1 Appendix 1 – Addendum to PAR

Major change of the product formulation

R4BP3 case no: BC-XH028640-35
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2 Content

2.1 Background

In the present application Remmers GmbH applies for a major change of the biocidal product family (BPF) Holzschutz Crème (last updated 7 December 2015).

The proposed changes refer to the composition of the products. The main difference in the composition of the products of the BPF is the replacement of the solvent Naphtha (petroleum), hydrodesulfurized heavy (CAS No. 64742-82-1) by the solvent "Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (EC-No.: 918-481-9)". Furthermore, for the products under META SPC 2, the content of the active ingredient IPBC was reduced from 0.94% to 0.5%.

The applicant has also applied for additional changes to the formulation of the Holzschutz-Crème BPF. This formulation change includes change of the active substance mixture as well as several changes to non-active co-formulants. These can be seen in the 'Confidential annex to the formulation change of Holzschutz-Creme Biocidal Product Family (former Aidol Holzschutz-Crème)'. The changes to the formulation have been accepted and the product family has been classified accordingly.

The applicant has also applied for two administrative changes, the first being a change of the company name of the biocidal product authorisation holder. This has already been authorised in Denmark by letter of January 17th 2017. The second administrative change applied for is the addition of a manufacturing location for the manufacturer of the active substance IPBC. However, this cannot be granted before a technical equivalence evaluation of the new source has been performed. This will however be done in connection with the upcoming renewal of the active substance IPBC.

The 'Confidential annex to the formulation change of Holzschutz-Creme Biocidal Product Family (former Aidol Holzschutz-Crème)' contains the product family formulation as well as the formulation of each meta SPC and the products within these. The Confidential annex also contains an excel sheet justifying the classification and another sheet comparing the new formulation to the currently authorised one.

2.1.1 Physical/chemical properties and storage stability

There are no fundamental changes regarding the physical properties of the product to be observed according to the information available at the time being. All relevant phys.-/chem. endpoints are supported through new studies with the new product composition (with 0.94% IPBC). The storage stability / the shelf life of the product has been determined in a new study.
An accelerated stability study with the product (0.5% IPBC) has been performed and a read across to the long term stability study is acceptable.
The product shows an acceptable degradation of active substance after 24 months stable, also after substitution of some components as described above. The product has shelf-life of 24 months in coated tin can protected from frost.
The product is regarded as being surface-active.

For the new composition of the products of the Holzschutz-Creme Biocidal Product Family a complete data set on physical, chemical and technical properties of the products is available. A summary of the endpoints, read-across argumentations and justifications is provided in the table below.

Property	Guideline and Method	Product tested	Results	Reference
Physical state at 20 °C and 101.3 kPa Colour at 20 °C and 101.3 kPa Odour at 20 °C and 101.3 kPa	Visual and olfactory inspection	Holzschultz-Crème "new", 0.94% IPBC	Before and after storage at 54 °C for 14 days: creamy, slowly flowing paste. Before and after storage at 54 °C for 14 days:Nut brown (RAL 8011) Before and after storage at 54 °C for 14 days:Typical, strong, as solvent	Affolter, 2016a
	Read-across argumentation to cover all products of the family: The appearance is described for a formulation identical to the teak-coloured products. The given description is that the test item is "a creamy, slowly flowing paste with a nut brown colour and a typical, strong odour with a smell of solvents." As the products of the biocidal product family differ from the test item only in their active substance content (0.5% resp. 1.5% instead of the test item's 0.94%) and the added pigment mixtures, all products of the biocidal product family are pastes with a typical, strong odour with a smell of solvents. The colour of the individual products is a direct and intended consequence of the addition of the pigment mixtures and has no effect on the risk assessments, thus individual description of the colours of the products is not considered necessary.			
Acidity / alkalinity	CIPAC MT 75.3	Holzschultz-Crème "new", 0.94% IPBC	Before storage: pH=5.02 (1% dilution in water) After storage at 54 °C for 14 days: pH=4.51 (1% dilution in water) The acidity / alkalinity was not determined as the pH value is between 4 and 10.	Affolter, 2016a
	CIPAC MT 75.3	Holzschultz-Crème "new", 0.94% IPBC	Before storage: pH=5.02 (1% dilution in water) After storage at 20°C ± 2°C for 24 months: pH=4.37 (1% dilution in water) The acidity / alkalinity was not determined as the pH value is between 4 and 10.	Affolter, 2017
	Read-across argumentation to cover all products of the family: pH is tested with a formulation identical to the teak-coloured products, except that the concentration of the active substance in the tested formulation is 0.94% w/w (nominal), resp. 1.01% w/w (measured). The products of the family have active substance contents of 0.5% and 1.5% (w/w), respectively. According to the Assessment Report (Denmark, September 2013), IPBC is neither an acid nor a base. Thus, the slightly differing active substance content is not considered to have a significant impact on the pH of the biocidal products with IPBC contents of 0.5% and 1.5%, respectively. Furthermore, the products of the family differ in the content and nature of dyes. However, none of those dyes are expected to alter pH significantly. Therefore, the study results for the tested teak-coloured formulation are considered as representative for all products in the biocidal product family.			
Relative density / bulk density	OECD Guideline 109 resp. EU method A.3 (Pycnometer)	Holzschultz-Crème "new", 0.94% IPBC	0.8915 g/cm^3 (20 ± 0.4 °C)	Henke, 2015a
	Read-across argumentation to cover all products of the family: The density is tested with a formulation identical to the teak-coloured products, except that the concentration of the active substance in the tested formulation is 0.94%. The products of the family have active substance contents of 0.5% and 1.5% (w/w), respectively. In addition, the products of the family differ in the content and nature of dyes. None of those variations in the formulations are expected to alter density significantly, so that no significant impact on the risk assessments is resulting. Therefore, the study results for the teak-coloured formulation are considered as representative for all products in the biocidal product family.			
Storage stability test – **accelerated storage**	CIPAC MT 46 (54 °C for 14 days)	Holzschultz-Crème "new", 0.94% IPBC	IPBC content before storage: 1.007% IPBC content after 14 d storage: 0.979% Variation: - 2.8%	Affolter, 2016a

			No significant changes of physicochemical properties were observed	
	Read-across to cover all products of the family: The accelerated storage is tested with a formulation identical to the the teak-coloured products, except that the concentration of the active substance in the tested formulation is 0.94% w/w (nominal), resp. 1.01% w/w (measured). The products of the family, as defined in section 2.3, have active substance contents of 0.5% and 1.5% (w/w), respectively. In addition, the products of the family differ in the content and nature of dyes. None of those variations in the formulations are expected to alter the stability of the formulations during storage significantly. Therefore, the study results for the tested teak-coloured formulation are considered as representative for all products in the biocidal product family.			
Storage stability test – **long term storage at ambient temperature**	Storage of the biocidal product for two years at 20 +/- 2 °C (coated tin plate container)	Holzschultz-Crème "new", 0.94% IPBC	IPBC content: Before storage: 1.007% 6 months storage: 0.899% (**89.3%**) 12 months storage: 0.954% (**94.8%**) 24 months storage: 0.916% (**90.9%**) No significant optical changes in the properties of physical state, colour, and odour were detected when comparing the initial observations to the observations after the storage. The deviations from active substance content following storage compared with prior to storage slightly exceeds 10% af 6 months storage. However as the deviations after 12 and 24 months storage are within the acceptable 10%, DK CA consider that IPBC can be stated as stable after 24 months storage.	Affolter, 2017
Storage stability test – **accelerated storage**	CIPAC MT 46 (54 °C for 14 days)	Holzschultz-Crème 0.5% IPBC, Batch no. 0031107920	IPBC content before storage: 0.512% IPBC content after 14 d storage: 0.497% Variation: - 2.8% No change in physical state, colour, odour and pH after storage. The study is acceptable and is considered sufficient for a read across to the long term study with the 0.94 %IPBC composition.	Affolter, 2019
Storage stability test – **low temperature stability test for liquids**	Not applicable because the biocidal product should be stored frost-protected.			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Not required. The product is packaged in coated metal cans, protecting the product from light			
Effects on content of the active substance and technical characteristics of the biocidal	**Temperature:** The influence of temperature was investigated in the Accelerated Storage Stability Study No significant influence was observed. **Humidity:** The product is packaged in tightly closed metal cans, protecting the product from humidity.			

product – **temperature and humidity**				
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	.	.	No significant optical changes in the physical state and no corrosion on the container material were detected when comparing the observations at day 0 to the observations after 25 months.	Affolter, 2017
Surface tension	OECD Guideline 115 resp. EU Method A.5	Holzschultz-Crème "new", 0.94% IPBC	43.64-45.69 mN/m (20.0 ± 0.5 °C). The product is regarded as being surface-active as the measured surface tension is lower than 60 mN/m (according to EU Method A.5).	Henke,2015b
	Read-across to cover all products of the family: The surface tension is tested with a formulation identical to the teak-coloured products, except that the concentration of the active substance in the tested formulation is 0.94%. The products of the family have active substance contents of 0.5% and 1.5% (w/w), respectively. In addition, the products of the family differ in the content and nature of dyes. None of those variations in the formulations are expected to alter the surface tension of the formulations significantly. Therefore, the study results for the tested teak-coloured formulation are considered as representative for all products in the biocidal product family.			
Viscosity	OECD 114 (Falling Ball Viscosimeter)	Holzschultz-Crème "new", 0.94% IPBC	Dynamic viscosity: >>70000 mPa*s (20 and 40 °C)	Affolter, 2016
	Read-across to cover all products of the family: The viscosity is tested with a formulation identical to the teak-coloured products, except that the concentration of the active substance in the tested formulation is 0.94% w/w (nominal), resp. 1.01% w/w (measured). The products of the family, as defined in section 2.3, have active substance contents of 0.5% and 1.5% (w/w), respectively. In addition, the products of the family differ in the content and nature of dyes. None of those variations in the formulations are expected to alter the viscosity of the formulations significantly. Therefore, the study results for the tested teak-coloured formulation are considered as representative for all products in the biocidal product family.			

Conclusion on the physical, chemical and technical properties of the product
The provided studies for the physical, chemical and technical properties were found acceptable. Products within the BPF are regarded as being surface-active. The accelerated stability study showed an acceptable degradation of the active substances at 54°C for 2 weeks. No unacceptable effects on the physical parameters were observed during storage. A new accelerated stability study has been performed with a formulation with the composition 0.5% IPBC (batch no. 0031107920). No unacceptable effects on the physical parameters were observed during storage, this study is acceptable and sufficient for a read across to the long term stability study with the 0.94 % IPBC composition. The long-term stability study showed an acceptable degradation of the active substances at room temperature (20°C ± 2 °C) for 2 years. The long-term stability study was performed in coated tin containers. A claim for 2 years shelf-life can therefore be accepted.

2.1.2 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Not applicable. Due to known experience the members of the biocidal product family do not present explosive properties. None of the formulants of the biocidal product family is classified as explosive. Moreever, none of the formulants of the biocidal product family bears any chemical groups associated with explosive or self reactive properties.			
Flammable liquids	EU Method A.9	Holzschutz-Creme new (LM93-8), 0.5 % IPBC	68.0°C	Krebs, 2016
	Read-across to cover all products of the family: The flammability is tested with a formulation identical to the composition for the teak-coloured product with an active substance concentration of 0.5% IPBC. The products of the family have active substance contents of 0.5% and 1.5% (w/w), respectively. In addition, the products of the family differ in the content and nature of dyes. According to its harmonized classification, IPBC is not classified for physical-chemical hazards. As the products of the biocidal product family are solvent based formulations, the flammability of the product is mainly influenced by the solvents in the composition. Thus, the slightly higher active substance content of the Holzschutz-Creme Plus products (1.5% IPBC) is not considered to have a significant impact on the flammability, and the study results are considered as representative for all products in the biocidal product family.			
Self-reactive substances and mixtures	Not applicable. Due to known experience the members of the biocidal product family are not self-reactive. None of the formulants of the biocidal product family is classified as self-reactive. None of the formulants of the biocidal product family bears any chemical groups associated with explosive or self reactive properties.			
Pyrophoric liquids	Not applicable. Due to known experience in handling of the products of the biocidal product family, the products of the biocidal product family do not ignite spontaneously on coming into contact with air at normal temperatures.			
Self-heating substances and mixtures	Not applicable. Due to known experience in handling of the products of the biocidal product family, the products of the biocidal product family are not liable to self-heating.			
Substances and mixtures which in contact with water emit flammable gases	Not applicable. Water is part of the composition of the biocidal product family. An emission of flammable gases in contact with water can therefore be excluded.			
Oxidising liquids	Not applicable. None of the formulants of the biocidal product family is classified as oxidising. Where the formulants of the biocidal product family contain oxygen or halogen atoms, these atoms are chemically bonded to carbon or hydrogen only.			
Organic peroxides	Not applicable, no organic peroxides contained in the biocidal product family.			
Corrosive to metals	Not applicable, the members 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)	EU Method A-15	Holzschultz-Crème “new”, 0.94% IPBC	405 °C.	Henke, 2015c

Conclusion on the physical hazards and respective characteristics of the product
All products pertaining to the Holzschutz-Creme Biocidal Product Family are solvent based RTU products. Their physical hazards and respective characteristics can generally be derived based on their formulation type 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 the products of the BPF.

2.1.3 Methods for detection and identification

An analytical method validation for the determination of IPBC in the biocidal products of the Holzschutz-Creme BPF covering the new compositions of the products has been performed. A summary is provided in the table below.

Analytical methods for the determination of the active substance in relevant media (soil, air and water) as well as in human body fluids and tissues and food and feedstuff are covered by the justifications given in the Product Assessment Report of the Holzschutz-Creme Biocidal Product Family (last updated 7 December 2015).

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** *(each conc. Measured twice)*	**Specificity**	**Accuracy** .			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
IPBC	GC-FID	2x2	8 conc., 39.9-349 mg/L r=0.99984	Chromatographic purification prior to analysis. Chromatograms of test item incl. IPBC prior and after purification is present. Recovery for the purification step was determined. Recovery: 80.4% (RSD=2.3%)	78.2% - 82.2 %	80.4 %	2.3%	Lowest calibration standard: 39.9 mg/L	Affolter, 2016b
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 Holzschutz-Creme Biocidal Product Family with respect to specificity, linearity, precision and recovery. Read-across to cover all products of the family: The test material which is analysed in the study "Validation of an Analytical Method using GC/FID for the determination of the stability of the active ingredients Propiconazole and IPBC in different formulations (Induline...; Induline..; HK-Lasur "new", 0.94% IPBC; Holzschutz-Creme "new", 0.94% IPBC)" (Affolter, 2016) differs from the products of the updated Holzschutz-Creme biocidal product family only slightly. There is variability in content and nature of pigments and/or in active substance content which is 0.94% w/w for the test material, while the products of the family have active substance contents of 0.5% and 1.5% (w/w), respectively. However, these differences are not expected to have an impact on the applicability of the validated method and the validation results should be considered as representative for all products in the biocidal product family									

2.1.4 Classification and labelling

Classification and labelling for the biocidal products of the Holzschutz-Creme BPF has changed for the new compositions when compared to the products currently on the marked. The major change to the product family consists of changes to some coformulants, and a reduction of the active substance concentration in Meta SPC 2. Instead of classification with H372; STOT RE 1, the new compositions result in classification of the products in Meta SPC 1 with H373; STOT RE 2 (May cause damage to organs (larynx) through prolonged or repeated exposure (inhalation)), while classification for STOT RE is no longer required for Meta SPC 2. The new compositions also results in the BPF no longer requiring classification with H315; Skin Irrit. 2, and results in Meta SPC 2 longer requiring

classification with H319; Eye Irrit. 2. The classification and labelling of Holzschutz-Creme BPF resulting from the current major change are presented below, as is the previous classification of the Aidol Holzschutz-Crème BPF.

Classification relating to the major change of Holzschutz-Creme BPF

(Details on classification and justifications are provided in the Excel classification document embedded in the 'Confidential annex to the formulation change of Holzschutz-Creme Biocidal Product Family (former Aidol Holzschutz-Crème)'.)

Meta SPC 1 (1.5% IPBC)

Hazard statements

H317: Skin Sens. 1: May cause an allergic skin reaction
H319; Eye Irrit. 2: Causes serious eye irritation
H373; STOT RE 2 May cause damage to organs (larynx) through prolonged or repeated exposure (inhalation)
H412; Aquatic chronic 3: Harmful to aquatic life with long-lasting effects

Pictograms and signal word

GHS07, GHS08
Danger

Supplementary Hazard statements

EUH066: Repeated exposure may cause skin dryness or cracking.

Substances of Concern (SoC)

Please refer to the 'Confidential annex to the formulation change of Holzschutz-Creme Biocidal Product Family (former Aidol Holzschutz-Crème)'. IUPAC names (for the SoCs) will be be stated at the SPC.

P-phrases

P101, P102, P260, P273, P280, P302+P352, P305+P351+P338, P314, P333+P313, P337+P313, P501.

Meta SPC 2 (0.5% IPBC)

Hazard statements

H412 Aquatic chronic 3: Harmful to aquatic life with long-lasting effects

Pictograms and signal word

None

Supplementary Hazard statements

EUH066: Repeated exposure may cause skin dryness or cracking
EUH208: Contains IPBC. May produce an allergic reaction.

Substances of Concern (SoC)

Please refer to the 'Confidential annex to the formulation change of Holzschutz-Creme Biocidal Product Family (former Aidol Holzschutz-Crème)'. IUPAC names (for the SoCs) will be be stated at the SPC.

P-phrases

P273, P501

Previous classification of Aidol Holzschutz-Crème BPF (PAR Annex 9; last updated 07 December 2015)

Meta SPC 1 (1.5% IPBC)

H315 Skin Irrit. 2
H319; Eye Irrit. 2
H317; Skin Sens. 1
H372; STOT RE 1
H412; Aquatic Chronic 3

Meta SPC 2 (0.94% IPBC)

H315; Skin Irrit. 2
H319; Eye Irrit. 2
H372; STOT RE 1
H412; Aquatic Chronic 3
EUH 208 ("contains IPBC...")

2.1.5 Efficacy

The concentration of the active substance IPBC in the products under Meta SPC 2 has been reduced from 0.94% to 0.5%. To document the efficacy against blue stain fungi, one study according to EN 152: 2011 was submitted (MPA Test report no. 32/15/9943/01A dated 27.07.2016) based on Holzschutz-Creme new – Teak that contains 0.50% IPBC, 40.599% solvent D 60 and 1.256% pigments.

Furthermore, the applicant submitted new efficacy studies for products under Meta SPC 1 with the new formulation (replacement of solvent). For the claim against wood destroying fungi two studies according to EN 839: 2014 with aging according to EN 73 and EN 84, separately, was submitted (MPA Test reports no 32/16/9908/07 dated 29.07.2017 and 32/16/9908/08 dated 19.05.2017). The product tested contained 1.5% IPBC, 37.266% solvent D 60 and 1.256% pigments.

In EN 599-1 (2009+A1, 2013), Annex A, A.2.2.e it is stated that the amount of pigment must not exceed the amount in the tested product. For EN 152 tests EN 599 Table 2 demands that a minimum zone of at least 1 mm and an average zone of at least 1.5 mm inside the wood is free of blue stain. The efficacy test demonstrated an average zone of 3.3 mm (minimum of 2.5 mm), thus covering a larger zone than required by the standard. This leaves some margin for reduced penetration of products containing higher pigment contents than the product tested. Therefore we accept the suggested pigment range up to 13.275%.

In the Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C), Section 5.5.8.2.2.3 it is stated that for Use class 2 and higher efficacy against wood destroying fungi must be demonstrated. However, in note 28 it is mentioned that efficacy against blue stain fungi only may be authorised if the exemption from the efficacy against wood destroying fungi can be justified.

The applicant has stated that the products in Meta SPC 2 should only be used on non-load bearing timber, which is not susceptible to wood destroying fungi. This explanation is acceptable to the DK CA and the following sentence is added in the use instructions under Meta SPC 2:

"Only use this product on wooden surfaces of non-load bearing timber which are susceptible to infestation by blue stain fungi but not threatened by wood destroying fungi due to the wood quality or the use conditions."

SPC 1:

The product, Holzschutz-Creme (MST-671-04139) may be approved for use against wood destroying and blue stain fungi with the specified amount for superficial application methods on softwoods in use class 2 and 3 for all products in the BPF with a pigment content of 7.2% or lower and with a content of D 60 between 31.60 and 38.80%.
A top coat is not required.

SPC 2:

The product, HK ff (MST-671-01140) may only be approved for use against blue stain fungi in use class 2 and 3 if justification for exemption from efficacy against wood destroying fungi can be provided as mentioned in note 28 described above.
A top coat is not required.

2.1.6 Impact of change on human health

2.1.6.1 Dermal absorption values

The dermal absorption value of 30% as used in the Product Assessment Report "Aidol Holzschutz-Creme" (Holzschutz-Creme Biocidal Product Family; updated 7 December 2015) is considered to also apply to Holzschutz-Creme Plus (Meta SPC 1). This assumption is based on read-across to dermal absorption studies evaluated in the context of the active substance dossier on IPBC (see IPBC Assessment Report for PT13, DK 2015; latest update of dermal absorption values valid for all PTs). Concentrations of 17%, 2.4% and 0.6% IPBC were tested, resulting in dermal absorption values of 1.6%, 10% and 30%, respectively. Thus, for Holzschutz-Creme Plus containing 1.5% IPBC (Meta SPC 1), the dermal absorption value of 30% (as determined for a product containing 0.6% IPBC) is considered to be appropriate.

Since the lowest tested IPBC concentration was 0.6%, a *pro rata* correction was considered appropriate for Holzschutz-Creme containing 0.5% IPBC (Meta SPC 2) in line with the 'Guidance on Dermal Absorption', section 5.5 (EFSA Scientific Opinion, 2012) to extrapolate the dermal absorption value. Application of *pro rata* correction results in a dermal absorption value of 36% (i.e. 0.6% IPBC / 0.5% IPBC x 30% dermal absorption).

According to the EFSA Guidance, application of *pro rata* correction requires, in principle, a linear relationship between exposure concentration and dermal absorption. The existing dermal absorption data for IPBC (see above) rather show an exponential relationship. However, when comparing the extrapolation from a best-fit (exponential) curve with that of the linear (*pro rata*) approach, both dermal absorption values are of the same magnitude (~ 36%). Thus, it is considered justifable to apply *pro rata* correction to derive a dermal absorption value of 36% for Holzschutz-Creme containing 0.5% IPBC (Meta-SPC 2).

For dried solutions, the dermal absorption value of 1.6%, obtained for the highest tested concentration of 17.1% IPBC, is used.

2.1.6.2 Exposure assessment for Meta SPC 2 due to change in active substance level

The intended uses assessed and approved for Holzschutz-Creme BPF have not changed (see Product Assessment Report (PAR) for Aidol Holzschutz-Creme; last update 07 December 2015).

The new compositions of the biocidal products of the Holzschutz-Creme BPF do not require an update of the human health exposure and risk assessment (HHERA) for Holzschutz-Creme Plus containing 1.5% IPBC (Meta SPC 2) as assessed in the PAR for Aidol Holzschutz-Creme BPF of 07 December 2015. However, an updated HHERA is required for Holzschutz-Creme containing 0.5% IPBC (Meta SPC 2) due to the change (reduction) in the concentration of IPBC and the resulting revision of the dermal absorption value identified for the products in the meta SPC (as dicussed in Section 2.1.6.2).

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	no	yes	yes	no	yes	yes	n.a.
Dermal	no	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 for Holzschutz-Creme (Meta SPC 2) are based on model calculations using recent models and default values from the Biocides Human Health Exposure Methodology (vers. 1, Oct. 2015), HEEG opinions and HEAdhoc recommendations. Justifications for deviations from the above mentioned models and default values are provided in the respective description of the scenarios.

As a first step, primary exposure assessments are performed for Holzschutz-Creme (Meta SPC 2) for all individual scenarios (work tasks) which are relevant for wood preservatives in PT8 (see table 'List of scenarios' below) considering the concentration of the active substance IPBC during application and post-application by professionals and non-professionals (for more details, please refer to 'General considerations' provided in the following section).

In the second step, the exposure calculated for the individual scenarios / work tasks such as mixing and loading, application and post-application are combined (summed).

Furthermore, secondary (indirect) exposure is assessed. Secondary exposure may result from professional or amateur application, and includes dermal contact with treated surfaces, and handling of contaminated work clothing prior to laundering. Oral exposure following dermal contact (hand-to-mouth transfer) from treated wood objects is related to infants, toddlers and children. Secondary exposure can be a single event (acute exposure) or long-term (chronic exposure). Exposure via food is not expected when the products in Holzschutz-Creme BPF are use as directed.

General considerations:

The biocidal product Holzschutz-Creme (Meta SPC 2) is a solvent-based ready-to-use (RTU) wood preservative containing IPBC at a concentration of 0.5%. The RTU product is used by professionals and non-professionals to protect wood in outdoor areas against soft rot and blue stain fungi, and is applæied by brush application only.

The dermal absorption value used for IPBC at a concentration of 0.5% is obtained from read-across to dermal absorption studies evaluated in the context of the active substance dossier on IPBC, i.e. IPBC Assessment Report for PT13, DK 2015 (latest update of dermal absorption values for all PTs, derived from the same studies). Since the lowest IPBC concentration tested in these studies was 0.6%, the extrapolation of the dermal absorption by *pro rata* correction is considered appropriate for 0.5% IPBC in Holzschutz-Creme (Meta SPC 2) according to the Guidance on Dermal Absorption (EFSA Scientific Opinion, 2012). Thus, a dermal absorption value of 36% is used for the exposure assessments of the professional and non-professional application and post-application tasks.

Secondary exposure of the general public towards dried wood preservative (e.g. adults sanding treated wood, children/infants playing on playground structure outdoors, inhalation of volatilised residue from treated timber indoors) is assessed considering an application rate of 250 mL/m^2. For dried wood preservatives, a dermal absorption value of 1.6% is considered for IPBC.

Exposure calculations for all primary and secondary exposure scenarios are provided in Annex I.

The protection factors for personal protective equipment (PPE, RPE) used for the exposure assessments are defaults from the HEEG opinion 9 (2010) 'Default protection factors for protective clothing and gloves' and the Biocides Human Health Exposure Methodology (vers. 1, Oct. 2015, p. 154).

These general considerations apply to all scenarios provided in the following 'List of scenarios'. Consequently, these considerations are not repeated in the descriptions of the individual scenarios.

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 Exposure of professionals			
1.1	Application – brush treatment	The activities of the professional users are stirring the wood preservative and applying it outdoors to wood using a brush.	Professionals
1.2	Post-application – cleaning of brush	After the application, the brush is washed out.	Professionals
1.3	Secondary exposure - Sawing and sanding treated wood	Cutting and sanding treated wood by professional worker (chronic exposure).	Professionals
2 Exposure of non-professionals			
2.1	Application – brush treatment	The activities of the non-professional users are stirring the wood preservative and applying it outdoors to wood using a brush.	Non-professionals
2.2	Post-application – cleaning of brush	After the application, the brush is washed out.	Non-professionals
3 Exposure of the general public			
3.1	Secondary exposure - sawing and sanding treated wood	Cutting and sanding treated wood by the general public (acute exposure).	General public (adult)
3.2	Secondary exposure - chewing wood cut-off	Infant picks up and chews wood cut-off, which has been treated with wood preservative (acute exposure).	General public (infant)
3.3	Secondary exposure - playing on playground structure outdoors and mouthing	Infants and children may have contact to treated surfaces which are dried, e.g. during playing on weathered structure outdoors. Dermal as well as oral (after licking of hands) exposure has to be considered (chronic exposure).	General public (infant, child)

3.4	Secondary exposure – laundering work clothes at home	People at risk are adults using a washing machine to launder contaminated coveralls at home. The worst-case exposure is via the dermal route from handling the contaminated clothing prior to introduction into the washing machine.	General public (adult)
3.5	Secondary exposure – inhalation of residues, indoors	Inhaling volatilised residue from treated timber indoors	General public (infant, child)

Industrial exposure

Not relevant.

Professional exposure

Scenario [1.1] Application – brush treatment

Description of Scenario [1.1] Application – brush treatment

The activities of the professional users are stirring the wood preservative and applying it outdoors to wood using a brush.

For the brush treatment by professionals, the dermal and inhalation (aerosol) exposure assessment is performed according to the Biocides Human Health Exposure Methodology (vers. 1, Oct. 2015, p. 120) – PT8 "Professional brush treatment" (based on the summary report "Human Exposure to Wood Preservatives"; Lingk W., Reifenstein H., Westphal D., Plattner E.; BfR Wissenschaft, 2006).

The brushing task lasts 4 hours per day for professionals.

The following assumptions are considered in the model:

- Application area:
  The application area is calculated using the median work rate of 7.6 min/m^2 (acc. to TNsG 2002 "Consumer product painting model 3"). Considering an exposure duration of 240 min, the application area results in 31.6 m^2 (calculation: 1/7.6 min/m^2 * 240 min = 31.6 m^2).
- The indicative values as given below are normalized to a product containing 1% active substance and are referring to the exposure when brushing an area of 1 m^2 (acc. to summary report "Human Exposure to Wood Preservatives"; Lingk W., Reifenstein H., Westphal D., Plattner E.; BfR Wissenschaft, 2006).

  Indicative values from model (for a product containing 1% active substance):
  - indicative value for hand exposure: 0.5417 mg a.s./m^2
  - indicative value for body exposure: 0.2382 mg a.s./m^2
  - indicative value for inhalation exposure: 0.0016 mg a.s./m^2

  For the calculations, the indicative values were extrapolated to the active substance content in Holzschutz-Creme, i.e. 0.5% IPBC.

	Parameters	Value
Tier 1	Weight fraction of a.s.	IPBC: 0.5%
	Body weight (acc. to HEEG Opinion 17, 2013)	Adults: 60 kg
	Inhalation rate (short-and long-term) (acc. to HEEG Opinion 17, 2013)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Dermal penetration	IPBC: 36%
	Exposure duration (acc. to Biocides Human Health Exposure Methodology, vers. 1, Oct. 2015)	240 min
	Indicative value for dermal exposure (adjusted to a.s. in product) (acc. to Biocides Human Health Exposure Methodology, vers. 1, Oct. 2015)	for 0.5% IPBC: 0.2709 mg/m^2
	Indicative value for body exposure (adjusted to a.s. in product) (acc. to Biocides Human Health Exposure Methodology, vers. 1, Oct. 2015)	for 0.5% IPBC: 0.1191 mg/m^2

	Indicative value for inhalation exposure (adjusted to a.s. in product) (acc. to Biocides Human Health Exposure Methodology, vers. 1, Oct. 2015)	for 0.5% IPBC: 0.0008 mg/m^2
	No PPE	0% protection
Tier 2	Gloves	90% protection
	Coated coverall	90% protection

Calculations for Scenario [1.1] Application – brush treatment

Calculations are provided in Annex 1.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [1.1] – 0.5% IPBC	Tier 1 / none	4.21E-04	7.39E-02	-	7.44E-02
	Tier 2 / gloves, coverall	4.21E-04	7.39E-03	-	7.81E-03

Further information and considerations on scenario [1.1] Application – brush treatment

Not relevant.

Scenario [1.2] Post-application – cleaning of brush

Description of Scenario [1.2] Post-application – cleaning of brush		
After applying the wood preservative outdoors to wood by brushing, the brush is washed out. This is performed in 3 washing steps. The dermal exposure assessment is performed according to HEEG Opinion 11, 2010 – "Washing out of a brush which has been used to apply a paint". According to this model, inhalation exposure is considered to be negligible.		
	Parameters	Value
Tier 1	Weight fraction of a.s.	IPBC: 0.5%
	Body weight (acc. to HEEG Opinion 17, 2013)	Adults: 60 kg
	Inhalation rate (short-and long-term) (acc. to HEEG Opinion 17, 2013)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Brush size (large)	10 x 10 x 2 cm with a corresponding value volume of 200 ml
	Volume remaining in brush after painting (assumed to be 1/8th of brush volume)	25 ml
	Density of product	0.89 g/ml
	Weight of paint remaining in brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	22.13 g
	Minimum volume of each washing solution	400 ml
	Percentage of residues remaining in brush after each washing step	10%
	Following each washing step, percentage of residues remaining in brush after squeezing	50%
	90%	Percentage of residues absorbed by the cloth
	Dermal penetration	IPBC: 36%
	Exposure duration (acc. HEEG Opinion 11, 2010)	3 washing steps
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [1.2] Post-application – cleaning of brush

Calculations are provided in Annex 1.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [1.2] – 0.5% IPBC	Tier 1 / none	-	3.52E-03	-	3.52E-03
	Tier 2 / gloves	-	3.52E-04	-	3.52E-04

Further information and considerations on scenario [1.2] Post-application – cleaning of brush

Not relevant.

Scenario [1.3] Secondary exposure – sawing and sanding treated wood

Description of Scenario [1.3] Secondary exposure – sawing and sanding treated wood		
Cutting and sanding treated wood by professional worker is considered a chronic exposure scenario. An application rate of 250 mL/m^2 is considered for the solvent-based product, taking into account 0.5% IPBC. According to TNsG User Guidance (vers. 1, 2002), the model exposure data used in these calculations are derived from exposure studies on amateurs who did not wear gloves. Therefore, the following calculated dermal exposure levels for professionals are an overestimate, since professionals would usually wear gloves. Furthermore, the acute sanding scenario is extrapolated to the chronic situation by assuming that the exposure time is 6 hours per day. During sawing/sanding of treated wood, dermal and inhalation exposure of workers is considered. This secondary exposure scenario is based on the TNsG User Guidance (vers. 1, 2002, p. 55) and TNsG 2002, part III (p. 50).		
	Parameters	Value
Tier 1	Weight fraction of a.s.	IPBC: 0.5%
	Application rate	250 mL/m^2
	Density of product	0.8915 g/mL
	Hand area (palms of both hands) (acc. to HEEG Opinion 17, 2013)	Adults: 410 cm^2
	Percentage of hand area contaminated (acc. to TNsG User Guidance, vers. 1, 2002, p. 56)	20%
	Dermal penetration	IPBC: 1.6%
	Body weight (acc. to HEEG Opinion 17, 2013)	Adults: 60 kg
	Inhalation rate (short-and long-term) (acc. to HEEG Opinion 17, 2013)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Indicative value for generated dust (acc. to TNsG 2002, part III, p. 50)	5 mg/m^3
	Exposure duration	6 h
	Density of wood (acc. to TAB, 2016)	400 mg/cm^3
	No PPE	0% protection

Calculations for Scenario [1.3] Secondary exposure – sawing and sanding treated wood

Calculations are provided in Annex 1.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [1.3] – 0.5% IPBC	Tier 1 / none	2.33E-04	4.87E-05	-	2.82E-04

Further information and considerations on scenario [1.3] Secondary exposure – sawing and sanding treated wood

Not relevant.

Combined scenarios

For professional uses, the relevant exposure estimates as calculated for the individual scenarios / work tasks, i.e. application by **brush treatment** [1.1] and the post-application - cleaning of brush [1.2], are combined (added up).

Summary table: combined systemic exposure from industrial uses					
Scenarios combined	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenarios [1.1; 1.2] – 0.5% IPBC	Tier 1 / none	4.21E-04	7.75E-02	-	7.79E-02
	Tier 2 / gloves, coverall	4.21E-04	7.75E-03	-	8.17E-03

Non-professional exposure

Scenario [2.1] Application – brush treatment

Description of Scenario [2.1] Application – brush treatment		
The activities of the non-professional users are stirring the wood preservative and applying it outdoors to wood using a brush. For the brush treatment by non-professionals, the dermal and inhalation (aerosol) exposure assessment is performed according the HEAdhoc Recommendation no. 10, 2016 – 'The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling'. Based on this HEAdhoc Recommendation, for dermal exposure estimate the BEAT model "Austrian wood preservatives water-based/solvent-based" and for inhalation exposure estimate "Consumer product painting model 3" (TNsG 2002, part 2, p. 202) is used. The exposure duration is 150 min (acc. to TNsG User Guidance, vers. 1, 2002, p. 51) for non-professionals).		
	Parameters	Value
Tier 1	Weight fraction of a.s.	IPBC: 0.5%
	Density of product	0.8915 g/mL
	Body weight (acc. to HEEG Opinion 17, 2013)	Adults: 60 kg
	Inhalation rate (short-and long-term) (acc. to HEEG Opinion 17, 2013)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Dermal penetration	IPBC: 36%
	Exposure duration (acc. to TNsG User Guidance 2002)	150 min
	Indicative value for dermal exposure (acc. to HEAdhoc no. 10, 2016)	9.14 µl/min
	Indicative value for body exposure (acc. to HEAdhoc no. 10, 2016)	1.12 µl/min
	Indicative value for inhalation exposure (acc. to HEAdhoc no. 10, 2016)	1.63 mg/m^3
	No PPE	0% protection

Calculations for Scenario [2.1] Application – brush treatment

Calculations are provided in Annex 1.

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [2.1] – 0.5% IPBC	Tier 1 / none	4.24E-04	4.12E-02	-	4.16E-02

Further information and considerations on scenario [2.1] Application – brush treatment

Not relevant.

Scenario [2.2] Post-application – cleaning of brush

Description of Scenario [2.2] Post-application – cleaning of brush		
After applying the wood preservative outdoors to wood by brushing, the brush is washed out. This is performed in 3 washing steps. The dermal exposure assessment is performed according to HEEG Opinion 11, 2010 – "Washing out of a brush which has been used to apply a paint". According to this model, inhalation exposure is considered to be negligible.		
	Parameters	Value
Tier 1	Weight fraction of a.s.	IPBC: 0.5%
	Density of product	0.8915 g/mL
	Body weight (acc. to HEEG Opinion 17, 2013)	Adults: 60 kg
	Inhalation rate (short-and long-term) (acc. to HEEG Opinion 17, 2013)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Dermal penetration	IPBC: 36%
	Exposure duration (acc. to HEEG Opinion 11, 2010)	3 washing steps
	No PPE	0% protection

Calculations for Scenario [2.2] Post-application – cleaning of brush

Calculations are provided in Annex 1.

Summary table: estimated exposure from non-professional use					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [2.2] – 0.5% IPBC	Tier 1 / none	-	3.52E-03	-	3.52E-03

Further information and considerations on scenario [2.2] Post-application – cleaning of brush

Not relevant.

Combined scenarios

For non-professional uses, the relevant exposure estimates as calculated for the individual scenarios / work tasks, i.e. application by **brush treatment** [2.1] and post-application - cleaning of brush [2.2], are combined (summed).

Summary table: combined systemic exposure from non-professional use					
Scenarios combined	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenarios [2.1; 2.2] – 0.5% IPBC	Tier 1 / none	4.24E-04	4.47E-02	-	4.51E-02

Exposure of the general public

Scenario [3.1] Secondary exposure – sawing and sanding treated wood

Description of Scenario [3.1] Secondary exposure – sawing and sanding treated wood		
Cutting and sanding treated wood by professional worker is considered a chronic exposure scenario. An application rate of 250 mL/m^2 is considered for the solvent-based product, taking into account 0.5% IPBC. According to TNsG User Guidance (vers. 1, 2002), the model exposure data used in these calculations are derived from exposure studies on amateurs who did not wear gloves. During sawing/sanding of treated wood, dermal and inhalation exposure of workers is considered. This secondary exposure scenario is based on the TNsG User Guidance (vers. 1, 2002, p. 55) and TNsG 2002, part III (p. 50).		
	Parameters	Value
Tier 1	Weight fraction of a.s.	IPBC: 0.5%
	Application rate	250 mL/m^2
	Density of product	0.8915 g/mL
	Hand area (palms of both hands) (acc. to HEEG Opinion 17, 2013)	Adults: 410 cm^2
	Percentage of hand area contaminated (acc. to TNsG User Guidance 2002, p. 56)	20%
	Dermal penetration	IPBC: 1.6%
	Body weight (acc. to HEEG Opinion 17, 2013)	Adults: 60 kg
	Inhalation rate (short-and long-term) (acc. to HEEG Opinion 17, 2013)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Indicative value for generated dust (acc. to TNsG 2002, part III, p. 50)	5 mg/m^3
	Exposure duration	1 h
	Density of wood (acc. to TAB, 2016)	400 mg/cm^3
	No PPE	0% protection

Calculations for Scenario [3.1] Secondary exposure – sawing and sanding treated wood

Calculations are provided in Annex 1.

Summary table: estimated secondary exposure					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [3.1] – 0.5% IPBC	Tier 1 / none	3.89E-05	4.87E-05	-	8.76E-05

Further information and considerations on scenario [3.1] Secondary exposure – sawing and sanding treated wood

Not relevant.

Scenario [3.2] Secondary exposure – chewing wood cut-off

Description of Scenario [3.2] Secondary exposure – chewing wood cut-off		
Infant picks up and chews wood off-cut, which has been treated with wood preservative. This scenario is considered an acute exposure scenario. An application rate of 250 mL/m^2 is considered for the water-based product, taking into account 0.5% IPBC. For infants 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 16 cm^3 chip (4 cm × 4 cm x 1 cm) and in doing so extracts 10% of the active substance. For children this scenario is not relevant according to TNsG 2002. In comparison to infants, this scenario is regarded as unrealistic for children, because children are highly unlikely to chew treated wood in any significant amounts. Thus, as a worst-case, exposure is only estimated for infants. This secondary exposure scenario is based on TNsG User Guidance (vers. 1, 2002, p. 56) and TNsG 2002, part III (p. 50).		
	Parameters	Value
Tier 1	Weight fraction of a.s.	IPBC: 0.5%
	Application rate	250 mL/m^2
	Density of product	0.8915 g/mL
	Size of piece of wood	16 cm^3
	Oral uptake by extraction of a.s. from the wood (acc. to TNsG User Guidance, 2002)	10%
	Body weight (acc. to HEEG Opinion 17, 2013)	Infant: 8 kg
	No PPE	0% protection

Calculations for Scenario [3.2] Secondary exposure – chewing wood cut-off

Calculations are provided in Annex 1.

Summary table: estimated secondary exposure					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [3.2] – 0.5% IPBC	Tier 1 / none	-	-	2.99E-02	2.99E-02

Further information and considerations on scenario [3.2] Secondary exposure – chewing wood cut-off

Not relevant.

Scenario [3.3] Secondary exposure – playing on playground structure and mouthing

Description of Scenario [3.3] Secondary exposure – playing on playground structure and mouthing		
Infants and children may have contact to treated surfaces which are dried, e.g. during playing on weathered playgrounds. Dermal as well as oral (after licking of hands) exposure has to be considered. This scenario is considered a chronic exposure scenario. As a worst-case, exposure estimates are only performed for infants. An application rate of 250 mL/m^2 is considered for the water-based product, taking into account 0.5% IPBC. This secondary exposure scenario is based on TNsG 2002, part 3 (p. 51). While playing, 20% of the hand area (palms and backs of both hands) are contaminated. Furthermore, a transfer coefficient of 3% is considered for the transfer of dried wood preservative from treated surface to hand, i.e. painted wood (MDF) according to the Biocides Human Health Exposure Methodology (vers. 1, 2015, p. 171). It is further assumed, that 50% of the amount on hands are taken up orally after licking of hands (acc. to HEEG Opinion 7, 2009, and HEAdhoc recommendation no. 5, 2015).		
	Parameters	Value
Tier 1	Weight fraction of a.s.	IPBC: 0.5%
	Application rate	250 mL/m^2
	Density of product	0.8915 g/mL
	Hand area (palms and backs of both hands) (acc. to HEEG Opinion 17, 2013)	Infant: 196.8 cm^2
	Percentage of hand area contaminated (acc. to TNsG 2002, part 3, p. 57)	20%
	Transfer coefficient of dried wood preservative from treated surface to hand (painted wood, MDF) (acc. to Biocides Human Health Exposure Methodology, vers. 1, 2015)	3%
	Dermal penetration	IPBC: 1.6%
	Body weight (acc. to HEEG Opinion 17, 2013)	Infant: 8 kg
	Oral uptake after licking of hands (acc. to HEEG Opinion 7, 2009)	50%
	No PPE	0% protection

Calculations for Scenario [3.3] Secondary exposure – infant playing on playground structure and mouthing

Calculations are provided in Annex 1.

Summary table: estimated secondary exposure					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [3.3] – 0.5% IPBC	Tier 1 / none	-	2.63E-04	8.22E-03	8.49E-03

Further information and considerations on scenario [3.3] Secondary exposure – playing on playground structure and mouthing

Not relevant.

Scenario [3.4] Secondary exposure – laundering work clothes at home

Description of Scenario [3.4] Secondary exposure – laundering work clothes at home		
It is proposed that the people at risk are adults using a washing machine to launder contaminated coveralls at home. Exposure is via the dermal route (hands) from handling the contaminated clothing prior to introduction into the washing machine. The exposure is intermittent though chronic. Contamination of a coverall would be highest following non-professional brush treatment (see Scenario [2.1] brush treatment by non-professionals). However, as noted in that scenario, non-professionals are not expected to wear PPE (e.g. a coverall). Never-the-less, as a worst case for the laundering scenario, the non-professional is assumed to have worn a coverall and that 100% of the contamination was retained on the surface of the coverall. It is assumed that the coverall is washed weekly, after wearing for 5 days, and that the total outer surface of a medium sized coverall is 22700 cm^2. The transfer coefficient for contamination (dried fluid) from cotton and knitwear to wet hands is 30% (acc. to the Biocides Human Health Exposure Methodology, vers. 1, Oct. 2015, p. 171). Palms and backs of both hands are considered to be relevant for the exposure estimate.		
	Parameters	Value
Tier 1	Weight fraction of a.s.	IPBC: 0.5%
	Contamination of coverall, indicative value for body from model (predicted to be highest for 'brush treatment by non-professionals')	1.12 µL/min
	Exposure duration	180 min
	Number of working days	5
	Surface areas of a medium sized coverall	22700 cm^2
	Hand area (palms and backs of both hands) (acc. to HEEG Opinion 17, 2013)	Adults: 820 cm^2
	Transfer coefficient for dried fluids from cotton and knitwear to wet hands (acc. to Biocides Human Health Exposure Methodology, vers. 1, October 2015)	30%
	Dermal penetration	IPBC: 1.6%
	Body weight (acc. to HEEG Opinion 17, 2013)	Adult: 60 kg
	No PPE	0% protection

Calculations for Scenario [3.4] Secondary exposure – cleaning work clothes at home

Calculations are provided in Annex 1.

Summary table: estimated secondary exposure					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [3.4] – 0.5% IPBC	Tier 1 / none	-	1.30E-05	-	1.30E-05

Further information and considerations on scenario [3.4] Secondary exposure – cleaning work clothes at home

Not relevant.

Scenario [3.5] Secondary exposure (chronic) for an infant inhaling volatilised residue from treated timber indoors

The HEEG opinion 13 on the assessment of inhalation exposure to volatilised biocides provides a screening tool and assessment information to determine whether inhalation exposure can be considered not to be a potential risk. IPBC has a molecular weight of 281.1 g/mol and a vapour pressure of 2.36-4.5 × 10^{-3} Pa (at 25°C) at 20°C. The AEL (long term) is 0.2 mg/kg bw/d.

The first simple screening test (equation below) resulted in a value > 1 (using 0.0045 Pa).

$$0.328 \cdot \frac{mw \cdot vp}{AEL_{long-term}} \leq 1$$

Therefore, further assessment was calculated. Assuming 100% SVS (saturated vapour concentration) resulted in exceedance of AEL (long term). In the final calculation 1% of SVS (Tier II) was considered for exposure in a room with moderate ventilation.

The exposure estimates has been done according to HEEG Opinion no. 13 and calculated as worst case for infants with a bw of 8 kg. Inhalation of volatilised residue from IPBC treated timber indoors resulted 2 % of $AEL_{longterm.}$

Calculations are provided in Annex 1.

Combined scenarios

Not relevant for exposure of the general public.

Monitoring data

Concerning human exposure, no monitoring data are available.

Dietary exposure

Not required since the biocidal products of the Holzschutz Creme 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 products 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.

Disposal of the biocidal product

The disposal of the products and solutions should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Surplus and non-recyclable products should be disposed via a licensed waste disposal contractor. Waste packaging should be recycled.

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]**
Brush treatment [1.1] – 0.5% IPBC	Professionals	Tier 1 / none	7.44E-02
		Tier 2 / gloves, coverall	7.81E-03
Cleaning of brush [1.2] – 0.5% IPBC	Professionals	Tier 1 / none	3.52E-03
		Tier 2 / gloves	3.52E-04
Sawing and sanding treated wood [1.3] – 0.5% IPBC	Professionals	Tier 1 / none	2.82E-04
Brush treatment [2.1] – 0.5% IPBC	Non-professionals	Tier 1 / none	4.16E-02
Cleaning of brush [2.2] – 0.5% IPBC	Non-professionals	Tier 1 / none	3.52E-03
Sawing and sanding treated wood [3.1] – 0.5% IPBC	General public (adult)	Tier 1 / none	8.76E-05
Chewing wood cut-off [3.2] – 0.5% IPBC	General public (infant)	Tier 1 / none	2.99E-02
Playing on playground structure and mouthing [3.3] – 0.5% IPBC	General public (infant)	Tier 1 / none	8.49E-03
Cleaning work clothes at home [3.4] – 0.5% IPBC	General public (adult)	Tier 1 / none	1.30E-05

2.1.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation for IPBC

Reference	Study	NOAEL [mg/kg bw/d]	AF[1]	Correction for oral absorption	Value [mg/kg bw/d]
$AEL_{short\text{-}term}$	90-day gavage rat study	35	100	-	0.35
$AEL_{medium\text{-}term}$	-	-	-	-	-
$AEL_{long\text{-}term}$	2-years rat study	20	100	-	0.2
ARfD	n.r.				
ADI	n.r.				

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

n.r.: not relevant

Risk for industrial users

Not relevant.

Risk for professional users

Systemic effects

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)
Brush treatment [1.1] – 0.5% IPBC	Tier 1 / none	20	0.20	7.44E-02	37.2	yes
	Tier 2 / gloves, coverall	20	0.20	7.81E-03	3.9	yes
Cleaning of brush [1.2] – 0.5% IPBC	Tier 1 / none	20	0.20	3.52E-03	1.8	yes
	Tier 2 / gloves, coverall	20	0.20	3.52E-04	0.2	yes
Sawing and sanding treated wood	Tier 1 / none	20	0.20	2.82E-04	0.1	yes

[1.3] – 0.5% IPBC						

Combined scenarios

Scenarios combined	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)
Brush treatment [1.1; 1.2] – 0.5% IPBC	Tier 1 / none	20	0.20	7.79E-02	38.9	yes
	Tier 2 / gloves, coverall	20	0.20	8.17E-03	4.1	yes

Conclusion

Brush treatment (combined scenarios)
Without considering PPE (Tier 1), exposure during professional brush treatment, including cleaning of brush, results in 38.9% of the long-term AEL.
When considering PPE (gloves, coated coverall; Tier 2), during professional brush treatment, exposure estimates result in 4.1% of the long-term AEL.

Sawing and sanding treated wood
Without considering PPE (Tier 1), exposure during professional sawing and sanding of treated wood results in 0.14% of the long-term AEL.

The very low exposure (~ 2% of the long-term AEL) that a professional may also have as a member of the general public (i.e. laundering work clothes at home, inhalation of volatilised residues indoors (the latter exposure assumed to be lower than for infants)) does not alter the acceptability of combined exposure.

Risk for non-professional users

Systemic effects

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)
Brush treatment [2.1] – 0.5% IPBC	Tier 1 / none	35	0.35	4.16E-02	11.9	yes
Cleaning of brush [2.2] – 0.5% IPBC	Tier 1 / none	35	0.35	3.52E-03	1.0	yes

Combined scenarios

Scenarios combined	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)
Brush treatment [2.1; 2.2] – 0.5% IPBC	Tier 1 / none	35	0.35	4.51E-02	12.9	yes

Conclusion

Brush treatment (combined scenarios)
Exposure during non-professional brush treatment, including cleaning of brush, results in 12.9% of the short-term AEL.

The very low exposure (~ 2% of the long-term AEL) that a non-professional may also have as a member of the general public (i.e. sawing and sanding treated wood, laundering work clothes at home, inhalation of volatilised residues indoors (the latter exposure assumed to be lower than for infants)) does not alter the acceptability of combined exposure.

Risk for the general public

Systemic effects

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)
Sawing and sanding treated wood [3.1] – 0.5% IPBC	Tier 1 / none	35	0.35	8.76E-05	0.03	yes
Chewing wood cut-off [3.2] – 0.5% IPBC	Tier 1 / none	35	0.35	2.99E-02	8.5	yes
Playing on playground structure and mouthing [3.3] – 0.5% IPBC	Tier 1 / none	20	0.20	8.49E-03	4.2	yes
Cleaning work clothes at home [3.4] – 0.5% IPBC	Tier 1 / none	20	0.20	1,30E-05	0.01	yes
Secondary exposure (chronic) for an infant inhaling volatilised residue from treated timber indoors	General public (infant)	-	. 0.20	-	2	yes

Conclusion

Sawing and sanding treated wood
Exposure during sawing and sanding treated wood by the general public (adults) results in 0.03% of the short-term AEL.

Chewing wood cut-off
Exposure during chewing wood cut-off by infants results in 8.5% of the short-term AEL.

Playing on playground structure and mouthing
Exposure during playing on playground structure and mouthing as calculated for infants (worst-case) results in 4.2% of the long-term AEL.

Laundering work clothes at home
Exposure during laundering of work clothes at home by adults results in 0.01% of the long-term AEL.

Inhalation of volatilised residue from treated timber indoors by infants
Exposure from inhalation of volatilised residue from treated timber indoors by infants results in 2% of the long-term AEL.

Combined secondary exposure for the adult general public (i.e. sanding and sawing treated wood, laundering work clothes at home, plus inhalation of volatilised residues indoors) is ~ 2% of the long-term AEL (when sawing and sanding treated wood is also compared with the long-term AEL, and adult exposure due to inhalation of volatilised residues indoors is assumed to be lower than for infants), and thus acceptable.

The combined exposure for non-adult (infant is worst-case) general public (i.e. playing on playground structure and mouthing plus inhalation of volatilised residues indoors) is 6.2% of the long-term AEL and thus acceptable.

As contact of the general public to wet/freshly painted surfaces was not considered for Holzschutz-Creme containing 0.5% IPBC (Meta SPC 2), the RMM "Keep children and pets away from treated surfaces until dried." (RMM N-315) has been included in Section 5.2 of Meta SPC 2. As such exposure was likewise not considered for Holzschutz-Creme Plus containing 1.5% IPBC (Meta SPC 1), RMM N-315 has been included in Section 5.2 of Meta SPC 1.

Risk for consumers via residues in food

Not relevant.

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

Not relevant.

2.1.6.4 Semi-quantitative exposure assessment for local effects via inhalatory route

Holzschutz-Creme Plus containing 1.5% IPBC (Meta SPC 1) is classified with STOT RE 2; H373: 'May cause damage to organs (larynx) through prolonged or repeated exposure (inhalation)'. According to the Guidance on the Biocidal Products Regulation (BPR), Volume III, Human Health – Assessment & Evaluation (vers. 2.1, Feb. 2017), a local risk assessment should be performed for products classified with STOT RE 2, H373. The hazard category for this classification is 'Low' according to Table 24 of the above mentioned guidance (p. 245 f).

Local risk assessment for IPBC is also addressed in the Assessment Report on IPBC in PT13 (DK 2015). It was concluded that no respiratory irritation is anticipated during application of liquid, diluted products and thus, a quantitative exposure and risk assessment for local effects via the inhalation route is not required. However, a qualitative risk assessment for local effects has been considered. A reference value (NOAEC) of 1.16 mg/m^3 was derived from a 90-day inhalation study in

rats. However, it is stated in the Assessment Report that the identified NOAEC for larynx effects is only valid for solid IPBC (corresponding to 100% IPBC) and not for formulated products.
In the absence of a reference value for products and the assignment of a 'low' hazard category according to the Guidance on BPR, a fully quantitative risk assessment is not performed for Holzschutz-Creme Plus containing 1.5% IPBC (Meta SPC 1) in line with the Assessment Report (IPBC in PT13, DK 2015).

Nevertheless, when comparing the local air concentration for products containing 1.5% IPBC with the NOAEC of 1.16 mg/m^3 (for solid IPBC) following professional or non-professional application, the resulting estimates are considerably lower than the local reference value. For example, as a worst-case during non-professional brush treatment, the local air concentration, as derived from the indicative value of the relevant model (i.e. 1.63 mg/m^3), results in 0.02 mg IPBC/m^3 for products containing 1.5% IPBC, utilising only 2% of the NOAEC for solid IPBC. Thus, the outcome of the local risk assessment is expected to be acceptable for all relevant professional and non-professional applications (brushing only) given the large margin of safety for the highly diluted (1.5% IPBC) Holzschutz-Creme Plus products (Meta SPC 1).

Holzschutz-Creme containing 0.5% IPBC (Meta SPC 2) is not classified with respect to potential damage to larynx on repeated exposure by inhalation (STOT RE 2; H373). Thus, a local risk assessment is not required for Holzschutz-Creme (Meta SPC 2).

2.1.7 Risk assessment for animal health

Not relevant. Exposure of pets and livestock directly, or via their food or drinking water, to Holzschutz-Creme containing 0.5% IPBC (Meta SPC 2) can be excluded when products in the meta-SPC are applied according to the intended uses. As the risk of exposure of pets during/shortly after application (i.e. to freshly treated wood) has not been evaluated directly, or via reference to a relevant general public scenario, the safety phrase "Keep out of reach of children" has been replaced by "Keep out of reach of children and pets." in Section 5.3 of Meta SPC 1 and Meta SPC 2, i.e. both meta SPCs in the BPF.

2.1.8 Impact of change on environmental risk assessment

The concentration of the active substance is lowered from 0.94 % to 0.5 % in the products under Meta SPC 2. This should not influence the current risk assessment and conclusions for the original Meta SPC and the subsequent amended appendix' to the PAR.

2.1.8.1 In-situ treatment

Since the original PAR is from 2012 the calculations have been conducted according to the "OECD Emission Scenario Document for Wood Preservatives (Part 1 and 2)" (OECD, 2003) and where necessary, the "Technical Guidance Document for Risk Assessment" (European Commission, 2003). The calculation for risk to surface water and soil from in-situ treatment of the wood has been calculated by taking degradation into consideration. For this product, we would need to calculate the risk to the environment from in-situ treatment based on the current guidance, i.e. based on current scenario document ("OECD Emission Scenario Document for Wood Preservatives" (OECD, 2013) and "Guidance on the Biocidal Products Regulation Vol. IV, Part B". This results in risk to the soil (from use by professionals and non-professionals) and surface water compartments (from use by non-professionals) from in-situ treatment of wood.

PEC and PEC/PNEC for IPBC from in-situ brushing of wood				
	PECsoil (mg/kg wwt)	PEC/PNECsoil	PECwater (µg/L)	PEC/PNECwater
In-situ treatment by professionals	0.191	**44**	0.338	0.675
In-situ treatment by non-professionals	0.318	**73.3**	0.563	**1.13**

A risk is identified for soil (from professional and non-professional use) and surface water (from non-professional use) from in-situ treatment of wood by brushing. Therefore, the following risk mitigation measures should be included:

- During in-situ application to timbers and whilst surfaces are drying, do not contaminate soil. All losses of the product have to be contained (by covering the soil) and disposed of in a safe way.
- Do not apply near bodies of surface water or in the area of water protection zones.

Since the *in-situ* treatment was calculated using the same method in Meta SPC 1 and 2, the sentences have been proposed added to both Meta SPCs and the applicant has agreed to this approach. Therefore, the two RMMs regarding in-situ treatment have been added to the family SPC.

2.1.8.2 Environmental risk assessment of iodine

The environmental risk assessment of Holzschutz-Creme also includes the risk from the metabolite PBC, however, the other metabolite from IPBC, iodine, was not included. In the assessment report for IPBC in PT8 the risk assessment of iodine was left out, as iodine was evaluated by SE CA as an active substance for disinfection. At the TMII in 2012 it was agreed to include iodine in future evaluations in PT8 and base the calculations on the CAR for iodine. As a worst-case the values from the existing ERA are used, i.e. for the product with 1.5 % IPBC.

Iodine is not a xenobiotic substance but an essential dietary trace element and is thus naturally present in the environment. Therefore, the background levels of iodine in the environment has to be taken into consideration in the risk assessment. Iodine has a natural cycle in the environment and can be present in different forms, which is largely dependent on redox potential and pH. Iodine and iodate are the dominant iodine species in soil and surface water.

The table below gives the background concentrations of iodine in the environmental compartments. These have been taken from the Assessment Report for iodine (PT 1, 3, 4 and 22) from December 2013.

Background concentration of iodine in the environment	
Compartment	Background level (as iodine)
Soil	Typically 0.5 - 20 mg/kg dwt but with extremes up to 98 mg/kg Global mean value of 5 mg/kg
Groundwater	Mean concentration: 1 µg/l Range: < 1-70 µg/l with extremes up to 400 µg/l
Freshwater (river and lake)	0.5 - 20 µg/l
Marine water	45 - 60 µg/L
Rainwater	0.1-15 µg/l
Freshwater sediment	Typically: 6 mg/kg
Marine sediment	Typically: 3-400 mg/kg
Air	Atmosphere: 10-20 ng/m3 Atmospheric concentration: over land 2-14 ng/m^3; over ocean 17-52 ng/m^3 Marine air contains: 100 µg/l (may refer to local inhalable air)

The PNEC values for iodine/iodate/iodide in the relevant environmental compartments are listed in the table below.

Table of PNEC values for iodine/iodate/iodide	
	Iodine/Iodate/iodide
Soil (mg/kg wwt)	0.0118 / 0.304 / 0.0043
STP (mg/L)	2.9
Water (µg/L)	0.59 / 58.5 / 0.83
Sediment (mg/kg wwt)	Covered by surface water

The PEC calculations for iodine follow the available guidance documents (ESD for PT8 from 2013 and Vol IV, Part B). Only the worst-case scenarios (highest IPBC output values) for each relevant environmental compartment has to be calculated.

In the assessment of iodine released from IPBC, a 100 % formation of iodide and iodate is considered, which is worst-case as the formation of iodine species is expected to be lower. However, for calculating the concentration in soil it is assumed that the total iodine concentration in soil is transformed into 14 % iodide and 100 % iodate (CAR for IPBC, PT6 (2013) and agreed to use for PT8 products at TM II 2012).

If 100 % transformation of IPBC is assumed the molar fraction of PBC produced is 0.552 and for iodine (I_2) it is 0.451 (2 moles of IPBC to form one mole of I_2). Further, it is assumed that all iodine is

transformed either to iodide or iodate. As one mole of iodine (I_2) form two moles of iodide (I^-) the molar fraction between iodine and iodide is 1, whereas for iodate (IO_3^-) the molar fraction is 1.38.

PEC/PNEC in the STP
The intended uses of the product family is only by brushing. According to the ESD for PT 8 (OECD, 2013) page 16 and 22, the noise barrier scenario (for which the STP is the environmental compartment considered) is not a relevant scenario for brushing treatment. Therefore, the risk to the STP from iodine is also not a relevant scenario.

PEC/PNEC in the surface water
Iodine is an inorganic compound and is therefore not biodegradable. Thus, it is assumed that the whole IPBC emission might accumulate during the service life of the wood. For the surface water compartment, the "bridge over pond" scenario during the surface life has been chosen as worst-case, as it represents an intake into a static water body.
In the original ERA the worst case concentration of IPBC in surface water was from the scenario "in service – bridge over pond, 5 years", with 120 µg/L IPBC, which does not include any degradation during the service life. However, since these calculations the ESD for PT8 has been updated to include the volume of water of 1000 m^3 instead of 20 m^3. Therefore, the worst-case concentration of IPBC (in service – bridge over pond, 5 years) is 2.4 µg/L IPBC. Using mole weight correction assuming that all leached IPBC is converted into iodine, this results in 1.08 µg/L iodine in the surface water.
This value is slightly above the $PNEC_{surface\ water}$ but still well below the background concentrations of iodine, and thus, no risk to the surface water is identified.

PEC/PNEC in the soil
The risk assessment of iodine for the soil compartment followed the same procedure as for surface water, using the house scenario and a service life of 5 years with no degradation (worst-case). IPBC emissions are assumed to accumulate over these 5 years, which yields an IPBC concentration of 2.06 mg/kg wwt. Using mole weight correction, this results in an iodine concentration of 0.93 mg/kg wwt. This value is below background concentrations of iodine, and thus, no risk to the soil is identified.

PEC/PNEC in the sediment
In the CAR (2008) for IPBC the reported PNEC for the sediment was derived using the equilibrium method. Therefore, the risk for the sediment compartment is the same as that assessed for the surface water. Therefore, the calculation of PECsediment is not necessary.

PEC in the air
Exposure to air is not considered relevant, as iodine speciates into non-volatile iodide and iodate in the different compartments.

PEC in the groundwater
The environmental fate and behaviour of IPBC and PBC indicate that these substances are not expected to migrate to groundwater during outdoor service life of treated wood since it is rapidly degraded in soil. However, iodine might reach the groundwater, and thus, an assessment is necessary. The release of IPBC from treated wood over a service life of 5 years is 93 mg/m^2 based on the in service – House scenario. IPBC is transformed to PBC (100%), and the total iodine content in soil is transformed to iodide (14 %) and to iodate (100%).

FOCUS PEARL results, i.e. the 80th percentile of the annual average concentrations in the upper groundwater, for idodide as metabolite of IPBC are presented below.

FOCUS PEARL results for iodide in the groundwater (µg/L)	
Chateaudun	0.914
Hamborg	1.017

Jokioinen	0.200
Kremsmuenster	0.767
Okehampton	0.868
Piacenza	1.014
Porto	0.532
Sevilla	0.700
Thiva	1.066

All values for iodide are below the upper range of the background concentration of iodine in the groundwater of 70 µg/L, therefore no risk to groundwater from iodide is expected.

2.1.9 Change of label instructions

The products under Meta SPC 2 as applied for may be used by the general public in addition to (trained-)professionals.

The products under Meta SPC 2 as applied for are required to be labelled with the following information under 'Directions for use': "Only use this product on wooden surfaces of non-load bearing timber which are susceptible to infestation by blue stain fungi but not threatened by wood destroying fungi due to the wood quality or the use conditions." (see Section 2.1.5).

As contact of the general public (and pets) to wet/freshly painted surfaces has not been assessed, an RMM is required to be added to the label for both meta SPCs in the product family (see Section 2.1.6.3).

As a risk assessment for animal health has not been performed, an existing RMM requires revisions for both meta SPCs in the product family (see Section 2.1.7).

Due to the risk for soil and surface water from *in-situ* use, two RMMs are required to be added to the label for both meta SPCs in the product family (see Section 2.1.8).

The following 'Other information' is required to be added to the label for both meta SPCs in the product family: Use biocides safely. Always read label and product information before use. Should the authorisation holder become aware of reports of resistance this should be reported to the competent authorities.

2.1.10 Overall conclusion

The applicant applied for a change in the formulation of the products in the Holzschutz-Creme Biocidal Product Family (BPF) by replacement of the solvent Naphtha (petroleum), hydrodesulfurized heavy (CAS No. 64742-82-1) by the solvent 'Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (EC-No.: 918-481-9)'. This was done in order to remove the classification STOT RE 1 (H372) from the BPF, especially from Meta SPC 2 in order to permit non-professional use. STOT RE 1 became a cut-off criteria according to the Biocidal Product Regulation article 19 (4) (b) indent 5, meaning that products (this was after the initial approval of this product) with this classification cannot be authorised for non-professional use. The formulation change applied for also included a decrease of the active substance for products under Meta SPC 2 from 0.94% to 0.5% IPBC. Minor changes were made in several other coformulants in the BPF.

Overall, the formulation changes have resulted in a down-classification of (Aidol) Holzschutz-Creme BPF (both in Meta SPC 1 and Meta SPC 2).

The applicant has submittet new long-term storage stability study. There was no significant change in physical state, colour, odour or pH after storage. There was not detected any change in container material after storage. The degradation of active substance was 9.1% after 24 months storage and this is within the limit. The product is surface active. The shelf-life is 24 months.

The applicant also submitted a new efficacy study to support the efficacy claim, which was acceptable.

Since the content of IPBC in Meta SPC 1 remains unchanged, the former systemic risk assesments is still valid and therefore not re-calculated. For Meta SPC 2, however, a new systemic human health risk assessment was necessary due to a lower IPBC content requiring use of a different dermal absorption value for IPBC.

A harmonised classification for IPBC has became available, resulting in a different classification than the first one proposed in the CAR for PT8, and a local risk assessment for Meta SPC 1 (not done on first authorisation of the products) has been performed in line with what in CAR for IPBC in PT13. A local risk assessment is not required for Holzschutz-Creme (Meta SPC 2).

Acceptable use for both professionals (PPE; gloves) and non-professionals have been identified in the human health systemic risk assesments for both Meta SPC 1 (former risk assessment unchanged) and Meta SPC 2 for the major change of Holzschutz-Creme BPF. As contact of the general public to wet/ freshly painted surfaces has not been assessed, and as a risk assessment for animal health has not been performed, an appropriate RMM has been included for both meta SPCs in the product family.

The environmental risk assessment for the product had to be re-assessed regarding the *in-situ* treatment of wood, due to new guidance. This resulted in risk to the surface water and soil and therefore, two RMMs have to be included for both meta SPCs in the product family. Lastly, the risk from iodine (metabolite from IPBC) was calculated for all relevant environmental compartments and no risk was identified.

List of Appendixes:

BPR datapoint	Study/Report No	Author	Year	Title	Data Protection	Owner of data
B3.1_key.002, B3.2_key.002, B3.4.1.1_key.002, B3.9_key.002	15081304N978	Affolter, O.	2016a	Determination of the accelerated storage of Holzschutz-Creme „new", 0.94 % IPBC according to CIPAC MT 46 LAUS GmbH, Kirrweiler, Germany GLP: no Published: no	yes	Remmers GmbH
B3.3_key.002	15081304N912	Henke, W.	2015a	Determination of the density of Holzschutz-Creme "new", 0.94 % IPBC according to OECD 109 resp. EU A.3 LAUS GmbH, Kirrweiler, Germany GLP: no Published: no	yes	Remmers GmbH
B3.4.1.2_key.002	15081304N001	Affolter, O.	2017	Determination of the storage stability of Holzschutz-Creme „new", 0.94 % IPBC at room temperature (duration two years) LAUS GmbH, Kirrweiler, Germany GLP: no Published: no	yes	Remmers GmbH
B3.8_key.002	15081304N960	Henke, W.	2015b	Determination of the surface tension of an aqueous solution of Holzschutz-Creme "new", 0.94 % IPBC according to OECD 115 resp. EU A.5 LAUS GmbH, Kirrweiler, Germany GLP: no Published: no	yes	Remmers GmbH
B4.6_key.002	15081304N964	Krebs, F.	2016	Determination of the flash point of Holzschutz-Creme new (LM93-8) according to EU A.9 LAUS GmbH, Kirrweiler, Germany GLP: no Published: no	yes	Remmers GmbH

BPR datapoint	Study/Report No	Author	Year	Title	Data Protection	Owner of data
B4.17.1_key.002	15081304N962	Henke, W.	2015c	Determination of the auto ignition temperature of Holzschutz-Creme "new", 0.94 % IPBC according to EU A.15 LAUS GmbH, Kirrweiler, Germany GLP: no Published: no	yes	Remmers GmbH
B5.1_key.002	15081301N926	Affolter, O.	2016b	Validation of an Analytical Method using GC/FID for the determination of the stability of the active ingredients Propiconazole and IPBC in different formulations (Induline...; Induline..; HK-Lasur "new", 0.94 % IPBC; Holzschutz-Crème "new", 0.94 % IPBC) LAUS GmbH, Kirrweiler, Germany GLP: no Published: no	yes	Remmers GmbH
B6.7_key.005	32/15/9943/01A	Fennert, E.-M.; Hoffmann, S.	2016	Laboratory method for determining the protective effectiveness of a preservative treatment against blue stain according to EN 152 (2011) after 4 weeks artificial weathering. MPA, Eberswalde; Germany GLP: -- Published: no	yes	Remmers GmbH
B10.3_Creme_old_key.002	657958-4	Venås, Thomas Mark; Klamer, Morten	2016	Estimation of Emissions of IPBC from Holzschutz-Crème “old” Treated Wood in Use Class 3 using the Laboratory Test CEN/TS 15119-1 Danish Technological Institute, Taastrup, Denmark GLP: not specified Published: no	yes	Remmers GmbH

BPR datapoint	Study/Report No	Author	Year	Title	Data Protection	Owner of data
B10.3_Creme_new_key.003	657958-3	Venås, Thomas Mark; Klamer, Morten	2016	Estimation of Emissions of IPBC from Holzschutz-Crème “new” Treated Wood in Use Class 3 using the Laboratory Test CEN/TS 15119-1 Danish Technological Institute, Tasstrup, Denmark GLP: not specified Published: no	yes	Remmers GmbH

Annex 1: HUMAN EXPOSURE CALCULATION

(only concerning Meta SPC 2)

Primary exposure

1.1 Application - Brush treatment (professional use) **Biocides Human Health Exposure Methodology (version 1, October 2015, p. 120) – PT8 "Professional brush treatment" (based on Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenschaft, 2006)**			
0.5% IPBC		**Tier-1**	**Tier-2 Gloves, coverall**
Product	**Units**		
Active substance	% (w/w)	0,5	0,5
Density	g/mL	0,89	0,89
Body weight	kg	60	60
Dermal absorption	%	36	36
Dermal exposure			
Hand exposure			
Indicative value from model** [1% a.s.]	mg/m²	0,5417	0,5417
Indicative value from model** [0.5% a.s.]	mg/m²	0,2709	0,2709
Duration	min	240	240
Application area*	m²	31,6	31,6
Potential external hand exposure [a.s.]	mg	8,6	8,6
Penetration through gloves	%	100	10

Actual external hand exposure [a.s.]	mg	8,6	0,9
Body exposure			
Indicative value from model** [1% a.s.]	mg/m²	0,2382	0,2382
Indicative value from model** [0.5% a.s.]	mg/m²	0,1191	0,1191
Duration	min	240	240
Application area*	m²	31,6	31,6
Potential external body exposure [a.s.]	mg	3,76	3,76
Clothing penetration	%	100	10
Actual external body exposure [a.s.]	mg	3,76	0,38
Total external dermal exposure (hand & body) [a.s]	mg	12,32	1,23
Total internal dermal exposure (hand & body) [a.s.]	mg	4,44	0,44
Total systemic dermal exposure [active substance]	**mg/kg bw/day**	**7,39E-02**	**7,39E-03**
$AEL_{long-term}$	**mg/kg bw/day**	**0,2**	**0,2**
% $AEL_{long-term}$	**%**	**36,97**	**3,70**
Exposure by inhalation			
Indicative value from model** [1% a.s.]	mg/m²	0,0016	0,0016
Indicative value from model** [0.5% a.s.]	mg/m²	0,0008	0,0008
Duration	min	240	240
Application area*	m²	31,6	31,6
External inhalation exposure [product]	mg	0,0253	0,0253
Assigned protection factor (APF) for mask	% penetration	100	100
Total systemic inhalation exposure [a.s.]	mg	0,025	0,025
Total systemic inhalation exposure [active substance]	**mg/kg bw/day**	**4,21E-04**	**4,21E-04**
$AEL_{long-term}$	**mg/kg bw/day**	**0,2**	**0,2**
% $AEL_{long-term}$	**%**	**0,21**	**0,21**

Total systemic exposure (dermal & inhalation) [active substance]	**mg/kg bw/day**	**7,44E-02**	**7,81E-03**
$AEL_{long-term}$	**mg/kg bw/day**	**0,2**	**0,2**
% $AEL_{long-term}$	**%**	**37,18**	**3,91**

*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).

1. 2 Post-application - Cleaning of brush (professional use)

HEEG opinion 11 (2010) - "Washing out of a brush which has been used to apply a paint", for application of non-water-based paints

0.5% IPBC		Tier-1	Tier-2 Gloves
Parameters	**Units**		
Volume of brush (corresponding to a brush size of 10 x 10 x 2 cm)	mL	200	200
Volume of product remaining on brush after application (1/8 of 200mL)	mL	25	25
Density of product	g/mL	0,89	0,89
Volume of each washing solution (at least)	mL	400	400
Percentage of residues remaining in brush after each washing step	%	10	10
Percentage of residues remaining in brush after squeezing (following each washing step)	%	50	50
Percentage of residues absorbed by cloth	%	90	90
Percentage of residues available to contaminate the hand	%	10	10
Body weight	kg	60	60
Dermal absorption	%	36	36
Concentration of a.s. in the product	% (w/w)	0,50	0,50
After application			
Weight on brush after application [product]	mg	22288	22288
Weight on brush after application [active substance]	mg	111,44	111,44
After 1st washing			
Residues on brush			
Residues on brush [active substance]	mg	11,14	11,14
Amount removed from the brush into the cleaning fluid [active substance]	mg	100,29	100,29
Weight squeezed out from brush onto cloth [active substance]	mg	5,57	5,57
Weight on brush after 1st washing and sqeezing [active substance]	mg	5,57	5,57

Dermal exposure			
Weight available to contaminate the hand [active substance]	mg	0,56	0,56
Penetration through gloves	%	100	10
Weight on hand [active substance]	mg	0,56	0,06
Internal hand exposure [active substance]	mg	0,20	0,02
After 2nd washing			
Residues on brush			
Residues on brush [active substance]	mg	0,56	0,56
Amount removed from the brush into the cleaning fluid [active substance]	mg	5,01	5,01
Weight squeezed out from brush onto cloth [active substance]	mg	0,28	0,28
Weight on brush after 2nd washing and sqeezing [active substance]	mg	0,28	0,28
Dermal exposure			
Weight available to contaminate the hand [active substance]	mg	0,03	0,03
Penetration through gloves	%	100	10
Weight on hand [active substance]	mg	0,03	0,00
Internal hand exposure [active substance]	mg	0,01	0,001
After 3rd washing			
Residues on brush			
Residues on brush [active substance]	mg	0,03	0,03
Amount removed from the brush into the cleaning fluid [active substance]	mg	0,25	0,25
Weight squeezed out from brush onto cloth [active substance]	mg	0,01	0,01
Weight on brush after 3rd washing and sqeezing [active substance]	mg	0,01	0,01
Dermal exposure			
Weight available to contaminate the hand [active substance]	mg	0,001	0,001
Penetration through gloves	%	100	10

Weight on hand [active substance]	mg	0,001	0,0001
Internal hand exposure [active substance]	mg	0,001	0,0001
Total internal hand exposure [active substance]	**mg**	**0,211**	**0,021**
Total systemic dermal exposure [active substance]	**mg/kg bw/day**	**3,52E-03**	**3,52E-04**
$AEL_{long-term}$	**mg/kg bw/day**	**0,2**	**0,2**
% $AEL_{long-term}$	**%**	**1,76**	**0,18**

Summary brush prof.

Dermal penetration: 36%

Exposure scenario Model used	PPE	Concentration [% IPBC]	Dermal Exposure [mg/kg bw/day]	Inhalation Exposure [mg/kg bw/day]	Total Exposure [mg/kg bw/day]	% $AEL_{long-term}$ of 0.2 mg/kg bw/d
Mixing/Loading	-	Not applicable for the RTU product which is applied direct from can.				
Application Brushing: 240 min Dermal penetration: **36%** **PT8 "Professional brush treatment" (Methodology, 2015)**	Tier 1 / none	0,50	7,39E-02	4,21E-04	7,44E-02	37,18
	Tier 2 / gloves	0,50	7,39E-03	4,21E-04	7,81E-03	3,91
Post-Application Cleaning out of brush: in 3 steps Dermal penetration: **36%**	Tier 1 / none	0,50	3,52E-03	considered to be negligible	3,52E-03	1,76

"Washing out of a brush" (HEEG opinion 11, 2010)	Tier 2 / gloves	0,50	3,52E-04	considered to be negligible	3,52E-04	0,18
Combined Application + Post-Application	Tier 1 / none	0,50	7,75E-02	4,21E-04	7,79E-02	38,94
	Tier 2 / gloves	0,50	7,75E-03	4,21E-04	8,17E-03	4,08

2.1 Application - Brush treatment (non-professional use)

HEAdhoc Recommendation no. 10 (2016)
Dermal exposure: BEAT model (Austrian wood preserv. water-based/solvent-based)
Inhalation exposure: Consumer product painting model 3, TNsG 2002

0.5% IPBC		Tier-1
Product	**Units**	
Active substance	% (w/w)	0,5
Density	g/mL	0,89
Body weight	kg	60
Inhalation rate	m^3/min	0,021
Dermal absorption	%	36
Dermal exposure		
Hand exposure		
Indicative value from model*	µl/min	9,14
Duration	min	150
Potential external hand exposure [product]	mL	1,37
Potential external hand exposure [product]	mg	1222
Penetration through gloves	%	100
Actual external hand exposure [product]	mg	1222
Body exposure		
Indicative value from model	µl/min	1,12
Duration	min	150
Potential external body exposure [product]	mL	0,17
Potential external body exposure [product]	mg	149,8
Clothing penetration	%	100
Actual external body exposure [product]	mg	149,77

Total external dermal exposure (hand & body) [product]	mg	1372
Total external dermal exposure (hand & body) [active substance]	mg	6,86
Total internal dermal exposure (hand & body) [active substance]	mg	2,47
Total systemic dermal exposure [active substance]	**mg/kg bw/day**	**4,12E-02**
$AEL_{short-term}$	**mg/kg bw/day**	**0,35**
% $AEL_{short-term}$	**%**	**11,76**
Exposure by inhalation		
Indicative value from model	mg/m^3	1,63
Duration	min	150
Inhaled volume	m^3	3,1
External inhalation exposure [product]	mg	5,09
External inhalation exposure [active substance]	mg	0,025
Assigned protection factor (APF) for mask	% penetration	100
Total systemic inhalation exposure [active substance]	mg	0,025
Total systemic inhalation exposure [active substance]	**mg/kg bw/day**	**4,24E-04**
$AEL_{short-term}$	**mg/kg bw/day**	**0,35**
% $AEL_{short-term}$	**%**	**0,12**
Total systemic exposure (dermal & inhalation) [active substance]	**mg/kg bw/day**	**4,16E-02**
$AEL_{short-term}$	**mg/kg bw/day**	**0,35**
% $AEL_{short-term}$	**%**	**11,88**

2.2 Post-application - Cleaning of brush (non-professional use)

HEEG opinion 11 (2010) - "Washing out of a brush which has been used to apply a paint", for application of non-water-based paints

0.5% IPBC		Tier-1
Parameters	**Units**	
Volume of brush (corresponding to a brush size of 10 x 10 x 2 cm)	mL	200
Volume of product remaining on brush after application (1/8 of 200mL)	mL	25
Density of product	g/mL	0,89
Volume of each washing solution (at least)	mL	400
Percentage of residues remaining in brush after each washing step	%	10
Percentage of residues remaining in brush after squeezing (following each washing step)	%	50
Percentage of residues absorbed by cloth	%	90
Percentage of residues available to contaminate the hand	%	10
Body weight	kg	60
Dermal absorption	%	36
Concentration of a.s. in the product	% (w/w)	0,50
After application		
Weight on brush after application [product]	mg	22288
Weight on brush after application [active substance]	mg	111,44
After 1st washing		
Residues on brush		
Residues on brush [active substance]	mg	11,14
Amount removed from the brush into the cleaning fluid [active substance]	mg	100,29
Weight squeezed out from brush onto cloth [active substance]	mg	5,57
Weight on brush after 1st washing and sqeezing [active substance]	mg	5,57

Dermal exposure		
Weight available to contaminate the hand [active substance]	mg	0,56
Penetration through gloves	%	100
Weight on hand [active substance]	mg	0,56
Internal hand exposure [active substance]	mg	0,20
After 2nd washing		
Residues on brush		
Residues on brush [active substance]	mg	0,56
Amount removed from the brush into the cleaning fluid [active substance]	mg	5,01
Weight squeezed out from brush onto cloth [active substance]	mg	0,28
Weight on brush after 2nd washing and sqeezing [active substance]	mg	0,28
Dermal exposure		
Weight available to contaminate the hand [active substance]	mg	0,03
Penetration through gloves	%	100
Weight on hand [active substance]	mg	0,03
Internal hand exposure [active substance]	mg	0,01
After 3rd washing		
Residues on brush		
Residues on brush [active substance]	mg	0,03
Amount removed from the brush into the cleaning fluid [active substance]	mg	0,25
Weight squeezed out from brush onto cloth [active substance]	mg	0,01
Weight on brush after 3rd washing and sqeezing [active substance]	mg	0,01
Dermal exposure		
Weight available to contaminate the hand [active substance]	mg	0,001
Penetration through gloves	%	100

Weight on hand [active substance]	mg	0,001
Internal hand exposure [active substance]	mg	0,001
Total internal hand exposure [active substance]	**mg**	**0,211**
Total systemic dermal exposure [active substance]	**mg/kg bw/day**	**3,52E-03**
$AEL_{short-term}$	**mg/kg bw/day**	**0,35**
% $AEL_{short-term}$	**%**	**1,01**

Summary brush non- prof.

Dermal penetration: 36%

Exposure scenario Model used	Tier / PPE	Concentration [% IPBC]	Dermal Exposure [mg/kg bw/day]	Inhalation Exposure [mg/kg bw/day]	Total Exposure [mg/kg bw/day]	% $AEL_{long\text{-}term}$ of 0.35 mg/kg bw/d
Mixing/Loading	-	Not applicable for the RTU product which is applied direct from can.				
Application Brushing: 180 min Dermal penetration: **36%** **HEAdhoc Recom. no. 10, 2016**	Tier 1 / none	0,50	4,12E-02	4,24E-04	4,16E-02	11,88
Post-Application Cleaning out of brush: in 3 steps Dermal penetration: **36%** **"Washing out of a brush" (HEEG opinion 11)**	Tier 1 / none	0,50	3,52E-03	considered to be negligible	3,52E-03	1,01
Combined Application + Post-Application	Tier 1 / none	0,50	4,47E-02	4,24E-04	4,51E-02	12,89

Secondary exposure

1.3 Secondary exposure: Sawing and sanding treated wood by professionals			
0.5% IPBC	**Units**	**Tier 1**	**Comment**
Concentration [active substance]	% (w/w)	0,5	
Density [product]	g/mL	0,8915	
Application rate [product]	mL/m^2	250	2 x, in total 250 mL
Applied amount [product]	g/m^2	222,88	
Applied amount [active substance]	mg/cm^2	0,111	
Surface area of wooden post	cm^2	4032	4 surfaces à 4cm x 250cm + 2 surfaces à 4cmx4cm
Volume of wooden post	cm^3	4000	4 x 4 x 250 cm
Volume of inner core of post, untreated	cm^3	992	2 x 2 x 248 cm
Volume of the outer 1 cm layer	cm^3	3008	
Amount of a.s. on total surface of treated wooden post (conservative assumption that the entire retained a.s. is present on the surface	mg	449,32	
Amount of a.s. in the volume of the outer 1 cm layer	mg/cm^3	0,149	
Dermal exposure			
Hand area (palms of both hands of adults)	cm^2	410	acc. to HEEG 17, 2013
Percentage of hand area contaminated (adult)	%	20	acc. User Guidance 2002, p.56
Hand area contaminated (adult)	cm^2	82	
Amount on hands [active substance]	mg	9,14	
Transfer coefficient of dried paint from rough sawn wood	%	2	acc. to TNsG, 2002
Dermal penetration	%	1,6	
Dermal exposure [active substance]	mg	0,0029	
Body weight (adult)	kg	60	acc. to HEEG 17, 2013

Dermal exposure [active substance]	**mg/kg bw/d**	**4,87E-05**	
Inhalation exposure			
Indicative value for generated dust	mg/m^3	5	acc. to TNsG, 2002, part III
Duration	h	6	
Inhalation rate (adult)	m^3/h	1,25	acc. to HEEG 17, 2013
Generated dust	mg	37,5	
Density of wood	mg/cm^3	400	acc. to TAB, 2016
Volume of dust	cm^3	0,09	
Amount in dust [active substance]	mg	0,01	
Body weight (adult)	kg	60	acc. to HEEG 17, 2013
Inhalation exposure [active substance]	**mg/kg bw/d**	**2,33E-04**	
Combined dermal and inhalation exposure (adult)	**mg/kg bw/d**	**2,82E-04**	
$AEL_{long\text{-}term}$	**mg/kg bw/d**	**0,2**	
% $AEL_{long\text{-}term}$	**%**	**0,14**	

3.1 Secondary exposure: Sawing and sanding treated wood by non-professionals (adults)			
0.5% IPBC	**Units**	**Tier 1**	**Comment**
Concentration [active substance]	% (w/w)	0,5	
Density [product]	g/mL	0,8915	
Application rate [product]	mL/m^2	250	2 x, in total 250 mL
Applied amount [product]	g/m^2	222,88	
Applied amount [active substance]	mg/cm^2	0,111	
Surface area of wooden post	cm^2	4032	4 surfaces à 4cm x 250cm + 2 surfaces à 4cmx4cm
Volume of wooden post	cm^3	4000	4 x 4 x 250 cm
Volume of inner core of post, untreated	cm^3	992	2 x 2 x 248 cm
Volume of the outer 1 cm layer	cm^3	3008	
Amount of a.s. on total surface of treated wooden post (conservative assumption that the entire retained a.s. is present on the surface	mg	449,32	
Amount of a.s. in the volume of the outer 1 cm layer	mg/cm^3	0,149	
Dermal exposure			
Hand area (palms of both hands of adults)	cm^2	410	acc. to HEEG 17, 2013
Percentage of hand area contaminated (adult)	%	20	acc. User Guidance 2002, p.56
Hand area contaminated (adult)	cm^2	82	
Amount on hands [active substance]	mg	9,14	
Transfer coefficient of dried paint from rough sawn wood	%	2	acc. to TNsG, 2002
Dermal penetration	%	1,6	
Dermal exposure [active substance]	mg	0,0029	
Body weight (adult)	kg	60	acc. to HEEG 17, 2013
Dermal exposure [active substance]	**mg/kg bw/d**	**4,87E-05**	

Inhalation exposure			
Indicative value for generated dust	mg/m^3	5	acc. to TNsG, 2002, prat III
Duration	h	1	
Inhalation rate (adult)	m^3/h	1,25	acc. to HEEG 17, 2013
Generated dust	mg	6,25	
Density of wood	mg/cm^3	400	acc. to TAB, 2016
Volume of dust	cm^3	0,02	
Amount in dust [active substance]	mg	0,00	
Body weight (adult)	kg	60	acc. to HEEG 17, 2013
Inhalation exposure [active substance]	**mg/kg bw/d**	**3,89E-05**	
Combined dermal and inhalation exposure (adult)	**mg/kg bw/d**	**8,76E-05**	
$AEL_{short-term}$	**mg/kg bw/d**	**0,35**	
% $AEL_{short-term}$	**%**	**0,03**	

3.2 Secondary exposure: Infant chewing treated wood cut-off			
0.5% IPBC	**Units**	**Tier 1**	**Comment**
Concentration [active substance]	% (w/w)	0,5	
Density [product]	g/mL	0,8915	
Application rate [product]	mL/m^2	250	2 x, in total 250 mL
Applied amount [product]	g/m^2	222,88	
Applied amount [active substance]	mg/cm^2	0,111	
Surface area of wooden post	cm^2	4032	4 surfaces à 4cm x 250cm + 2 surfaces à 4cmx4cm
Volume of wooden post	cm^3	4000	4 x 4 x 250 cm
Volume of inner core of post, untreated	cm^3	992	2 x 2 x 248 cm
Volume of the outer 1 cm layer	cm^3	3008	
Amount of a.s. on total surface of treated wooden post (conservative assumption that the entire retained a.s. is present on the surface	mg	449,32	
Amount of a.s. in the volume of the outer 1 cm layer	mg/cm^3	0,149	
Oral exposure			
Volume of the piece of wood	cm^3	16	4 x 4 x 1 cm
Amount in 1 cm outer layer of the piece of wood [active substance]	mg	2,39	
Extraction by chewing [active substance]	%	10	acc. to User Guidance, 2002
Oral exposure [active substance]	mg	0,24	
Body weight (infant)	kg	8	acc. to HEEG 17, 2013
Oral exposure [active substance]	**mg/kg bw/d**	**0,03**	
Oral exposure (infant)	**mg/kg bw/d**	**2,99E-02**	

3.3 Secondary exposure: playing on playground structure outdoors and mouthing (infant and child)			
0.5% IPBC	**Units**	Value	**Comment**
Concentration [active substance]	% (w/w)	0,5	
Density [product]	g/mL	0,8915	
Application rate [product]	mL/m^2	250	2 x, in total 250 mL
Applied amount [product]	g/m^2	222,88	
Applied amount [active substance]	mg/cm^2	0,111	
Surface area of wooden post	cm^2	4032	4 surfaces à 4cm x 250cm + 2 surfaces à 4cmx4cm
Volume of wooden post	cm^3	4000	4 x 4 x 250 cm
Volume of inner core of post, untreated	cm^3	992	2 x 2 x 248 cm
Volume of the outer 1 cm layer	cm^3	3008	
Amount of a.s. on total surface of treated wooden post (conservative assumption that the entire retained a.s. is present on the surface	mg	449,32	
Amount of a.s. in the volume of the outer 1 cm layer	mg/cm^3	0,149	
Dermal exposure			
Hand area (palms and backs of both hands, infant)	cm^2	196,8	acc. to HEEG 17, 2013
Hand area (palms and backs of both hands, child)	cm^2	427,8	acc. to HEEG 17, 2013
Percentage of hand area contaminated (infant, child)	%	20	acc. to Headhoc Recom. No. 5
Hand area contaminated (infant)	cm^2	39,36	
Hand area contaminated (child)	cm^2	85,56	
Amount on hands (infant) [active substance]	mg	4,39	
Amount on hands (child) [active substance]	mg	9,53	
Dislodgeable fraction (for dried objects on wood)	%	3	acc. to TNsG 2007
Dermal penetration	%	1,6	
Dermal exposure (infant) [active substance]	mg	0,0021	

Dermal exposure (child) [active substance]	mg	0,0046	
Body weight (infant)	kg	8	acc. to HEEG 17, 2013
Body weight (child)	kg	23,9	acc. to HEEG 17, 2013
Dermal exposure (infant) [active substance]	**mg/kg bw/d**	**2,63E-04**	
Dermal exposure (child) [active substance]	**mg/kg bw/d**	**1,91E-04**	
Oral exposure			
Oral uptake (infant, child) after licking of hand	%	50	acc. to HEAdhoc Recom. no. 5
Oral exposure (infant) [active substance]	mg	0,07	
Oral exposure (child) [active substance]	mg	0,14	
Body weight (infant)	kg	8	
Body weight (child)	kg	23,9	
Oral exposure (infant) [active substance]	**mg/kg bw/d**	**8,22E-03**	
Oral exposure (child) [active substance]	**mg/kg bw/d**	**5,98E-03**	
Combined dermal and oral exposure (infant)	**mg/kg bw/d**	**8,49E-03**	
Combined dermal and oral exposure (child)	**mg/kg bw/d**	**6,18E-03**	
$AEL_{long\text{-}term}$	**mg/kg bw/d**	**0,2**	
% $AEL_{long\text{-}term}$ (infant)	**%**	**4,24**	
% $AEL_{long\text{-}term}$ (child)	**%**	**3,09**	

3.4 Secondary exposure: Cleaning work clothes at home			
0.5% IPBC	**Units**	**Tier 1**	**Comment**
Concentration [active substance]	% (w/w)	0,5	
Density [product]	g/mL	0,8915	
Contamination of coverall, indicative value for body from model	µL/min	1,12	predicted to be highest for non-professional workers during brushing
Exposure duration	min	180	
Contamination of coverall with product	mL	0,202	
Contamination of coverall with product	mg	179,73	
Contamination of coverall with active substance	mg	0,90	
Number of working days	counts	5	
Total residues accumulated on a coverall after 5 days	mg	4,49	Assumption: coverall is washed weekly, corresponds to 5 working days
Surface areas of a medium sized coverall	cm^2	22700	
Accumulated residue on a coverall	mg/cm^2	0,0002	
Dermal exposure			
Hand area (palms and backs of both hands, adults)	cm^2	820	acc. to HEEG 17, 2013
Amount on hands [active substance]	mg	0,16	
Transfer coefficient for dried fluids from cotton and knitwear to wet hands	%	30	acc. to TNsG 2002
Dermal penetration	%	1,6	
Dermal exposure [active substance]	mg	0,00	
Body weight (adult)	kg	60	acc. to HEEG 17, 2013
Dermal exposure [active substance]	**mg/kg bw/d**	**1,30E-05**	
Dermal exposure [active substance]	**mg/kg bw/d**	**1,30E-05**	
$AEL_{long-term}$	**mg/kg bw/d**	**0,2**	
% $AEL_{long-term}$	**%**	**0,01**	

SCENARIO 3.5 HEEG opinion no 13 - Inhalation of residues, indoors	
	IPBC
Concentration a.s. % (w/w	0,50%
Saturated vapour pressure	
Vapour pressure Pa	4,50E-03
Molecular weight g/mol	281,1
Gas constant	8,31
Temperature K	298
Saturated vapour concentration (SVC) mg/m^3	5,11E-01
1% of SVCmg/m3	5,11E-03
Adult exposure by inhalation	
Inhalation rate m^3/d	16
Body weight kg	60
Systemic exposure mg/kg bw/d	1,36E-03
AEL mg/kg bw/d	0,2
% AEL	0,7%
Child exposure by inhalation	
Inhalation rate m^3/d	12
Body weight kg	23,9
Systemic exposure mg/kg bw/d	2,56E-03
AEL mg/kg bw/d	**0,2**
% AEL	1,28%
Infant exposure by inhalation	
Inhalation rate m^3/d	5,4
Body weight kg	8
Systemic exposure mg/kg bw/d	3,45E-03
AEL (long-term) mg/kg bw/d	**0,2**
% AEL	1,72%