transport hazard class(es)

No dangerous goods in sense of this transport regulation.

Packing group

No dangerous goods in sense of this transport regulation.

Environmental hazards

No dangerous goods in sense of this transport regulation.

Special precautions for user

None

Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustions gases etc.

Suitable extinguishing media

Carbon dioxide (CO₂) alcohol resistant foam Water spray jet Extinguishing powder Sand

Unsuitable extinguishing media

None

Special hazards arising from the substance or mixture

None.

Advice for firefighters

In case of fire toxic gases may be formed. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

Special protective equipment for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

Reactivity

No dangerous reactions known.

Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

Possibility of hazardous reactions

No dangerous reactions known.

Conditions to avoid

No information available.

Incompatible materials

No information available.

Hazardous decomposition products

No information available.

Additional information

None

Particulars of likely direct or indirect adverse effects

Most important symptoms and effects, both acute and delayed

May produce an allergic reaction.

First aid instructions, antidotes

General information

Change contaminated, saturated clothing. When in doubt or if symptoms are observed, get medical advice. Never give anything by mouth to an unconscious person or a person with cramps.

Following inhalation

Remove casualty to fresh air and keep warm and at rest. Provide fresh air.

In case of skin contact

After contact with skin, wash immediately with plenty of water and soap. In case of skin reactions, consult a physician.

After eye contact

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

Do NOT induce vomiting. Rinse mouth thoroughly with water.

Self-protection of the first aider

First aider: Pay attention to self-protection!

Information to physician

Treatment: Treat symptomatically.

Indication of any immediate medical attention and special treatment needed

None

Emergency measures to protect environment in case of accident

Environmental precautions

Do not allow to enter into surface water or drains. Prevent spread over a wide area (e.g. by containment or oil barriers).

Methods and material for containment and cleaning up

For cleaning up: Take up mechanically. Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid - or universal binding agents). Collect in closed and suitable containers for disposal.

Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms (relevant for biocidal products only)

Not required for biocidal products of product type 08 (wood preservatives).

Possibility of destruction or decontamination following release in or on the following:

Air

No specific instruction available.

Water, including drinking water

No specific instruction available.

Soil

No specific instruction available.

Procedures for waste management of active substance/biocidal product, and if appropriate, its packaging:

Possibility of reuse or recycling

Reuse or recycling is not foreseen.

Possibility of neutralization of effects

Please refer to 'Emergency measures to protect environment in case of accident' above.

Conditions for controller discharge including leachate qualities on disposal

No specific instruction available.

Conditions for controller incineration

No specific instruction available.

Instructions for safe disposal of the biocidal product and its packaging for different groups of users (relevant for biocidal products only)

Waste treatment methods

Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste. Consult the appropriate local waste disposal expert about waste disposal.

Product/Packaging disposal

Waste treatment options

Appropriate disposal/Product:

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Appropriate disposal/Package:

Handle all contaminated materials, packaging, waste water (e.g. from cleaning the brush) and spillage in the same way as the product itself.

Procedures, if any, for cleaning application equipment (relevant for biocidal products only)

Not available.

2.2.10 Assessment of a combination of biocidal products

The assessment of a combination of biocidal products is not required as the product Koralan GL 220 Biocidal Product Family is not intended to be used in combination with other products.

2.2.11 Comparative assessment

Not relevant, the active substance is not candidate for substitution.

3 ANNEXES

3.1 List of studies for the biocidal product family

The list of studies for the biocidal product is provided in the excel file embedded below:



List of
studies_Koralan GL 2:

Output tables from exposure assessment tools

Human Health Risk Assessment

Appendix 1

Scenario 1.2.1. Application – Automated spraying by industrials

Application - Automated spraying by industrials (water-based)		
Biocides Human Health Exposure Methodology (version 1, October 2015) – PT8		
"Professional automated dipping/immersion of wood articles"		
Handling model 1 water-based (User Guidance, 2002) - HEEG opinions 8 and 18 - 2009/2013		
0.96% IPBC		
		Tier 2
Product	Units	
Active substance	% w/w	0.96
Body weight	kg	60
Dermal penetration rate	%	50
Potential dermal exposure		
Actual hand exposure inside gloves		
Indicative value inside gloves	mg/cycle	1080
Cycles		4
Actual hand deposit	mg	4320
Potential body exposure		
Indicative value	mg/cycle	8570
Cycles		4
Potential dermal deposit	mg	34280
Clothing penetration	%	10
Actual dermal deposit	mg	3428
Total dermal exposure		
Total dermal deposit [a.s.]	mg	74.38
Factor for reduction of the dermal exposure*		4
Total dermal deposit [a.s.]	mg	18.595
Penetration through skin [a.s.]	mg	9.30
Systemic exposure via dermal route		
	mg/kg bw/day	0.155
AEL _{long-term}	mg/kg bw/day	0.2
% AEL _{long-term}	%	77.48
Exposure by inhalation		
Indicative value	mg/m ³	1.9
Duration	min	240
Inhalation rate	m ³ /min	0.021
Inhaled volume	m ³	5.04
Inhaled product	mg	9.576
Inhaled a.s.	mg	0.09193
Inhaled a.s.	mg/m ³	0.01824
Systemic exposure via inhalation route		
	mg/kg bw/day	1.53E-03
AEL _{long-term}	mg/kg bw/day	0.2
% AEL _{long-term}	%	0.766
Active substance, inhaled per m³	mg/m³	0.01824
Total systemic exposure		
	mg/kg bw/day	0.1565
AEL _{long-term}	mg/kg bw/day	0.2
% AEL _{long-term}	%	78.26

*According to the HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4.

Appendix 2

Scenario 1.2.2. Application – Automated dipping by industrials

Application - Automated dipping by industrials (water-based)		
Biocides Human Health Exposure Methodology (version 1, October 2015) – PT8		
“Professional automated dipping/immersion of wood articles”		
Handling model 1 water-based (User Guidance, 2002) - HEEG opinions 8 and 18 - 2009/2013		
0.96% IPBC		
		Tier 2
Product	Units	
Active substance	% w/w	0.96
Body weight	kg	60
Dermal penetration rate	%	50
Potential dermal exposure		
Actual hand exposure inside gloves		
Indicative value inside gloves	mg/cycle	1080
Cycles		4
Actual hand deposit	mg	4320
Potential body exposure		
Indicative value	mg/cycle	8570
Cycles		4
Potential dermal deposit	mg	34280
Clothing penetration	%	10
Actual dermal deposit	mg	3428
Total dermal exposure		
Total dermal deposit [a.s.]	mg	74.381
Factor for reduction of the dermal exposure*		4
Total dermal exposure [a.s.]	mg	18.595
Penetration through skin[a.s.]	mg	9.298
Systemic exposure via dermal route		
	mg/kg bw/day	0.155
AEI_{long-term}	mg/kg bw/day	0.2
% AEI_{long-term}	%	77.48
Exposure by inhalation		
Indicative value	mg/m ³	1.9
Duration	min	240
Inhalation rate	m ³ /min	0.021
Inhaled volume	m ³	5.04
Inhaled product	mg	9.576
Inhaled a.s.	mg	0.090972
Inhaled a.s.	mg/m ³	0.01805
Systemic exposure via inhalation route		
	mg/kg bw/day	1.53E-03
AEI_{long-term}	mg/kg bw/day	0.2
% AEI_{long-term}	%	0.766
Active substance, inhaled per m³	mg/m³	1.82E-02
Total systemic exposure		
	mg/kg bw/day	0.1565
AEI_{long-term}	mg/kg bw/day	0.2
% AEI_{long-term}	%	78.26

*According to the HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4.

Appendix 3 Scenario 1.2.3. Application – Manual dipping by industrials and professionals**Application - Manual dipping by industrials**

Biocides Human Health Exposure Methodology (version 1, October 2015) – PT8

“Professional manual dipping of wood articles”

Dipping model 1 (User Guidance, 2002) - HEEG opinion 8 - 2009

This model includes mixing/loading.

0.96% IPBC**Tier 2**

Product	Units	
Active substance	% w/w	0.96
Body weight	kg	60
Dermal penetration rate	%	50
Potential dermal exposure		
Actual hand exposure inside gloves		
Indicative value inside gloves	mg/min	25.7
Duration	min	30
Actual hand deposit	mg	771.0
Potential body exposure		
Indicative value	mg/min	178
Duration	min	30
Potential dermal deposit	mg	5340
Clothing penetration	%	10
Actual dermal deposit	mg	534
Total dermal exposure		
Total dermal deposit [a.s.]	mg	12.528
Penetration through skin [a.s.]	mg	6.264
Systemic exposure via dermal route		
	mg/kg bw/day	0.104
AEL_{long-term}	mg/kg bw/day	0.2
% AEL_{long-term}	%	52
Exposure by inhalation		
Indicative value	mg/m ³	1
Duration	min	30
Inhalation rate	m ³ /min	0.030*21
Inhaled volume	m ³	0.63
Inhaled product	mg	0.63
Inhaled a.s.	mg	0.00605
Inhaled a.s.	mg/m ³	0.0095
Systemic exposure via inhalation route		
	mg/kg bw/day	1.01E-04
AEL_{long-term}	mg/kg bw/day	0.2
% AEL_{long-term}	%	0.05
Active substance, inhaled per m³	mg/m³	0.0095
Total systemic exposure		
	mg/kg bw/day	1.041E-01
AEL_{long-term}	mg/kg bw/day	0.2
% AEL_{long-term}	%	52.05

Appendix 4

Scenario 1.2.4. Application -Flow coating (deluging) by industrials

Application - Flow coating by industrials		
Handling model 1 water-based (User Guidance, 2002) - HEEG opinions 8 and 18 - 2009/2013		
0.96% IPBC		
		Tier 2
Product	Units	
Active substance	% w/w	0.96
Body weight	kg	60
Dermal penetration rate	%	50
Potential dermal exposure		
Actual hand exposure inside gloves		
Indicative value inside gloves	mg/cycle	1080.0
Cycles		1
Actual hand deposit	mg	1080.0
Potential body exposure		
Indicative value	mg/cycle	8570
Cycles		1
Potential dermal deposit	mg	8570
Clothing penetration	%	10
Actual dermal deposit	mg	857
Total dermal exposure		
Total dermal deposit [a.s.]	mg	18.59
Penetration through skin [a.s.]	mg	9.298
Systemic exposure via dermal route		0.155
AEL _{long-term}	mg/kg bw/day	0.2
% AEL _{long-term}	%	77.487
Exposure by inhalation		
Indicative value	mg/m ³	1.9
Duration	min	60
Inhalation rate	m ³ /min	0.021
Inhaled volume	m ³	1.26
Inhaled product	mg	2.394
Inhaled a.s.	mg	0.022743
Inhaled a.s.	mg/m ³	0.01805
Systemic exposure via inhalation route		1.53E-03
AEL _{long-term}	mg/kg bw/day	0.2
% AEL _{long-term}	%	0.766
Active substance, inhaled per m ³	mg/m ³	1.82E-02
<hr/>		
Total systemic exposure		0.1565
AEL _{long-term}	mg/kg bw/day	0.2
% AEL _{long-term}	%	78.26

		Tier 1	Tier-2
Application - Brushing/rolling - outdoors (water-based) by professionals			
Biocides Human Health Exposure Methodology (version 1, October 2015) – PT8 “Professional brush treatment”			
(based on Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenschaft, 2006)			
0.96% IPBC			
Product	Units		
Active substance	% w/w	0.96	0.96
Body weight	kg	60	60
Dermal penetration rate	%	50	50
Potential dermal exposure			
Potential hand exposure			
Indicative value**	mg/m ²	0.5417	0.5417
Duration	min	240	240
Application area*	m ²	31.6	31.6
Potential hand deposit	mg	17.1	17.1
Penetration through gloves	%	100	10
Actual hand deposit	mg	17.1	1.71
Potential body exposure			
Indicative value	mg/m ²	0.2382	0.2382
Duration	min	240	240
Application area*	m ²	31.6	31.6
Potential dermal deposit	mg	7.53	7.53
Clothing penetration	%	100	100
Actual dermal deposit	mg	7.53	7.53
Total dermal exposure			
Total dermal deposit [a.s.]	mg	23.41	9.25
Penetration through skin [a.s.]	mg	11.70	4.62
Systemic exposure via dermal route	mg/kg bw/day	1.95E-01	7.7E-02
AE_{long-term}	mg/kg bw/day	0.2	0.2
% AE_{long-term}	%	97.50	38.50
Exposure by inhalation			
Indicative value**	mg/m ²	0.0016	0.0016
Duration	min	240	240
Application area*	m ²	31.6	31.6
Inhaled a.s.	mg	0.05	0.05
Systemic exposure via inhalation route	mg/kg bw/day	8.01E-04	8.01E-04
AE_{long-term}	mg/kg bw/day	0.2	0.2
% AE_{long-term}	%	0.40	0.40
Total systemic exposure			
AE_{long-term}	mg/kg bw/day	1.958E-01	7.78E-02
% AE_{long-term}	%	97.90	38.90

*According to Biocides Human Health Exposure Methodology (2015), the application area is calculated using the median work rate of 7.6 min/m² (acc. to TNsG 2002 “Consumer painting Model 3” and the exposure duration of 240 min. Calculation: 1/7.6 min/m² * 240 min = 31.6 m²)

**Note: The indicative values refer to product containing 1% a.s. Furthermore, the indicative values are referring to the exposure when brushing an area of 1 m² (acc. to Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenschaft, 2006).

Appendix 6**Scenario 2.3. Post-application – Washing out of a brush by professionals**

Post-Application - Cleaning of brush (water-based) by professionals	
Washing out of a brush which has been used to apply a paint (HEEG 2010)	
0.96% IPBC	
	Tier 1 Units
Volume of brush	200 mL
Volume of paint remaining on brush after application	25 mL
Density of product (1/8 of 200mL)	1.01 g/mL
Weight of product on brush after application	25.25 g
Concentration of a.s. in the product	0.96 %
A. Weight of a.s. on brush after application	242.40 mg
B. Residues of a.s. on brush after 1st washing (10% of A)	24.24 mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	218.16 mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	12.12 mg
Cloth absorbs 90% of a.s. squeezed out of brush: Weight of a.s. available to contaminate the hand = 10% of C.	1.212 mg
Penetration of a.s. through gloves	100 %
Weight of a.s. on hand	1.212 mg
Dermal absorption of a.s.	50 %
Weight of a.s. entering the body	0.606 mg
D. Weight of a.s. left on the brush after 1st washing and squeezing (B-C)	12.12 mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	1.212 mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	10.908 mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0.606 mg
Cloth absorbs 90% of a.s. squeezed out of brush: Weight of a.s. available to contaminate the hand = 10% of F.	0.0606 mg
Penetration of a.s. through gloves	100 %
Weight of a.s. on hand	0.0606 mg
Dermal absorption of a.s.	50 %
Weight of a.s. entering the body	0.0303 mg
G. Weight of a.s. left on the brush after 2nd washing and squeezing (E-F)	0.606 mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	0.0606 mg
Amount of a.s. removed from the brush into the cleaning fluid (G-H)	0.5454 mg
I. Weight of a.s. squeezed out from brush onto cloth (50% of H)	0.0303 mg
Cloth absorbs 90% of a.s. squeezed out of brush: Weight of a.s. available to contaminate the hand = 10% of I.	0.00303 mg
Penetration of a.s. through gloves	100 %
Weight of a.s. on hand	0.00303 mg
Dermal absorption of a.s.	50 %
Weight of a.s. entering the body	0.001515 mg
Total weight of a.s. entering the body	0.6378 mg
Body weight	60 kg
Total systemic dermal dose of a.s.	0.0106 mg a.s./kg bw/day
Total systemic dermal dose of a.s.	1.06E-02 mg a.s./kg bw/day
AEL_{long-term}	0.2 mg a.s./kg bw/day
% AEL_{long-term}	5.31 %

Appendix 7

Scenario 4.1.1. Secondary exposure - Sawing and sanding treated wood by professionals

Parameter	Calculation		
	IPBC	Unit	
Active substance			
Application rate of product	180	ml/m ²	
Density of product	1.01	g/ml	acc. to MSDS
Concentration of a.s. in product	0.96	%	
Amount of a.s. on treated wood	0.174	mg/cm²	= 1.74 g/m ²
Amount of a.s. in 1 cm outer layer	0.174	mg/cm ³	
Volume of wooden post	4032	cm ³	4 x 4 x 250 [cm]
Untreated inner core of post	992	cm ³	2 x 2 x 248 [cm]
Volume of the outer 1cm layer	3006	cm ³	
Amount of a.s. in the volume of the outer 1 cm layer	0.233	mg/cm ³	
Amount of a.s. on the surface of treated wood (conservative assumption that the entire retained a.s. is present on the surface)	0.233	mg/cm²	
Dermal exposure			
Hand area (palms of both hands) (adult) (acc. to HEEG 2013)	410	cm ²	
Assuming that 20% of hand area will be contaminated (adult).	82	cm ²	
Amount of a.s. on hands (adult)	19.106	mg/d	
Transfer coefficient (acc. to TNsG 2007 for dried fluids on rough sawn wood)	2	%	
Dermal penetration	1.6	%	
Dermal exposure (adult) towards a.s.	6.11E-03	mg/d	
Considering a body weight of 60 kg (adult)	1.02E-04	mg/kg bw/d	
Inhalation exposure			
Generated dust / m ³ of sanded treated wood. U.K. WEL of 5 mg/m ³ wood dust (8-hour time-weighted average)	5 mg/m ³		
Duration (worker)	8 h		
Inhalation rate	1.25 m ³ /h		
Generated dust /8 h	50 mg		
Density of wood (Mota version 5, 2013)	400 mg/cm ³	0.4 g/cm ³	
Volume of the dust (8 h)	0.13 cm ³		
Amount of a.s. on the surface of treated wood (conservative assumption that the entire retained a.s. is present on the surface)	0.233	mg/cm²	
Total amount of a.s. in dust (8 h)	3.03E-02 mg/d		
Considering a body weight of 60 kg (worker)	5.05E-04 mg/kg bw/d		
Combined dermal and inhalation exposure (worker)	6.07E-04 mg/kg bw/d		
AEL_{long-term}	0.20 mg/kg bw/d		
% AEL_{long-term} (worker)	0.30 %		

Appendix 8

Scenario 3.2. Application – Brushing and rolling by non professionals

**Application - Brushing/roller - outdoor (water-based RTU)
by non-professionals**Biocides Human Health Exposure Methodology (version 1, October 2015) –
TNsG 2002 “Consumer painting model 3” (equivalent to TNsG 2007 “2.
Brushing sheds and fences, outdoor”)

0.96% IPBC

Tier 1		
Product	Units	Tier 1
Active substance	% w/w	0.96
Body weight	kg	60
Dermal penetration rate	%	50
Potential dermal exposure		
Potential hand exposure		
Indicative value	mg/min	5.91
Duration	min	150
Potential hand deposit	mg	887
Potential body exposure		
Indicative value	mg/min	16.9
Duration	min	150
Potential dermal deposit	mg	2535
Clothing penetration	%	100
Actual dermal deposit	mg	2535
Total dermal exposure		
Total dermal deposit [a.s.]	mg	32.504
Penetration through skin [a.s.]	mg	16.425
Systemic exposure via dermal route		
	mg/kg bw/day	2.74E-01
AEL_{short-term}	mg/kg bw/day	0.35
% AEL_{short-term}	%	78.21
Exposure by inhalation		
Indicative value	mg/m ³	1.63
Duration	min	150
Inhalation rate	m ³ /min	0.021
Inhaled volume	m ³	3.15
Inhaled product	mg	5.1345
Inhaled a.s.	mg	0.0492
Inhaled a.s.	mg/m ³	0.01565
Systemic exposure via inhalation route		
	mg/kg bw/day	2.60E-04
AEL_{short-term}	mg/kg bw/day	0.35
% AEL_{short-term}	%	0.07
Active substance, inhaled per m³	mg/m³	1.55E-02
Total systemic exposure		
	mg/kg bw/day	2.742E-01
AEL_{short-term}	mg/kg bw/day	0.35
% AEL_{short-term}	%	78.28

Appendix 9**Scenario 3.3. Post-application – Washing out of a brush by non-professionals**

Post-Application - Cleaning of brush (water-based) by professionals		
Washing out of a brush which has been used to apply a paint (HEEG 2010)		
0.96% IPBC		
	Tier 1	Units
Volume of brush	200	mL
Volume of paint remaining on brush after application	25	mL
Density of product (1/8 of 200mL)	1.01	g/mL
Weight of product on brush after application	25.25	g
Concentration of a.s. in the product	0.96	%
A. Weight of a.s. on brush after application	242.40	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	24.24	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	218.16	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	12.12	mg
Cloth absorbs 90% of a.s. squeezed out of brush: Weight of a.s. available to contaminate the hand = 10% of C.	1.212	mg
Penetration of a.s. through gloves	100	%
Weight of a.s. on hand	1.212	mg
Dermal absorption of a.s.	50	%
Weight of a.s. entering the body	0.606	mg
D. Weight of a.s. left on the brush after 1st washing and squeezing (B-C)	12.12	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	1.212	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	10.908	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0.606	mg
Cloth absorbs 90% of a.s. squeezed out of brush: Weight of a.s. available to contaminate the hand = 10% of F.	0.0606	mg
Penetration of a.s. through gloves	100	%
Weight of a.s. on hand	0.0606	mg
Dermal absorption of a.s.	50	%
Weight of a.s. entering the body	0.0303	mg
G. Weight of a.s. left on the brush after 2nd washing and squeezing (E-F)	0.606	mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	0.0606	mg
Amount of a.s. removed from the brush into the cleaning fluid (G-H)	0.5454	mg
I. Weight of a.s. squeezed out from brush onto cloth (50% of H)	0.0303	mg
Cloth absorbs 90% of a.s. squeezed out of brush: Weight of a.s. available to contaminate the hand = 10% of I.	0.00303	mg
Penetration of a.s. through gloves	100	%
Weight of a.s. on hand	0.00303	mg
Dermal absorption of a.s.	50	%
Weight of a.s. entering the body	0.001515	mg
Total weight of a.s. entering the body	0.6378	mg
Body weight	60	kg
Total systemic dermal dose of a.s.	0.0106	mg a.s./kg bw/day
Total systemic dermal dose of a.s.	1.06E-02	mg a.s./kg bw/day
AE_Lshort-term	0.35	mg a.s./kg bw/day
% AE_Lshort-term	3.02	%

Appendix 10

Scenario 4.1.2. Sawing and sanding treated wood by general public

Parameter	Calculation	
	IPBC	Unit
Active substance		
Application rate of product	180,00	ml/m ²
Density of product	1,01	g/ml
Concentration of a.s. in product	0,96	%
Amount of a.s. on treated wood	0,173	mg/cm ²
Amount of a.s. on the surface of treated wood (conservative assumption that the entire retained a.s. is present on the surface)	0.233	mg/cm ²
Dermal exposure		
Hand area (palms of both hands) (adult) acc. to HEEG 2013)	410,00	cm ²
Assuming that 20% of hand area will be contaminated (adult).	82,00	cm ²
Amount of a.s. on hands (adult)	19.11	mg/d
Transfer coefficient (acc. to TNsG 2007 for dried fluids on rough sawn wood)	2,00	%
Dermal penetration	1,60	%
Dermal exposure (adult) towards a.s.	6.11E-03	mg/d
Considering a body weight of 60 kg (adult)	1.02E-04	mg/kg bw/d
Inhalation exposure		
Generated dust/m ³ of sanded treated wood. U.K. WEL of 5 mg/m ³ wood dust (8-hour weighted average)	5,00	mg/m ³
Duration (general public adult)	1	h
Inhalation rate	1,25	m ³ /h
Generated dust/h	6,25	mg
Density of wood (Mota version 6 2013)	400,00	mg/cm ³
Volume of the dust (1h)	0,02	cm ³
Amount of a.s. on the surface of treated wood (conservative assumption that the entire retained a.s. is present on the surface)	0.233	mg/cm ²
Total amount of a.s. in dust (1h)	4.66E-03	mg/d
Considering a body weight of 60 kg (general public adult)	7.77E-05	mg/kg/bw
Combined dermal and inhalation exposure (general public adult)	1.80E-04	mg/kg/bw
AEL _{short-term}	0,35	mg/kg bw/d
% AEL _{short-term} (general public adult)	0.05	%

Appendix 11

Scenario 4.2. Chewing wood off-cut

Parameter	Calculation	
	IPBC	Unit
Application rate of product	180,00	ml/m ²
Density of product	1,01	g/ml
Concentration of a.s. in product	0,96	%
Amount of a.s. on treated wood	0.233	mg/cm ²
Amount of a.s. in 1 cm outer layer	0.233	mg/cm ³
Volume of the piece of wood	16,000	cm ³
Amount of a.s. in 1cm outer layer of the piece of wood	3.73	mg
Oral uptake by extraction of a.s. from the wood (acc. to User Guidance (2002))	10	%
Oral exposure towards a.s. considering a body weight of 8kg (infant) (acc. to HEEG opinion 17 (2013))	4.66E-02	mg/kg bw/d
AEL _{short-term}	0,35	mg/kg bw/d
% AEL _{short-term} (general public infant)	13.31	%

Appendix 12

Scenario 4.3. Playing on playground structure outdoors and mouthing

Parameter	Calculation	
	IPBC	Unit
Active substance		
Application rate of product	180,00	ml/m ²
Density of product	1,01	g/ml
Concentration of a.s. in product	0.96	%
Amount of a.s. on treated wood	0.23	mg/cm ²
Amount of a.s. on the surface of treated wood (conservative assumption that the entire retained a.s. is present on the surface)	0.23	mg/cm ²
Dermal exposure		
Area of hands - both palms and backs of hands (infant) (acc. to HEEG opinion 17 (2013))	196,80	cm ²
Area of hands - both palms and backs of hands (Child) (acc. to HEEG opinion 17 (2013))	427,80	cm ²
Assuming that 20% of hand area will be contaminated (infant).	39,36	cm ²
Assuming that 20% of hand area will be contaminated (child).	85,56	cm ²
Dislodgeable fraction (acc. to TNsG 2007 for dried objects on wood)	2,00	%
Amount of a.s. on hands (infant)	0.181	mg/d
Amount of a.s. on hands (child)	0.394	mg/d
Dermal penetration	1,60	%
Dermal exposure (infant) towards a.s.	2.89E-03	mg/d
Dermal exposure (child) towards a.s.	6.3E-03	mg/d
Considering a body weight of 8 kg (infant) (acc. to HEEG opinion 17 (2013))	3.62E-04	mg/kg bw/d
Considering a body weight of 23,9 kg (child) (acc. to HEEG opinion 17 (2013))	2.64E-04	mg/kg bw/d
Oral exposure		
Oral uptake after licking of hands (infant/child) (ConsExpo) (50% of the potential dermal exposure, amount of a.s. on hands)	50,00	%
Oral exposure (infant) towards a.s.	9.05E-2	mg
Oral exposure (child) towards a.s.	0.197	mg
Considering a body weight of 8 kg (infant) (acc. to HEEG opinion 17 (2013))	1.13E-02	mg/kg bw/d
Considering a body weight of 23,9 kg (child) (acc. to HEEG opinion 17 (2013))	8.24E-03	mg/kg bw/d
Combined dermal and oral exposure (infant)	1.17E-02	mg/kg bw/d
Combined dermal and oral exposure (child)	8.50E-03	mg/kg bw/d
AEL _{long-term}	0,2	mg/kg bw/d

% AEL _{long-term} (infant)	5.85	%	
% AEL _{long-term} (child)	4.25	%	

Appendix 13

Scenario 4.4. Inhalation of volatilized residues

Secondary exposure: Inhalation of volatilized residues by general public (infant, child, adult)

Parameter	Calculation		
	IPBC	Unit	
Vapour pressure of a.s.	4,5E-03	Pa	
MW of a.s.	281,1	g/mol	
concentration in air (ConsExpo: mean event concentration)	3,10E-04	mg/m ³	ConsExpo - evaporation model: treatment of a door and window frame
IR (inhalation rate) of infant	5,4	m ³ / 24 h	
IR of child	12	m ³ / 24 h	
IR of adult	16	m ³ / 24 h	
Body weight of 8 kg (infant)	2,09E-04	mg/kg bw /d	
Body weight of 23.9 kg (child)	1,56E-04	mg/kg bw /d	
Body weight of 60 kg (adult)	8,27E-05	mg/kg bw /d	
AEL_{long-term}	0,20	mg/kg bw/d	
% AEL_{long-term} (infant)	0,10	%	
% AEL_{long-term} (child)	0,08	%	
% AEL_{long-term} (adult)	0,04	%	

Environmental Risk Assessment

Appendix 14

Scenario 1: Application - Automated spraying by industrials (calculations for IPBC)

Parameter/variable	Symbol	Value	Unit	Origin
Inputs				
Wood treated per day - small plants	$AREA_{wood-treated}$	2000	$[m^2 \cdot d^{-1}]$	D
Wood treated per day - big plants	$AREA_{wood-treated}$	20000	$[m^2 \cdot d^{-1}]$	D
Application rate of the active substance	Q_{ai}	1.78E-03*	$[kg \cdot m^{-2}]$	S
Fraction released to facility drain	$F_{facilitydrain}$	0.03	[-]	D
Fraction released to air	F_{air}	0.001	[-]	D
Fraction of spray drift deposition	F_{drift}	0.001	[-]	D
STP flow	STP flow	2000	$[m^3 \cdot d^{-1}]$	D
Output				
Local emission rate to air - small plants	$E_{local_{air}}$	7.13E-03	$[kg \cdot d^{-1}]$	O
Local emission rate to air - big plants	$E_{local_{air}}$	7.13E-02	$[kg \cdot d^{-1}]$	O
Local emission rate to facility drain - small plants	$E_{local_{facilitydrain}}$	1.07E-01	$[kg \cdot d^{-1}]$	O
Local emission rate to facility drain - big plants	$E_{local_{facilitydrain}}$	1.07E+00	$[kg \cdot d^{-1}]$	O
Concentration in the influent - small plants	$C_{influent} = PEC_{STP \text{ for IPBC}}$	5.35E-02	$[mg \cdot L^{-1}]$	O
Concentration in the influent - big plants	$C_{influent} = PEC_{STP \text{ for IPBC}}$	5.35E-01	$[mg \cdot L^{-1}]$	O
Model Calculations				
$E_{local_{air}} = Q_{ai} \cdot AREA_{wood-treated} \cdot (F_{air} + F_{drift})$				
$E_{local_{facilitydrain}} = Q_{ai} \cdot AREA_{wood-treated} \cdot F_{facilitydrain}$				
$C_{influent} = E_{local_{facilitydrain}} / STP \text{ flow}$				

* Considering 0.95% of IPBC as the active substance in PT 8 and 0.01% of IPBC being the in-can preservative of some b.p. within Koralan GL 220 Biocidal Product Family.

Appendix 15

Scenario 2: Application - Dipping by industrials (calculations for IPBC)

Parameter/variable	Symbol	Value	Unit	Origin
Inputs				
Volume of wood treated per day	$VOLUME_{wood-treated}$	100	[m ³ ·d ⁻¹]	D
Application rate: quantity of a.i. applied per 1 m ³ of wood area	Q_{ai}	7.13E-02*	[kg·m ⁻³]	S
Fraction released to facility drain	$F_{facilitydrain}$	0.03	[-]	D
Fraction released to air	F_{air}	0.001	[-]	D
STP flow	STP flow	2000	[m ³ ·d ⁻¹]	D
Output				
Local emission rate to air	$E_{local_{air}}$	7.13E-03	[kg·d ⁻¹]	O
Local emission rate to facility drain	$E_{local_{facilitydrain}}$	2.14E-01	[kg·d ⁻¹]	O
Concentration in the influent	$C_{influent} = PEC_{STP}$ for IPBC	1.07E-01	[mg·L ⁻¹]	O
Model Calculations				
$E_{local_{air}} = Q_{ai} \cdot VOLUME_{wood-treated} \cdot F_{air}$ $E_{local_{facilitydrain}} = Q_{ai} \cdot VOLUME_{wood-treated} \cdot F_{facilitydrain}$ $C_{influent} = E_{local_{facilitydrain}} / STP \text{ flow}$				

* Considering 0.95% of IPBC as the active substance in PT 8 and 0.01% of IPBC being the in-can preservative of some b.p. within Koralan GL 220 Biocidal Product Family.

Appendix 16

Scenario 3: Automated spraying – storage of treated wood (calc. for IPBC)

Parameter/variable	Symbol	Value	Unit	Origin
Inputs				
Effective surface area	$AREA_{wood-expo}$	11	$[m^2 \cdot m^{-2}]$	D
Surface area of the storage place	$AREA_{storage}$	79	$[m^2]$	D
Small plants		790		
Large plants				
Duration of storage of treated wood prior to shipment	$TIME_{storage}$	3	[d]	D
Duration of the initial assessment period	$TIME_1$	30	[d]	D
Duration of the longer assessment period	$TIME_2$	5475	d]	D
Average daily FLUX	$FLUX_{storage}$	9.16E-07	$[kg \cdot m^{-2} \cdot d^{-1}]$	S
Volume of treated wood stucked	$VOLUME_{woodstacked}$	2	$[m^3 \cdot m^{-2}]$	D
Bulk den sity soil	RHO_{soil}	1700	$[kg \cdot m^{-3}]$	D
Depth soil	$DEPTH_{soil}$	0.5	[m]	D
Fractio of rainwater running off the storage site	Frunoff	0.5	[-]	D
Volume of wet soil	Vsoil	39.5	$[m^3]$	D
Small plant		395		
Large plant				
Flow rate of surface water (creek/river)	$FLOW_{surfacewater}$	0.3	$[m^3 \cdot d^{-1}]$	D
Output small plant Tier 1 (without degradation)				
Cumulative quantity of a substance, leached due to rainfall from stored treated wood, over the initial assessment period	$Q_{leachstorage, time1}$	2.39E-02	kg	O
Cumulative quantity of a substance, leached due to rainfall from stored treated wood, over a longer assessment period	$Q_{leachstorage, time2}$	4.36E+00	kg	O
Local concentration in soil at the end of the initial assessment period	$C_{localsoil, time1}$	1.78E-01	$[mg \cdot kg_{wwt}^{-1}]$	O
Local concentration in soil at the end of the longer assessment period	$C_{localsoil, time2}$	3.25E+00	$[mg \cdot kg_{wwt}^{-1}]$	O
Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over the initial assessment period	$E_{localsurfacewater, time1}$	3.98E-04	$[kg \cdot d^{-1}]$	O

Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over a longer assessment period	$E_{local,surfacewater,time\ 2}$	3.98E-04	[kg·d ⁻¹]	0
Local surface water concentration at the end of the initial assessment period	$C_{local,surfacewater,time1}$	1.54E-05	[mg·L⁻¹]	0
Local surface water concentration at the end of the longer assessment period	$C_{local,surfacewater,time2}$	1.54E-05	[mg·L⁻¹]	0
Output big plant Tier 1 (without degradation)				
Cumulative quantity of a substance, leached due to rainfall from stored treated wood, over the initial assessment period	$Q_{leachstorageTime1}$	2.39E-01	kg	0
Cumulative quantity of a substance, leached due to rainfall from stored treated wood, over a longer assessment period	$Q_{leachstorageTime2}$	4.36E+01	kg	0
Local concentration in soil at the end of the initial assessment period	$C_{local,soil,time1}$	1.78E-01	[mg·kg _{wwt} ⁻¹]	0
Local concentration in soil at the end of the longer assessment period	$C_{local,soil,time2}$	3.25E+01	[mg·kg _{wwt} ⁻¹]	0
Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over the initial assessment period	$E_{local,surfacewater,TIME1}$	3.98E-03	[kg·d ⁻¹]	0
Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over a longer assessment period	$E_{local,surfacewater,TIME2}$	3.98E-03	[kg·d ⁻¹]	0
Local surface water concentration at the end of the initial assessment period	$C_{local,surfacewater,time1}$	1.54E-04	[mg·L⁻¹]	0
Local surface water concentration at the end of the longer assessment period	$C_{local,surfacewater,time2}$	1.54E-04	[mg·L⁻¹]	0
Model Calculations – Tier 1 without degradation				
$Q_{leachstorage, time, x} = FLUX_{storage} \cdot AREA_{wood-expo} \cdot AREA_{storage} \cdot TIME_x$ $C_{local,soil,time, x} = Q_{leachstorage, time, x} \cdot (1 - Frunoff) / (V_{soil} \cdot RHO_{soil})$ $E_{local,surfacewater,time, x} = Q_{leachstorage, time, x} \cdot Frunoff / TIME_x$ $C_{local,surfacewater,time, x} = E_{local,surfacewater,time, x} / FLOW_{surfacewater}$				
Additional Inputs for Tier 2 for soil				

First order rate constant for removal from soil	k	3.539	[d ⁻¹]	S
Output small plant Tier 2 (with degradation for soil)				
Concentration in soil after the initial assessment period	$C_{local\,soil,time1}$	1.67E-03	[mg·kg _{wwt} ⁻¹]	O
Local concentration in soil at the end of the longer assessment period	$C_{local\,soil,time2}$	1.67E-03	[mg·kg _{wwt} ⁻¹]	O
Output big plant Tier 2 (with degradation for soil)				
Concentration in soil after the initial assessment period	$C_{local\,soil,time1}$	1.67E-03	[mg·kg _{wwt} ⁻¹]	O
Local concentration in soil at the end of the longer assessment period	$C_{local\,soil,time2}$	1.67E-03	[mg·kg _{wwt} ⁻¹]	O
Model Calculations – Tier 2 with degradation for soil				
$E_{local\,soil} = FLUX_{storage} \cdot AREA_{wood-expo} \cdot AREA_{storage} \cdot (1 - Frunoff)$ $C_{local\,soil\,Time,x} = E_{local\,soil} / (V_{soil} \cdot RHO_{soil} \cdot k) - [E_{local\,soil} / (V_{soil} \cdot RHO_{soil} \cdot k)] \cdot e^{-time,x \cdot k}$				

Appendix 17
Scenario 4: Dipping – storage of treated wood (calc. for IPBC)

Parameter/variable	Symbol	Value	Unit	Origin
Inputs				
Effective surface area	$AREA_{wood-expo}$	11	[m ² ·m ⁻²]	D
Surface area of the storage place	$AREA_{storage}$	700	[m ²]	D
Duration of storage of treated wood prior to shipment	$TIME_{storage}$	14	[d]	D
Duration of the initial assessment period	$TIME_1$	30	[d]	D
Duration of the longer assessment period	$TIME_2$	5475	[d]	D
Average daily FLUX	$FLUX_{storage}$	9.16E-07	[kg·m ⁻² ·d ⁻¹]	S
Bulk density of wet soil	RHO_{soil}	1700	[kg·m ⁻³]	D
Depth soil	$DEPTH_{soil}$	0.5	[m]	D
Fraction of rainwater running off the storage site	Frunoff	0.5	[-]	D
Volume of wet soil	Vsoil	350	[m ³]	D
Flow rate of surface water (creek/river)	$FLOW_{surfacewater}$	0.3	[m ³ ·d ⁻¹]	D
Output				
Cumulative quantity of a substance, leached due to rainfall from stored treated wood, over the initial assessment period	$Q_{leachstorage, time1}$	2.12E-01	kg	O
Cumulative quantity of a substance, leached due to rainfall from stored treated wood, over a longer assessment period	$Q_{leachstorage, time2}$	3.86E+01	kg	O
Local concentration in soil at the end of the initial assessment period	$C_{localsoil, time1}$	1.78E-01	[mg·kg _{wwt} ⁻¹]	O
Local concentration in soil at the end of the longer assessment period	$C_{localsoil, time2}$	3.25E+01	[mg·kg _{wwt} ⁻¹]	O
Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over the initial assessment period	$E_{localsurfacewater, TIME1}$	3.53E-03	[kg·d ⁻¹]	O
Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over a longer assessment period	$E_{localsurfacewater, TIME2}$	3.53E-03	[kg·d ⁻¹]	O

Local surface water concentration at the end of the initial assessment period	$Clocal_{surfacewater, time1}$	1.36E-04	[mg·L ⁻¹]	O
Local surface water concentration at the end of the longer assessment period	$Clocal_{surfacewater, time2}$	1.36E-04	[mg·L ⁻¹]	O
Model Calculations – Tier 1 without degradation				
$Q_{leachstorage, time, x} = FLUX_{storage} \cdot AREA_{wood-expo} \cdot AREA_{storage} \cdot TIME_x$ $Clocal_{soil, time, x} = Q_{leachstorage, time, x} \cdot (1 - Frunoff) / (V_{soil} \cdot RHO_{soil})$ $Elocal_{surfacewater, time, x} = Q_{leachstorage, time, x} \cdot Frunoff \cdot TIME_x$ $Clocal_{surfacewater, time, x} = Elocal_{surfacewater, time, x} / FLOW_{surfacewater}$				
Additional Inputs for Tier 2 for soil				
First order rate constant for removal from soil	k	3.539	[d ⁻¹]	S
Output small plant Tier 2 (with degradation for soil)				
Concentration in soil after the initial assessment period	$Clocal_{soil, time1}$	1.67E-03	[mg·kg _{wwt} ⁻¹]	O
Local concentration in soil at the end of the longer assessment period	$Clocal_{soil, time2}$	1.67E-03	[mg·kg _{wwt} ⁻¹]	O
Output big plant Tier 2 (with degradation for soil)				
Concentration in soil after the initial assessment period	$Clocal_{soil, time1}$	1.67E-03	[mg·kg _{wwt} ⁻¹]	O
Local concentration in soil at the end of the longer assessment period	$Clocal_{soil, time2}$	1.67E-03	[mg·kg _{wwt} ⁻¹]	O
Model Calculations – Tier 2 with degradation for soil				
$Elocal_{soil} = FLUX_{storage} \cdot AREA_{wood-expo} \cdot AREA_{storage} \cdot (1 - Frunoff)$ $Clocal_{soil, Time, x} = Elocal_{soil} / (V_{soil} \cdot RHO_{soil} \cdot k) - [Elocal_{soil} / (V_{soil} \cdot RHO_{soil} \cdot k)] \cdot e^{-time, x \cdot k}$				

Appendix 18**Scenario 5: House scenario****Brushing/rolling by professionals/non-professionals – *in-situ* application**

Parameter/variable	Symbol	Value	Unit	Origin
Input				
Treated wood area	AREA _{house}	125	[m ²]	D
Application rate of the product	Q _{applic,product}	0.18	[L·m ⁻²]	S
Content of a substance in product	f _{ai}	0.0096*	[-]	S
Density of product	RHO _{product}	1032	[kg·m ⁻³]	S
Fraction of product lost to soil during application	F _{soil,brush}		[-]	D
- Professionals		0.03		
- Amateurs		0.05		
(wet) soil volume	V _{soil}	13	[m ³]	D
Bulk density of wet soil	RHO _{soil}	1700	[kg _{wwt} ·m ⁻³]	D
Output for professionals				
Emission of substance to soil during the day of application	E _{soil,brush}	6.69E-03	[kg]	O
Concentration in local soil at the end of the day of application	C _{local,soil,brush}	3.03E-01	[mg·kg _{wwt} ⁻¹]	O
Output for amateurs				
Emission of substance to soil during the day of application	E _{soil,brush}	1.11E-02	[kg]	O
Concentration in local soil at the end of the day of application	C _{local,soil,brush}	5.04E-01	[mg·kg _{wwt} ⁻¹]	O
Model Calculations				
$E_{soil,brush} = AREA_{house} \cdot Q_{applic,product} \cdot f_{ai} \cdot RHO_{product} \cdot F_{soil,brush} \cdot 10^{-3}$ $C_{local,soil,brush} = E_{soil,brush} / (V_{soil} \cdot RHO_{soil})$				

* Considering 0.95% of IPBC as the active substance in PT 8 and 0.01% of IPBC being the in-can preservative of some b.p. within Koralan GL 220 Biocidal Product Family.

Appendix 19

Scenario 6: Bridge over pond scenario - brushing/rolling by professionals/ non-professionals – *in-situ* application (calculations for IPBC)

Parameter/variable	Symbol	Value	Unit	Origin
Input				
Treated wood area	AREA _{bridge}	10	[m ²]	D
Application rate of the product	Q _{applic,product}	0.18	[L·m ⁻²]	S
Content of a substance in product	f _{ai}	0.0096*	[-]	S
Density of product	RHO _{product}	1032	[kg·m ⁻³]	S
Fraction of product lost to water during application	F _{water,brush}	0.03	[-]	D
- Professionals				
- Amateurs		0.05		
Water volume under bridge	V _{water}	1000	[m ³]	D
Output for professionals				
Emission of substance to water during the day of application	E _{water,brush}	5.35-04	[kg·d ⁻¹]	O
Concentration in local water at the end of the day of application	C _{local} _{water,brush}	5.35-04	[mg·L ⁻¹]	O
Output for amateurs				
Emission of substance to water during the day of application	E _{water,brush}	8.92E-04	[kg·d ⁻¹]	O
Concentration in local water at the end of the day of application	C _{local} _{water,brush}	8.92E-04	[mg·L ⁻¹]	O
Model Calculations				
$E_{\text{water,brush}} = \text{AREA}_{\text{bridge}} \cdot Q_{\text{applic,product}} \cdot f_{\text{ai}} \cdot \text{RHO}_{\text{product}} \cdot F_{\text{water,brush}} \cdot 10^{-3}$ $C_{\text{local,water,brush}} = E_{\text{water,brush}}/V_{\text{water}}$				

* Considering 0.95% of IPBC as the active substance in PT 8 and 0.01% of IPBC being the in-can preservative of some b.p. within Koralan GL 220 Biocidal Product Family.

Appendix 20

Scenario 7: Service life House

Scenario 7a: House service life 30 days and 5 years

Parameter/variable	Symbol	Value	Unit	Origin
Input				
Leachable area of a façade proposed in the relevant scenarios	AREA _{house}	125	[m ²]	D
Duration of the initial assessment period	time1	30	[d]	D
Duration of the long-term assessment period	time2	1825	[d]	D
Cumulative quantity of substance leached out of 1 m ² of treated wood over the initial assessment period	Q* _{leach,time1}	2.75E-05	[kg·m ⁻²]	S
Cumulative quantity of substance leached out of 1 m ² of treated wood over a longer assessment period	Q* _{leach,time2}	8.17E-05	[kg·m ⁻²]	S
Soil volume adjacent to surface treated	V _{soil}	13	[m ³]	D
Bulk density of wet soil	RHO _{soil}	1700	[kg _{wwt} ·m ⁻³]	D
First order rate constant for removal from soil	k	3.54	[d ⁻¹]	S
Output without degradation				
Concentration in local soil after the initial assessment period	C _{local, soil, time 1}	1.55E-01	[mg/kg _{wwt}]	O
Concentration in local soil after a longer duration	C _{local, soil, time 2}	4.62E-01	[mg/kg _{wwt}]	O
Output with degradation				
Average daily emission of active ingredient due to leaching over the initial assessment period	E _{soil, leach,time 1}	1.15E-04	[kg/d]	O
Average daily emission of active ingredient due to leaching over a longer duration	E _{soil, leach time 2}	5.59E-06	[kg/d]	O
Concentration in local soil after the initial assessment period	C_{local, soil, time 1}	1.46E-03	[mg/kg_{wwt}]	O
Concentration in local soil over a longer duration	C_{local, soil, time 2}	7.15E-05	[mg/kg_{wwt}]	O
Model Calculations				
without degradation				
$C_{\text{local soil, Time, x}} = (AREA_{\text{wood}} \cdot Q^*_{\text{leach,time}_x}) / V_{\text{soil}} \cdot RHO_{\text{soil}}$				

with degradation

$$E_{soil,leach,Time\ x} = AREA_{wood} \cdot Q^*_{leach,time\ x} / Time\ x$$

$$C_{local\ soil\ Time,\ x} = E_{soil,leach,Time\ x} / (V_{soil} \cdot RHO_{soil} \cdot k) - E_{soil,leach,Time\ x} / (V_{soil} \cdot RHO_{soil} \cdot k) \cdot e^{-time,\ x \cdot k}$$

Scenario 7b: House service life 30 days and 15 years

Parameter/variable	Symbol	Value	Unit	Origin
Input				
Leachable area of a façade proposed in the relevant scenarios	AREA _{house}	125	[m ²]	D
Duration of the initial assessment period	time1	30	[d]	D
Duration of the long-term assessment period	time2	5475	[d]	D
Cumulative quantity of substance leached out of 1 m ² of treated wood over the initial assessment period	Q* _{leach,time1}	2.75E-05	[kg.m ⁻²]	S
Cumulative quantity of substance leached out of 1 m ² of treated wood over a longer assessment period	Q* _{leach,time2}	9.61E-05	[kg.m ⁻²]	S
Soil volume adjacent to surface treated	V _{soil}	13	[m ³]	D
Bulk density of wet soil	RHO _{soil}	1700	[kg _{wwt} .m ⁻³]	D
Output without degradation				
Concentration in local soil after the initial assessment period	C _{local, soil, time 1}	1.55E-01	[mg/kg _{wwt}]	O
Concentration in local soil after a longer duration	C _{local, soil, time 2}	5.44E-01	[mg/kg _{wwt}]	O
Output with degradation				
Average daily emission of active ingredient due to leaching over the initial assessment period	E _{soil, leach, time 1}	1.15E-04	[kg/d]	O
Average daily emission of active ingredient due to leaching over a longer duration	E _{soil, leach time 2}	2.20E-06	[kg/d]	O
Concentration in local soil after the initial assessment period	C_{local, soil, time 1}	1.46E-03	[mg/kg_{wwt}]	O
Concentration in local soil over a longer duration	C_{local, soil, time 2}	2.81E-05	[mg/kg_{wwt}]	O
Model Calculations				
without degradation				
C _{local soil, Time, x} = (AREA _{wood} · Q* _{leach,time,x})/V _{soil} · RHO _{soil}				
with degradation				
E _{soil,leach,Time x} = AREA _{wood} · Q* _{leach,time,x} / Time x				
C _{local soil Time,x} = E _{soil,leach,Time x} / (V _{soil} · RHO _{soil} · k) - E _{soil,leach,Time x} / (V _{soil} · RHO _{soil} · k) · e ^{-time,x · k}				

Appendix 21**Scenario 8: Bridge over pond - service life****Scenario 8a: Bridge over pond service life 30 days and 5 years**

Parameter/variable	Symbol	Value	Unit	Origin
Input				
Leachable wood area	AREA _{bridge}	10	[m ²]	D
Duration of the initial assessment period	time1	30	[d]	D
Duration of the long-term assessment period	time2	1825	[d]	D
Cumulative quantity of substance leached out of 1 m ² of treated wood over the initial assessment period	Q* _{leach,time1}	2.75E-05	[kg·m ⁻²]	S
Cumulative quantity of substance leached out of 1 m ² of treated wood over a longer assessment period	Q* _{leach,time2}	8.17E-05	[kg·m ⁻²]	S
Water volume under bridge	V _{water}	1000	[m ³]	D
First order rate constant for removal from water	k	5.37	[d ⁻¹]	S
Output without degradation				
Concentration in local water after the initial assessment period	C _{local,water,leach,time1}	2.75E-04	[mg·L ⁻¹]	O
Concentration in local water after a longer duration period	C _{local,water,leach,time2}	8.17E-04	[mg·L ⁻¹]	O
Output with degradation				
Average daily emission of active ingredient due to leaching over the initial assessment period	E _{water,leach,time1}	9.16E-06	[kg/d]	O
Average daily emission of active ingredient due to leaching over a longer duration	E _{water,leach,time2}	4.50E-07	[kg/d]	O
Concentration in local water after the initial assessment period	C _{local,water,leach,time1}	1.70E-06	[mg·L ⁻¹]	O
Concentration in local water over a longer duration	C _{local,water,leach,time2}	8.34E-08	[mg·L ⁻¹]	O
Model Calculations				

without degradation

$$C_{\text{local water, Time, x}} = (AREA_{\text{wood}} \cdot Q^*_{\text{leach, time x}}) / V_{\text{water}}$$

with degradation

$$E_{\text{water, leach, Time x}} = AREA_{\text{wood}} \cdot Q^*_{\text{leach, time x}} / \text{Time x}$$

$$C_{\text{local water Time, x}} = E_{\text{water, leach, Time x}} / (V_{\text{water}} \cdot k) - [1 - ((1 - e^{-\text{time, x} \cdot k}) / (\text{time, x} \cdot k))]$$

Scenario 8b: Bridge over pond service life 30 days and 15 years (with degradation)

Parameter/variable	Symbol	Value	Unit	Origin
Input				
Leachable wood area	AREA _{bridge}	10	[m ²]	D
Duration of the initial assessment period	time1	30	[d]	D
Duration of the long-term assessment period	time2	5475	[d]	D
Cumulative quantity of substance leached out of 1 m ² of treated wood over the initial assessment period	Q* _{leach, time1}	2.75E-05	[kg·m ⁻²]	S
Cumulative quantity of substance leached out of 1 m ² of treated wood over a longer assessment period	Q* _{leach, time2}	9.61E-05	[kg·m ⁻²]	S
Water volume under bridge	V _{water}	1000	[m ³]	D
First order rate constant for removal from water	k	5.37	[d ⁻¹]	S
Output without degradation				
Concentration in local water after the initial assessment period	C _{local water, leach, time1}	2.75E-04	[mg·L ⁻¹]	O
Concentration in local water after a longer duration period	C _{local water, leach, time2}	9.61E-04	[mg·L ⁻¹]	O
Output with degradation				
Average daily emission of active ingredient due to leaching over the initial assessment period	E _{water, leach, time1}	9.16E-06	[kg/d]	O
Average daily emission of active ingredient due to leaching over a longer duration	E _{water, leach, time2}	1.80E-07	[kg/d]	O
Concentration in local water after the initial assessment period	C _{local water, leach, time1}	1.70E-06	[mg·L ⁻¹]	O
Concentration in local water over a longer duration	C _{local water, leach, time2}	3.27E-08	[mg·L ⁻¹]	O
Model Calculations				
without degradation				
C _{local water, Time, x} = (AREA _{wood} · Q* _{leach, time x}) / V _{water}				

with degradation

$$E_{\text{water,leach,Time } x} = \text{AREA}_{\text{wood}} \cdot Q^*_{\text{leach,time } x} / \text{Time } x$$

$$C_{\text{local water Time } x} = E_{\text{water,leach,Time } x} / (V_{\text{water}} \cdot k) - [1 - ((1 - e^{-\text{time},x \cdot k}) / (\text{time},x \cdot k))]$$

Appendix 22**Scenario 9: Noise barrier - service life****Scenario 9a: Noise barrier service life - 30 days and 5 years**

Parameter/variable	Symbol	Value	Unit	Origin
Input				
Leachable wood area	AREA _{noise-barrier}	3000	[m ²]	D
Duration of the initial assessment period	time1	30	[d]	D
Duration of the long-term assessment period	time2	1825	[d]	D
Cumulative quantity of substance leached out of 1 m ² of treated wood over the initial assessment period	Q* _{leach,time1}	2.75E-05	[kg·m ⁻²]	S
Cumulative quantity of substance leached out of 1 m ² of treated wood over a longer assessment period	Q* _{leach,time2}	8.17E-05	[kg·m ⁻²]	S
Soil volume adjacent to surface treated	V _{soil(a)}	250	[m ³]	D
Bulk density of wet soil	RHO _{soil}	1700	[kg _{wwt} ·m ⁻³]	D
Fraction released to soil	F _{soil}	0.3	[-]	D
Fraction released to the STP	F _{STP}	0.7	[-]	D
STP FLOW	STP FLOW	2000	[m ³ ·d]	D
Outputs - emission via STP				
Local daily emission rate to the STP following leaching from treated wood during the initial assessment period	E _{STP,time1}	1.92E-03	[kg·d ⁻¹]	O
Local daily emission rate to the STP following leaching from treated wood during the longer assessment period	E _{STP,time2}	9.40E-05	[kg·d ⁻¹]	O
Concentration in the influent Time 1	C_{influent} = PEC_{STP} for IPBC	9.62E-04	[mg·L⁻¹]	O
Concentration in the influent Time 2	C_{influent} = PEC_{STP} IPBC	4.70E-05	[mg·L⁻¹]	O
Model Calculations for emission via STP				
$E_{\text{STP, Time, } x} = \text{AREA treated} \cdot F_{\text{STP}} \cdot Q^*_{\text{leach,time } x} / \text{TIME } x$ $C_{\text{influent}} = E_{\text{STP, Time, } x} / \text{STP flow}$				
Outputs - emission to soil				
Cumulative quantity of substance, leached over the initial assessment period	Q _{leach,time1}	8.25E-02	[kg]	O
Cumulative quantity of substance, leached over a longer assessment period	Q _{leach,time2}	2.45E-01	[kg]	O

Average daily emission of active ingredient due to leaching over the initial assessment period	Esoil, leach time 1	8.24E-04	[kg·d ⁻¹]	O
Average daily emission of active ingredient due to leaching over a longer duration	Esoil, leach, time 2	4.03E-05	[kg·d ⁻¹]	O
Concentration in local soil after the initial assessment period	Clocal, soil, time 1	5.48E-04	[mg/kg_{wwt}]	O
Concentration in local soil over a longer duration	Clocal, soil, time 2	2.68E-05	[mg/kg_{wwt}]	O
Model Calculations				
$E_{\text{soil,leach,Time } x} = \text{AREA}_{\text{wood}} \cdot Q^*_{\text{leach,time } x} \cdot F_{\text{soil}} / \text{Time } x$ $C_{\text{local soil Time, } x} = E_{\text{soil,leach,Time } x} / (V_{\text{soil}} \cdot \text{RH}_{\text{soil}} \cdot k) - E_{\text{soil,leach,Time } x} / (V_{\text{soil}} \cdot \text{RH}_{\text{soil}} \cdot k) \cdot e^{-\text{time, } x \cdot k}$				

Scenario 9b: Noise barrier service life - 30 days and 15 years

Parameter/variable	Symbol	Value	Unit	Origin
Input				
Leachable wood area	AREA _{noise-barrier}	3000	[m ²]	D
Duration of the initial assessment period	time1	30	[d]	D
Duration of the long-term assessment period	time2	5475	[d]	D
Cumulative quantity of substance leached out of 1 m ² of treated wood over the initial assessment period	Q* _{leach,time1}	2.75E-05	[kg·m ⁻²]	S
Cumulative quantity of substance leached out of 1 m ² of treated wood over a longer assessment period	Q* _{leach,time2}	9.61E-05	[kg·m ⁻²]	S
Soil volume adjacent to surface treated	V _{soil(a)}	250	[m ³]	D
Bulk density of wet soil	RH _{soil}	1700	[kg _{wwt} ·m ⁻³]	D
Fraction released to soil	F _{soil}	0.3	[-]	D
Fraction released to the STP	F _{STP}	0.7	[-]	D
STP FLOW	STP FLOW	2000	[m ³ ·d]	D
Outputs - emission via STP				
Local daily emission rate to the STP following leaching from treated wood during the initial assessment period	E _{STP,time1}	1.92E-03	[kg·d ⁻¹]	O
Local daily emission rate to the STP following leaching from treated wood during the longer assessment period	E _{STP,time2}	3.69E-05	[kg·d ⁻¹]	O
Concentration in the influent Time 1	C_{influent} = PEC_{STP} for IPBC	9.62E-04	[mg·L⁻¹]	O
Concentration in the influent Time 2	C_{influent} = PEC_{STP} IPBC	1.84E-05	[mg·L⁻¹]	O
Model Calculations for emission via STP				
$E_{\text{STP, Time, } x} = \text{AREA}_{\text{treated}} \cdot F_{\text{STP}} \cdot Q^*_{\text{leach,time } x} / \text{TIME } x$ $C_{\text{influent}} = E_{\text{STP, Time, } x} / \text{STP flow}$				

Outputs - emission to soil				
Cumulative quantity of substance, leached over the initial assessment period	$Q_{\text{leach,time1}}$	8.25E-02	[kg]	0
Cumulative quantity of substance, leached over a longer assessment period	$Q_{\text{leach,time2}}$	2.88E-01	[kg]	0
Average daily emission of active ingredient due to leaching over the initial assessment period	Esoil, leach time 1	8.24E-04	[kg·d ⁻¹]	0
Average daily emission of active ingredient due to leaching over a longer duration	Esoil, leach, time 2	1.58E-05	[kg·d ⁻¹]	0
Concentration in local soil after the initial assessment period	$C_{\text{local, soil, time 1}}$	5.48E-04	[mg/kg_{wwt}]	0
Concentration in local soil over a longer duration	$C_{\text{local, soil, time 2}}$	1.05E-05	[mg/kg_{wwt}]	0
Model Calculations				
$E_{\text{soil,leach,Time } x} = \text{AREA}_{\text{wood}} \cdot Q_{\text{leach,time } x}^* \cdot F_{\text{soil}} / \text{Time } x$ $C_{\text{local soil Time, } x} = E_{\text{soil,leach,Time } x} / (V_{\text{soil}} \cdot \text{RH}_{\text{soil}} \cdot k) - E_{\text{soil,leach,Time } x} / (V_{\text{soil}} \cdot \text{RH}_{\text{soil}} \cdot k) \cdot e^{-\text{time, } x \cdot k}$				

3.2 Residue behaviour

Not relevant

3.3 Summaries of the efficacy studies (B.5.10.1-xx)¹⁷

IUCLID file with study summaries is available.

3.4 New information on the active substance

No data available.

3.5 Other - Information on the substance(s) of concern

Please refer to section 2.2.8 and the Confidential Annex.

¹⁷ If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.