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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

FKR-ACQ EXTRA

Product type 8

Copper Dihydroxide and Didecyldimethylammonium Chloride as included in the Union list of approved active substances

Case Number in R4BP: BC- HG019840-50

Evaluating Competent Authority: Spain

Date: February 2021

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1 CONCLUSION

The biocidal product FKR-ACQ EXTRA contains 4.12 %w/w Didecyldimethylammonium chloride and 12.86 %w/w Copper (II) Hydroxide and given the nature of the formulation it is not considered explosive, oxidizing, highly flammable or auto-flammable. Therefore, there not be hazards associated with the physico-chemical properties of the product under normal conditions of use.
There are not substances of concern in the biocidal product, hence there are some substances different to the active substance that do not contribute to the product hazard classification with regard to physical chemical properties according to hazardous (Regulation (EC) No 1272/2008).
A validated analytical method is available for determining the concentration of Didecyldimethylammonium chloride and Copper (II) Hydroxide in the biocidal product. Validated analytical methods are also available for the determination of Didecyldimethylammonium chloride and Copper (II) Hydroxide in soil, water and air matrices. Other analytical methods are not required.

Efficacy
The efficacy studies submitted demonstrated the activity of FKR-ACQ EXTRA as:
- Temporary preventive wood preservative against blue stain fungi and mould fungi for green timber.
For temporary preservation of green timber, application by immersion in dilutions of 0.2% (v/v) in water for 20 seconds and open stacking storage is sufficient to prevent infestations of blue stain and mould fungi.

- Preventive wood preservative against termites (*Reticulitermes spp*) for UC 1.
The product application is by vacuum pressure impregnation. The application doses are:
For UC 1 retention of 26 kg/m^3 (3% (v/v) dilution)

Human health:

In addition to the active substances, there is a substance of concern which contribute to the product hazard classification with regard to toxicological properties according to CLP (Regulation (EC) No 1272/2008).
Primary exposure of trained professional users has been shown not to pose an unacceptable risk when gloves and coated coverall are worn. The need to wear gloves and coated coverall is part of the instruction to trained professional (Industrial) users for the application of FKR-ACQ EXTRA.
For secondary exposure, no unacceptable risks were identified for trained professionals and no-professionals. For general public the product is safe if the suitable instructions are followed. The risk is controlled for toddlers.
Assessment indicates an acceptable risk for exposure animals to the trated wood taking into account the suitable instructions. The risk is cotrolled for pets and house animals.

Conclusion on environmental risk assessment

The application of the biocidal product FKR-ACQ EXTRA is carried out at industrial sites in closed vessels or autoclaves, and all stages of treating process remain in a closed system. The application of the biocidal product at industrial sites and storage of treated wood is considered of no concern when risk mitigation measures to avoid releases are taken.

For preventive treatment of wood classes 1 and 2, emissions during service life of treated wood are considered negligible. Therefore, the risks for the service life of treated wood are therefore acceptable for treatment of wood in classes 1 and 2.

The risk characterisation of treated wood in service for wood classes 3 and 4a indicates that the biocidal product FKR-ACQ EXTRA, applied by the industrial processes –dipping/immersion and vacuum impregnation– presents unacceptable risks to the environment for the uses of treated wood in outdoor use classes 3 and 4a except for the Bridge over Pond scenario (UC 3) when the product is applied by dipping immersion at a biocidal product concentration of 0.2 % (retention of 0.26 $g \cdot m^{-2}$).

Therefore, the product FKR-ACQ EXTRA can only be authorized for:

- Treatment of wood classes 1 and 2 when the biocidal product is applied at industrial sites by vacuum impregnation;
- Treatment of green timber of wood classes 1 and 2 when the biocidal product is applied at industrial sites by dipping/immersion;
- Treatment of green timber of wood class 3 (NOT timber that, once installed, will affect the soil or groundwater, as it happens in a cladded house, fence, noise barrier, etc.), when the product is applied by dipping/immersion.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
FKR-ACQ EXTRA	SPAIN

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	FKR QUÍMICA S.L.
	Address	Ctra. Morella km 1.7 Nave 2 12500- Vinaros Spain
Authorisation number	ES/APP(NA)-2020-08-00733	
Date of the authorisation		
Expiry date of the authorisation	31/01/2025	

2.1.1.3 Manufacturer of the product

Name of manufacturer	FKR QUÍMICA S.L.
Address of manufacturer	Ctra. Morella km 1.7 Nave 2 12500- Vinaros Spain
Location of manufacturing sites	Ctra. Morella km 1.7 Nave 2 12500- Vinaros Spain

2.1.1.4 Manufacturers of the active substances

Active substance	**Didecyldimethilammonium chloride(DDAC)**
Name of manufacturer	THOR ESPECIALIDADES S.A
Address of manufacturer	Pol. Ind. El Pla Avenida de la Industria 1 08297-Castellgali, Barcelona Spain
Location of manufacturing sites	Polígono Industrial El Pla Avda. de la Industria 1 08297 Castellgali, Barcelona Spain
Active substance	**Copper (II) hydroxide**
Name of manufacturer	Spiess-Urania Chemicals Gmbh
Address of manufacturer	Frankenstrasse 18b 20097 – Hamburg

	Germany
Location of manufacturing sites	AURUBIS AG c/o Spiess Urania Chemicals GmbH Hovestrasse 50 20539 Hamburg

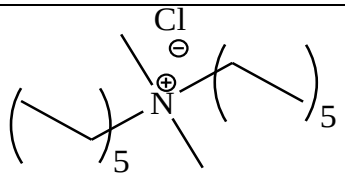
2.1.2 Product composition and formulation

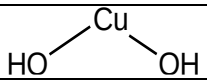
NB: the full composition of the product has been provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance*

Main constituents	
ISO name	Didecyldimethylammonium chloride (DDAC)
IUPAC or EC name	N,N-Didecyl-N,N-dimethylammonium Chloride
EC number	230-525-2
CAS number	7173-51-5
Index number in Annex VI of CLP	612-131-00-6
Minimum purity / content	>87.0% w/w
Structural formula	

Main constituents	
ISO name	Copper dihydroxide
IUPAC or EC name	Copper (II) hydroxide
EC number	243-815-9
CAS number	20427-59-2
Index number in Annex VI of CLP	029-021-00-3
Minimum purity / content	>96.5% w/w
Structural formula	

2.1.2.2 Candidate(s) for substitution

There are no indications that Didecyldimethylammonium chloride (DDAC) and copper (II) hydroxide would fulfil the exclusion criteria specified in article 5(1), nor the substitution criteria specified in Article 10 (1) of Regulation (EU) No 528/2012.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Dicecyldimethilammonium chloride DDAC	N,N-Didecyl-N,N-dimethylammonium Chloride	Active substance	7173-51-5	230-525-2	4.117
Copper dihydroxide	Copper (II) hydroxide	Active substance	20427-59-2	243-815-9	12.86
Propan-2-ol		Non-active substance	67-63-0	200-661-7	1.65
Ethanolamine	2-aminoethanol	Non active substance Solvent	141-43-5	205-483-3	38

Details of the **full composition** are presented in the confidential annex.

2.1.2.4 Information on technical equivalence

The manufacturing sites for the production of didecyldimethylammonium chloride and copper (II) hydroxide are the same as that assessed during the application for inclusion the Union list of approved active substances. Therefore no check for equivalence is necessary.

2.1.2.5 Information on the substance of concern

The substance of concern Monoethanolamine (non-active substance) is considered for the risk calculations for human health. Data sources of these substances are given in section 2.2.6.2 of this document.
Regarding enviromental assessment:
Two substances of concern have been identified:
-Propan-2-ol (IPA)
-2-amminoethanol (MEA)
See confidential annex 3.6.

2.1.2.6 Type of formulation

SL··Soluble concentrate

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Acute toxic 4 Acute toxic 4 Skin corrosion 1 Eye damage 1 Specific Target Organ Toxicity-Single Exposure 3

	(Respiratory Tract Irritation) Aquatic Acute 1. Aquatic Chronic 1
Hazard statements	H302: Harmful if swallowed H332: Harmul if inhaled H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H335: May cause respiratory irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Pictograms	 GHS05 GHS07 GHS09
Signal words	Danger
Hazard statements	H302+H332: Harmful if swallowed or if inhaled H314: Causes severe skin burns and eye damage. H335: May cause respiratory irritation H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P260: Do not breathe the spray P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/… P301+P330+P331+P310: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor/… P303 + P361 + P353+P310: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Immediately call a POISON CENTER/doctor/… P305+P351+P338+ P310: if in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/… P312: Call a POISON CENTER or doctor if you feel unwell. P391: Collect spillage. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations
Note	

2.1.4 Authorised uses

2.1.4.1 Use description 1

Table 1. Use # 1 –Preventive treatment against termites- Pressure process.

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	FKR-ACQ EXTRA is a wood preservative product with insecticidal properties against termites, for treatment of wood class 1
Target organism (including development stage)	Subterranean termites (e.g. *Reticulitermes spp.*, workers/soldiers/nymphs)
Field of use	Solid softwood in service Use class 1: situation in which the wood or wood based product is inside a contruction, not exposed to the weather and wetting.
Application methods	Penetrating process: Vacuum pressure impregnation.
Application rate.	Product needs dilution in water before application. Application rate: 3% (V/V) dilution (Retention 22.18 Kg/m^3)
Category of users	Trained professional users (Industrial users)
Pack sizes and packaging material	Plastic (HDPE) container with 60 L (IBC) or 1000 L (Drum)

2.1.4.1.1 Use-specific instructions for use

FKR-ACQ EXTRA is a wood preservative treatment against termites in industrial sites for solid softwood in service.

The product must not be mixed/applied with other products simultaneously.

The application steps are:

1- The autoclave is loading with the wood.

2- Vacuum is applied (200 hPa) for 30-40 minutes

3- The autoclave is filled with the product previously diluted in vacuum conditions

4- The pressure is increased till 9000-12000 hPa. The pressured conditions are maintained diring 40 to 80 minutes depending on the type if wood.

5- The product is pumped out and vacuum is applied again (300 hPa) during 10-20 minutes

Drying and fixing period:
The treated wood has to be stored at room temperature in a well ventilated and covered and paved place in order to fix the biocidal product an achieve the complete drying.

The biocidal product shall not be used for treatment of wood which is intended for contact with food, feed or livestock**.**

2.1.4.1.2 Use-specific risk mitigation measures

The biocidal product may only be applied to wood, which will be protected from weather and not to be used above or close to surface waters or in direct contact with soil.

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

See section 5.1.5.3

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

See section 5.1.5.4

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

See section 5.1.5.5

2.1.4.2 Use description 2

Table 2. Use # 2 – Temporary preventive treatment of green timber.

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	Temporary preventive wood preservative for green timber. Protection of freshly felled lumber against colonization by blue stain and saptains.
Target organism (including development stage)	Blue stain fungi Mould fungi
Field of use	Green timber.
Application method	Superficial application: dipping treatment. Immersion for 20 seconds.
Application rate and frequency.	Product needs dilution in water before application. Application rate: Immersion for 20 seconds in water dilution at 0.2% (v/v) (retention 0.26g/m²).
Category of users	Trained professional users (Industrial users)
Pack sizes and packaging material	Plastic (HDPE) container with 60 L (IBC) or 1000 L (Drum)

2.1.4.2.1 Use-specific instructions for use

Temporary preventive wood preservative for green timber. The product gives protection againsts colonization by blue stain and saptains. The product must not be mixed/applied with other products simultaneously. Do not apply the product to timber that, once installed, may affect the soil or groundwater, e.g. a cladded house, fence, noise barrier, etc. Drying and fixing period: Green wood should be done in piles with battens The treated wood has to be stored at room temperature in a well ventilated and covered and paved place in order to fix the biocidal product an achieve the complete drying.

2.1.4.2.2 Use-specific risk mitigation measures

The biocidal product may only be applied to wood, which will be protected from weather and not to be used above or close to surface waters or in direct contact with soil.

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

See section 5.1.5.3

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

See section 5.1.5.4

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

See section 5.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

2.1.5.2 Risk mitigation measures

Exposure control/PPE accordingly with the mixture classification and the precautionary statements: Respiratory protection: Wear protective face mask with cartridge filter type ABEK (EN 141) during product handling phase in case of formation of organic vapors. Hand protection: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Direct contact with the product should always be avoided. Select the appropriate means to prevent splashes or accidental projections Eye protection: Wear safety goggles adjustable to eye contour during product handling phase (EN 166). Trained professionals must wear gloves (90% efficacy), impermeable coverall (95 % efficacy) and protection glasses in industrial use General measures for protection and hygiene: Do not drink, eat or smoke during handling. Workplaces should be provided with efficient ventilation, safety showers and eyewash stations. Environmental exposure control: Do not let into surface water or the sewage system. Keep unauthorised people, children and pets away from treated surfaces until dry. Do not apply the product on wood which may come into contact with food, feedstuff or livestock

- Prevent any release of the biocidal product to the sewage system or the environment during the product application phase as well as during the storage and the transport of treated timber;
- All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
- Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer;
- Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water and that any losses of the product shall be collected for reuse or disposal.
- Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

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

Response precautionary statements related to first aid instructions in point 3 of this PAR shall apply in this section. In adition:
IF SWALLOWED: Call a POISON CENTER/doctor/… if you feel unwell.
Rinse mouth.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND
AND CONTACT THE POISON CONTROL CENTER
Phone 91 562 04 20

To incorporate this phone into the label you must make the corresponding notification to the INTCF according to the procedure established in Order JUS/909/2017

Emergency measures to protect environment in case of accident Protection for the Environment accordingly with the mixture classification and precautionary statements:
Avoid spillages to drains, sewage and water streams. Collect the spillage and reuse the product. The working and storage place must be paved and provided with spillage collection pits. If collection is not possible, contain the spillage with appropriate absorption material (vermiculite, sand ...). Keep the contaminated absorbent in closed drums appropriate for disposal according to local regulation
Air:
The biocidal product is not significantly volatile therefore this is not a concern
Water including drinking water:
During routine operations the product should be kept away from sewers, waterways, ground and drinking water paying special attention to keep spills and clean-up residuals out of municipal sewers, ditches, streams, rivers, lakes or any open body of water. Where possible, contain any spilt material. For small spillage in a contained waterway. Collect mechanically if possible. Treat with a neutralising solution to deactivate.
Soil:
Place in a suitable container for disposal according local regulation.

2.1.5.4 Instructions for safe disposal of the product and its packaging

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

- Code the waste according Decision 2014/955/EU.
- Do not release to soil, ground, surface water or any kind of sewer.

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

Shelf-life: 2 years.
Protect from frost.
Storage in fresh and well ventilated place.
Keep the product in the original packaging, well closed.
Due to its alkalinity, keep away from acids or acid formers.
Acordingly to the Spanish Storage Regulation for Chemicals (MIE-APQ), keep away from strong oxidisers and peroxides.
It is recommended to avoid temperatures above 40ºC

2.1.6 Other information

Definitions:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
IBC (intermediate bulk container)	1000 L	HPDE	HPDE	Trained professional (Industrial)	Yes
DRUM	60 L	HDPE	HDPE	Trained professional (Industrial)	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted. All new information relates to the biocidal product described within this application.

Four toxicology studies submitted were performed with the product FKR-ACQ. The applicant indicated that the composition of the product FKR-ACQ-EXTRA is exactly the same than the composition of the product FKR-ACQ.

The reference list (including updates) for the studies submitted in support of the 2016 BPD dossier has been included in Annex 3.1 whilst the reference list for the studies considered confidential has been included in the confidential Annex.

2.1.8.2 Access to documentation

The applicant has submitted the following letters of access:

- ✓ a letter of access from Thor Especialidades S.A. (notifier and having on all the data included in the dossier for Didecyldimethylammonium chloride presented by Thor Especialidades S.A.) to all the documents about the active substance associated to the Annex I listing.
- ✓ a letter of access from Spiess-Urania Chemicals GmbH (notifier and having on all the data included in the dossier for Copper (II) hydroxide presented by Spiess-Urania Chemicals GmbH) to all the documents about the active substance associated to the Annex I listing.

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant

Table 2. Intended use # 1 – Green wood preservative treatment in industrial sites

Product Type(s)	PT8: Wood preservatives
Where relevant, an exact description of the authorised use	The product is applied in vacuum/pressure autoclave conditions. The product has to be previously diluted in water at concentrations between 2 and 3%. The application takes place indoor in industrial facilities in closed conditions (autoclave) by professional workers. The product must not be applied simultaneously or mixed with other products or substances
Target organism (including development stage)	hylotrupes bajulus larvae, basidiomycete xylophagous fungi, soft rot fungi and blue stain fungus. The product is also effective for the Use Class 4a, according to EN-335 classification
Field of use	Control of the growth of bacteria and fungi in the water of the systems of refrigeration and washing of air
Application method(s)	The product is applied once in fresh timbers in closed conditions
Application rate(s) and frequency	The product dilution dose depends on the wood class of use that finally the treated wood will be used: - Classes 1-2-3: dilute at 2% in water - Class 4.1: dilute at 2.7% in water - Anti-termites treatment: dilute at 3% in water The process steps are: 1- The autoclave is loading with the fresh timbers 2- Vacuum is applied (200 hPa) for 30-40 minutes 3- The autoclave is filled with the product previously diluted in vacuum conditions 4- The pressure is increased till 9000-12000 hPa. The pressured conditions are maintained diring 40 to 80 minutes depending on the type if wood 5- The product is pumped out and vacuum is applied again (300 hPa) during 10-20 minutes Drying and fixing period: The treated wood has to be stored at room temperature in a well ventilated and covered and paved place in order to fix the biocidal product an achieve the complete drying
Category(ies) of user(s)	Professional
Pack sizes and packaging material	IBC made of HDPE with 1000 L. Drum made of HPDE with 60L.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Echa Guidance (PNT-QM-154-00)	FKR-ACQ Batch: 630219	Initially: Opaque Liquid	See confidential annex.
		FKR-ACQ Batch: 510612	Initially: Opaque Liquid After 14 days at 54ºC: Opaque Liquid with particles	See confidential annex.
		FKR-ACQ EXTRA Batch: 510612	Initially: Opaque Liquid After 6 and 12 months at 18-22ºC: Opaque Liquid After 18 and 24 months at 18-22ºC: Opaque Liquid with particles	See confidential annex.
Colour at 20 °C and 101.3 kPa	Echa Guidance (PNT-QM-154-00)	FKR-ACQ Batch: 630219	Initially: Dark blue	See confidential annex.
		FKR-ACQ Batch: 510612	Initially: Blue After 14 days at 54ºC: Blue	See confidential annex.
		FKR-ACQ EXTRA Batch: 510612	Initially: Dark blue After 6, 12, 18 and 24 months at 18-22ºC: Dark blue	See confidential annex.
Odour at 20 °C and 101.3 kPa	Echa Guidance (PNT-QM-154-00)	FKR-ACQ Batch: 630219	Initially: ammonia-like	See confidential annex.
		FKR-ACQ EXTRA Batch: 510612	Initially: ammonia-like After 6, 12, 18 and 24 months at 18-22ºC: ammonia-like	See confidential annex.
Acidity / alkalinity	European Pharmacopeia	FKR-ACQ Batch: 510603	273.96 ± 0.01 mg HCl	See confidential annex.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	OECD 122 (PNT-QM-156-01)	FKR-ACQ EXTRA Batch: ACQX250619	354.42 mg H_2SO_4	See confidential annex.
		FKR-ACQ EXTRA Batch: ACQX250619	pH (1%) = 11.26 (20ºC)	See confidential annex.
		FKR-ACQ Batch: 630219	pH = 13.36 (20ºC)	See confidential annex.
		FKR-ACQ EXTRA Batch: 630219	Initially: pH= 13.36 After 3 months at 18-22ºC: pH= 13.59 After 6 months at 18-22ºC: pH= 13.52	See confidential annex.
		FKR-ACQ EXTRA Batch: 510612	After 12 months at 18-22ºC: pH= 13.69 After 18 months at 18-22ºC: pH= 13.52 After 24 months at 18-22ºC: pH= 13.16	
Relative density / bulk density	pycnometer method	FKR-ACQ Batch: 510603	1.13 g/mL	See confidential annex.
	OECD 109	FKR-ACQ EXTRA Batch: 710524	1.12 g/mL (20ºC)	See confidential annex.
Storage stability test – **accelerated storage**	CIPAC MT 46	FKR-ACQ Batch: 510612	DDAC: Stable after 14 days at 54ºC $Cu(OH)_2$: Unnestable after 14 days at 54ºC	See confidential annex.
Active Substance content: Copper (II) Hydroxide DDAC	 European Pharmacopeia 01/2008:1610 PNT-QM-034-00		 Initially: **13.49 % w/w** After 14 days at 54°C: **11.35 % w/w** Diference: -15.86 % w/w Initially: **4.18 % w/w** After 14 days at 54°C:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			4.05 % w/w Diference: -3.11 % w/w	
Homogeneity of application			Not available	
Appearance and stability of the package			Not available	
Storage stability test – **long term storage at ambient temperature**	GIFAP (CropLife International, "Technical Monograph No 17, Guidelines for Specifying the Shelf Life of Plant Protection Products)	FKR-ACQ EXTRA Batch: 510612	Stable after 2 years at 25ºC	See confidential annex.
Active Substance content: Copper (II) Hydroxide	European Pharmacopeia 01/2008:1610		Initially: **13.49 % w/w** After 6 months at 18-22°C: **13.50 % w/w** Diference: 0.07 % w/w After 12 months at 18-22ºC: **13.50 % w/w** Diference: 0.07 % w/w After 18 months at 18-22ºC: **12.58 % w/w** Diference: -6.74 % w/w After 24 months at 18-22ºC: **13.51 % w/w** Diference: 0.15 % w/w	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
DDAC	UNE EN ISO 2871-2:2010 (PNT-QM-034-01)		Initially: **4.18 % w/w** After 6 months at 18-22°C: **4.18 % w/w** Diference: 0.0 % w/w After 12 months at 18-22ºC: **4.29 % w/w** Diference: 2.63 % w/w After 18 months at 18-22ºC: **4.36 % w/w** Diference: 4.31 % w/w After 24 months at 18-22ºC: **4.25 % w/w** Diference: 1.67 % w/w	
Storage stability test – **low temperature stability test for liquids**			Not available	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The product is stable at normal storage conditions.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			The product is stable at normal storage conditions.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			31HA1: type of container Y: Packaging groups II / III BAM: Submission number MASCHIO 2: Manufacturer anagram 100: Test pressure gauge	See confidential annex.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(Kpa)	
Wettability			Not applicable *(the product is an aqueous solution, SL)*	
Suspensibility, spontaneity and dispersion stability			Not applicable *(the product is an aqueous solution, SL)*	
Wet sieve analysis and dry sieve test			Not applicable *(the product is an aqueous solution, SL)*	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable *(the product is an aqueous solution, SL)*	
Disintegration time			Not relevant	
Particle size distribution, content of dust/fines, attrition, friability			Not applicable *(the product is an aqueous solution, SL)*	
Persistent foaming	CIPAC MT 47.2	FKR-ACQ EXTRA Batch: ACQX250619	98 mL (t=10s) 95 mL (t=1min) 95 mL (t=3min) 94 mL (t=12min)	See confidential annex.
Flowability/Pourability/Dustability			Not applicable *(the product is an aqueous solution, SL)*	
Burning rate — smoke generators			Not applicable	
Burning completeness — smoke generators			Not applicable	
Composition of smoke — smoke generators			Not applicable	
Spraying pattern — aerosols			Not applicable	
Physical compatibility			Avoid strong acids strong oxidisers	See confidential annex.
Chemical compatibility			Avoid strong acids strong oxidisers	See confidential annex.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Degree of dissolution and dilution stability			Relevant in SL formulations. Not available	
Surface tension	IQS-STANG-PNT-A-0117 (plate method)	FKR-ACQ	26.9 mN/m	See confidential annex.
Viscosity	rotational viscometer (dynamic)	FKR-ACQ Batch: 510603	18 mPa*s (20ºC)	See confidential annex.
	OECD 114	FKR-ACQ EXTRA Batch: 710524	20.10 mPa*s (20ºC) 10.75 mPa*s (40ºC)	See confidential annex.

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

Note

Several studies were performed with the product FKR-ACQ which is not manufactured anymore. Therefore, the applicant has ensured that the composition of the product FKR-ACQ EXTRA is exactly the same as the composition of the old product FKR-ACQ.

Appearance

Aqueous solution of inorganic copper salt and organic substances (quaternary ammonium salt). The product is an ammonia-like dark blue opaque liquid.

Acidity / alkalinity

Alkalinity is calculated from mg of HCl or H_2SO_4 used for neutralizing the free OH^- in 1g of product because the neat pH > 10.

Relative density / bulk density

The density was determined with a pycnometer at start and then a new test according OECD109 was submitted.

Accelerated storage

The study was performed according to the guideline CIPAC MT 46 "Accelerated storage procedure" .

The results show that whereas the DDAC is stable at test conditions the Copper Hydroxyde precipitate and the concentration in the solution decreases a 16%. Therefore has to be indicated that the product is not stable at 54ºC during 14 days.

Long term storage at ambient temperature

The study was performed according to the guideline GIFAP. The results show that DDAC and Copper Hydroxyde are stable 2 years at 25ºC.

Low temperature stability test for liquids

As the low temperature storage has not been performed, a phrase like 'protect from frost' must be included in the label.

Effects of light
The product application is not affected by light. Applicant years of experience shows that the product is stable under normal conditions of storage. The long term stability study supports this statement.

Effects of temperature and humidity
The product is not affected by temperature and humidity if stored at room temperature. The test of accelerated stability at 54ºC showed that the product partially decomposes. Avoid temperature above 40ºC. On the other hand the long term stability test shows that the product is stable at room temperature.

Effects of towards container material
The HDP is an approved and resistant material for the transport of the product FKR-ACQ-EXTRA. Years of experince shows that the product has not reactivity towards the container material employed. The containers compile with the transport specifications (ADR).

Technical characteristics of the biocidal product
For the application of the product, the following characteristics are not relevant: wettability, suspensibility, spontaneity, dispersion stability, wet sieve analysis, dry sieve test, emulsifiability, re-emulsifiability, emulsion stability, disintegration time, particle size distribution, content of dust/fines, attrition and friability.
Solution stability: the diluted solution could be stable after 18 h at 20ºC.
Persistent foaming: the persistence of foaming is stable over 12 min. The persistence of foaming of FKR-ACQ EXTRA in a 100 mL cylinder was determined to be 95 mL after 1 min. The acceptable limit is 60 mL, therefore the phrase 'the product is foaming' must be included in the label showing that there is no unacceptable risk to operators following use of the preparation through the appropriate application equipment.

Physical and chemical compatibility with other products
The product must be used as such, diluted in water at the recommended use concentration. No mixture with other products or substances is expected.
Test regarding compatibility between the product FKR-ACQ EXTRA and other biocidal products was not performed since the product must be appiled alone.
The compatibility between both active substances in the product, DDAC and Copper dihydroxide, is supported by years of Registrant experience formulating this biocidal product.

Surface tension
The test was performed in a product sample. No batch identified. The applicant has not stated if the used method is appropriate or not.
The surface tension is lower than 60 mN/m under the conditions of the plate method, therefore the biocidal product should be regarded as a surface-active material.

Viscosity
Viscosity was determined by a rotational viscosimeter at start and then a new study following OECD 114 was submitted.

Conclusions
The product is an ammonia-like dark blue opaque liquid.
The accelerated storage study shows that whereas the DDAC is stable at test conditions

the Copper Hydroxyde precipitate and the concentration in the solution decreases a 16%. Therefore has to be indicated that the product is not stable at 54ºC during 14 days.
The long term storage stability study show that DDAC and Copper Hydroxyde are stable 2 years at 25ºC.
There is no increased risk resulting from the surface tension or viscosity of the product.

The phrase 'the product is foaming' must be included in the label because the persistent foaming value is not acceptable.

The phrase 'protect from frost' must be included in the label because the low temperature stability test has not been submitted by the applicant.

The product is not affected by light, temperature, humidity and reactions towards container material.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Theoretical assessment	-	The biocidal product is not explosive	-
Flammable gases			Not applicable	-
Flammable aerosols	-	-	Not applicable	-
Oxidising gases	-	-	Not applicable	-
Gases under pressure	-	-	Not applicable	-
Flammable liquids	Theoretical assessment	-	The biocidal product is not flammable	-
Flammable solids	-	-	Not applicable	-
Self-reactive substances and mixtures	-	-	Not applicable	-
Pyrophoric liquids	-	-	Not relevant	
Pyrophoric solids	-	-	Not applicable	-
Self-heating substances and mixtures	-	-	Not applicable	-
Substances and mixtures which in contact with water emit flammable gases	Theoretical assessment		The product is water based, therefore it is not expected that in contact with water, release flammable gas.	
Oxidising liquids	Theoretical assessment		The biocidal product has not oxidising properties	
Oxidising solids	-	-	Not applicable	-
Organic peroxides	-	-	Not applicable	-
Corrosive to metals	ASTM G31-72	Not available	The product is not corrosive to carbon	See confidential

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			steel.	annex.
Auto-ignition temperatures of products (liquids and gases)	ASTM E659-14	FKR-ACQ EXTRA Batch: 100719	T = 443ºC	
Relative self-ignition temperature for solids	-	-	Not applicable	-
Dust explosion hazard	-	-	Not applicable	-

Conclusion on the physical hazards and respective characteristics of the product

Note
Several studies were performed with the product FKR-ACQ which is not manufactured anymore. Therefore, the applicant has ensured that the composition of the product FKR-ACQ EXTRA is exactly the same as the composition of the old product FKR-ACQ.

Explosives
The product is an aqueos solution. None of their components has been classified as explosive. Therefore explosivity is not expected.

Flammability
The product is an aqueos solution. Only one of their components is flammable (co-formulant 1) but the concentration is very low: 1,65%. Therefore flammability is not expected.

Oxidising properties
None of the solution components has oxidising properties. Therefore oxidising properties are not expected.

Corrosive to metals
The biocidal product as such or at 3% dilution in water is not corrosive to carbon steel. Carbon steel was choosen as the most common material which the biocidal product could be in contact with.

Auto-ignition temperature (liquids and gases)
The product is an aqueous solution (43% w/w of water). The auto ignition temperature has been determined to be 443ºC, therefore auto-ignition is not expected.

Conclusions
Copper (II) hydroxide does not exhibit any particularly hazardous physical-chemical properties. DDAC does not exhibit hazardous physico-chemical properties.
Therefore, it does not need to be classified regarding physical and chemical hazards as it is not flammable, not oxidising or explosive and does not self-ignite.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Cu in Copper (II) Hydroxide in biocidal product (FKR-ACQ - Batch: 510612)	Electrogravimetric Method. complexometric titratyion with EDTA using Murexide as indicator							not applicable	CIPAC 1993: Copper in technical copper compounds: method 44/TC/M3.1 European Pharmacopeia 01/2008:1610
Impurities in Copper (II) Hydroxide in biocidal product (FKR-ACQ - Batch: 510612)	Gravimetry (loss on drying)							Not determined	DIN 18121-1
Impurities in Copper (II) Hydroxide in biocidal product (FKR-ACQ - Batch: 510612)	TOC determination (combustion with IR detection)							Not determined	DIN EN 13137:2001
Didecyldimethylammonium chloride (DDAC) in biocidal product (FKR-ACQ - Batch: 510612)	HPLC-ELSD Titration in the presence of an indicator consisting of mixed anionic and cationic dyes Titration in the presence of								A.R.(2015) EN ISO 2871-2 ASTM D 5584 – 94

	Sodium lauryl sulfate as the titrant and methylene blue as the color indicator.								

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

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Cu	AAS							Instrument detection limit: 0.03 mg/L No LOQ for copper but it is necessary → not acceptable	EPA 7210, 220.1
DDAC in loamy sand	RP-HPLC/MS-MS	0.05 mg/kg / n = 5 0.5 mg/kg / n =	0.5-32.0 µg/L (single determinations at 7 concentration levels)	Highly specific	95-117 89-117	106 98	6.98 12.0	0.05 mg/kg (lower fortification level)	A.R. (2015)

		5	calibration curve equation: y = 792.107x, R^2 = 0.999897						

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

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Cu	AAS- furnace							Instrument detection limit: 0.002 mg/L No LOQ for copper but it is necessary → not acceptable	EPA 220.2, 7211

DDAC in tap water	RP-HPLC/MS-MS	0.1 µg /L / n = 5 1.0 µg /L / n = 5	0.5-16.0 µg/L (single determinations at 76 concentration levels) calibration curve equation: y = 3451.09 + 17096.9x, R^2 = 0.999897	Highly specific	92-104 80-107	100 98	4.93 11.6	0.1 µg /L (lower fortification level)	A.R.(2015)
DDAC in surface water	RP-HPLC/MS-MS	0.1 µg /L / n = 5 1.0 µg /L / n = 5	0.5-16.0 µg/L (single determinations at 76 concentration levels) calibration curve equation: y = 3451.09 + 17096.9x, R^2 = 0.999897	Highly specific	94-105 96-110	99 104	4.67 6.78	0.1 µg /L (lower fortification level)	A.R.(2015)

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

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

Conclusion on the methods for detection and identificationof the product

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

Methods for total copper determination, not specific to Copper (II) hydroxide. Purity can be calculated from the total copper content because other copper forms (i.e. metallic and cuprous) are not expected to be present in the technical material. Methods of analysis for the relevant impurities were not provided and must be provided before the product authorization stage. Further data must be provided to fully validate the analytical method for the determination of the active substance in the biocidal product.

The submitted HPLC-ELSD method for the determination of DDAC in formulations is sufficiently specific and precise.

Analytical methods for soil

Validation data for the methods of analysis copper in soil were not provided and must be provided.

The method submitted for the determination of DDAC in soil matrices is deemed adequately accurate, precise, and specific.

Analytical methods for air

The active substances are not volatiles and moreover there will be no exposition via the respiratory system when used in wood preservatives.

Analytical methods for water

Validation data for the methods of analysis copper in soil were not provided and must be provided.
The method submitted for the determination of DDAC in water matrices is deemed adequately accurate, precise, and specific.

Analytical methods for animal and human body fluids and tisues
Not relevant as the active substances are neither toxic nor highly toxic.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
Not available for lack of exposure for Copper (II) Hydroxide.
For DDAC, eCA believes that no analytical method for food and feedstuff is necessary for PT 8 as DDAC-containing biocidal product is not intended for use in areas where food for human consumption is prepared, consumed or stored, or where the feedingstuff for livestock is prepared, consumed or stored.

Conclusion
The methods are indicated in the Assessment Reports for the inclusion of the active substances in the annex I (PT08). The applicant has clarified the requirements for further information included in the Copper (II) hydroxide assessment report. These requirements were submitted as Confirmatory Data to France being the Rapporteur Member State on 30 July 2013, by the Article 95 applicant. This submission included:
- Fully validated methods for As, Cd and Ni
- Validation of an analytical method for the determination of bioavailable copper in soil samples
- Validation of the determination of Cu in water that meets the requirements of SANCO/825/00, 20 June 2000
- Validated method of analysis for the determination copper in the wood preservation product that was presented in the EU listing procedure as the relevant model formulation.

The applicant has submitted the letter of access granted by Thor Especialidades S.A. for information on analytical methods for the DDAC active substance and to the letter of access granted by Spiess-Urania Chemicals GmbH for information on analytical methods for the Copper (II) hydroxide active substance.

Appropriate validated analytical methods are available for the determination of active substances in the biocidal formulation.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

FKR-ACQ EXTRA a product that provides preventive protection in solid softwood in service against termites and temporary preventive protection for green sawn wood against blue stain and saptain.

The preventive treatment is performed by penetrating process (vacuum/pressure impregnation) at industrial facilities by industrial operators for wood in service. In case of treatment of green timber for temporary preservation, application by immersion is sufficient to support the minimum efficacy.

The following matrix of categories and codes for product are applicable to FKR-ACQ EXTRA:

Table 2.2.1.1 Categories and codes for product FKR-ACQ EXTRA used for UC 1

User category	Industrial applicators	A.20
Wood category	Softwood	B.10
Wood product	Solid wood	C.10
Application aim	Preventive treatment- use class	D.40
Field of use	Use class 1	E.10
Method of application	Pressure process / vacuum pressure impregnation	F.31
Target organisms	Termites (genus *Reticulitermes*)	G.50

Table 2.2.1.1 Categories and codes for product FKR-ACQ EXTRA used for green timber

User category	Industrial applicators	A.20
Wood category	Softwood	B.10
Wood product	Green wood (newly sawn timber)	C.10
Application aim	Temporary preventive treatment/ green sawn timber	D.20
Field of use	Green sawn timber (Use Class not relevant)	-
Method of application	Superficial application / immersion.	F.31
Target organisms	Blue stain fungi Mould fungi	G.21.2 G.22

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

FKR-ACQ EXTRA is a preventive wood preservative for green sawn timber. It produces temporary control of wood discolouring fungi (blue stain and mould fungi).

FKR-ACQ EXTRA is a preventive wood preservative for solid wood. only against termites.

2.2.5.3 Effects on target organisms, including unacceptable suffering

FKR-ACQ EXTRA contains two active substances: copper hydroxide and DDAC, which have different target organisms and different effects on these organisms.

Copper hydroxide acts as a fungicide by impairing germination of fungi. It also acts as insecticide by killing them.

DDAC acts as a fungicide by impairing cell walls which may facilitate the uptake of other biocides. It also has some efficacy toward insects.

2.2.5.4 Mode of action, including time delay

FKR-ACQ EXTRA contains two active substances: copper hydroxide and DDAC, which have different modes of action.

Copper hydroxide is the precursor substance releasing of Cu^{2+} ion which acts as active substance. Upon contact with the fungicide layer, the spores passively take up copper II cations which hinder germination. Copper II cations have a high binding affinity to amino- and carboxyl-groups and therefore act on many sites in the fungal metabolism. They combine with the sulfhydryl groups of amino acids and with carboxyl groups of the cell or membrane proteins. These reactions are unspecific and varied. Metabolism is interrupted through inhibition of many enzyme reactions.

Copper II cations compete with other metals and their derivates in the cell through formation of chelates. Amongst others the influence of copper II cations in the organism causes unspecific denaturation of proteins and enzymes. For this reason it also acts as a feeding and cell poison in insects.

DDAC is a cationic surfactant type active substance. Since it is surface active, it has fair wetting properties and reacts strongly with cell walls of microorganisms. Due to its interaction with phospholipid-bilayer structures, it severely alters the cell wall permeability, disturbs membrane-bound ion-translocation mechanisms, and may facilitate the uptake of other biocides. Against fungi, there exists a selective activity spectrum.

While DDAC has some efficacy toward insects, in general, the mode of action on insects is not fully understood. It is proposed that the mode of action includes disruption the digestive process of the insect, although no definitive evidence has been identified.

2.2.5.5 Efficacy data.

The applicant has provided a battery of tests to claim uses against insects, fungi, termites and rot fungi for uses classes 1-4.
During the evaluation, several discrepancies / deviations were found that made many trials unacceptable.
The applicant has decided not to support/submitt new tests and has withdrawn these claims and continue with the application only with those organisms whose tests have been accepted.
The efficacy table lists all the tests provided by the applicant and the reason for the non-acceptance. (rows in gray).
Accepted tests are blank and have been developed in the usual way.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Preventive treatment – UC 1, 2, 3.1, 4	FKR ACQ EXTRA	Essay not accepted by: - Protocol expired at the time of the request. - Deviations in the number of larvae per sample. - Treatment time shorter than required that does not validate the efficacy dose.				[redacted] Report: MTF/6/07 (2007)
Fungicide	Preventive treatment of green timber.	FKR ACQ	Wood discolouring fungi: *-Blue stain fungi* *-Mould fungi*	CEN/TS 15,082:2005 Field study Reference product: Mitrol PQ8 (copper 8-quinolinolate)	Dipping procedure Softwood (*Pinus pinaster*) Concentration of the product dilution tested: 0.2, 0.5, 1% v/v Exposure: immersion for 20 seconds Solution retentions (mean): 0.26, 0.53, 1.16 g/m²	Average fungal attack: -with wood strip: 0.72, 0.78 and 0.82 at the three dilutions tested, respectively. Controls: 3.20. -without wood strip: 3.96, 3.5 and 3.78 at the three dilutions tested, respectively. Controls: 3.90.	[redacted] Report: 29734 (2012)
Penetration and retention test	Preventive treatment – UC 4	FKR-ACQ	It is not a relevant test for the evaluation of the efficacy of the product.*				[redacted] Report: 14_08515
Fungicide	Preventive treatment – UC 4	FKR-ACQ	The trial has not been accepted because of numerous errors, protocol deviations, discrepancies and lack of data that make it very unreliable.				[redacted] Report: MTF/ACQ/08 (2008)
Fungicide	Preventive treatment – UC 3 and 4	FKR-ACQ	Essay not accepted by: - Lack of data on the loss of mass of each sample for the test according to EN73 aging. -The loss of mass corrected for all concentrations with EN84 exceeds 3%, therefore, for the obligatory fungus *P. placenta*, the test does not demonstrate the concentration at which it is effective.				[redacted] Report: MTF/ACQ-2/08 (2008) & Addendum

							09/19 (2019)
Insecticide	Preventive treatment – UC 1, 2, 3, 4	FKR ACQ	Termites: *Reticulitermes grassei* 250 Workers, 6 nymphs, and 3 soldiers	EN 117 EN 73, ageing by evaporation	Impregnation by vacuum/pressure. Softwood samples (*Pinus sylvestris*, sapwood) were tested at product dilutions: 0, 2.31, 2.89, 3.32, 3.61, and 4.04% (w/w).	Mid-toxic value: 2.31 % and 2.89% (w/w), corresponding to retention levels of: 17.78 to 22.18 Kg/m³	[redacted] Report: 15_09007-1-a (2015)
Insecticide	Preventive treatment – UC 1, 2, 3, 4	FKR ACQ	Termites: *Reticulitermes grassei* 250 Workers, 5 nymphs, and 2 soldiers	EN 117 EN 84, ageing by leaching	Impregnation by vacuum/pressure. Softwood samples (*Pinus sylvestris*, sapwood) were tested at product dilutions: 0, 2.31, 2.89, 3.32, 3.61, and 4.04% (w/w).	Mid toxic value: 2.31 % and 2.89% (w/w), corresponding to retention levels of: 18.25 to 22.08 Kg/m³	[redacted] Report: 15_09007-2-a (2015) + Addendum (2019)

The Technical Construction Regulation specifies the different retentions that the treated wood must meet according to the class of use to which it belongs. For a product of use class 4, the protective product must achieve a penetration corresponding to the **NP5 code, that is, a total penetration of the sapwood.*

The penetration verification is carried out according to EN 21152: 1986.

The results show that it reaches 100% sapwood and a retention of 24.09Kg/m^3.

There is no raw data.

Conclusion on the efficacy of the product

The Applicant states that FKR ACQ is exactly the same formulation as FKR-ACQ EXTRA. Only tests against termites and tests for green sawn timber have been accepted.

Subterranean termites:
FKR-ACQ EXTRA was tested following EN 117 + EN 73 + EN 84 against *Reticulitermes grassei* in pine samples. Mid-toxic values are defined by the range of concentrations with the upper limit being the lowest concentration which shows all samples with attack ≤ 1 (but one sample can have attack = 2) and the lower limit being the concentration below the upper limit with at least 2 samples with attack ≥2. Thus, the mid-toxic values is

- According to EN73: 2.31% and 2.89% (w/w), corresponding to retention levels of: 17.78 to 22.18 Kg/m³
- According to EN84: 2.31 % and 2.89% (w/w), corresponding to retention levels of: 18.25 to 22.08 Kg/m³

According to the EN5991 standard, these tests are sufficient for use classes 1 to 4.

As we mentioned at the beginning of this efficacy section, the product has only been authorized for termites when it comes to woods in service. This means that, according to the general standard EN599-1, it can only be accepted for use class 1, since it has not provided acceptable tests for wood-destroying fungi, neccessary to grant the UC2-4

Therefore we can conclude that the FKR AQC EXTRA at a concentration of 3% (V/V) is effective against subterranean termites in penetrating processes for softwoods for UC1. .

Blue stain and sapstain:
The test provided against blue stain and sapstains is necessary to demonstrate the preventive efficacy of the product for temporary preventive green timber.

The product was diluted at 0.2, 0.5, 1% (v/v) in water and applied by dipping procedure. Mean solution retentions after immersion were 0.26, 0.53 and 1.16 g/m². The test is considered valid since the results of controls and the tests with the reference product fulfilled the requirements of the standard. The test was achieve the minimum efficacy by immersion for 20 seconds with all dilutions only with battens.

Therefore, FKR AQC EXTRA at a minimum concentration of 0.2%(V/V) is effective against blue stain and sapstain by dipping of 20 secons with battens.

2.2.5.6 Occurrence of resistance and resistance management

Copper hydroxide
There is no information showing that target fungi can develop resistance to copper. However there are strains of some species of wood destroying fungi that exhibit some tolerance to copper, according to the final CAR of copper hydroxide. In addition the Fungicide Resistance Action Committee (FRAC) considers copper salts as a low risk group of fungicides in terms of resistance.

There is no evidence either of insects being naturally tolerant or being able to develop resistance to copper at the level of copper used for biocidal purposes in wood preservation.

DDAC
There is no evidence showing that any organism has developed resistance to DDAC in the field of wood protection.

Since several a.s. from different chemical classes are contained in FKR-ACQ EXTRA, it is not expected that this product may produce resistance in fungi or insects. In addition the product acts by preventing growth of fungi and insects, therefore this should reduce the potential for resistant organisms to develop.

2.2.5.7 Known limitations

There are not limitations known.

2.2.5.8 Evaluation of the label claims

The following label claims were assessed:
- Wood preservative for temporary preventive treatment for green wood. against wood discolouring fungi:
- Blue stain fungi
- Mould fungi

- Wood preservative for preventive treatment for UC 1 for softwood against:
- Subterranean termites (e.g. *Reticulitermes grassei*).

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

The product is not intended to be authorised for use with other biocidal products

2.2.6 Risk assessment for human health

GLP compliant studies have been supplied to address the acute oral and dermal toxicity and skin sensitisation. These studies were performed with the product FKR ACQ. According to the applicant's statement must be pointed out that the composition of the product FKR-ACQ-EXTRA is exactly the same than the composition of the old product FKR-ACQ.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

No human and animal data on skin corrosion and irritation with FKR-ACQ-EXTRA were submitted by the Applicant.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	FKR-ACQ-EXTRA is corrosive for the skin.
Justification for the value/conclusion	FKR-ACQ-EXTRA has an extreme pH value of 13.36.
Classification of the product according to CLP	Skin corr. 1 H314: Causes severe skin burns and eye damage

Data waiving	
Information requirement	Study with the product is scientifically unjustified.
Justification	In the absence of any other information, a mixture is considered corrosive to skin (Skin Corrosion Category 1) if it has a pH ≤ 2 or a pH ≥ 11,5. Where it is decided to base the classification of a mixture upon consideration of pH alone, Skin Corrosion Category 1 should be applied.

Eye irritation

No human and animal data on eye irritation with FKR-ACQ-EXTRA were submitted by the Applicant.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	FKR-ACQ-EXTRA causes serious eye damage.
Justification for the value/conclusion	FKR-ACQ-EXTRA has an extreme pH value of 13.36.
Classification of the product according to CLP	Eye damage 1 H318: Causes serious eye damage

Data waiving	
Information requirement	Study with the product is scientifically unjustified.
Justification	In the absence of any other information, a mixture is considered to cause serious eye damage (Category 1) if it has a pH ≤ 2 or ≥ 11,5.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	FKR-ACQ-EXTRA has a component classified as "Specific target organ toxicity — single exposure" category 3 due to Respiratory tract irritation (RTI), with a SCL of ≥5%. In the mixture this component has a concentration >5%, therefore it triggers the classification of the mixture as STOT-SE 3 – RTI (H335: May cause respiratory irritation)
Classification of the product according to CLP	"Specific target organ toxicity — single exposure" category 3; H335: May cause respiratory irritation

Data waiving	
Information requirement	Data on respiratory tract irritation.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008.

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure**	**Results**	**Remarks**	**Reference**
OECD TG 406 (Skin Sensitisation-GPMT) B.6 GLP R.I. 1	Albino Dunkin-Hartley Guinea pig, CRL (HA)BR,SPF; males; 10 (test) and 5 (control) 6 (pretest)	FKR ACQ, Vehicle: water Doses: 1% intradermal induction; 5% epidermal induction; 1% epidermal first challenge and sedond challenge	Nº. of animals sensitized/ total nº. of animals: - 24h after first epidermal challenge: Test 3/10, Control 0/5 - 48h after first epidermal challenge: Test 2/10, Control 0/5 - 24h after second epidermal challenge: Test 0/10 - 48h after	Second challenge was performed 2 weeks after first challenge to clarify skin reactions	[redacted] 2008

			second epidermal challenge: Test 0/10 No mortality and no signs of toxicity		

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	FKR-ACQ EXTRA is not skin sensitizer
Justification for the value/conclusion	based on the results of the first and second challenge, it can be concluded that the skin reactions observed in the first challenge after application of the test ítem at 1% were non-specific irritant origin and consequently irreproducible by rechallenging the test animals. This consideration is supported by the general opinión that even weak first challenge reactions which are truly of allergic origin can be reproduced, and that rechallenge normally acts as "booster" up-regulating both the frequency and intesity of elicited skin reaction in sensitized animals. Furthermore, none of the components of the product is a skin sensitiser.
Classification of the product according to CLP	No classification is proposed.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	FKR ACQ EXTRA is not a respiratory sensitiser
Justification for the value/conclusion	Neither the active substances nor the other components of the mixture are classified as respiratory sensitisers. Moreover, given the conclusion that it is unlikely to induce skin sensitisation, FKR ACQ EXTRA is unlikely to be a respiratory sensitiser.
Classification of the product according to CLP	No classification is proposed.

Data waiving	
Information requirement	Data on respiratory sensitization
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008.

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD TG 420 (Acute Oral Toxicity - Fixed Dose Method) B.1 bis GLP R. I. 1	Wistar Hannover HsdRccHan Rat Females 5/dose	FKR ACQ Single dose, 300 mg/kg bw Gavage	1 animal died approximately 22 h after administration. Abnormal gait and huched back in all animals, between 0 - 5 h. Piloerection in 3 animals between 1 - 3 h. Brachypnea in 1 animal at 0-0.5 h. Hunched back persisted in 2 animals until days 3 and 5, respectively. Reddish urine at day 1 in 1 animal as well as pallor between 3 - 5 d. 1 animal showed decreased muscle tone on day 2 and abnormal gait on day 3. No clinical signs observed from day 6 onwards. Stomach adhered to a hepatic lobe and increased stomach whitish mucosa were seen in 2 animals sacrificed at the end of the study. No macroscopic findings recorded at necropsy.	300 < LD50 ≤ 2000 mg/kg bw	None	[redacted] 2008

No human data on acute oral toxicity was sumitted by the Applicant.

Value used in the Risk Assessment – Acute oral toxicity	
Value	300 < ATE mixture ≤ 2000 mg/kg bw
Justification for the selected value	According to the results obtained in the former study on Acute toxicity by the oral route, the formulation FKR-ACQ should be classified in category 4: 300 < LD50 ≤ 2000 mg/kg bw.
Classification of the product according to CLP	FKR-ACQ EXTRA should be classified as Acute Tox. 4 H302: Harmful if swallowed

Acute toxicity by inhalation

No human and animal data on acute inhalation toxicity with FKR-ACQ-EXTRA were submitted by the Applicant.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Acute tox 4; H332
Justification for the selected value	The product contains one active substance (copper dihydroxide) classified as Acute Tox. 2 (H330) and ethanolamine classified as Acute Tox. 4 (H332) which are ≥1% w/w. According to Assessment Report of cooper dihydroxide (September 2011, France) a CL_{50}-range (rat-4h): 0.205 < LC_{50} < 1.08 mg/l air is proposed. However, the RAC opinion (December 2014) concludes that a LC_{50} value of 0.5 mg/L should be used as basis for classification. On the other hand, according to ethanolamine SDS, the route of administration by inhalation is vapour, hence a acute toxicity estimate (ATE) value of 11mg/l is appropriate. For mixtures containing some substance(s) tested for inhalation toxicity as vapours and others as dust/mist or gas, the additivity formula cannot be used directly as the ATE ranges are different.(*Guidance on the Application of the CLP Criteria, Ver.5.0, July 2017, pag.247)* Therefore for acute inhalation toxicity additivity has initially to be used separately for each relevant physical form (i.e. gas, vapour and/or dust/mist), using the appropriate category limit in CLP Annex I, Table 3.1.1. As a first step, the fraction of toxicity is calculated for each form/state: fraction = Σ (limit / ATE) x concentrations /100 Where limit = the upper border of the range of ATE values of a hazard category (Table 3.1.1 of CLP) for the state/form in question and concentrations = the concentration (%) of components tested for this state/form. The most severe category where the sum of fractions is ≥ 1 that category is applicable to the mixture. Therefore: -Category 1 is not applicable as none of the ingredients are classified as category 1. -Category 2: (0.5/0.5) x 12.860/100 (cooper dihydroxide) + (2/11) x

	38/100 (ethanolamine) = 0.13 + 0.07 = 0.20 which is below 1 meaning not category 2 -Category 3: (1/0.5) x 12.860/100 (cooper dihydroxide) + (10/11) x 38/100 (ethanolamine) = 0.26 + 0.34 = 0.60 which is below 1 meaning not category 3 -Category 4: (5/0.5) x 12.860/100 (cooper dihydroxide) + (20/11) x 38/100 (ethanolamine) = 1.30 + 0.69 = 1.99 which is above 1 meaning category 4 Thus the FKR ACQ EXTRA is classified as Acute Tox. 4 (H332).
Classification of the product according to CLP	FKR-ACQ EXTRA should be classified as Acute Tox. 4; H332: Harmful if inhaled

Data waiving	
Information requirement	Study with the product is scientifically unjustified.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity**	**LD50**	**Remarks**	**Reference**
OECD TG 402 (Acute Dermal Toxicity) B.3 GLP R. I. 1	Sprague-Dawley Rat 1 female/ 1 male	FKR ACQ Limit dose, 2000 mg/kg bw Semiocclusive coverage	After test item administration, the male showed ptosis palpebral during the first 30 min and vocalization during the first hour . During study day 2, both animals showed several clinical signs such as decreased motor activity, abnormal gait, decreased muscular tone,	DL50 was not estimated	Administering animals at a lower dose was considered inappropriate due to test item corrosive properties. Given corrosive properties, the experimental phase could not be completed so FKR-ACQ was not	[redacted]2008

			hunched back and ptosis palpebral. The female also showed paleness and piloerection. After 24 h, semiocclusive patches were removed, the application site was bluish, hard to the touch and with a burn appearance Given the dermal lesions and clinical sings observed, both animals were sacrificed for ethical reasons.		placed in any category	

No human data on acute dermal toxicity with FKR-ACQ-EXTRA was sumitted by the Applicant.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	FKR-ACQ-EXTRA is not classified for acute dermal toxicity
Justification for the selected value	A study on acute toxicity via dermal route was conducted but it could not be completed due to skin corrosivity, thus the LD_{50} was not estimated. Therefore the acute toxicity estimate (ATE) of the mixture is determined by calculation from the ATE values for all relevant ingredients (≥1% w/w) according to the additivity formula for dermal toxicity: $100/ATEmix=\sum(Ci/ATEi)$ Where: 100/ATEmix=38/1025* (ethanolamine) *According to ethanolamine SDS :DL_{50}(rabbit-dermal):1025mg/kgbw Therefore: ATE mixture (dermal) = 2697mg/kg bw Thus the mixture is not classified regarding this hazard class.
Classification of the product according to CLP	No classification is proposed.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Copper dihydroxide	Didecyldimethylammonium chloride (DDAC)	Ethanolamine (2-aminoethanol)
Value(s) *	5% for in-use dilution 100% for concentrate formulation	No dermal absorption value for DDAC in the product has been set.	100%
Justification for the selected value(s)	It was agreed during the TMIII09 that a dermal absorption of 5% has to be used for diluted solutions and 100% for the concentrated product.	The dermal absorption of DDAC was discussed at WG-II-2015[1]. An approach was agreed to be based on risk characterisation for local effects, as it had been concluded earlier that there are no systemic effects but all the observed effects are secondary to irritation and corrosion. As no systemic risk characterization will be performed for DDAC, no dermal absorption value for DDAC in the product will be set. [1]WGII2015_TOX_6.2_DDAC_QUATs_agreements	The substance was included in the CoRAP and the Substance Evaluation Report was concluded in September 2016. The *in vitro human* data indicated that dermal absorption in humans could be low but insufficient information was available to derive a more definitive value. Therefore 100% should be used in exposure calculations.

Data waiving	
Information requirement	Study with the product is scientifically unjustified.
Justification	No dermal absorption studies with FKR-ACQ EXTRA have been conducted.The product is classified as Skin Corrosive category 1 and is also classified as Serious Eye Damage category 1. The Applicant therefore assumed that there will be significant skin penetration due to damage to the skin barrier function and 100% dermal penetration can be used for the purposes of risk characterisation.

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

The biocidal product FKR-ACQ-EXTRA contains two active substances and other coformulants. The active substances are copper dihydroxide (12.86% w/w) and DDAC (4.12% w/w).

Two non-active substances contained in the mixture are classified in terms of human health hazards. One of them has concentrations below the GCL for the hazard classes in which it is classified. Thus it is not considered a substance of concern.

The other substance (i.e. ethanolamine) has harmonized classification and labelling according to Annex VI of CLP Regulation and is present in concentrations above the GCL or SCL for the hazard classes in which it is classified. Furthermore, an indicative occupational exposure limit (IOELV) is in place for ethanolamine. According to the Scientific Expert Group on Occupational Exposure Limits, a 8-hour-TWA of 2.5 mg/m^3, a short-term exposure level STEL (15 mins) of 7.6 mg/m^3 has been established In addition, it is associated with a "skin notation" Thus it is considered a substance of concern.
According to Annex A of the document "Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 2.1 February 2017": For SoCs for which Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) have been set, a quantitative inhalation risk assessment for the professional operator against the IOELV should always be conducted. If the IOELV is associated with a "skin notation" and is driven by systemic effects (rather than local effects), then route-to-route extrapolation should be performed (using standard parameters for body weight and ventilation rate) to derive a dermal or a systemic IOELV. This should then be used to conduct a dermal quantitative risk assessment for the professional operator (band C). Therefore, a quantitative risk assessment for ethanolamine will be provided.

Ethanolamine (2-aminoethanol) was included in the Community Rolling Action Plan (CoRAP) of Regulation (EU) No. 1907/2006. The Substance Evaluation Report of 2-aminoethanol was concluded in September 2016 including reference values to be used in risk characterisation. As reference values, DNELs calculated by eMSCA have been considered for the dermal and inhalation route of exposure in the human health exposure and risk assessment. (see confidential annex).

Please see more information in the Confidential Annex

Available toxicological data relating to a mixture

None.

Other

No other additional tests are considered necessary.

Due to the intended use pattern of the product FKR ACQ EXTRA it will not come into contact with food, foodstuffs or feeding stuffs.

Endocrine Disruting Properties

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disrupting properties assessment of active substance and co-formulants is mandatory according to the article 19 of BPR.
According to the assessment Report of of copper (II) Hydroxide (September 2011, France) there is no data of endocrine potential of the copper (II) Hydroxide. The further evaluation of the potential ED-properties of Copper (II) Hydroxide could be handled in the renewal process under the biocides regulation.
The assessment Report of Didecyldimethylammonium chloride (DDAC) (June 2015, Italy) indicates: *"Based on available experimental results, there is no indication that DDAC affects the endocrine system. Structural characteristics and SAR do not hint to possible effects of DDAC as endocrine disruptor".*

After reviewing the potential ED properties of co-formulants, FKR-ACQ EXTRA contains no substances suspected of having endocrine disrupting properties.
Several sources were considered to check the potential endocrine disrupting properties of the co-formulants contained in the biocidal product.
For further details please refer to the Confidential Annex.

2.2.6.2 Exposure assessment

FKR-ACQ EXTRA contains two active substances: DDAC (4,12% w/w) and Copper (II) hydroxide (12,86% w/w) and one substance of concern: monoethanolamine (38 %).

FKR-ACQ EXTRA is a wood preservative product (non-RTU) for the preventive treatment of solid wood at industrial sites. The application is restricted to a vacuum/pressure autoclave (vacuum pressure impregnation) by (trained professionals) professional workers in industrial sites. The product has to be diluted at a concentration between 2-3% and the product retention considered is 22.18 kg/m^3.

FKR-ACQ EXTRA is also a wood preservative product (non-RTU) for the temporary preventive treatment of green timber at industrial sites. The application is restricted to a dipping treatment (superficial application) by (trained professionals) professional workers in industrial sites. The product has to be diluted at a concentration between 0.2-1% and the product retention considered is among 0.26-1.16 g/m^2.

Considerations concerning didecyldimethylammonium chloride (DDAC) in relation to exposure assessment

According to the CAR for DDAC (IT CA, 2015), systemic effects observed in studies of this active substance are regarded as secondary to the local irritation/corrosion caused by the test substance and, consequently, no adverse systemic effects were identified. Due to the lack of systemic effects in the absence of local effects, derivation of an AEL was not considered appropriate and, consequently, a systemic exposure assessment was not considered necessary. This approach was agreed on at WGII2015 (WGII2015_TOX_6.2_DDAC_QUATs_agreements). Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Considerations concerning ethanolamine in relation to exposure assessment

Monoethanolamine has harmonized classification and labelling according to Annex VI of CLP Regulation and is present in concentrations above the GCL or SCL for the hazard classes in which it is classified. According to the Scientific Expert Group on Occupational Exposure Limits, a 8-hour-TWA of 2.5 mg/m^3, a short-term exposure level STEL (15 mins) of 7.6 mg/m^3 has been established. These values have been used as reference values for the inhalation route of exposure in the human health exposure and risk assessment. In addition, it is associated with a "skin notation" This requires an estimation of the exposure via the dermal route. Thus, a systemic dermal exposure and risk assessment was performed for ethanolamine. As reference value, Worker DNEL long-term dermal – systemic of 3 mg/kg bw/d from Substance Evaluation Report has been considered for the dermal route of exposure in the human health exposure and risk assessment.

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure ***			**Secondary (indirect) exposure**			
	Trained professional (Industrial) use	**Professional use**	**Non-professional use**	**Trained professional (Industrial) use**	**Professional use**	**General public**	**Via food**
Inhalation[1]	Yes	No	No	Yes	No	Yes	No
Dermal	Yes	No	No	Yes	No	Yes[2]	No
Oral	No	No	No	No	No	Yes[2]	No[3]

** To Spanish CA, professional users are considered similar to non-professional users. Therefore, exposure assessment and risk characterisation are calculated in the same way for both users.*

[1] exposure via inhalation route is not considered negligible due to the vapour pressure of the substance of concern monoethanolamine (50 Pa, 20ºC).

[2] secondary exposure is only considered for toddlers via dermal and hand to mouth contact after application of liquid.

[3] in the event that the product is applied e.g., in the food industry, livestock farming installations or in kitchens at private homes (professional and non-professional uses) the liquid formulation applied as dipping precludes surface contamination (hence, dietary exposure). In addition, the label must include restrictions and instructions of use to avoid food contamination and exposure of animals (livestock and companion animals).

List of scenarios

Summary table: scenarios for preventive treatment 1			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Timber treatment	**Primary exposure:** application of 'FKR-ACQ EXTRA' to sawn/solid timber using the water-based vacuum/pressure impregnation process	Trained Professional (Industrial application)
2.	Sanding treated timber	**Secondary exposure:** chronic phase Adult sending treated timber (trained professional)	Trained Professional (Industrial application)
3.	Sanding treated timber	**Secondary exposure:** acute phase Adult sanding treated timber (non professional)	Non-professional
4.	Cleaning	**Secondary exposure:** acute phase	Non-

Summary table: scenarios for preventive treatment 1			
	work wear	Adult cleaning work clothes at home	professional
5.	Ingestion of treated timber	**Secondary exposure:** acute phase Infant chewing wood off-cut	General public
6.	Playing on treated structures	**Secondary exposure**: chronic phase Infant playing on weathered playground structures	General public
7.	Inhalation volatized residues	**Secondary exposure** : General public - Inhalation volatized residues indoors (chronic exposure)	General public

Summary table: scenarios for preventive treatment 2			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
8.	Preventive Timber treament	**Primary exposure:** application of 'FKR-ACQ EXTRA' to green timber using the fully automatic dipping treatment (superficial application)	Trained Professional (Industrial application)
9.	Timber treatment	**Primary exposure:** application of 'FKR-ACQ EXTRA' to green timber using the manual dipping treatment (superficial application)	Trained Professional (Industrial application)
10.	Sanding treated timber	**Secondary exposure:** chronic phase Adult sending treated timber (trained professional)	Trained Professional (Industrial application)
11.	Sanding treated timber	**Secondary exposure:** acute phase Adult sanding treated timber (non professional)	Non-professional
12.	Cleaning work wear	**Secondary exposure:** acute phase Adult cleaning work clothes at home	Non-professional
13.	Ingestion of treated timber	**Secondary exposure:** acute phase Infant chewing wood off-cut	General public
14.	Playing on treated structures	**Secondary exposure:** chronic phase Infant playing on weathered playground structures	General public
15.	Inhalation	**Secondary exposure:** General public -	General public

Summary table: scenarios for preventive treatment 2			
	volatized residues	Inhalation volatized residues indoors (chronic exposure)	

In line with the TNsG on Human Exposure to Biocidal Products, the ES CA has carried out an exposure assessment for human health based on a tiered approach.

Trained professional exposure (Industrial application)

Primary exposure

Scenario [1] Preventive Timber treatment 1

Description of Scenario [1]
Vacuum / pressure application The product is applied in vacuum / pressure autoclave conditions. The product has to be previously diluted in water at concentrations between 2 and 3%. The application takes place indoor in industrial facilities in closed conditions (autoclave) by professional workers. The wood is submitted to vacuum conditions in order to extract the air from the wood. The autoclave is filled with the product previously diluted at a concentration between 2-3%, still under vacuum. Then, pressure is applied in order to achieve the product penetration inside the wood and assure that the laburnum has been impregnated. At the end of the pressure period, the preservative is drained from the cylinder, and surplus preservative is removed from the wood with a final vacuum step. The steps of the process are essentially the following: 1. The charge of wood is sealed in the treating cylinder, and a preliminary vacuum is applied for 30 to 40 minutes to remove the air from the cylinder and as much as possible from the wood. 2. The preservative (diluted as was stated before), at ambient or elevated temperature depending on the system, is admitted to the cylinder without breaking the vacuum. 3. After the cylinder is filled, pressure is applied until the wood will take no more preservative or until the required retention of preservative is obtained. 4. When the pressure period is completed (40-80 min), the preservative is withdrawn from the cylinder. 5. A short final vacuum may be applied to free the charge from dripping preservative (10-20 min). After the treatment the wood is stored during 15 to 20 days at room temperature in order to fix the the product and achieve a complete drying. The product must not be applied simultaneously or mixed with other products or substances. Trained professional user exposure to DDAC, copper (II) hydroxide and monoethanolamine during the application of 'FKR_ACQ EXTRA' by industrial vacuum / pressure impregnation has been assessed using the TNsG Handling Model 1[1]. This model is derived from data relating to industrial timber treatment using vacuum/pressure plants applying water-based or solvent-based liquid formulations. Exposure values obtained from the model reflect the intermittent manual handling of water-wet or solvent-damp wood and associated equipment.

Description of Scenario [1]		
Indicative (75th percentile) exposure values derived from Handling Model 1 are used in this assessment. One cycle for solvent-based products has a typical duration of 60 minutes. It is assumed that 6 cycles (360 minutes) are performed each day. In view of the automated nature of the industrial vacuum/pressure impregnation process, it is unlikely that operators will routinely undertake manual mix/loading activities. Any manual mix/loading is, therefore, likely to be infrequent and represent a minor contribution to the overall level of exposure as predicted by the TNsG Handling Model 1. negligible. For non-volatile compounds, the assessment of vapour is not necessary.		
	Parameters	Value
Tier 1	% of active substance in the biocidal product Copper (II) hydroxide Cu (II)	 0.39% 0.25%
	% of substance of concern in the biocidal product Monoethanolamine (MEA)	 1.14%
	Dilution of the applied product	3% (worst case)
	Body weight	60 kg
	Inhalation rate[2]	1.25 m^3/h
	Indicative body dermal exposure[1]	8570 mg/cycle
	Potential dermal exposure on hands (gloves)[1]	1080 mg/cycle
	Indicative inhalation exposure[1]	1.9 mg/m^3
	Dermal absorption[3]: Copper (II) MEA	 5% 100%
	Penetration through PPE (body) = no PPE	100%
	Exposure duration[4]	6 dipping cycle per day
	Penetration through RPE	100%
Tier 2	Clothing penetration (Coated coverall)[5]	10%

[1] BHHEM, 2015, p.301: Industrial wood preservation, intermittent handling of water-wet wood and associated equipment.
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products. Inhaled uptake 100% (TNsG User Guidance p. 45 and MOTA v. 6)
[3] CAR and CoRAP.
[4] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure 'Methods and models to assess exposure to biocidal products in different product types' Version 4.
[5] HEEG opinion 9 - Default protection factors for protective clothing and gloves.

Calculations for Scenario [1]

See calculations in Annex 3.2

Summary table: estimated systemic exposure to Cu (II) from industrial uses (mg/kg bw/d)

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 1	1/gloves	9.95E-05	1.21E-01	--	1.21E-01
Scenario 1	2/gloves & coated coverall	9.95E-05	1.40E-02	--	1.41E-02
Summary table: estimated systemic exposure to MEA from industrial uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1	1/gloves	4.51E-04	1.10E+01	--	1.10E+01
Scenario 1	2/gloves & coated coverall	4.51E-04	1.27E+00	--	1.27E+00

Further information and considerations on scenario [1]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Scenario [8] Preventive timber treatment 2

Description of Scenario [8]
Fully Dipping treatment (superficial application) For temporary preservation of green timber, application by immersion in dilutions of ≥1% (v/v) in water for 20 seconds (retention of ≥1 g/m^2) and open stacking storage is sufficient to prevent infestations of blue stain and mould fungi. Trained professional user exposure to DDAC, copper (II) hydroxide and monoethanolamine during the application of 'FKR_ACQ EXTRA' by dipping treatment (superficial application) has been assessed using the TNsG Handling Model 1[1]. **Automated dipping** includes the following operations: an operator using a fork-lift truck or similar equipment lowers the wood into the dipping tank or transfers the wood to a bathing tray. The wood stays in the wood preservative for a few minutes or for a few hours before being lifted out of the tank by the fork-lift truck (or similar). The wood is then transferred by the fork-lift truck (or similar) to a storage area where it is placed to dry. As a reasonable default value a number of 4 cycles should be used for automated dipping. **Dermal exposure** For dipping using a fork-lift truck the operator exposure arises from handling the wet preservative-treated timber. A study observed qualitatively that the dermal exposure

Description of Scenario [8]

pattern of automated dipping is comparable to that of vacuum pressure process. Based on this assumption the appropriate model to assess the automated dipping process is Handling model 1. This model is used to assess the professional intermittently handling water-wet or solvent-damp wood and associated equipment after vacuum pressure processes (p. 26 of User Guidance, 2002). The dermal exposure is assessed as mg of a.s. per cycle.

Inhalation exposure
Measurements of a study determined no inhalation exposure for waterbased solution since no aerosol formation was observed. Therefore, for water-based in use formulations, there should be negligible inhalation exposure.

	Parameters	Value
Tier 1	% of active substance in the biocidal product Copper (II) hydroxide Cu (II)	 0.13% 0.084%
	% of substance of concern in the biocidal product Monoethanolamine (MEA)	 0.38%
	Dilution of the applied product	1% (worst case)
	Body weight[2]	60 kg
	Inhalation rate[2]	1.25 m^3/h
	Indicative body dermal exposure[1]	8570 mg/cycle
	Potential dermal exposure on hands (gloves)[1]	1080 mg/cycle
	Indicative inhalation exposure[1]	0.0 mg/m^3
	Dermal absorption[3]: Copper (II) MEA	 5% 100%
	Penetration through PPE (body) = no PPE	100%
	Exposure duration[4]	4 cycles
	Penetration through RPE	100%
Tier 2	Clothing penetration (Coated coverall)[5]	10%

[1] BHHEM, 2015, p.301: Industrial wood preservation, intermittent handling of water-wet wood and associated equipment.
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products. Inhaled uptake 100% (TNsG User Guidance p. 45 and MOTA v. 6)
[3] CAR and CoRAP.
[4] HEEG Opinion 8: Defaults and appropriate models to assess human exposure for dipping processes (PT 8). Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure 'Methods and models to assess exposure to biocidal products in different product types' Version 4.
[5] HEEG opinion 9 - Default protection factors for protective clothing and gloves.

Calculations for Scenario [8]

See calculations in Annex 3.2

Summary table: estimated systemic exposure to Cu (II) from industrial uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 8	1/gloves	--	2.69E-02	--	2.69E-02
Scenario 8	2/gloves & coated coverall	--	5.41E-03	--	5.41E-03
Summary table: estimated systemic exposure to MEA from industrial uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 8	1/gloves	--	2.44E+00	--	2.44E+00
Scenario 8	2/gloves & coated coverall	--	4.91E-01	--	4.91E-01

Further information and considerations on scenario [8]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Scenario [9] Preventive timber treatment 2

Description of Scenario [9]
Dipping treatment (superficial application) For temporary preservation of green timber, application by immersion in dilutions of ≥1% (v/v) in water for 20 seconds (retention of ≥1 g/m^2) and open stacking storage is sufficient to prevent infestations of blue stain and mould fungi. Trained professional user exposure to DDAC, copper (II) hydroxide and monoethanolamine during the application of 'FKR_ACQ EXTRA' by dipping treatment (superficial application) has been assessed using the TNsG Dipping Model 1[1]. This model is derived from data relating to a survey dipping activities (tanks and coating with fluid by pouring and scrubbing). In manual dipping operations, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts by his/her gloved hand the wooden article from the dipping tank and stacks the article to dry. Indicative (75th percentile) exposure values derived from Dipping Model 1 are used in this assessment.

Description of Scenario [9]		
Since this is a very strenuous activity, it is reasonable to assume that operators would only spend a relatively short time dipping, i.e. 30 minutes dipping, once a day (User Guidance, version 1, June 2002, page 44). Manual dipping is undertaken by small companies making for example sheds, window frames and fencing. Such companies only make a few items a day and then dip them in preservative. This means that manual dipping is undertaken during a very short time during the day. For manual dipping the Dipping Model 1 data (p. 26 of User Guidance, 2002) is recommended as it covers manual dipping of wooden articles in open tanks. The model is appropriate to assess the dermal and inhalation exposure to aerosols.		
	Parameters	Value
Tier 1	% of active substance in the biocidal product Copper (II) hydroxide Cu (II)	 0.13% 0.084%
	% of substance of concern in the biocidal product Monoethanolamine (MEA)	 0.38%
	Dilution of the applied product	1% (worst case)
	Body weight[2]	60 kg
	Inhalation rate[2]	1.25 m^3/h
	Indicative body dermal exposure[1]	178 mg/min
	Potential dermal exposure on hands (gloves)[1]	25.7 mg/min
	Indicative inhalation exposure[1]	< 1 mg/m^3
	Dermal absorption[3]: Copper (II) MEA	 5% 100%
	Penetration through PPE (body) = no PPE	100%
	Exposure duration[4]	30 min
	Penetration through RPE	100%

[1] BHHEM, 2015, p.309: Dipping wooden articles (fences, window frames) in tanks and coating with fluid by pouring and scrubbing.
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products. Inhaled uptake 100% (TNsG User Guidance p. 45 and MOTA v. 6)
[3] CAR and CoRAP.
[4] HEEG Opinion 8: Defaults and appropriate models to assess human exposure for dipping processes (PT 8). Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure 'Methods and models to assess exposure to biocidal products in different product types' Version 4.

Calculations for Scenario [9]

See calculations in Annex 3.2

Summary table: estimated systemic exposure to Cu (II) from industrial uses (mg/kg bw/d)

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 9	1/gloves	--	4.27E-03	--	4.27E-03
Summary table: estimated systemic exposure to MEA from industrial uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 9	1/gloves	--	3.87E-01	--	3.87E-01

Further information and considerations on scenario [9]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Combined scenarios
Not applicable

Secondary exposure

Trained professional secondary exposure is foreseen for this product when activities are performed on the treated wood. The exposed professional for this type of work is supposed different than the professional doing the primary exposure. This task will induce an inhalation and dermal exposure.

Scenario [2] Sanding treated timber

Description of Scenario 2		
Secondary exposure – Adult (trained professional) sanding treated timber (chronic phase) Exposure of professional towards dust during sanding of treated wood was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50 (when in dermal contact with treated timber, the user is exposed to the active substance contained in the outer 1 cm layer of the timber). The highest application rate of 22.18 g product/m^3 of timber is equivalent to 0.03 mg/cm^3 DDAC, 0.09 mg/cm^3 copper (II) hydroxide and 0.25 mg/cm^3 monoethanolamine. Exposure is through the inhalation and dermal routes.		
	Parameters	Value
Tier 1	Product retention	22.18 g/m^3

	% of active substance in the biocidal product (worst case dilution of 3%) Cooper (II) hydroxide Cu (II)	 0.39 % 0.25%
	% of substance of concern in the biocidal product (worst case dilution of 3%) Monoethanolamine (MEA)	1.14 %
	Depth of treated timber containing active substance to which user is exposed	1 cm
	Exposure$_{inhalation}$	
	Inhalation rate[2]	1.25 m^3/h
	Body weight adult[2]	60 kg
	Exposure for wood dust during sanding for 60 min[1]	5 mg/m^3
	Duration of the work	360 minutes (6 hours)
	Density of wood[3]	0.4 g/cm^3
	Air inhaled in 6h	7.5 m^3
	Total amount of wood dust inhaled	37.5 mg
	Volume of wood inhaled	9.37E-02 cm^3
	Inhalatory uptake	100%
	Exposure$_{dermal}$	
	Hand inner surface area (half of both hands area[2])	410 cm^2
	% of hand contaminated during sanding[4]	20%
	Transfer coefficient (rough sawn wood, dried fluid)[2]	2%
	Dermal absorption[5]: Copper (II) Monoethanolamine (MEA)	 5% 100%

[1] *TNsG on Human Exposure (2002) Part 3, Page 50*
[2] *Biocides Human Health Exposure Methodology, Oct 2015*
[3] *MOTA, 2013 from TM III 2008*
[4] *TNsG 2002, User Guidance version 1, p52*
[5] *CAR and CoRAP.*

Calculations for Scenario 2: Trained Professional – sanding treated wood posts
Please for details calculations refer to annex 3.2.

Summary table: estimated systemic exposure to Cu (II) from trained professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 2	1/none	8.66E-05	7.58E-05	--	1.62E-04
Summary table: estimated systemic exposure to MEA from trained professional uses (mg/kg bw/d)					

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 2	1/none	3.95E-04	6.91E-03	--	7.31E-03

Further information and considerations on Scenario [2]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Further Calculations for Scenario [2]
Not applicable

Scenario [10] Sanding treated timber

Description of Scenario 10		
Secondary exposure – Adult (trained professional) sanding treated timber (chronic phase) Exposure of professional towards dust during sanding of treated wood was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50 (when in dermal contact with treated timber, the user is exposed to the active substance contained in the outer 1 cm layer of the timber). The highest application rate of 1.16 g product/m^2 of timber. Exposure is through the inhalation and dermal routes.		
	Parameters	Value
Tier 1	Product retention	0.116 mg/cm^2
	% of active substance in the biocidal product (worst case dilution of 1%) Cooper (II) hydroxide Cu (II)	 0.13 % 0.084%
	% of substance of concern in the biocidal product (worst case dilution of 1%) Monoethanolamine (MEA)	0.38 %
	Depth of treated timber containing active substance to which user is exposed	1 cm
	$Exposure_{inhalation}$	
	Inhalation rate[2]	1.25 m^3/h
	Body weight adult[2]	60 kg
	Exposure for wood dust during sanding for 60 min[1]	5 mg/m^3
	Duration of the work	360 minutes (6 hours)

	Density of wood[3]	0.4 g/cm^3
	Air inhaled in 6h	7.5 m^3
	Total amount of wood dust inhaled	37.5 mg
	Volume of wood inhaled	9.37E-02 cm^3
	Inhalatory uptake	100%
	Exposure$_{dermal}$	
	Hand inner surface area (half of both hands area[2])	410 cm^2
	% of hand contaminated during sanding[4]	20%
	Transfer coefficient (rough sawn wood, dried fluid)[2]	2%
	Dermal absorption[5]: Copper (II) Monoethanolamine (MEA)	 5% 100%

[1] TNsG on Human Exposure (2002) Part 3, Page 50
[2] Biocides Human Health Exposure Methodology, Oct 2015
[3] MOTA, 2013 from TM III 2008
[4] TNsG 2002, User Guidance version 1, p52
[5] CAR and CoRAP.

Calculations for Scenario 10: Trained Professional – sanding treated wood posts
Please for details calculations refer to annex 3.2.

Summary table: estimated systemic exposure to Cu (II) from trained professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 11	1/none	1.53E-07	1.33E-07	--	2.87E-07
Summary table: estimated systemic exposure to MEA from trained professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 11	1/none	6.94E-07	1.20E-05	--	1.27E-05

Further information and considerations on Scenario [10]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Further Calculations for Scenario [10]

Not applicable

Combined scenarios
Total exposure of trained professionals (industrial users) for the use of FKR-ACQ EXTRA is estimated by a combination of different scenarios:

Summary table: estimated systemic exposure to Cu (II) from trained professional uses (mg/kg bw/d)					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 1+2	1	1.86E-04	1.41E-02	--	1.43E-02
Scenarios 9+11	1	1.53E-07	5.41E-03	--	5.41E-03
Scenarios 10+11	1	9.42E-06	4.28E-03	--	4.29E-03
Summary table: estimated systemic exposure to MEA from trained professional uses (mg/kg bw/d)					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 1+2	1	8.46E-04	1.28E+00	--	1.28E+00
Scenarios 9+11	1	6.94E-07	4.91E-01	--	4.91E-01
Scenarios 10+11	1	4.03E-05	3.87E-01	--	3.87E-01

Professional users
Not applicable

Non-Professional users
General public secondary exposure is possible for this product. There is a situation where secondary exposure may be expected:

- Acute exposure
  - Non-professional user manipulating the treated wood (Processing treated dried wood)

Scenario [3] Sanding treated wood posts

Description of Scenario 3 – Non-Professional – sanding treated wood posts
Non-Professional – sanding treated wood (acute exposure) Exposure of professional towards dust during sanding of treated wood was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 35.

	Parameters	Value
Tier 1	Product retention	22.18 g/m^3
	Preservative are evenly concentrated in outer wood.	1 cm
	% of active substance in the biocidal product (worst case dilution of 3%) Cooper (II) hydroxide Cu (II)	 0.39 % 0.25 %
	% of substances of concern in the biocidal product (worst case dilution of 3%) Monoethanolamine	 1.14 %
	Exposure$_{inhalation}$	
	Inhalation rate[2]	1.25 m^3/h
	Body weight adult[2]	60 kg
	Exposure for wood dust during sanding for 60 min[1]	5 mg/m^3
	Duration of the work	60 minutes (1 hour)
	Density of wood[3]	0.4 g/cm^3
	Air inhaled in 1 h	1.25 m^3
	Total amount of wood dust inhaled	6.25 mg
	Volume of wood inhaled	1.52E-02 cm^3
	Inhalatory uptake[5]	36% ($Cu(OH)_2$) 100% (MEA)
	Exposure$_{dermal}$	
	Hand inner surface area (half of both hands area[2])	410 cm^2
	% of hand contaminated during sanding[4]	20%
	Transfer coefficient (rough sawn wood, dried fluid)[2]	2%
	Dermal absorption[5]	5% ($Cu(OH)_2$) 100% (MEA)

[1] TNsG on Human Exposure (2002) Part 3, Page 50
[2] Biocides Human Health Exposure Methodology, Oct 2015
[3] MOTA, 2013 from TM III 2008
[4] TNsG 2002, User Guidance version 1, p52
[5] CAR and CoRAP.

Calculations for Scenario [3]: Non-Professional – sanding treated wood posts
Please for details calculations refer to annex 3.2.

Summary table: estimated systemic exposure to Cu (II) from non-professional uses (mg/kg bw/d)

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 3	1/none	1.44E-05	7.58E-05	--	9.02E-05
Summary table: estimated systemic exposure to Monoethanolamine from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 3	1/none	6.58E-05	6.91E-03	--	6.98E-03

Further information and considerations on Scenario [3]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Further Calculations for Scenario [3]
Not applicable

Combined scenarios
Not applicable

Scenario 4 – Cleaning work wear

Description of Scenario 4
Secondary exposure – Adult cleaning work clothes at home (acute phase) At TM III08 it was decided that this scenario should be considered where there was a possibility of workers taking soiled work wear home to launder (e.g. for small-scale dipping processes), but that this exposure scenario was not relevant when wood preservatives were applied under industrial conditions. For industrial treatments, it is assumed that the employer would use professional means (such as a contractor) to launder contaminated work wear and contact with contaminated clothes would be insignificant. This scenario has therefore not been considered any further for this exposure assessment.

Calculations for Scenario [4]:
Not required.

Further information and considerations on scenario [4]:
Not required.

Combined scenarios
Not required.

Scenario [11] Sanding treated wood posts

Description of Scenario 11 – Non-Professional – sanding treated wood posts		
Non-Professional – sanding treated wood (acute exposure) Exposure of professional towards dust during sanding of treated wood was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 35.		
	Parameters	Value
Tier 1	Product retention	0.116 mg/cm^2
	Preservative are evenly concentrated in outer wood.	1 cm
	% of active substance in the biocidal product (worst case dilution of 3%) Cooper (II) hydroxide Cu (II)	 0.13 % 0.084 %
	% of substances of concern in the biocidal product (worst case dilution of 3%) Monoethanolamine	 0.38 %
	Exposure$_{inhalation}$	
	Inhalation rate[2]	1.25 m^3/h
	Body weight adult[2]	60 kg
	Exposure for wood dust during sanding for 60 min[1]	5 mg/m^3
	Duration of the work	60 minutes (1 hour)
	Density of wood[3]	0.4 g/cm^3
	Air inhaled in 1 h	1.25 m^3
	Total amount of wood dust inhaled	6.25 mg
	Volume of wood inhaled	1.52E-02 cm^3
	Inhalatory uptake[5]	36% ($Cu(OH)_2$) 100% (MEA)
	Exposure$_{dermal}$	
	Hand inner surface area (half of both hands area[2])	410 cm^2
	% of hand contaminated during sanding[4]	20%
	Transfer coefficient (rough sawn wood, dried fluid)[2]	2%
	Dermal absorption[5]	5% ($Cu(OH)_2$) 100% (MEA)

[1] TNsG on Human Exposure (2002) Part 3, Page 50
[2] Biocides Human Health Exposure Methodology, Oct 2015
[3] MOTA, 2013 from TM III 2008
[4] TNsG 2002, User Guidance version 1, p52.
[5] CAR and CoRAP.

Calculations for Scenario [11]: Non-Professional – sanding treated wood posts

Please for details calculations refer to annex 3.2.

Summary table: estimated systemic exposure to Cu (II) from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 11	1/none	2.56E-08	1.33E-07	--	1.59E-07
Summary table: estimated systemic exposure to Monoethanolamine from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 11	1/none	1.16E-07	1.20E-05	--	1.22E-05

Further information and considerations on Scenario [11]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Further Calculations for Scenario [11]
Not applicable

Combined scenarios
Not applicable

Scenario 12 – Cleaning work wear

Description of Scenario 12
Secondary exposure – Adult cleaning work clothes at home (acute phase) At TM III08 it was decided that this scenario should be considered where there was a possibility of workers taking soiled work wear home to launder (e.g. for small-scale dipping processes), but that this exposure scenario was not relevant when wood preservatives were applied under industrial conditions. For industrial treatments, it is assumed that the employer would use professional means (such as a contractor) to launder contaminated work wear and contact with contaminated clothes would be insignificant. This scenario has therefore not been considered any further for this exposure assessment.

Calculations for Scenario [12]:
Not required.

Further information and considerations on scenario [12]:
Not required.

Combined scenarios

Not required.

Indirect exposure of the general public

General public (non-professional) secondary exposure is possible for this product. There are different situations where indirect exposure may be expected.

- Acute exposure: toddler chewing wood off-cut.
- Chronic exposure: toddler playing and mouthing weathered playground structure outdoors.

Scenario [5] - Toddler chewing wood off-cut

Description of Scenario 5 – Toddler chewing wood off-cut		
Toddler, general public – Toddler chewing wood off-cut (acute exposure) The relevant exposure route is oral. This is an incidental event and the exposure duration is therefore best described as acute. This scenario is considered to represent the worst case for secondary oral exposure. Exposure of toddler chewing wood off-cut was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50.		
	Parameters	Value
Tier 1	Product retention	22.18 g/m^3
	Size of the wood chip[1]	16 cm^3
	Preservative are evenly concentrated in outer wood.	1 cm
	% of active substance in the biocidal product (worst case dilution of 3%) Cooper (II) hydroxide Cu (II)	 0.39 % 0.25 %
	% of substances of concern in the biocidal product (worst case dilution of 3%) Monoethanolamine	 1.14 %
	Extraction of active substance when chewing[1]	10%
	Oral absorption[3]: Copper (II) hydroxide Monoethanolamine	 36% 100%
	Body weight toddler[2]	10 kg

[1] *TNsG 2002, User Guidance version 1, p56*
[2] *Biocides Human Health Exposure Methodology, Oct 2015.*
[3] *CARs and CoRAP.*

Calculations for Scenario [5]: Toddler chewing wood off-cut
Please for details calculations refer to annex 3.2.

Summary table: estimated systemic exposure to Cu (II) from non-professional uses (mg/kg bw/d)

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 5	1/none	--	--	3.21E-03	3.21E-03
Summary table: estimated systemic exposure to monoethanolamine from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 5	1/none	--	--	4.05E-02	4.05E-02

Further information and considerations on scenario [5]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Further Calculations for Scenario [5]
Not applicable

Combined scenarios
Not applicable

Scenario [6] – Playing on and mouthing weathered structure outdoors

Description of Scenario 6 – Toddler– playing on and mouthing weathered structure outdoors		
Toddler, general public – Toddler– playing on and mouthing weathered structure outdoors (chronic exposure) The relevant exposure routes are dermal and oral. Duration can be up to chronic, assuming that playing in the environment may happen daily. This scenario is considered to represent the worst case for secondary chronic exposure. Exposure of toddler playing on and mouthing weathered structure outdoors the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50.		
	Parameters	Value
Tier 1	Product retention	22.18 g/m^3
	% of active substance in the biocidal product (worst case dilution of 3%) Cooper (II) hydroxide Cu (II)	 0.39 % 0.25 %

	% of substances of concern in the biocidal product (worst case dilution of 3%) Monoethanolamine	 1.14 %
	Body weight[2]	10 kg
	Exposure$_{dermal}$	
	Hand surface area[2]	230.4 cm^2
	% of hand contaminated[1]	20%
	Transfer coefficient (rough sawn wood, dried fluid)[2]	2%
	Dermal absorption[3]: Copper (II) hydroxide Monoethanolamine	 5% 100%
	Exposure$_{inhalation}$	
	surface of wood chip ingested	50 cm^2
	Oral absorption[3]: Copper (II) hydroxide Monoethanolamine	 36% 100%

[1] TNsG 2002, User Guidance version 1, p53
[2] Biocides Human Health Exposure Methodology, Oct 2015
[3] *CARs and CoRAP.*

Calculations for Scenario 6: Toddler– playing on and mouthing weathered structure outdoors
Please for details calculations refer to annex 3.2.

Summary table: estimated systemic exposure to Cu (II) from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 6	1/none	--	2.57E-04	9.98E-03	1.02E-02
Summary table: estimated systemic exposure to monoethanolamine from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 6	1/none	--	1.26E-01	2.34E-02	1.50E-01

Further information and considerations on scenario [6]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Combined scenarios
Not applicable

Scenario 7 – Inhalation of volatilised residues indoors (chronic exposure)

Professional and general public may be exposed to volatilised residues from treated wood installed indoors. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, it might not be necessary to calculate the exposure to volatilised residues:

- For copper (II) hydroxide:

$$\frac{0.328\,.mw\,.vp}{AEL_{long-term}} = \frac{0.328 * 97.54 * 1.0 * 10^{-5}}{0.063} = 5.08 * 10^{-3}$$

  Remark: the mw (molecular weight), vp (vapour pressure) and $AEL_{long\text{-}term}$ come from the Assessment Report on copper (II) hydroxide (RMS FR, September 2011).

- For Monoethanolamine:

$$\frac{0.410\,.mw\,.vp}{AEC_{long-term\,(workers)}} = \frac{0.410 *\ 68{,}10 * 50}{2.5} = 558$$

$$\frac{0.410\,.mw\,.vp}{AEC_{long-term\,(general\ public)}} = \frac{0.410 *\ 68{,}10 * 50}{0.5} = 2790$$

  Remark: the mw (molecular weight), vp (vapour pressure) and $AEC_{long\text{-}term}$ come from the ECHA database.

The result of this equation is lower than 1 for copper (II) hydroxide. The **exposure to volatilised residues indoor** can be considered **negligible** for professional and general public for these active substances.

The result of this equation is higher than 1 for monoethanolamine (substance of concern). The **exposure to volatilised residues** indoor cannot be considered negligible for professional and general public for this substance. This exposure is therefore considered into the scenarios **for monoethanolamine only**.

Description of Scenario 7– Inhalation of volatilised residues indoors		
For copper (II) hydroxide exposure to volatilized residues indoor can be considered negligible based on HEEG opinion 13 (see above). However, for monoethanolamine, based on HHEG opinion 13, exposure to volatilized residues indoor can not be considered negligible and have been calculated. A model for inhalation of volatilised residue from treated wood indoors has been provided in the TNsG (Part 3, p.50). The model assumes that the room is moderately ventilated, that 1% of the saturated vapour concentration (SVC) will be available for inhalation and that residence time is 18 hours per day. The model has been superseded by HEEG Opinion 13, MOTA Version 5 (published 2013) which stipulates that a 24 hour exposure period and no ventilation rate (100% SVC available for inhalation) are assumed as part of the first tier assessment.		
	Parameters	Value
Tier 1	Vapour pressure[1]	50 Pa (20°C)
	Molecular weight[1]	68.10 g/mol
	Gas constant	8.314 J/mol/K

	Temperature (degrees Kelvin)	298 K
	Saturated vapour concentration (SVC)	1.37 g/m^3
	Body weight[2]	Adult: 60 kg Child: 23.9 kg Toddler: 10 kg Infant: 8 kg
	Inhalation rate[2]	Adult: 16.0 m^3 air/24h Child: 12.0 m^3 air/24h Toddler: 8.00 m^3 air/24h Infant: 5.4 m^3 air/24h
	Duration	24 hours

[1] ECHA database and monoethanolamine SDS.
[2] Biocides Human Health Exposure Methodology, Oct 2015.

Calculations for Scenario 7 – Inhalation of volatized residues indoors
Please for details calculations refer to annex 3.2.

Summary table: estimated systemic exposure to MEA from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 7	1/none	366 (adult) 689 (child) 1100 (toddler) 926 (infant)	--	--	366 (adult) 689 (child) 1100 (toddler) 926 (infant)

Further information and considerations on scenario [7]

For DDAC no systemic exposure assessment is required as only local effects (irritation/corrosion) have been identified. No AEC for respiratory irritation is available, but considering the low volatility of the substance (vapour pressure in the order of magnitude of 0.000001 Pa) no concern has been identified with regard to this endpoint.

For pure monoethanolamine (MEA), the screening criterion according to HEEG Opinion 13 is above 1. However, the product does not contain pure monoethanolamine but a compound of monoethanolamine with cooper (II) hydroxide. No vapour pressure data is available for this complex mixture but volatility is assumed to be significantly reduced compared to that of monoethanolamine. Also the toxicity of this compound is considered to be lower based on the limited data available. Thus, no risk is anticipated with regard to inhalation of volatilized residues of the adduct of MEA with cooper (II) hydroxide.

Combined scenarios
Total exposure of non-professionals (general public) for the use of FKR-ACQ EXTRA is estimated by a combination of different scenarios:

Summary table: combined secondary systemic exposure to Cu (II) from non-professional uses (mg/kg bw/d)

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 5+6 (toddler)	1/none	--	1.32E-02	2.57E-04	1.34E-02
Summary table: combined secondary systemic exposure to MEA from non-professional uses (mg/kg bw/d)					
Scenario 5+6 (toddler)	1/none	--	1.67E-01	2.34E-02	1.90E-01

Scenario [13] - Toddler chewing wood off-cut

Description of Scenario 13 – Toddler chewing wood off-cut		
Toddler, general public – Toddler chewing wood off-cut (acute exposure) The relevant exposure route is oral. This is an incidental event and the exposure duration is therefore best described as acute. This scenario is considered to represent the worst case for secondary oral exposure. Exposure of toddler chewing wood off-cut was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50.		
	Parameters	Value
Tier 1	Product retention	0.116 mg/cm^2
	Size of the wood chip[1]	16 cm^2
	Preservative are evenly concentrated in outer wood.	1 cm
	% of active substance in the biocidal product (worst case dilution of 3%) Cooper (II) hydroxide Cu (II)	 0.13 % 0.084 %
	% of substances of concern in the biocidal product (worst case dilution of 3%) Monoethanolamine	 0.38 %
	Extraction of active substance when chewing[1]	10%
	Oral absorption[3]: Copper (II) hydroxide Monoethanolamine	 36% 100%
	Body weight toddler[2]	10 kg

[1] *TNsG 2002, User Guidance version 1, p56*
[2] *Biocides Human Health Exposure Methodology, Oct 2015.*
[3] *CARs and CoRAP.*

Calculations for Scenario [13]: Toddler chewing wood off-cut
Please for details calculations refer to annex 3.2.

Summary table: estimated systemic exposure to Cu (II) from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 5	1/none	--	--	5.60E-06	5.60E-06

Summary table: estimated systemic exposure to monoethanolamine from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 5	1/none	--	--	7.05E-05	7.05E-05

Further information and considerations on scenario [13]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Further Calculations for Scenario [13]
Not applicable

Combined scenarios
Not applicable

Scenario [14] – Playing on and mouthing weathered structure outdoors

Description of Scenario 14 – Toddler– playing on and mouthing weathered structure outdoors		
Toddler, general public – Toddler– playing on and mouthing weathered structure outdoors (chronic exposure) The relevant exposure routes are dermal and oral. Duration can be up to chronic, assuming that playing in the environment may happen daily. This scenario is considered to represent the worst case for secondary chronic exposure. Exposure of toddler playing on and mouthing weathered structure outdoors the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50.		
	Parameters	Value
Tier 1	Product retention	0.116 mg/cm^2
	% of active substance in the biocidal product (worst case dilution of 3%) Cooper (II) hydroxide Cu (II)	 0.13 % 0.084 %

	% of substances of concern in the biocidal product (worst case dilution of 3%) Monoethanolamine	 0.38 %
	Body weight[2]	10 kg
	Exposure$_{dermal}$	
	Hand surface area[2]	230.4 cm^2
	% of hand contaminated[1]	20%
	Transfer coefficient (rough sawn wood, dried fluid)[2]	2%
	Dermal absorption[3]: Copper (II) hydroxide Monoethanolamine	 5% 100%
	Exposure$_{inhalation}$	
	surface of wood chip ingested	50 cm^2
	Oral absorption[3]: Copper (II) hydroxide Monoethanolamine	 36% 100%

[1] TNsG 2002, User Guidance version 1, p53
[2] Biocides Human Health Exposure Methodology, Oct 2015
[3] *CARs and CoRAP.*

Calculations for Scenario 14: Toddler– playing on and mouthing weathered structure outdoors
Please for details calculations refer to annex 3.2.

Summary table: estimated systemic exposure to Cu (II) from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 6	1/none	--	4.51E-07	1.75E-05	1.80E-05
Summary table: estimated systemic exposure to monoethanolamine from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 6	1/none	--	4.08E-05	2.20E-04	2.61E-04

Further information and considerations on scenario [14]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for DDAC. Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Scenario 15 – Inhalation of volatilised residues indoors (chronic exposure)
See scenario 7 for better information.

Combined scenarios
Total exposure of non-professionals (general public) for the use of FKR-ACQ EXTRA is estimated by a combination of different scenarios:

Summary table: combined secondary systemic exposure to Cu (II) from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 13+14 (toddler)	1/none	--	2.31E-05	4.51E-07	2.36E-05
Summary table: combined secondary systemic exposure to monoethanolamine from non-professional uses (mg/kg bw/d)					
Scenario 13+14 (toddler)	1/none	--	2.91E-04	4.08E-05	3.32E-04

Monitoring data
Not applicable.

Dietary exposure
No exposure is foreseen as regards to the intended use of the product. However the following RMM was found on the label and is highly advised in order to avoid any misuses of the product:

"Do not apply the product on wood which may come into contact with food, feedstuff or livestock".

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses of DDAC			
	Sector of use[1]	**Intended use**	**Reference value(s)[2]**
1.	Plant protection product	Disinfection of horticulture vessels, surfaces and equipment. Withdrawal authorisation by 20/06/2013. Max period of grace: 20/03/2014.[3]	MRL[4]
2.	Veterinary use	Pharmacologically active substance	MRL[5]
3.	Food additive	Indirect Additive	FDA Center for Food Safety and Applied Nutrition (CFSAN)[6]
Summary table of other (non-biocidal) uses of Copper (II) hydroxide			

	Sector of use[1]	**Intended use**	**Reference value(s)[2]**
1.	Plant protection product	Approved under Regulation Nº 1107/2009 [7]	MRL[8]
2.	Veterinary use	Pharmacologically active substance	MRL[9]

[1] e.g. plant protection products, veterinary use, food or feed additives
[2] e.g.: MRL: maximum residues levels
[3] 2009/70/EC, Reg. (EU) No 540/2011
[4] Reg. (EU) No 1119/2014
[5] EMEA/MRL/306/97-FINAL
[6] Title 21 of the U.S. Code of Federal Regulations (21 CFR): 178.1010
[7] Reg. (EU) No 232/2015
[8] Reg. (EC) No 149/2008
[9] EMEA/MRL/431/98-FINAL

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

DDAC, Copper (II) hydroxide and the biocidal product are produced in the EU. The exposure during the production of the active substances and the formulation of the biocidal product are not assessed by the rapporteur under the requirements of the BPR. However, the rapporteur assumes that the production is performed in conformity with national and European occupational safety and health regulations.

The workers of hazardous waste treatment facilities dealing with the unused biocidal product and with the contaminated packaging are also protected by other pieces of legislation than BPR.

The exposure from disassembling and disposal of the wooden articles at the end of their service life is covered by the dermal exposure for the scenario 'Sanding (professional)' (see above).

Aggregated exposure

Not applicable.

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake Cu(II) (mg / kg bw / d)**	**Estimated total uptake MEA (mg / kg bw / d)**
1. water-based double Vacuum pressure	Trained professional	Tier 1 / no PPE	1.21E-01	1.10E+01
		Tier 2 / Gloves and coated coverall	1.41E-02	1.27E+00
2. Processing Treated dried wood	Trained Professional	Tier 1 / no PPE	1.62E-04	7.31E-03
3. Processing Treated dried wood	Non-professional	Tier 1	9.02E-05	6.98E-03
4. Cleaning work wear	Non-professional	Tier 1	--	--
5. Chewing wood off-cut	General public	Tier 1	3.21E-03	4.05E-02
6. Playing and mouthing playground structure	General public	Tier 1	1.02E-02	1.50E-01
7. Inhalation volatized residues	General public	Tier 1	--	366 (adult) 689 (child) 1100 (toddler) 926 (infant)
8. Fully dipping treatment	Trained professional	Tier 1/gloves	2.69E-02	2.44E+00
		Tier 2/gloves & coated coverall	5.41E-03	4.91E-01
9. Manual dipping treatment	Trained professional	Tier 1/gloves	4.27E-03	3.87E-01
10. Sanding treatment timber	Trained professional	Tier 1/no PPE	2.87E-07	1.27E-05
11. Sanding treatment timber	Non-professional	Tier 1	1.59E-07	1.22E-05

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake Cu(II) (mg / kg bw / d)**	**Estimated total uptake MEA (mg / kg bw / d)**
12. Cleaning work wear	Non-professional	Tier 1	--	--
13. Chewing wood off-cut	General public	Tier 1	5.60E-06	7.05E-05
14. Paying and mouthing weathered	General public	Tier 1	1.80E-05	2.61E-04
15. Inhalation volatized residues	General public	Tier 1	--	366 (adult) 689 (child) 1100 (toddler) 926 (infant)

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation for DDAC

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$AEL_{short-term}$					-
$AEL_{medium-term}$					-
$AEL_{long-term}$					-
$NOAEC_{dermal}$	2-week skin irritation study with rats				0.3%
$NOAEC^{1}_{dermal}$	5 days application to rat skin				0.6%
$NOAEC_{oral}$	1-year oral gavage study in dogs				0.03%
$ARfD^{2}$					
ADI^{2}					

[1] *The CAR for DDAC (IT CA, 2015) derived a dermal NOAEC of 0.3% based on a 2-week repeated-exposure rat study, though a NOAEC for skin irritation in the rat of 0.6% was derived following 5 days application. The latter value can be considered to better reflect the acute irritant effects of DDAC, and at WGIV2017 (Conclusions – WGV2017_TOX_6-1) it was agreed that the dermal NOAEC of 0.6% should be used in risk assessment for the dermal route.*
[2] *An ARfD and an ADI have not been derived for DDAC used in biocidal products (PT 08).*

Reference values to be used in Risk Characterisation for Copper (II) hydroxide

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short-term}$	--	4.1 mg/kg bw/d	50 (inter-& intra-specific differences)	No (100%)	0.082 mg/kg bw/d
$AEL_{medium-term}$	--	4.1 mg/kg bw/d	50 (inter-& intra-specific differences)	No (100%)	0.082 mg/kg bw/d
$AEL_{long-term}$	--	4.1 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.041 mg/kg bw/d
$ARfD^{2}$					
ADI^{2}					0.15 mgCu/kg

					bw/d

[1] *EU agreed AEL values (please refer to the Assessment Report for Copper(II) hydroxide 2011)*
[2] *An ARfD and an ADI have not been derived for Copper (II) hydroxide used in biocidal products (PT 08). An ADI value of 0.15 mgCu/kg bw/d is nevertheless available in the literature (EFSA, 2008).*

Reference values to be used in Risk Characterisation for ethanolamine (calculated by eMSCA Susbtance Evaluation Report, UK 2016.)

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
DNEL Worker DNEL long-term dermal – systemic	Two-generation reproduction study in rats	300 mg/kg/d	100	100	3 mg/kg bw/d
DNEL Worker DNEL long-term inhalation – local/systemic	[1]SCOEL Recommendation: 8-hour TWA				2.5 mg/m^3
DNEL Worker DNEL acute inhalation	[1]SCOEL Recommendation: STEL (15 mins)				7.6 mg/m^3
DNEL General population DNEL acute inhalation	To take account of the greater intra-species variability of the general population compared with workers, an additional assessment factor of 2 will be applied to the STEL (15 minutes) of 7.6 mg/m^3				3.8 mg/m^3
DNEL General population DNEL long-term inhalation – local/systemic	To take account of the greater intra-species variability of the general population compared with workers, an additional factor of 2 will be applied to the 8-hour TWA of 2.5 mg/m^3, giving a value of 1.25 mg/m^3 (0.5 ppm). Adjustment of the 8-hour TWA to 24 hours (0.5 ppm x 8 hours / 24 hours = 0.2 ppm) gives a value of 0.5 mg/m^3.				0.5 mg/m^3
DNEL General population long-term dermal systemic	Two-generation reproduction study in rats	300 mg/kg/d	200	100	1.5 mg/kg.bw/d
DNEL General population long-term oral systemic	Two-generation reproduction study in rats	300 mg/kg/d	200	100	1.5 mg/kg.bw/d

[1] *Recommendation from Scientific Expert Group on Occupational Exposure Limits for ethanolamine (SCOEL/SUM/24). 1996.*

Maximum residue limits or equivalent
No MRL for biocidal uses of the active substances DDAC and Copper (II) hydroxide are set.

Risk for trained professional(industrial) users··· primary exposure
Trained professional users are expected to use the biocidal product on a daily basis. Hence exposure levels are compared to $AEL_{long\ term}$ (copper (II) hydroxide) or $DNEL_{long\ term\ (workers)}$ (monoethanolamine) for risk assessment purposes.
The exposure assessment for trained professional under reasonable worst case assumptions (water-based double vacuum process, fully automatic dipping or manual dipping), yields a potential dermal exposure leading to a systemic and local are shown in tables below.

The comparison to the respective $AEL_{long\ term}$ (copper (II) hydroxide) or $DNEL_{long\ term\ (workers)}$ shows that the use of FKR-ACQ EXTRA no cause health risk for trained professionals wearing protective equipment (Tier 2), as indicated by the resulting values expressed as %AEL or %DNEL.

Systemic effects

Systemic effects: exposure to Cu (II) from trained professional uses

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1	1	4.1	0.041	0.121	296	no
Scenario 1	2	4.1	0.041	0.0141	34.5	yes
Scenario 8	1	4.1	0.041	0.027	65.7	yes
Scenario 8	2	4.1	0.041	0.0054	13.2	yes
Scenario 9	1	4.1	0.041	0.0043	10.4	yes

Systemic effects: exposure to Monoethanolamine from trained professional uses

Task/ Scenario	Tier	$DNEL_{inhalation}$ mg/m³	Estimated uptake mg/m³	Estimated uptake/ $DNEL_{inhalation}$ (%)	Acceptable (yes/no)
Scenario 1	1	2.5	0.022	0.866	yes
Scenario 1	2	2.5	0.022	0.866	yes
Scenario 8	1	2.5	--	--	--
Scenario 8	2	2.5	--	--	--
Scenario 9	1	2.5	0.0038	0.15	yes

Task/ Scenario	Tier	NOAEL LOAEL mg/kg bw/d	$DNEL_{dermal}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ $DNEL_{dermal}$ (%)	Acceptable (yes/no)
Scenario 1	1	300	3	11	367	no
Scenario 1	2	300	3	1.27	42.4	yes
Scenario 8	1	300	3	2.44	81.5	yes
Scenario 8	2	300	3	0.49	16.4	yes
Scenario 9	1	300	3	0.39	12.9	yes

Task/ Scenario	Tier	Estimated uptake/ $DNEL_{oral}$ (%)	Estimated uptake/ $DNEL_{inhalation}$ (%)	Estimated uptake/ $DNEL_{dermal}$ (%)	Estimated uptake/ $DNEL_{TOTAL}$ (%)	Acceptable (yes/no)
Scenario 1	1	--	0.866	367	368	no
Scenario 1	2	--	0.866	42.4	43.3	yes

Scenario 8	1	--	--	81.5	81.5	yes
Scenario 8	2	--	--	16.4	16.4	yes
Scenario 9	1	--	0.15	12.9	13.1	yes

Combined scenarios
Not relevant.

Local effects

Scenario /Task	Effects in terms of classification	Hazard category	Task	Potential exposure route	Frequency and duration of potential exposure	Degree of potential exposure	RMMs	Necessary PPE	Conclusion on risk
Vacuum pressure treatment – dilution of the product	Skin Corr. 1B (H314) Eye Dam. 1 (H318) STOT SE 3 (H335)	High	Loading product from IBC into a treatment device, dilution with water	skin, eye, inhalation	<few minutes, <1/week	n.r.	Labelling according to the respective classification, transfer in closed system, good ventilation	Appropriate gloves, coated coverall, eye protection, face shield	Acceptable: +Trained workers +Use of appropriate PPE +Low task frequency and duration +Low likelihood of exposure
Vacuum pressure treatment – application	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	Low	Handling treated wood, mainly using a fork-lift truck; restacking fallen wood	skin, eye	<1 h/day, daily	Body potential ~ 25 g/day, hands inside gloves ~ 3 g/day	Transfer using a fork-lift truck, good ventilation	Gloves, coverall, eye protection	Acceptable: +Reversible effects +Trained workers +Use of appropriate PPE

Scenario /Task	Effects in terms of classification	Hazard category	Task	Potential exposure route	Frequency and duration of potential exposure	Degree of potential exposure	RMMs	Necessary PPE	Conclusion on risk
Fully automated dipping - dilution	Skin Corr. 1B (H314) Eye Dam. 1 (H318) STOT SE 3 (H335)	High	Loading product form an IBC into a dipping tank, dilution with water	Skin, eye, inhalation	<few minutes, <1/week	n.r.	Labelling accorging to the respective classification, transfer in a closed system, good ventilation	Appropriate gloves, coated coverall, eye protection, face shield	Acceptable: +Trained workers +Use of appropriate PPE +Low task frecuency and duration +Low likehood of exposure
Fully automated dipping - application	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	Low	Handling treated wood, mainly using a fork-lift truck; restacking fallen wood	Skin, eye	<1 h/day, daily	Body potential ~ 34 g/day, hands inside gloves ~ 4 g/day	Transfer using a fork-lift truck, good ventilation	Gloves, coverall, eye protection	Acceptable: +Reversible effects +Trained workers +Use of appropriate PPE
Manual dipping - dilution	Skin Corr. 1B (H314) Eye Dam. 1 (H318) STOT SE 3 (H335)	High	Loading product into a dipping vessel, dilution with water	Skin, eye, inhalation	<few minutes, <1/week	n.r.	Labelling accorging to the respective classification, good ventilation	Appropriate gloves, coated coverall, eye protection	Acceptable: +Trained workers +Use of appropriate PPE +Low task frecuency and duration

Scenario /Task	Effects in terms of classification	Hazard category	Task	Potential exposure route	Frequency and duration of potential exposure	Degree of potential exposure	RMMs	Necessary PPE	Conclusion on risk
Manual dipping - application	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	Low	Placing wood into a dipping tank, handling wet treated wood with a gloved hand.	Skin, eye	<30 min/day	Body potential ~ 5 g/day, hands inside gloves ~ 0.8 g/day	Immersion of (gloved) hands is avoided, the wood is held in the dipping vessel using a stick.	Gloves, coated coverall, eye protection.	Acceptable: +Reversible effects +Trained workers +Use of appropriate PPE

Conclusion
The risk for industrial users is acceptable provided that appropriate PPE is used, i.e.:

- For dilution of the concentrate: gloves, eye protection, face shield, coated coverall.
- For application: gloves, coverall, eye protection (unless the operator is protected e.g. in the closed cab of a fork-lift truck).

Risk for trained professional and non-professional users – secondary exposure

Trained professional and non-professional secondary exposure is foreseen for this product when activities are performed on the treated wood. The exposed professional for this type of work is supposed different than the professional doing the primary exposure. This task will induce an inhalation and dermal exposure.
Hence, exposure estimates are compared to the relevant chronic AEL (Copper (II) hydroxide) and DNEL (monoethanolamine) for trained professional users and acute AEL (Copper (II) hydroxide) and DNEL (monoethanolamine) for non-professional users.
The exposure assessment for trained professional and non-professionals under reasonable worst case assumptions is showed in tables below.

Systemic effects for trained professional and non-profesional users

Systemic effects: exposure to Copper (II)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 2	1	4.1	0.041	1.62E-04	0.34	yes
Scenario 3	1	4,1	0.082	9.02E-05	0.11	yes
Scenario 10	1	4.1	0.041	2.87E-07	0.0007	yes
Scenario 11	1	4,1	0.082	1.59E-07	0.0002	yes

Systemic effects: exposure to Monoethanolamine

Task/ Scenario	Tier	$DNEL_{inhalation}$ mg/m^3	Estimated uptake mg/m^3	Estimated uptake/ $DNEL_{inhalation}$ (%)	Acceptable (yes/no)
Scenario 2	1	2.5	1.90E-02	0.76	yes
Scenario 3	1	0.5	3.16E-03	0.63	yes
Scenario 10	1	2.5	3.33E-05	0.0013	yes
Scenario 11	1	0.5	5.55E-06	0.0011	yes

Task/ Scenario	Tier	NOAEL (LOAEL) mg/ kg bw /d	$DNEL_{dermal}$ mg/ kg bw /d	Estimated uptake mg/ kg bw /d	Estimated uptake/ $DNEL_{dermal}$ (%)	Acceptable (yes/no)
Scenario 2	1	300	3	6.91E-03	0.23	yes
Scenario 3	1	300	1.5	6.91E-03	0.46	yes
Scenario 10	1	300	3	1.20E-05	4.02E-04	yes

Scenario 11	1	300	1.5	1.33E-07	8.88E-06	yes

Task/ Scenario	Tier	Estimated uptake/ $DNEL_{oral}$ (%)	Estimated uptake/ $DNEL_{inhalation}$ (%)	Estimated uptake/ $DNEL_{dermal}$ (%)	Estimated uptake/ $DNEL_{TOTAL}$ (%)	Acceptable (yes/no)
Scenario 2	1	--	0.76	0.23	0.99	yes
Scenario 3	2	--	0.63	0.46	1.09	yes
Scenario 10	1	--	0.0013	0.0004	0.0017	yes
Scenario 11	2	--	0.0011	0.000089	0.0012	yes

Combined scenarios
Not relevant.

Local effects for trained professional and non-profesional users
There are no local effects anticipated from sanding and other processing of the treated wood.

Conclusion
The risk for trained professional users and non-professional users is acceptable.

Risk for the indirect exposure

Systemic effects for the indirect exposure

Systemic effects: exposure to Copper (II) for toddlers

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 5	1	4,1	0.082	3.21E-03	3.92	yes
Scenario 6	1	4,1	0.082	1.02E-02	12.5	yes
Scenario 13	1	4,1	0.082	5.60E-06	6.83E-03	yes
Scenario 14	1	4,1	0.082	1,85E-05	2.19E-02	yes

Systemic effects: exposure to monoethanolamine for toddlers

Task/ Scenario	Tier	NOAEL (LOAEL) mg/kg bw/d	$DNEL_{oral}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ $DNEL_{oral}$ (%)	Acceptable (yes/no)
Scenario 5	1	300	1.5	4.05E-02	2.70	Yes
Scenario 6	1	300	1.5	1.26E-01	8.43	Yes
Scenario 13	1	300	1.5	7.05E-05	4.70E-03	yes

Scenario 14	1	300	1.5	2.20E-04	1.47E-02	Yes

Task/ Scenario	**Tier**	**NOAEL (LOAEL) mg/ kg bw /d**	**$DNEL_{dermal}$ mg/ kg bw /d**	**Estimated uptake mg/ kg bw /d**	**Estimated uptake/ $DNEL_{dermal}$ (%)**	**Acceptable (yes/no)**
Scenario 5	1	300	1.5	--	--	--
Scenario 6	1	300	1.5	2.34E-02	1.56	yes
Scenario 13	1	300	1.5	--	--	--
Scenario 14	1	300	1.5	4.08E-05	2.72E-03	yes

Task/ Scenario	**Tier**	**Estimated uptake/ $DNEL_{oral}$ (%)**	**Estimated uptake/ $DNEL_{inhalation}$ (%)**	**Estimated uptake/ $DNEL_{dermal}$ (%)**	**Estimated uptake/ $DNEL_{TOTAL}$ (%)**	**Acceptable (yes/no)**
Scenario 5	1	2.7	--	--	2.70	yes
Scenario 6	1	8.43	--	1.56	9.99	yes
Scenario 13	1	0.0047	--	--	0.0047	yes
Scenario 14	1	0.015	--	0.0027	0.017	yes

Combined scenarios

No combined exposure is foreseen.

Local effects

For the scenario 'Child on a playground structure' no local effects are anticipated.

In the case of an infant chewing an off-cut or licking a playground structure, light and transient irritation of oral mucosa is not excluded due to the content of monoethanolamine. However, this effect is of minor importance. In addition, these scenarios are considered uncommon occurrences as parents usually do not allow children to chew preservative treated wood or to lick larger areas on a daily basis.

Conclusion

The risk for the general public is acceptable.

Risk for consumers via residues in food

Not applicable.

No exposure is foreseen as regards to the intended use of the product. However the following RMM is highly advised on the label in order to avoid any misuses of the product:

"Do not apply the product on wood which may come into contact with food, feedstuff or livestock".

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

Cumulative risk assessment is performed according to Guidance on the BPR: Volume III, Assessment & Evaluation (Parts B+C), Version 2.1 – February 2017, (pp 261 & Appendix 4.7, pp 293).

Preliminary step:

According to the CAR for DDAC (IT CA, 2015), systemic effects observed in studies of this a.s. are regarded as secondary to its local irritation/corrosion effects and, consequently, no adverse systemic effects were identified (see under the heading Local effects in Risk assessment for trained professional users).

As the active substance is the Cu^{2+} ion, copper hydroxide is therefore described as the precursor to release of the cupric ion. As a consequence, most copper-containing formulations are described in terms of total copper. It is considered that the fungicidal properties of copper compounds are dependent on the affinity of the copper ion (Cu^{2+}) for different chemical groups within cells, particularly thiol groups, resulting in the non-specific denaturation of proteins and enzymes. In addition, it is thought that the ion can interfere with the activity of the pyruvate dehydrogenase system inhibiting the conversion of pyruvate to acetyl CoA within mitochondria. Copper reacts with most essential elements within a cell. It also reacts with ligands on the cell surface and this can interfere with membrane function. Copper may also act extracellulary in the case of fungi and inhibit the production of fungal extracellular enzymes. Copper in toxic doses acts as a stomach poison.

Ethanolamine is absorbed through the skin, lungs and gastrointestinal tract. It is a normal constituent of the body, and following condensation to phosphatidyl ethanolamine or transformation into phosphatidyl choline can be incorporated into cellular membranes. It can be converted into amino acids or deaminated and used as an energy source. The acute toxicity of ethanolamine is relatively low.

Given their mode of action we can assume that there is no indication of synergy within substances.

A summary of systemic exposures for the scenarios assessed are shown in table below.

Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake Cu(II) (mg / kg bw / d)**	**Estimated total uptake MEA (mg / kg bw / d)**
1. water-based double Vacuum pressure	Trained professional	Tier 1 / no PPE	1.21E-01	1.10E+01
		Tier 2 / Gloves and coated coverall	1.41E-02	1.27E+00
2. Processing Treated dried wood	Trained Professional	Tier 1 / no PPE	1.62E-04	7.31E-03

Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake Cu(II) (mg / kg bw / d)	Estimated total uptake MEA (mg / kg bw / d)
3. Processing Treated dried wood	Non-professional	Tier 1	9.02E-05	6.98E-03
4. Cleaning work wear	Non-professional	Tier 1	--	--
5. Chewing wood off-cut	General public	Tier 1	3.21E-03	4.05E-02
6. Playing and mouthing playground structure	General public	Tier 1	1.02E-02	1.50E-01
7. Inhalation volatized residues	General public	Tier 1	--	366 (adult) 689 (child) 1100 (toddler) 926 (infant)
8. Fully dipping treatment	Trained professional	Tier 1/gloves	2.69E-02	2.44E+00
		Tier 2/gloves & coated coverall	5.41E-03	4.91E-01
9. Manual dipping treatment	Trained professional	Tier 1/gloves	4.27E-03	3.87E-01
10. Sanding treatment timber	Trained professional	Tier 1/no PPE	2.87E-07	1.27E-05
11. Sanding treatment timber	Non-professional	Tier 1	1.59E-07	1.22E-05
12. Cleaning work wear	Non-professional	Tier 1	--	--
13. Chewing wood off-cut	General public	Tier 1	5.60E-06	7.05E-05
14. Paying and mouthing weathered	General public	Tier 1	1.80E-05	2.61E-04
15. Inhalation volatized residues	General public	Tier 1	--	366 (adult) 689 (child) 1100 (toddler) 926 (infant)

TIER 1 and TIER 2:

Tier 1 is an intermediary step to verify risk acceptability for each active ingredient used in the product, as currently performed. It is followed by Tier 2, which involves assessing the combined exposure to the substances of the mixture/biocidal product.

For the toxicological section, primary exposure of trained professionals has been considered and exposure estimations were compared to the chronic AEL for Copper (II) hydroxide or $DNEL_{long\text{-}term\ (workers)}$ for Monoethanolamine. Secondary exposure of consumers / non-professionals has been considered and exposure estimations were compared to the medium term AEL for Copper (II) hydroxide or $DNEL_{long\text{-}term\ (general\ public)}$ for monoethanolamine and also for trained professionals secondary exposure was compared to the chronic AEL for Copper (II) hydroxide or $DNEL_{long\text{-}term\ (workers)}$ for monoethanolamine. Secondary exposure for toddlers was performed according to a long/short term scenarios using chronic/acute AEL/DNEL.

Results of Tier 1 assessments are shown in the following table.

Primary exposure: Trained professional, chronic exposure

Scenario 1 with PPE	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	34.5 %AEL	43.3 %AEL	Acceptable
Tier 2	0.35	0.43	Acceptable
	HI = 0.78		
Scenario 8 with PPE	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	13.2 %AEL	16.4 %AEL	acceptable
Tier 2	0.13	0.16	acceptable
	HI = 0.29		
Scenario 9 without PPE	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	10.4 %AEL	13.1 %AEL	acceptable
Tier 2	0.10	0.13	acceptable
	HI = 0.23		

Secondary exposure: consumer/ non-professional, medium term exposure

Scenario 3	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	0.11 %AEL	1.09 %AEL	acceptable
Tier 2	1.10E-03	1.09E-02	acceptable
	HI = 1.20E-02		
Scenario 11	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	1.94E-04 %AEL	1.12E-03 %AEL	acceptable
Tier 2	1.94E-05	1.12E-05	acceptable
	HI = 1.31E-05		

Secondary exposure: professional, chronic exposure

Scenario 2	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	0.4 %AEL	0.99 %AEL	acceptable
Tier 2	0.004	0.01	acceptable

	HI = 0.014		
Scenario 10	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	6.99E-04 %AEL	1.73E-03 %AEL	acceptable
Tier 2	6.99E-06	1.73E-05	acceptable
	HI = 2.43E-05		

Indirect exposure: toddler, acute exposure

Scenario 5	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	3.92 %AEL	2.70 %AEL	acceptable
Tier 2	3.92E-02	2.70E-02	acceptable
	HI = 6.61E-02		
Scenario 13	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	6.83E-03 %AEL	4.70E-03 %AEL	acceptable
Tier 2	6.83E-05	4.70E-05	acceptable
	HI = 1.15E-04		

Indirect exposure: toddler, chronic exposure

Scenario 6	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	12.5 %AEL	9.99 %AEL	acceptable
Tier 2	0.13	0.1	acceptable
	HI = 0.23		
Scenario 14	**Copper (II)**	**Monoethanolamine**	**conclusion**
Tier 1	2.19E-02 %AEL	1.74E-02 %AEL	acceptable
Tier 2	2.19E-04	1.74E-04	acceptable
	HI = 3.94E-04		

Conclusion:

For trained professional use:

TIER I: Risk assessment is acceptable with gloves and coated coverall during industrial application.

TIER 2: Mixture Risk assessment is acceptable with gloves and coated coverall during industrial application as well.

For the secondary exposure for trained professionals and non-professionals:

TIER I: Risk assessment is acceptable for each substance individually in the product.

TIER 2: Mixture risk assessment is acceptable in T2.

For the indirect exposure of toddlers:

TIER I: Risk assessment is acceptable for each substance in the product after the refined exposure values used.

TIER 2: Mixture risk assessment is acceptable in T2.

Considering that FKR-ACQ EXTRA is only for professional use using PPE and it is assumed that treated wood is coated after drying before further use, and the SoC is expected to be completely evaporated at the time the wood is completely dry, the biocidal product could be considered to be safe. Hence, it can be concluded that the use of wood treated with

FKR-ACQ EXTRA does not pose an acute or chronic health risk for humans using gloves and coated coverall.

2.2.7 Risk assessment for animal health

Materials are treated with biocidal products to protect them from decay. Treated materials can be formed into structures that livestock animals have access to (e.g. wooden fence posts around paddocks), and may become part of animal housing and transport vehicles. In addition, existing structures may be treated with biocides. By chewing on (e.g. horses, rabbits, goats), rubbing against (large slaughter animals) or licking (e.g. ruminants) the treated materials, animals can take up residues of the biocidal product. In addition, volatile substances being released from the treated material may be inhaled. Only a fraction of the application amount will be available to animals and can be quantified by the amount of material an animal comes into contact with and the amount of residue that can be extracted from the material.

Calculation is developed following the example 3.1, in section 6.5.3.1 of the Guidance on the BPR (volume III parts B+C) version 4.0.

Description of Scenario – exposure of animals to treated wood		
For an exposure calculation, the following parameters may be needed. For a complete exposure assessment, the calculation needs to be repeated for beef and dairy cattle, pigs, and goats.		
	Parameters	Value
Tier 1	Product retention	22.18 g/m^3
	% of active substance in the biocidal product (worst case dilution of 3%) Cooper (II) hydroxide	0.39 %
	% of substance of concern in the biocidal product (worst case dilution of 3%) Monoethanolamine	1.14 %
	The outer layer wood	1 cm
	Thickness of surface layer of the wooden wall representing the amount of substance per square meter	0.05 mm
	Body weight	Horse: 400 kg Beef cattle: 500 kg Dairy cattle: 650 kg Fattening pig: 100 kg Breeding pig: 260 kg Slaughter goat: 13 kg Lactating goat: 70 kg
	Body surface area in contact with surface	Horse: 1.62 m^2 Beef cattle: 1.44 m^2 Dairy cattle: 1.68 m^2 Fattening pig: 0.45 m^2 Breeding pig: 0.84 m^2

Description of Scenario – exposure of animals to treated wood		
		Slaughter goat: 0.15 m^2 Lactating goat: 0.45 m^2
	Alveolar ventilation rate	Horse: 43 m^3/d (1773 L/h) Beef cattle: 51 m^3/d (2110 L/h) Dairy cattle: 62 m^3/d (2589 L/h) Fattening pig: 14 m^3/d (601 L/h) Breeding pig: 30 m^3/d (1267 L/h) Slaughter goat: 3 m^3/d (122 L/h) Lactating goat: 11 m^3/d (455 L/h)
	Wood consumption	Horse: 1.9E-05 m^3/d Beef cattle: 2,32E-05 m^3/d Dairy cattle: 3,02E-05 m^3/d Fattening pig: 4,64E-06 m^3/d Breeding pig: 1,21E-05 m^3/d Slaughter goat: 6,04E-07 m^3/d Lactating goat: 3,25E-06 m^3/d
	Wood density	0.4 g/cm^3
	Gas constant	8.314 J/mol/K
	Temperature (degrees Kelvin)	298 K
	Molecular weight (g/mol)	Copper (II) hydroxide: 97.54 Monoethanolamine: 68.10
	Vapor pressure (20ºC)	Copper (II) hydroxide: 1.0E-05 Pa Monoethanolamine: 50 Pa

Calculations for Scenario: exposure of horses to treated wood
Please for details calculations refer to annex 3.2.

Summary table: estimated systemic exposure to Cooper (II) hydroxide in treated woods (mg/kg bw/d)					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario/horse	1	4.30E-05	1.73E-02	3.98E-03	2.14E-02
Scenario/beef cattle	1	4.08E-05	1.23E-02	3.97E-03	1.63E-02
Scenario/dairy cattle	1	3.82E-05	1.11E-02	3.98E-03	1.51E-02
Scenario/fattening pig	1	5.61E-05	1.93E-02	3.97E-03	2.33E-02
Scenario/breeding pig	1	4.62E-05	1.38E-02	3.98E-03	1.79E-02
Scenario/slaughter goat	1	9.24E-05	4.94E-02	3.98E-03	5.34E-02
Scenario/lactating goat	1	6.29E-05	2.75E-02	3.97E-03	3.15E-02

Summary table: estimated systemic exposure to Monoethanolamine in treated woods (mg/kg bw/d)					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario/horse	1	1.50E+02	5.12E-02	1.18E-02	1.50E+02
Scenario/beef cattle	1	1.43E+02	3.64E-02	1.17E-02	1.43E+02
Scenario/dairy cattle	1	1.33E+02	3.27E-02	1.17E-02	1.33E+02
Scenario/fattening pig	1	1.96E+02	5.69E-02	1.17E-02	1.96E+02
Scenario/breeding pig	1	1.61E+02	4.08E-02	1.18E-02	1.61E+02
Scenario/slaughter goat	1	3.23E+02	1.46E-01	1.17E-02	3.23E+02
Scenario/lactating goat	1	2.20E+02	8.13E-02	1.17E-02	2.20E+02

Risk for exposure animals to wood treated

Systemic effects: exposure to Copper (II) hydroxide in treated wood

Exposure scenario	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenario/horse	1	4.1	0.063	2.14E-02	33.92	yes
Scenario/beef cattle	1	4.1	0.063	1.63E-02	25.95	yes
Scenario/dairy cattle	1	4.1	0.063	1.51E-02	23.94	yes
Scenario/fattening pig	1	4.1	0.063	2.33E-02	36.98	yes
Scenario/breeding pig	1	4.1	0.063	1.79E-02	28.36	yes
Scenario/slaughter goat	1	4.1	0.063	5.34E-02	84.89	yes
Scenario/lactating goat	1	4.1	0.063	3.15E-02	50.11	yes

Systemic effects: exposure to monoethanolamine in treated wood

Exposure scenario	**Tier**	**$DNEL_{inhalation}$ mg/m³**	**Estimated uptake mg/m³**	**Estimated uptake/ $DNEL_{inhalation}$ (%)**	**Acceptable (yes/no)**
Scenario/all	1	2.5	1.40E+03	5.60E+04	no

Conclusions:
Every result calculated in Tier I shows that the animal exposure is upper than the default exposure value given in the the Guidance on the BPR (volume III parts B+C) version 4.0,

which is 0.004 mg/kg bw/day. However, if these values are compared to the AEL values for copper (II) hydroxide and monoethanolamine, these suggest that there is risk to the animals due to the co-formulant.

No exposure is foreseen as regards to the intended use of the product. Therefore the risk is controlled for livestock exposure. However the following RMM is highly advised on the label in order to avoid any misuses of the product:

"The biocidal product shall not be used for treatment of wood which is intended for contact with food, feed or livestock".

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The risk assessment provided by the applicant for the product FKR-ACQ EXTRA was con considered acceptable by ES-CA and a new complete evaluation is presented. The environmental exposure assessment of the product FKR-ACQ EXTRA containing DDAC, and Copper dihydroxide and formulated as a wood preservative, was assessed in accordance with the Guidance on the Biocidal Products Regulation (Volume IV Environment, version 2.0, October 2017) and the technical agreements for biocides (TAB, Version 2.1, December 2019). This assessment was likewise performed following the recommendations of the Revised Emission Scenario Document for Wood Preservatives (OECD, 2013)

FKR-ACQ EXTRA is intended to be used for the preventive treatment of wood by industrial, trained professional users, by dipping/immersion and vacuum pressure impregnation for use classes 1 – 4a.

According to OECD (2013), industrial emissions are considered to occur during the treatment process including post-treatment conditioning as well as during storage of treated wood prior to shipment. No quantitative exposure assessment has been carried out for the life cycle stages "production" and "formulation of the biocidal product" as environmental exposure due to manufacturing of the active substance is covered by other legislation and will therefore not be considered here.

Industrial local floors are cemented, so run-off is generally collected and recycled via drip pads. Release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, and the corresponding emission pathway (facility drain to surface water via STP) has not been considered, providing specific risk mitigation measures instead to minimize the environmental concern at this stage.

According to the OECD Series on Emission Scenario Documents, Nº 2, Part 1 (Emission Scenario Document for Wood Preservatives), potential emissions from treated wood as "Use Class 1" and "Use Class 2" to the outer environment are considered negligible and therefore, no exposure assessment has been performed for the life cycle stage "service life of the treated wood" intended for use classes 1 and 2.

Following the "Thematic Strategy on Sustainable Use of Plant Protection Products" (Federal Germany Environmental Agency, 2012) pressure methods such as double-vacuum pressure treatments in closed facilities are considered to be the safest application methods. Furthermore, deep penetrating treatments of wood under pressure result in a better (i.e. deeper) penetration of the wood preservative into the wood thus reducing the leachability and emission from the wood during its service life. However, no field-leaching test has been performed to support these findings for FKR-ACQ EXTRA. Therefore, the emissions to the environment of active substances as well as substances of concern from the stage treated wood in-service were calculated assuming 50% of leaching at time 1 and 100% of leaching at time 2, following the approach agreed during the 2nd EU Leaching Workshop on Wood Preservatives.

The product contains the active substances Didecyldimethylammonium chloride at 4.12 % w/w, Copper dihydroxide at 12.86 % w/w. Additionally, the product contains two substances of concern:

- Propan-2-ol (IPA): is an approved active substance for PT 1, 2 and 4and is present in the biocidal product at a concentration above the threshold of 0.1%.

- 2-aminoethanol (MEA): according to the current knowledge this substance is classified as Aquatic Chronic 3. This substance is added in order to fix copper in the treated wood by the formation of the complex tetraamminecopper hydroxide. It is present in the biocidal product at concentration leading the product to be regarded as dangerous.

Therefore, both IPA and MEA were considered into the quantitative risk assessment of the biocidal product.

FKR-ACQ EXTRA is applied diluted with the following application rates:
-Dipping/immersion: dilution at 0.2-1%, with a product retention of 0.26-1.16 g/m^2,
-Vacuum pressure: dilution at 3%, with a product retention of 22.18 kg/m^3.

Background levels

As copper (Cu) is a natural endogenous compound, the releases due to its use as wood preservative have been added to the background environmental concentration. In a first step, the added predicted concentrations of Cu were calculated, in line with the equation given by the ESD. In a second step, the values were corrected in order to integrate the natural/pristine or the regional background concentrations in Cu (as agreed under the Council Regulation (EEC) 793/93 on Existing Substances - EU-RAR):

- Natural/pristine background Cu concentrations in water, sediment and soil were taken from the FOREGS Geochemical Baseline Programme (FGBP) database published in March 2004 (http://www.gsf.fi/foregs/geochem/),

- Regional background Cu concentrations in water, sediment and soil were taken from the EU Existing Chemical Regulation.

Summary table of background levels			
Compartment	**Natural/pristine background concentration**	**Regional background concentration**	**Unit**
Surface water	0.88	2.9	$\mu g.L^{-1}$
Ground water	0.88	2.9	$\mu g.L^{-1}$
Soil	12 10.6	24.4 21.6	$mg.kg_{dwt}^{-1}$ $mg.kg_{wwt}^{-1}$
Sediment	21 4.56	67.5 14.7	$mg.kg_{dwt}^{-1}$ $mg.kg_{wwt}^{-1}$

In the specific case of Cu release to soil, decrease of Cu toxicity with ageing has to be taken into account as stated in the Copper dihidroxide Assessment Report (September 2011). Therefore, an ageing factor of 2 was applied on the total Cu concentrations in soil for the values calculated in TIME 2, in order to consider the phenomenon of Cu ageing in soil.

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

Since there are valid data available on each of the components in the mixture, classification of the mixture has been made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

In the case of the active substance Didecyldimethylammonium chloride, the lowest acute aquatic toxicity endpoint is an EC_{50} of 0.062 mg/L for the invertebrate *Daphnia magna*. The lowest chronic aquatic toxicity endpoint is a NOEC of 0.014 mg/L reported for a *Daphnia magna* study. In accordance with the guidance on application of the CLP criteria, the classification of Didecyldimethylammonium chloride is therefore, Aquatic Acute 1 (M-factor 10) H400, Aquatic Chronic 2 H411.

In the case of the active substance Copper dihydroxide the lowest acute toxicity endpoint is an LC_{50} of 8.1 µg/L for the fish *Pimephales promelas.* The lowest chronic aquatic toxicity endpoint is a NOEC of 7.4 µg/L reported for the invertebrate *Ceriodaphnia dubia*. In accordance with the guidance on application of the CLP criteria, the classification of Copper dihydroxide is therefore, Aquatic Acute 1 (M-factor 10) H400, Aquatic Chronic 1 (M-factor 10) H410.

Taking account of the concentration of Didecyldimethylammonium chloride and Copper dihydroxide in the biocidal product, the minimum environmental classification of the product can be calculated as follows:

Acute Environmental Classification of Product:
Acute 1 x M ≥25% = Acute 1

(4.12% x 10) + (12.86% x 10) = 169.8 **≥25%**

Chronic Environmental Classification of Product:
Chronic 1 x M ≥ 25% + chronic 1

(12.86% x 10) = 128.6 **≥25%**

Therefore, the environmental classification according to CLP Regulation (EC) No 1272/2008 is Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410).

It is considered that the ecotoxicological information on the active substances, Didecyldimethylammonium chloride and Copper dihydroxide and the data provided on the components of the product are sufficient to assess any potential risk to the environment from use of the product. A study using the formulated product is therefore not considered necessary.

Derived PNEC Values

The following table shows the PNEC values for the active substances Didecyldimethylammonium chloride and Copper dihydroxide and the substances of concern Propan-2-ol and 2-amminoethanol used in the environmental risk assessment of the biocidal product FKR-ACQ EXTRA.

Summary table on PNEC					
PNEC	**DDAC[1]**	**Cu2+[1]**	**IPA[1]**	**MEA[2]**	**Unit**
$PNEC_{STP}$	0.14	0.23	10	100	$mg \cdot L^{-1}$
$PNEC_{water}$	0.0011	7.8	2.82	0.085	$mg \cdot L^{-1}$
$PNEC_{sed}$	3.56	18.9	2.41	0.0942	$mg \cdot kg_{wwt}^{-1}$
$PNEC_{soil}$	1.4	40.35	0.496	0.0325	$mg \cdot kg_{wwt}^{-1}$

[1] Values obtained from the CAR of the active substances.

[2] Values obtained form the Substance Evaluation Report CoRAP (v.2, Sept. 2016).

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides.

No further ecotoxicological studies are available for FKR-ACQ EXTRA. The product was not tested for potential endocrine disruption properties. FKR-ACQ EXTRA contains the active substance Copper dihidroxide, DDAC and various co-formulates (see annex 3.6).

For the active substance, no ED assessment is required because for active substances that have been approved, the EU assessment should be followed.

For the co-formulates a screening was performed by consulting:

- ECHA data for identification of ED and PBT, under REACH, BPR or CLP
- Identified as ED by United States EPA (https://comptox.epa.gov/dashboard/)
- Identified as ED by the United Nations Environment (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

During screening performance any co-formulate triggered an alert for ED property.

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

Please refer to section 2.2.8.2 Fate and distribution in exposed environmental compartments.

Leaching behaviour (ADS)

A field leaching test has not been performed for wood after application of FKR-ACQ EXTRA. Therefore, the emissions to the environment of active substances as well as substances of concern were calculated assuming 50% of leaching at time 1 (30 days) and 100% of leaching at time 2 (7300 days for vacuum pressure impregnation and 5475 days for dipping/immersion application), following the approach agreed during the 2nd EU Leaching Workshop on Wood Preservatives.

2.2.8.2 Exposure assessment

The environmental exposure assessments of the active substances were determined with the Emission Scenario Document (ESD) developed for Product Type 08 (wood preservatives) by OECD: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario Document for Wood Preservatives. The emission scenarios estimate the emission of wood preservatives from two stages of their life cycle:

- Application and storage of treated wood prior to shipment;
- Treated wood in service.

The application at industrial sites and storage of treated wood scenarios have not been assessed and emissions were not calculated because these stages are subjected to specific regulation within the EU. Therefore, product application and **freshly treated timber must be stored on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal**.

In the case of treated wood in service, the following emission scenarios have been run for use class 3 and 4a: House, Fence, Noise barrier, Bridge over pond and Transmission pole. For the emission scenarios of treated wood in service, calculations of emissions into soil have been done with substance **removal processes in soil taken into account**; according to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Part 3.

For the two FKR-ACQ EXTRA active substances and substances of concern, the environmental risk assessment has been calculated assuming 50% of leaching at time 1 and 100 % leaching at time 2, as no leaching test was performed with the product FKR-ACQ EXTRA.

General information

Assessed PT	PT 8: Wood preservatives
Assessed scenarios	**Scenario 1:** Vacuum pressure • Product application • Storage of treated wood prior to shipping **Scenario 2:** Dipping/Immersion • Product application • Storage of treated wood prior to shipping **Scenario 3:** In-service leaching from treated wood UC1 & UC2 **Scenario 4:** In-service leaching from treated wood UC3 & UC4a - <u>Vacuum pressure</u> • *House*

	• *Fence* • *Bridge over pond* • *Noise Barrier* • *Transmission pole* **Scenario 5:** In-service leaching from treated wood UC3 & UC4a - <u>Dipping/Immersion</u> • *House* • *Fence* • *Bridge over pond* • *Noise Barrier* • *Transmission pole*
ESD(s) used	Emission Scenario Document for Product Type 8: OECD Series on Emission Scenario Documents No 2, Revised ESD for Wood Preservatives (September 2013).
Approach	Average consumption
Distribution in the environment	Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C)" version 2.0 October 2017. Technical Agreements for Biocides (TAB) – ENV v.2.1, December 2019.
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: No Service life: Yes
Remarks	The product is intended to be used for the UC 1, UC 2, UC 3 and UC 4a. According to the OECD ESD PT 08 no emission scenarios are available for UC 1 and UC 2, since the potential emissions from treated wood to the outer environment are considered negligible. Therefore, no emission and exposure calculation are performed for the UC 1 and UC 2.

Emission estimation

Input parameters for calculating the local emission and concentration		
Input	**Value**	**Unit**
Application rate of biocidal product (Vacuum impregnation)	22.18	$Kg \cdot m^{-3}$
Application rate of biocidal product (Immersion)	2.60E-04	$Kg \cdot m^{-2}$
First order rate constant for removal from soil (*k*) (k = kvolat + kleach + kbiosoil)		
DDAC	2.32E-05	d^{-1}
Cu	1.85E-06	d^{-1}
IPA	3.89E-02	d^{-1}
MEA	3.33E-02	d^{-1}

Fraction released to facility drain ($F_{facilitydrain}$)		
DDAC	0.03	-
Cu	0.003	-
IPA	0.03	-
MEA	0.03	-
Fraction released to air (F_{air})		
DDAC	0	-
Cu	0	-
IPA	0.075	-
MEA	0.075	-

Scenario 1 (Product application and storage of treated wood prior to shipment - Vacuum)

Application and storage phases

No emission values are presented for these stages as they are subjected to specific regulation within the EU. However, risk mitigation measures are included in the product label to minimize potential environmental risks derived from product application in industrial premises and storage prior to shipment (please see section 2.2.8.3).

Scenario 2 (Product application and storage of treated wood prior to shipment - Immersion)

Application and storage phases

No emission values are presented for these stages as they are subjected to specific regulation within the EU. However, risk mitigation measures are included in the product label to minimize potential environmental risks derived from product application in industrial premises and storage prior to shipment (please see section 2.2.8.3).

Scenario 3 (In-service leaching from treated wood UC1 & UC2)

Negligible emissions are expected when treated wood or wood products are placed indoors or outdoors under a roof when protected from frequent wetting and weather.

No calculations for in-service risk have been provided due to the assumption of negligible emissions and therefore zero risk from UC1 and 2.

Emissions are possible during application and storage phases and this risk is already covered by Scenarios 1 & 2. Nevertheless, risk should be mitigated by addition of the following text to the product label:

- The biocidal product may only be applied to wood, which will be protected from weather and not to be used above or close to surface waters or in direct contact with soil.

Scenario 4 (In-service leaching from treated wood UC3 & UC4a - Vacuum pressure)

During service life of UC 3 and UC 4a treated wood, emissions into the environment can occur due to leaching of active substances out of the wood due to rainfall.

Emissions due to leaching of the active substances out of the wood may occur into the soil, the surface water and into the Sewage Treatment Plant (STP) after run-off.

The calculated concentrations (Clocal) in the receiving environmental compartments represent the concentration at the end of the assessment time period taking into account removal processes of the substance from the receiving compartment for example due to degradation, volatilisation, or leaching to groundwater.

House

The input parameters for calculating the local emission and concentration into the soil following leaching are presented in the following table.

Input parameters for calculating the local emission					
Service life – House scenario					
Input		**Nomenclature**	**Value**	**Unit**	**Remarks**
Application rate of biocidal product[1]	DDAC	*Qai*	2.28E-02	$Kg \cdot m^{-2}$	S
	Copper dihydroxide	*Qai*	4.65E-02	$Kg \cdot m^{-2}$	S
	IPA	*Qai*	9.15E-03	$Kg \cdot m^{-2}$	S
	MEA	*Qai*	2.11E-01	$Kg \cdot m^{-2}$	S
Leachable wood area		$AREA_{house}$	125	m^2	D
Duration of the initial assessment period		*TIME 1*	30	d	D
Duration of the long-term assessment period		*TIME 2*	7300	d	D
Soil volume		V_{soil}	13	m^3	D
Bulk density of wet soil		RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	D
First order rate constant for removal from soil		*k*	**See above**	d^{-1}	S

[1] *Based on a maximum retention of the biocidal product of 22.18 kg/m³ and Wood area:wood volume conversion factor of 40 m²/m³ provided in ESD PT8, Appendix 1.*

The cumulative quantity of substance leached out of 1 m² of treated wood over each assessment periods are calculated as following:

$$Q^*_{leach,time1} = Qai \cdot 0.5$$
$$Q^*_{leach,time2} = Qai \cdot 1$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Q^*_{leach,time1}$	1.14E-02	2.32E-02	4.57E-03	1.05E-01	$Kg \cdot m^{-2}$
$Q^*_{leach,time2}$	2.28E-02	4.65E-02	9.15E-03	2.11E-01	$Kg \cdot m^{-2}$

Calculations

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8 as following:

$$E_{soil,leach,time1} = AREA_{house} \cdot Q^{*}_{leach,\ time1} / TIME\ 1$$

$$E_{soil,leach,time2} = AREA_{house} \cdot Q^{*}_{leach,\ time2} / TIME\ 2$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$E_{soil,\ leach,time1}$	4.76E-02	9.68E-02	1.91E-02	4.39E-01	$Kg \cdot d^{-1}$
$E_{soil,leach,time2}$	3.91E-04	7.95E-04	1.57E-04	3.61E-03	$Kg \cdot d^{-1}$

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

$$\boldsymbol{C}local_{soil,TIME1} = [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIME1 \cdot k})$$

$$\boldsymbol{C}local_{soil,TIME2} = [E_{soil,leach,TIME2}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil,leach,TIME2}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIME2 \cdot k})$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Clocal_{soil,TIME1}$	6.46E-05	1.31E-04	1.53E-05	3.77E-04	$Kg \cdot kg_{wwt}^{-1}$
$Clocal_{soil,TIME2}$	1.19E-04	1.30E-04[1]	1.82E-07	4.90E-06	$Kg \cdot kg_{wwt}^{-1}$

[1]*Considering an ageing factor of 2.*

Fence

The input parameters for calculating the local emission and concentration into the soil following leaching are presented in the following table.

Input parameters for calculating the local emission					
Service life – Fence scenario					
Input		**Nomenclature**	**Value**	**Unit**	**Remarks**
Application rate of biocidal product[1]	DDAC	*Qai*	2.28E-02	$Kg \cdot m^{-2}$	S
	Copper dihydroxide	*Qai*	4.65E-02	$Kg \cdot m^{-2}$	S
	IPA	*Qai*	9.15E-03	$Kg \cdot m^{-2}$	S
	MEA	*Qai*	2.11E-01	$Kg \cdot m^{-2}$	S
Leachable wood area		$AREA_{fence}$	2	m^2	D
Duration of the initial assessment period		*TIME 1*	30	d	D
Duration of the long-term assessment		*TIME 2*	7300	d	D

period				
Soil volume	V_{soil}	0.25	m^3	D
Bulk density of wet soil	RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	D
First order rate constant for removal from soil	*k*	**See above**	d^{-1}	S

[1] *Based on a maximum retention of the biocidal product of 22.18 kg/m³ and Wood area:wood volume conversion factor of 40 m²/m³ provided in ESD PT8, Appendix 1.*

The cumulative quantity of substance leached out of 1 m² of treated wood over each assessment periods are calculated as following:

$$Q^*_{leach,time1} = Qai \cdot 0.5$$
$$Q^*_{leach,time2} = Qai \cdot 1$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Q^*_{leach,time1}$	1.14E-02	2.32E-02	4.57E-03	1.05E-01	$Kg \cdot m^{-2}$
$Q^*_{leach,time2}$	2.28E-02	4.65E-02	9.15E-03	2.11E-01	$Kg \cdot m^{-2}$

Calculations

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8 as following:

$$E_{soil,leach,time1} = AREA_{house} \,.\, Q^*_{leach,\,time1} \,/\, TIME\ 1$$

$$E_{soil,leach,time2} = AREA_{house} \,.\, Q^*_{leach,\,time2} \,/\, TIME\ 2$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$E_{soil,\,leach,time1}$	7.62E-04	1.55E-03	3.05E-04	7.02E-03	$Kg \cdot d^{-1}$
$E_{soil,leach,time2}$	3.13E-06	1.27E-05	1.25E-06	2.89E-05	$Kg \cdot d^{-1}$

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

$$\boldsymbol{C}local_{soil,TIME1} = [E_{soil,leach,TIME1}/(V_{soil} \,.\, RHO_{soil} \,.\, k)] - [E_{soil,leach,TIME1}/(V_{soil} \,.\, RHO_{soil} \,.\, k)] \,.\, (e^{-TIME1 \,.\, k})$$

$$\boldsymbol{C}local_{soil,TIME2} = [E_{soil,leach,TIME2}/(V_{soil} \,.\, RHO_{soil} \,.\, k)] - [E_{soil,leach,TIME2}/(V_{soil} \,.\, RHO_{soil} \,.\, k)] \,.\, (e^{-TIME2 \,.\, k})$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Clocal_{soil,TIME1}$	2.04E-06	2.04E-06	2.04E-06	2.04E-06	$Kg \cdot kg_{wwt}^{-1}$
$Clocal_{soil,TIME2}$	2.04E-06	2.04E-06[1]	2.04E-06	2.04E-06	$Kg \cdot kg_{wwt}^{-1}$

[1] *Considering an ageing factor of 2.*

Bridge over pond scenario

The removal processes is not taken into account in the bridge over pond scenario because the first order rate constant for removal from water corresponds to 0 for the 2 active substances and the substances of concern.

In accordance with the guide, it is assumed that the leachate resulting from rainfall ends up directly in the adjacent static surface water. The default value for the size of the receiving water body was set to 1000 m^3, this value is based on an evaluation made by UBA showing that a ratio of bridge surface to water volume of 1:100 is realistic. Taking into account a bridge surface of 10 m^2, this results in a default value for V_{water} of 1000 m^3 (10^6 L).

The input parameters for calculating the local emission and concentration into the surface water following leaching are presented in the following table.

Input parameters for calculating the local emission					
Service life – Bridge over pond scenario					
Input		**Nomenclature**	**Value**	**Unit**	**Remarks**
Application rate of biocidal product[1]	DDAC	*Qai*	1.69E-02	Kg·m^{-2}	S
	Copper dihydroxide	*Qai*	3.43E-02	Kg·m^{-2}	S
	IPA	*Qai*	6.75E-03	Kg·m^{-2}	S
	MEA	*Qai*	1.56E-01	Kg·m^{-2}	S
Leachable wood area		$AREA_{bridge}$	10	m^2	D
Duration of the initial assessment period		*TIME 1*	30	d	D
Duration of the long-term assessment period		*TIME 2*	7300	d	D
Water volume under bridge		V_{water}	1000	m^3	D
Sediment volume under bridge		V_{sed}	3	m^3	D

[1] *Based on a maximum retention of the biocidal product of 22.18 kg/m^3 and Wood area:wood volume conversion factor of 54.2 m^2/m^3 provided in ESD PT8, Appendix 1.*

The cumulative quantity of substance leached out of 1 m² of treated wood over each assessment periods are calculated as following:

$$Q^*_{leach,time1} = Qai \cdot 0.5$$
$$Q^*_{leach,time2} = Qai \cdot 1$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Q^*_{leach,time1}$	8.43E-03	1.71E-02	3.38E-03	7.78E-02	Kg·m^{-2}
$Q^*_{leach,time2}$	1.69E-02	3.43E-02	6.75E-03	1.56E-01	Kg·m^{-2}

Calculations

The local emissions into the water (the cumulative quantity of substance leached over 30 days and 20 years, $Q_{leach,time}$) are calculated according to the equations 3.63 and 3.64 from the revised ESD PT8 as following:

$$Clocal_{water,leach,TIME1} = Qleach,time1 / V_{water}$$

$$Clocal_{water,leach,TIME2} = Qleach,time2 / V_{water}$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Clolcal_{water,\ leach,time1}$	8.430E-08	1.714E-07	3.376E-08	7.775E-07	$Kg{\cdot}L^{-1}$
$Clocal_{water,leach,time2}$	1.686E-07	3.428E-07	6.752E-08	1.555E-06	$Kg{\cdot}L^{-1}$

Noise barrier scenario

In accordance with the OECD guide, it is assumed that the leachate resulting from rainfall either ends up directly in the adjacent soil or is collected in the gutter and sewer, and finally enters a municipal sewage treatment plant (STP). Emissions to air are considered negligible.

Due to the decision taken during the 23rd CA meeting, the receiving soil volume is calculated based on a distance of 0.5 m (vertically and horizontal) to the treated noise barrier.

The input parameters for calculating the local emission and concentration into the soil and surface water following leaching are presented in the following table.

Input parameters for calculating the local emission					
Service life – Noise barrier scenario					
Input		**Nomenclature**	**Value**	**Unit**	**Remarks**
Application rate of biocidal product[1]	DDAC	*Qai*	2.28E-02	$Kg{\cdot}m^{-2}$	S
	Copper dihydroxide	*Qai*	4.65E-02	$Kg{\cdot}m^{-2}$	S
	IPA	*Qai*	9.15E-03	$Kg{\cdot}m^{-2}$	S
	MEA	*Qai*	2.11E-01	$Kg{\cdot}m^{-2}$	S
Treated wood area		$AREA_{noise-barrier}$	3000	m^2	D
Duration of the initial assessment period		*TIME 1*	30	d	D
Duration of the long-term assessment period		*TIME 2*	7300	d	D
Soil volume (wet)		V_{soil}	250	m^3	D
Bulk density of wet soil		RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	D
Fraction released to soil		F_{soil}	0,3	-	D
Fraction released to the STP		F_{STP}	0,7	-	D
First order rate constant for removal from soil		k	**See above**	d^{-1}	S

[1] Based on a maximum retention of the biocidal product of 22.18 kg/m³ and Wood area:wood volume conversion factor of 40 m²/m³ provided in ESD PT8, Appendix 1.

The cumulative quantity of substance leached out of 1 m² of treated wood over each assessment periods are calculated as following:

$$Q^*_{leach,time1} = Qai \cdot 0.5$$
$$Q^*_{leach,time2} = Qai \cdot 1$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Q^*_{leach,time1}$	1.14E-02	2.32E-02	4.57E-03	1.05E-01	$Kg \cdot m^{-2}$
$Q^*_{leach,time2}$	2.28E-02	4.65E-02	9.15E-03	2.11E-01	$Kg \cdot m^{-2}$

Calculations

The local direct emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8 as following:

$$E_{soil,leach,time1} = AREA_{noisebarrier} \cdot Q^*_{leach,\ time1} / TIME\ 1$$

$$E_{soil,leach,time2} = AREA_{noisebarrier} \cdot Q^*_{leach,\ time2} / TIME\ 2$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$E_{soil,\ leach,time1}$	3.43E-01	6.97E-01	1.37E-01	3.16E+00	$Kg \cdot d^{-1}$
$E_{soil,leach,time2}$	2.82E-03	5.73E-03	1.13E-03	2.60E-02	$Kg \cdot d^{-1}$

The local daily emissions into the STP are calculated according to the equations 4.55 and 4.56 from the revised ESD PT08 as following:

$$E_{STP,time\ 1} = AREA_{noise\text{-}barrier} \times F_{STP} \times (Q^*_{leach,\ time1} / TIME\ 1)$$

$$E_{STP,time\ 2} = AREA_{noise\text{-}barrier} \times F_{STP} \times (Q^*_{leach,\ time1} / TIME\ 2)$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$E_{STP,time1}$	8.00E-01	1.63E+00	3.20E-01	7.37E+00	$Kg \cdot d^{-1}$
$E_{STP,time2}$	6.57E-03	1.34E-02	2.63E-03	6.06E-02	$Kg \cdot d^{-1}$

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

$$\boldsymbol{C}local_{soil,TIME1} = [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIME1 \cdot k})$$

$$\boldsymbol{C}local_{soil,TIME2} = [E_{soil,leach,TIME2}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil,leach,TIME2}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIME2 \cdot k})$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Clocal_{soil,TIME1}$	2.42E-05	4.92E-05	5.72E-06	1.41E-04	$Kg \cdot kg_{wwt}^{-1}$

$Clocal_{soil,TIME2}$	4.45E-05	4.89E-05[1]	6.82E-08	1.83E-06	$Kg \cdot kg_{wwt}^{-1}$

[1]*Considering an ageing factor of 2.*

Transmission pole

In accordance with the guidance, it is assumed that the emission from the treated wood to soil is a result of:

- Rainfall for the above soil part of the pole, and,
- Permanent contact with the soil water phase for the below ground part.

Due to the decision taken during the 23rd CA meeting, the receiving soil volume is calculated based on a distance of 0.5 m (vertically and horizontal) to the treated pole, and as a value default of Vsoil 2.97 m^3.

The input parameters for calculating the local emission and concentration into the soil following leaching are presented in the following table.

Input parameters for calculating the local emission					
Service life – Transmission pole scenario					
Input		**Nomenclature**	**Value**	**Unit**	**Remarks**
Application rate of biocidal product[1]	DDAC	*Qai*	5.71E-02	$Kg \cdot m^{-2}$	S
	Copper dihydroxide	*Qai*	1.16E-01	$Kg \cdot m^{-2}$	S
	IPA	*Qai*	2.29E-02	$Kg \cdot m^{-2}$	S
	MEA	*Qai*	1.58E-02	$Kg \cdot m^{-2}$	S
Treated wood area above soil		$AREA_{pole,\ above}$	5.5	m^2	D
Treated wood area bellow soil		$AREA_{pole,\ below}$	1.6	m^2	
Duration of the initial assessment period		*TIME 1*	30	d	D
Duration of the long-term assessment period		*TIME 2*	7300	d	D
Soil volume (wet)		V_{soil}	2.67	m^3	D
Bulk density of wet soil		RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	D
First order rate constant for removal from soil		k	**See above**	d^{-1}	S

[1] *Based on a maximum retention of the biocidal product of 22.18 kg/m^3 and Wood area:wood volume conversion factor of 16 m^2/m^3 provided in ESD PT8, Appendix 1.*

The cumulative quantity of substance leached out of 1 m² of treated wood over each assessment periods are calculated as following:

$$Q^*_{leach,time1} = Qai \cdot 0.5$$
$$Q^*_{leach,time2} = Qai \cdot 1$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Q^*_{leach,time1}$	2.86E-02	5.81E-02	1.14E-02	7.90E-03	$Kg \cdot m^{-2}$

$Q^*_{leach,time2}$	5.71E-02	1.16E-01	2.29E-02	1.58E-02	$Kg \cdot m^{-2}$

Calculations

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8as following:

$$E_{soil,leach,time1} = (AREA_{pole,above} + AREA_{pole,bellow}) \cdot Q^*_{leach,\ time1} / TIME\ 1$$

$$E_{soil,leach,time2} = (AREA_{pole,above} + AREA_{pole,bellow}) \cdot Q^*_{leach,\ time1} / TIME\ 2$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$E_{soil,\ leach,time1}$	6.76E-03	1.37E-02	2.71E-03	7.69E-06	$Kg \cdot d^{-1}$
$E_{soil,leach,time2}$	5.55E-05	1.13E-04	2.22E-05	1.54E-05	$Kg \cdot d^{-1}$

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

$$\boldsymbol{C}local_{soil,TIME1} = [E_{soil,leach,TIME1}/(V_{soil} \,.\, RHO_{soil} \,.\, k)] - [E_{soil,leach,TIME1}/(V_{soil} \,.\, RHO_{soil} \,.\, k)] \,.\, (e^{-TIME1 \,.\, k})$$

$$\boldsymbol{C}local_{soil,TIME2} = [E_{soil,leach,TIME2}/(V_{soil} \,.\, RHO_{soil} \,.\, k)] - [E_{soil,leach,TIME2}/(V_{soil} \,.\, RHO_{soil} \,.\, k)] \,.\, (e^{-TIME2 \,.\, k})$$

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Clocal_{soil,TIME1}$	4.01E-05	8.16E-05	9.49E-06	2.89E-08	$Kg \cdot kg_{wwt}^{-1}$
$Clocal_{soil,TIME2}$	7.39E-05	8.11E-05	1.13E-07	9.14E-08	$Kg \cdot kg_{wwt}^{-1}$

[1]*Considering an ageing factor of 2.*

Scenario 5 (In-service leaching from treated wood UC 3 & UC 4a - Immersion)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
UC 1 & UC 2 applied by vacuum-pressure impregnation at industrial plants.			
Application rate of biocidal product *(Vacuum pressure)*	0.26	$g \cdot m^{-2}$	
Concentration of active substances and SoC in the product identical to scenario 1			

The default parameters and equations used at each sub-scenario are similar as those presented in scenario 4. Therefore, we will not present them again in this section.

House

The input parameters for calculating the local emission and concentration into the soil following leaching are presented in the following table.

Input parameters for calculating the local emission					
Service life – House scenario					
Input		**Nomenclature**	**Value**	**Unit**	**Remarks**
Application rate of biocidal product[1]	DDAC	*Qai*	1.07E-05	$Kg \cdot m^{-2}$	S
	Copper dihydroxide	*Qai*	2.18E-05	$Kg \cdot m^{-2}$	S
	IPA	*Qai*	4.29E-06	$Kg \cdot m^{-2}$	S
	MEA	*Qai*	9.88E-05	$Kg \cdot m^{-2}$	S
Leachable wood area		$AREA_{house}$	125	m^2	D
Duration of the initial assessment period		*TIME 1*	30	d	D
Duration of the long-term assessment period		*TIME 2*	5475	d	D
Soil volume		V_{soil}	13	m^3	D
Bulk density of wet soil		RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	D
First order rate constant for removal from soil		*k*	**See above**	d^{-1}	S

[1] *Based on a maximum retention of the biocidal product of 22.18 kg/m³ and Wood area:wood volume conversion factor of 40 m²/m³ provided in ESD PT8, Appendix 1.*

The cumulative quantity of substance leached out of 1 m² of treated wood over each assessment periods are calculated as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Q^*_{leach,time1}$	5.36E-06	1.09E-05	2.15E-06	4.94E-05	$Kg \cdot m^{-2}$
$Q^*_{leach,time2}$	1.07E-05	2.18E-05	4.29E-06	9.88E-05	$Kg \cdot m^{-2}$

Calculations

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8 as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$E_{soil,\ leach,time1}$	2.23E-05	4.54E-05	8.94E-06	2.06E-04	$Kg \cdot d^{-1}$
$E_{soil,leach,time2}$	2.45E-07	4.97E-07	9.79E-08	2.26E-06	$Kg \cdot d^{-1}$

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Clocal_{soil,TIME1}$	3.03E-08	6.16E-08	7.16E-09	1.77E-07	$Kg \cdot kg_{wwt}^{-1}$

$Clocal_{soil,TIME2}$	5.69E-08	6.13E-08[1]	1.14E-10	3.06E-09	Kg· kg_{wwt}^{-1}

[1]*Considering an ageing factor of 2.*

Fence

The input parameters for calculating the local emission and concentration into the soil following leaching are presented in the following table.

Input parameters for calculating the local emission					
Service life – Fence scenario					
Input		**Nomenclature**	**Value**	**Unit**	**Remarks**
Application rate of biocidal product[1]	DDAC	*Qai*	1.07E-05	$Kg·m^{-2}$	S
	Copper dihydroxide	*Qai*	2.18E-05	$Kg·m^{-2}$	S
	IPA	*Qai*	4.29E-06	$Kg·m^{-2}$	S
	MEA	*Qai*	9.88E-05	$Kg·m^{-2}$	S
Leachable wood area		$AREA_{fence}$	2	m^2	D
Duration of the initial assessment period		*TIME 1*	30	d	D
Duration of the long-term assessment period		*TIME 2*	5475	d	D
Soil volume		V_{soil}	0.25	m^3	D
Bulk density of wet soil		RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	D
First order rate constant for removal from soil		*k*	**See above**	d^{-1}	S

[1] *Based on a maximum retention of the biocidal product of 22.18 kg/m^3 and Wood area:wood volume conversion factor of 40 m^2/m^3 provided in ESD PT8, Appendix 1.*

The cumulative quantity of substance leached out of 1 m² of treated wood over each assessment periods are calculated as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Q^*_{leach,time1}$	5.36E-06	1.09E-05	2.15E-06	4.94E-05	$Kg·m^{-2}$
$Q^*_{leach,time2}$	1.07E-05	2.18E-05	4.29E-06	9.88E-05	$Kg·m^{-2}$

Calculations

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8 as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$E_{soil,\ leach,time1}$	3.57E-07	7.26E-07	1.43E-07	3.29E-06	$Kg·d^{-1}$
$E_{soil,leach,time2}$	1.96E-09	7.96E-09	7.84E-10	1.80E-08	$Kg·d^{-1}$

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Clocal_{soil,TIME1}$	2.52E-08	5.12E-08	5.96E-09	1.47E-07	$Kg \cdot kg_{wwt}^{-1}$
$Clocal_{soil,TIME2}$	2.37E-08	5.10E-08[1]	4.74E-11	1.27E-09	$Kg \cdot kg_{wwt}^{-1}$

[1]*Considering an ageing factor of 2.*

Bridge over pond scenario

The input parameters for calculating the local emission and concentration into the surface water following leaching are presented in the following table.

Input parameters for calculating the local emission					
Service life – Bridge over pond scenario					
Input		**Nomenclature**	**Value**	**Unit**	**Remarks**
Application rate of biocidal product[1]	DDAC	*Qai*	1.07E-05	$Kg \cdot m^{-2}$	S
	Copper dihydroxide	*Qai*	2.18E-05	$Kg \cdot m^{-2}$	S
	IPA	*Qai*	4.29E-06	$Kg \cdot m^{-2}$	S
	MEA	*Qai*	9.88E-05	$Kg \cdot m^{-2}$	S
Leachable wood area		$AREA_{bridge}$	10	m^2	D
Duration of the initial assessment period		*TIME 1*	30	d	D
Duration of the long-term assessment period		*TIME 2*	5475	d	D
Water volume under bridge		V_{water}	1000	m^3	D
Sediment volume under bridge		V_{sed}	3	m^3	D

[1] *Based on a maximum retention of the biocidal product of 22.18 kg/m^3 and Wood area:wood volume conversion factor of 54.2 m^2/m^3 provided in ESD PT8, Appendix 1.*

The cumulative quantity of substance leached out of 1 m² of treated wood over each assessment periods are calculated as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Q^*_{leach,time1}$	5.36E-06	1.09E-05	2.15E-06	4.94E-05	$Kg \cdot m^{-2}$
$Q^*_{leach,time2}$	1.07E-05	2.18E-05	4.29E-06	9.88E-05	$Kg \cdot m^{-2}$

Calculations

The local emissions into the water (the cumulative quantity of substance leached over 30 days and 20 years, $Q_{leach,time}$) are calculated according to the equations 3.63 and 3.64 from the revised ESD PT8 as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit

$Clocal_{water,\ leach,time1}$	5.356E-11	1.089E-10	2.145E-11	4.940E-10	$Kg \cdot L^{-1}$
$Clocal_{water,leach,time2}$	1.071E-10	2.178E-10	4.290E-11	9.880E-10	$Kg \cdot L^{-1}$

Noise barrier scenario

The input parameters for calculating the local emission and concentration into the soil and surface water following leaching are presented in the following table.

Input parameters for calculating the local emission					
Service life – Noise barrier scenario					
Input		**Nomenclature**	**Value**	**Unit**	**Remarks**
Application rate of biocidal product[1]	DDAC	*Qai*	1.07E-05	$Kg \cdot m^{-2}$	S
	Copper dihydroxide	*Qai*	2.18E-05	$Kg \cdot m^{-2}$	S
	IPA	*Qai*	4.29E-06	$Kg \cdot m^{-2}$	S
	MEA	*Qai*	9.88E-05	$Kg \cdot m^{-2}$	S
Treated wood area		$AREA_{noise\text{-}barrier}$	3000	m^2	D
Duration of the initial assessment period		*TIME 1*	30	d	D
Duration of the long-term assessment period		*TIME 2*	5475	d	D
Soil volume (wet)		V_{soil}	250	m^3	D
Bulk density of wet soil		RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	D
Fraction released to soil		F_{soil}	0,3	-	D
Fraction released to the STP		F_{STP}	0,7	-	D
First order rate constant for removal from soil		k	**See above**	d^{-1}	S

[1] Based on a maximum retention of the biocidal product of 22.18 kg/m^3 and Wood area:wood volume conversion factor of 40 m^2/m^3 provided in ESD PT8, Appendix 1.

The cumulative quantity of substance leached out of 1 m² of treated wood over each assessment periods are calculated as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Q^*_{leach,time1}$	5.36E-06	1.09E-05	2.15E-06	4.94E-05	$Kg \cdot m^{-2}$
$Q^*_{leach,time2}$	1.07E-05	2.18E-05	4.29E-06	9.88E-05	$Kg \cdot m^{-2}$

Calculations

The local direct emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8 as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$E_{soil,\ leach,time1}$	1.61E-04	3.27E-04	6.44E-05	1.48E-03	$Kg \cdot d^{-1}$

$E_{soil,leach,time2}$	1.76E-06	3.58E-06	7.05E-07	1.62E-05	$Kg \cdot d^{-1}$

The local daily emissions into the STP are calculated according to the equations 4.55 and 4.56 from the revised ESD PT08 as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$E_{STP,time1}$	3.75E-04	7.62E-04	1.50E-04	3.46E-03	$Kg \cdot d^{-1}$
$E_{STP,time2}$	4.11E-06	8.35E-06	1.65E-06	3.79E-05	$Kg \cdot d^{-1}$

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

	DDAC	**Cu**	**IPA**	**MEA**	Unit
$Clocal_{soil,TIME1}$	1.13E-08	2.31E-08	2.68E-09	6.61E-08	$Kg \cdot kg_{wwt}^{-1}$
$Clocal_{soil,TIME2}$	2.13E-08	2.29E-08[1]	4.26E-11	1.15E-09	$Kg \cdot kg_{wwt}^{-1}$

[1]*Considering an ageing factor of 2.*

Transmission pole

The input parameters for calculating the local emission and concentration into the soil following leaching are presented in the following table.

Input parameters for calculating the local emission					
Service life – Transmission pole scenario					
Input		**Nomenclature**	**Value**	**Unit**	**Remarks**
Application rate of biocidal product[1]	DDAC	*Qai*	1.07E-05	$Kg \cdot m^{-2}$	S
	Copper dihydroxide	*Qai*	2.18E-05	$Kg \cdot m^{-2}$	S
	IPA	*Qai*	4.29E-06	$Kg \cdot m^{-2}$	S
	MEA	*Qai*	9.88E-05	$Kg \cdot m^{-2}$	S
Treated wood area above soil		$AREA_{pole,\ above}$	5.5	m^2	D
Treated wood area bellow soil		$AREA_{pole,\ below}$	1.6	m^2	
Duration of the initial assessment period		*TIME 1*	30	d	D
Duration of the long-term assessment period		*TIME 2*	5475	d	D
Soil volume (wet)		V_{soil}	2.67	m^3	D
Bulk density of wet soil		RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	D
First order rate constant for removal from soil		k	**See above**	d^{-1}	S

[1] *Based on a maximum retention of the biocidal product of 22.18 kg/m³ and Wood area:wood volume conversion factor of 16 m²/m³ provided in ESD PT8, Appendix 1.*

The cumulative quantity of substance leached out of 1 m² of treated wood over each assessment periods are calculated as following:

	DDAC	Cu	IPA	MEA	Unit
$Q^*_{leach,time1}$	5.36E-06	1.09E-05	2.15E-06	4.94E-05	$Kg \cdot m^{-2}$
$Q^*_{leach,time2}$	1.07E-05	2.18E-05	4.29E-06	9.88E-05	$Kg \cdot m^{-2}$

Calculations

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8as following:

	DDAC	Cu	IPA	MEA	Unit
$E_{soil,\ leach,time1}$	1.27E-06	2.58E-06	5.08E-07	6.41E-08	$Kg \cdot d^{-1}$
$E_{soil,leach,time2}$	1.39E-08	2.82E-08	5.56E-09	1.28E-07	$Kg \cdot d^{-1}$

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

	DDAC	Cu	IPA	MEA	Unit
$Clocal_{soil,TIME1}$	7.53E-09	1.53E-08	1.78E-09	2.41E-10	$Kg \cdot kg_{wwt}^{-1}$
$Clocal_{soil,TIME2}$	1.41E-08	1.52E-08[1]	2.83E-11	7.62E-10	$Kg \cdot kg_{wwt}^{-1}$

[1]*Considering an ageing factor of 2*

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway										
	Fresh-water		Freshwater sediment		STP	Soil		Ground-water		Other
	Direct Release	*Via* STP	Direct Release	*Via* STP		Direct Release	*Via* STP	Direct Release	*Via* STP	
Scenario 1	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.r
Scenario 2	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.r
Scenario 3	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.r
Scenario 4	Y	Y	Y	Y	Y	Y	N	Y	Y	n.r
Scenario 5	Y	Y	Y	Y	Y	Y	N	Y	Y	n.r

n.a.: not assessed
n.r.: not relevant

In the table below the relevant parameters from the active substance dossiers of DDAC, Copper hydroxide and IPA substances are presented. Parameters for MEA were obtained from the Substance Evaluation Report of CoRAP (v.2, Sept. 2016).

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

Input	Value				Unit
	DDAC	Cu	IPA	MEA	
Molecular weight	362.1	63.546	60.09	61.08	g/mol
Melting point	94	-	-89.5	4.00	°C
Boiling point	-	-	82.5	167.00	°C
Vapour pressure (at 20C)	1.50E-03	10E-05 (25ºC)	4100	50.00	Pa
Water solubility (at 20°C)	645000	1.237	10^6	>1000	mg/L
Log Octanol/water partition coefficient	-0.41	8.50E-07	0.05	-2.30	Log 10
Organic carbon/water partition coefficient (Koc)	562314	1.06E+05	3.3	1.167	L/kg
Henry's Law Constant (at 12 C)	5.30E-07	6.61E-03*	0.393	5.65E-08	Pa/m3/mol
Biodegradability	Yes	Inorganic	Yes	Yes	
DT50 for degradation in soil (at 12ºC)	30000	None (but 50% removal agreed)	30	30	d

**Calculated.*

Calculated fate and distribution in the STP					
Compartment	Percentage [%]				Remarks
	DDAC[1]	Cu[1]	IPA	MEA[1]	
Air	1.38E-08	0.00124	0.3	2.72E-08	
Water	6.212	12.86	12.5	8.02	
Sludge	18.96	24.52	0	3.69E-04	
Degraded in STP	8.695	0	87.1	91.97	

[1]Obtained via EUSES v4

PNEC values used in risk assessment				
Active	**$PNEC_{soil}$** ($mg \cdot kgwwt^{-1}$)	**$PNEC_{aquatic}$** ($mg \cdot L^{-1}$)	**$PNEC_{sediment}$** ($mg \cdot kgwwt^{-1}$)	**$PNEC_{stp}$** ($mg \cdot L^{-1}$)
DDAC	1.4	0.0011	3.56	0.14
Cu	40.35	0.0078	18.9	0.23
IPA	0.496	2.82	2.41	10
MEA	0.0325	0.085	0.0942	100

Calculated PEC values

Please note that no PEC values have been obtained for the stages of industrial product application and storage of treated wood prior to shipment. The obtained PEC values for treated wood in service are presented in the next tables.

Summary table on calculated PEC values										
DDAC	**PEC_{Sw}** (mg/l)		**PEC_{STP}** (mg/l)		**PEC_{Sed}** (mg/kg_{wwt})		**PEC_{soil}** (mg/kg_{wwt})		**PEC_{gw}** (µg/l)	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2

Service Life - Vacuum											
House								64.59	118.85	6.51	11.98
Fence								53.74	49.44	5.42	4.98
Noise barrier	Direct release							2,42E1	4,45E1	2,44	4,48
	via STP	1.35E-3	1.11E-5	2.48E-2	2.04E-4	1.65E1	1.35E-1	2.72	2.23E-2	0.27	0
Bridge over pond		8.43E-2	1.69E-1			1.03E3	2.06E3				
Transmission pole								40.14	73.87	4.05	7.44
Service Life - Immersion											
House								3.03E-2	5.69E-2	0.003	0.01
Fence								2.52E-2	2.37E-2	0.003	0.002
Noise barrier	Direct release							1.13E-2	2.13E-2	1.143E-3	2,146E-3
	via STP	6.32E-7	6.92E-9	1.16E-5	1.28E-7	7.72E-3	8.46E-5	1.27E-3	1.40E-5	1.28E-4	1,41E-6
Bridge over pond		5.36E-5	1.07E-4			6.55E-1	1.31				
Transmission pole								7.53E-3	1.41E-2	7.587E-4	1.425E-3

Summary table on calculated PEC values											
Cu		**PEC_{Sw}** (mg/l)		**PEC_{STP}** (mg/l)		**PEC_{Sed}** (mg/kg_{wwt})		**PEC_{soil}** (mg/kg_{wwt})		**PEC_{gw}** (µg/l)	
		T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
Service Life - Vacuum											
House								152.96	152.08		
Fence								130.89	130.16		
Noise barrier	Direct release							70.8	70.5		
	via STP	1.33E-2	2.99E-3	1.05E-1	8.59E-4	31.2	14.8	29	21.7		
Bridge over pond		1.74E-1	3.46E-1			1.14E3	2.27E3				
Transmission pole								103.25	102.70		
Service Life - Immersion											
House								21.66	21.66		
Fence								21.65	21.65		
Noise barrier	Direct release							2.16E1	2.16E1		
	via STP	2.90E-3	2.90E-3	4.90E-5	5.37E-7	1.47E1	1.47E1	2.16E1	2.16E1		
Bridge over pond		3.01-3	3.12E-3			1.54E1	1.61E1				
Transmission pole								21.62	21.62		

Summary table on calculated PEC values											
IPA		**PEC_{Sw}** (mg/l)		**PEC_{STP}** (mg/l)		**PEC_{Sed}** (mg/kg_{wwt})		**PEC_{soil}** (mg/kg_{wwt})		**PEC_{gw}** (µg/l)	
		T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
Service Life - Vacuum											
House								15.27	0.18	8.68E4	1.04E3
Fence								12.70	0.08	7.22E4	4.31E2
Noise	Direct							5.72	6.82	3.25E4	3.88E2

barrier	release										
	via STP	9.50E-4	1.64E-5	9.50E-3	1.64E-4	8.12E-4	1.41E-5	0	0	0	0
Bridge over pond		3.38E-2	6.75E-2			2.88E-2	5.77E-2				
Transmission pole								9.49	0.11	5.39E4	6.44E2
Service Life - Immersion											
House								7.16E-3	1.14E-4	40.70	0.65
Fence								5.96E-3	4.74E-5	33.86	0.27
Noise barrier	Direct release							2.68E-3	4.26E-5	15.24	0.24
	via STP	9.50E-4	1.03E-8	9.50E-3	1.03E-7	8.12E-4	8.79E-9	0	0	0	0
Bridge over pond		2.15 E-5	4.29E-5			1.83E-5	3.67E-5				
Transmission pole								1.78E-3	2.83E-5	10.12	0.16

Summary table on calculated PEC values											
MEA		**PEC_{sw}** (mg/l)		**PEC_{STP}** (mg/l)		**PEC_{Sed}** (mg/kg_{wwt})		**PEC_{soil}** (mg/kg_{wwt})		**PEC_{gw}** (µg/l)	
		T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
Service Life - Vacuum											
House								376.76	4.90	2.73E6	3.54E4
Fence								313.46	2.04	2.27E6	1.47E4
Noise barrier	Direct release							1.41E2	1.83	1.02E6	1.33E4
	via STP	2.96E-2	2.43E-4	2.96E-1	2.43E-3	2.39E-2	1.96E-4	3.20E-5	2.63E-7	0.23	1.90E-3
Bridge over pond		7.78E-1	1.56			6.28E-1	1.26				
Transmission pole								0.03	0.09	2.09E2	6.61E2
Service Life - Immersion											
House								0.18	3.06E-3	1.28E3	22.16
Fence								0.15	1.27E-3	1.06E3	9.22
Noise barrier	Direct release							6.61E-2	1.15E-3	478.44	8.3
	via STP	1.39E-5	1.52E-7	1.39E-4	1.52E-6	1.12E-5	1.23E-7	1.50E-8	1.65E-10	1.09E-4	1.19E-6
Bridge over pond		4.94E-4	9.88E-4			3.99E-4	7.98E-4				
Transmission pole								2.41E-4	7.62E-4	1.74	5.51

The estimations of releases of substances of concern to the groundwater compartment exceeded the threshold value of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC. Refinement with the FOCUS PEARL v.4.4.4 software was calculated only when the biocidal product is applied by immersion.

According to the PT08-ESD (2013), a groundwater assessment is only necessary for the house scenario, which can be considered to be the worst case for soil exposure and, thus

covering all other scenarios. Emissions into the soil during the service-life of the treated wood due to leaching are taken into account to estimate the contamination of the groundwater.

The scenario for the groundwater exposure assessment for wood preservatives described in the supplement of the appendix 4 of the PT08-ESD, based on leaching values.

Input parameter	Unit	Value	
		IPA	MEA
Physicochemical parameters			
Molar mass	$g.mol^{-1}$	60.09	61.08
Water solubility (25 °C)	$mg.l^{-1}$	>1000	>1000
Molar enthalpy of dissolution	$kJ.mol^{-1}$	27	27
Saturated vapour pressure	Pa	5780 (25ºC)	50 (20°C)
Molar enthalpy of vaporisation	$kJ.mol^{-1}$	95	95
Diffusion coefficient in water (20 °C)	$m^2.d^{-1}$	4.3E-05	4.3E-05
Diffusion coefficient in air (20 °C)	$m^2.d^{-1}$	0.43	0.43
Degradation parameters			
Half-life (12°C, pF2)	d	30	30
Arrhenius activation energy	$kJ.mol^{-1}$	65.4	65.4
Exponent of moisture correction function	-	0.7	0.7
Sorption parameters			
K_{oc} value	$l.kg^{-1}$	3.3	1.17
K_{om}value (20°C)	$ml.g^{-1}$	1.914	0.67865
Freundlich exponent 1/n	-	1	
Method of subroutine description	-	pH independent	
Application Schemes			
Q*leach, TIME2 (15 years)	$kg.m^{-2}$	5.72E-05	9.88E-05
Total leachable area	$m^2.ha^{-1}$	2 000	
Service life	year	15	
Number of application per year	-	10	
Dosage per FOCUS application	$kg.ha^{-1}$	5.72E-05	1.32E-03
Application type	-	To the soil surface	
Repeat interval for years	-	1	
Date	-	10/01/1901	
		15/02/1901	
		24/03/1901	
		29/04/1901	
		05/06/1901	
		11/07/1901	
		17/08/1901	
		22/09/1901	
		29/10/1901	

Input parameter	Unit	Value	
		IPA	MEA
		04/12/1901	
Crops Application			
Crop(s)	-	Grassland	
Selected Locations		CHATEAUDUN	
		HAMBURG	
		JOIKIONEN	
		KREMSMUENSTER	
		OKEHAMPTON	
		PIACENZA	
		PORTO	
		SEVILLA	
		THIVA	

The results are listed in the table below.

Scenario	IPA (µg.l^{-1})	MEA (µg.l^{-1})
CHATEAUDUN	0.007	0.168
HAMBURG	0.021	0.515
JOIKIONEN	0.027	0.706
KREMSMUENSTER	0.008	0.204
OKEHAMPTON	0.013	0.320
PIACENZA	0.008	0.199
PORTO	0.007	0.178
SEVILLA	0.004	0.091
THIVA	0.002	0.062

Primary and secondary poisoning

DDAC:
No data are available on the BCF earthworm and calculation according to TGD (eq. 82d) is not applicable to ionic substances, therefore bioaccumulation by terrestrial organisms cannot be estimated with the data available. Nevertheless, as indicated in the Assessment Report of the active substance (June 2015), a very high (unrealistic) BCF earthworm would be needed in order to conclude unacceptable risk of secondary poisoning of birds and mammals (PEC oral predator > PNECoral predator) via the terrestrial food chain.
From the information available, it can be concluded that DDAC has a low potential for bioaccumulation. No further assessment of secondary exposure via the food chain is therefore considered necessary.

Copper dihydroxide:
Cu is an essential trace element, well-regulated in all living organisms. Differences in copper uptake rates are related to essential needs, varying with the species, size, life stage, seasons, etc. Mechanisms to regulate Cu homeostasis are applicable across species

with specific processes being active depending on the species, life stages etc. Simple estimations on secondary poisoning are therefore not adequate.

There is several evidence to showing the absence of Cu biomagnification across the trophic chain in the aquatic and terrestrial food chains. Differences in sensitivity among species are not related to the level in the trophic chain but to the capability of internal homeostasis and detoxification. Field data have further provided evidence on the mechanisms of action of Cu in the aquatic and terrestrial environment and the absence of a need for concern for secondary poisoning.

IPA:
According to the CAR of propan-2-ol (2014), the relevance of a risk characterisation for secondary poisoning is not applicable for propan-2-ol. Due to its physical properties propan-2-ol has a low potential for bioaccumulation in the terrestrial and in the aquatic food chain. No further assessment of secondary exposure is considered necessary.

MEA:
MEA has a low bioaccumulation potential and is rapidly degradable. Given its low potential for bioaccumulation, exposure of predators is considered low. On this basis, a secondary poisoning scenario is not considered necessary.

2.2.8.3 Risk characterisation

Risk Characterisation Ratios (PEC/PNEC) are provided for the STP, the aquatic and terrestrial compartment in the following tables. If the PEC/PNEC ratio is below 1, this is interpreted as an acceptable risk to the environment. Calculated PEC/PNEC values are summarized below; values above 1 are marked with red colour.

NOTE: No risk assessment has been performed for the stages of product application at industrial sites and storage of treated wood prior to shipment, as they are subjected to specific regulation within the EU. However, the following risk mitigation measures are included in the product label to minimize potential environmental risks derived from product application in industrial premises and storage prior to shipment:

- Prevent any release of the biocidal product to the sewage system or the environment during the product application phase as well as during the storage and the transport of treated timber;
- All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
- Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer;
- Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water and that any losses of the product shall be collected for reuse or disposal.
- Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

Summary table on calculated PEC/PNEC values											
DDAC		**PEC/PNEC$_{Sw}$**		**PEC/PNEC$_{STP}$**		**PEC/PNEC$_{Sed}$**		**PECPNEC$_{soil}$**		**PEC$_{gw}$ (µg/l)**	
		T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
Service Life - Vacuum											
House								46.13	84.89	6.51	11.98
Fence								38.38	35.31	5.42	4.98
Noise barrier	Direct release							17.27	31.78	2.44	4.48
	via STP	1.22	0.01	0.18	1.46E-3	4.63	0.04	1.94	0.02	0.27	2,25E-3
Bridge over pond		76.64	153.27			289.49	578.97				
Transmission pole								28.67	52.76	4.05	7.44
Service Life - Immersion											
House								0.022	0.041	3E-3	0.01
Fence								0.018	0.017	3E-3	0.002
Noise barrier	Direct release							8.10E-3	1.52E-2	1.143E-3	2.146E-3
	via STP	5.74E-4	6.29E-6	8.32E-5	9.12E-7	2.17E-3	2.38E-5	9.10E-4	9.97E-6	1,28E-4	1,41E-6
Bridge over pond		4.87E-2	9.74E-2			1.84E-1	3.68E-1				
Transmission pole								5.38E-3	1.01E-2	7.587E-4	1.425E-3

Summary table on calculated PEC/PNEC values											
Cu		**PEC/PNEC$_{Sw}$**		**PEC/PNEC$_{STP}$**		**PEC/PNEC$_{Sed}$**		**PECPNEC$_{soil}$**		**PEC$_{gw}$ (µg/l)**	
		T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
Service Life - Vacuum											
House								3.79	3.77		
Fence								3.24	3.23		
Noise barrier	Direct release							1.75	1.75		
	via STP	1.71E-3	3.83E-4	0.45	3.74E-3	1.65	0.78	0.72	0.54		
Bridge over pond		22.35	44.32			60.4	120.02				
Transmission pole								2.56	2.55		
Service Life - Immersion											
House								0.54	0,54		
Fence								0.54	0,54		
Noise barrier	Direct release							0.54	0.54		
	via STP	3.72E-4	3.72E-4	2.13E-4	2.34E-6	0.78	0.78	0.54	0.54		
Bridge over pond		3.86E-1	4E-1			0.816	0.854				
Transmission pole								0,54	0,54		

Summary table on calculated PEC/PNEC values											
IPA		**PEC/PNEC$_{Sw}$**		**PEC/PNEC$_{STP}$**		**PEC/PNEC$_{Sed}$**		**PECPNEC$_{soil}$**		**PEC$_{gw}$ (µg/l)**	
		T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
Service Life - Vacuum											
House								30.78	0.37	8.68E4	1.04E3
Fence								25.61	0.15	7.22E4	4.31E2
Noise	Direct							11.52	0.14	3.25E4	3.88E2

barrier	release										
	via STP	3.37E-4	5.83E-6	9.50E-4	1.64E-5	3.37E-4	5.83E-6	0	0	0	0
Bridge over pond		0.01	0.02			0.01	0.02				
Transmission pole								19.13	0.23	5.39E4	6.44E2
Service Life - Immersion											
House								0.014	2.30E-4	40.70	0.65
Fence								0.012	9.55E-5	33.86	0.27
Noise barrier	Direct release							5.4E-3	8.60E-5	15.24	0,24
	via STP	3.37E-04	3.65E-09	9.50E-4	1.03E-8	3.37E-04	3.65E-9	0	0	0	0
Bridge over pond		7.71E-6	1.52. E-5			7.6E-6	1.52.E-5				
Transmission pole								3.59E-3	5.71E-5	10.12	0.16

Summary table on calculated PEC/PNEC values

MEA		PEC/PNEC$_{Sw}$		PEC/PNEC$_{STP}$		PEC/PNEC$_{Sed}$		PECPNEC$_{soil}$		PEC$_{gw}$ (µg/l)	
		T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
Service Life - Vacuum											
House								1.16E4	1.51E2	2.73E6	3.54E4
Fence								9.64E3	6.27E1	2.27E6	1.47E4
Noise barrier	Direct release							4.34E3	56.45	1.02E6	1.33E4
	via STP	3,48E-1	2,86E-3	2,96E-3	2,43E-5	2,54E-1	2,08E-3	9.85E-4	8.10E-6	0.23	1,90E-3
Bridge over pond		9.15	18.29			6.67	13.34				
Transmission pole								0.89	2.81	2.09E2	6.61E2
Service Life - Immersion											
House								5,44	0.09	1,28E3	22,16
Fence								4,52	0.04	1.06E3	9.22
Noise barrier	Direct release							2.04	3.53E-2	478,44	8,30
	via STP	1,63E-4	1,79E-6	1,39E-6	1,52E-8	1,19E-4	1,30E-6	4,62E-7	5,06E-9	1,09E-4	1,19E-6
Bridge over pond		5.81E-3	1.16E-2			4.24E-3	8.47E-3				
Transmission pole								7,40E-3	2,34E-2	1,74	5,51

Atmosphere

Conclusion:
As no risk to the atmosphere is expected from the active substances Cu and DDAC, no exposure assessment has been carried out. Regarding the substances of concern IPA and MEA, no ecotoxicological data are available for the air compartment. Therefore, no quantitative estimation of PNECair for these substances is possible.

Sewage treatment plant (STP)

Conclusion: the individual PEC/PNEC ratio for the assessed scenarios is below 1 for all substances in the STP compartment. Therefore, there is no unacceptable risk to this compartment for the proposed uses

Aquatic compartment

When the product is applied by vacuum impregnation, an unacceptable risk to this compartment was observed for all the assessed scenarios.

When the product is applied by dipping/immersion the individual PEC/PNEC ratio in the aquatic compartment is below 1 for all substances and assessed scenarios. Therefore, there is no unacceptable risk to this compartment for the proposed uses when the product is applied by dipping/immersion.

Conclusion: the emission to surface water during service life of treated wood is considered unacceptable when the product is applied by vacuum impregnation but acceptable when the product is applied by dipping/immersion

Terrestrial compartment

When the product is applied by vacuum impregnation and terrestrial compartment is primarily exposed, the individual PEC/PNEC ratios were above 1 for all the scenarios considered.

When the product is applied by dipping/immersion, the individual PEC/PNEC ratios were only considered acceptable for the transmission pole scenario.

Conclusion: the emission to soil during service life of treated wood is considered unacceptable when the product is applied by vacuum impregnation (both UC3 and UC 4a) and acceptable only for the scenario Transmission pole (UC 4a) when the product is applied by dipping/immersion.

Groundwater

The concentration in the soil's pore water derived by equilibrium partitioning according to the guidance are above the threshold value of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC. This limit is exceeded by the pore water concentration of the substances DDAC, IPA and MEA when the product is applied by vacuum impregnation and terrestrial compartment is primarily exposed.

Additionally, when the product is applied by vacuum impregnation the threshold value of 0.1 µg/L is also exceeded by the substance DDAC and MEA at time 1 when groundwater is exposed via STP sludge application to soil.

FOCUSPEARL 4.4.4 groundwater contamination simulation has not been deemed necessary to refine groundwater levels when the product is applied by vacuum impregnation as there have also been obtained unacceptable risks to other compartments for the intended uses.

When product is applied by dipping/immersion, the soil's pore water concentration is also above 0.1 µg/L as a consequence of direct release to soil for substances IPA and MEA. Focus Pearl 4.4.4 was used to refine the groundwater concentration values obtained for the substances of concern IPA and MEA. This refinement showed that IPA concentrations are expected to be under the threshold limit of 0.1 µg/L in all the assessed localities. However, groundwater expected concentrations FOR MEA are above this threshold for all localities except Seville and Thiva.

Conclusion: the emission to groundwater during service life of treated wood is considered unacceptable both when the product is applied by vacuum impregnation or dipping/ immersion.

Primary and secondary poisoning

Conclusion: Because the product is only applied indoors at industrial sites and not directly released to the environment, direct uptake by non-target organisms cannot be expected at this phase. Moreover, product leaching from treated wood in service is expected to occur. However, all active substances and substances of concern do not pose a risk to non-target organisms via secondary exposure through the food chain. Almost all of these substances are rapidly biodegradable and present low potential for bioaccumulation. In case of Cu, it is an essential element and its levels are regulated in all living organisms. Therefore, no risks from primary and secondary poisoning are expected.

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

Teat disinfectants: Emission pathways

- via direct release to soil and surface water compartments and/or
- via STP

Screening Step 2: Identification of relevant substances

According to the Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C) 2017 the following substances need to be considered as relevant for the mixture assessment:

1. active substance
2. substances of concern (SoC)
3. active substances from other PTs
4. other ingredients.

The products contain only two active substance and two substances of concern, one of which is an active substances from other PTs. No other ingredients that need consideration are contained. Thus, the number of relevant substances is 4: DDAC, Cu, IPA and MEA.

Screening Step 3: Screen on synergistic interactions

There are no synergistic effects between propan-2-ol and iodine since it does not affect the effectiveness of the product.

Screening step		
1	Significant exposure of environmental compartments?	Yes
2	Number of relevant substances >1?	Yes
3	Indication for synergistic effects for the product or its constituents in the literature?	No

A sum of PEC/PNEC ratio for substance of concern and active substances is not considered as relevant because obtained PEC/PNEC ratios are already higher than 1 and level of contamination of Cu is compared to the background concentrations.

Aggregated exposure (combined for relevant emmission sources)

There is currently no agreed method for estimating risk from aggregated exposure, so no further assessment can be made.

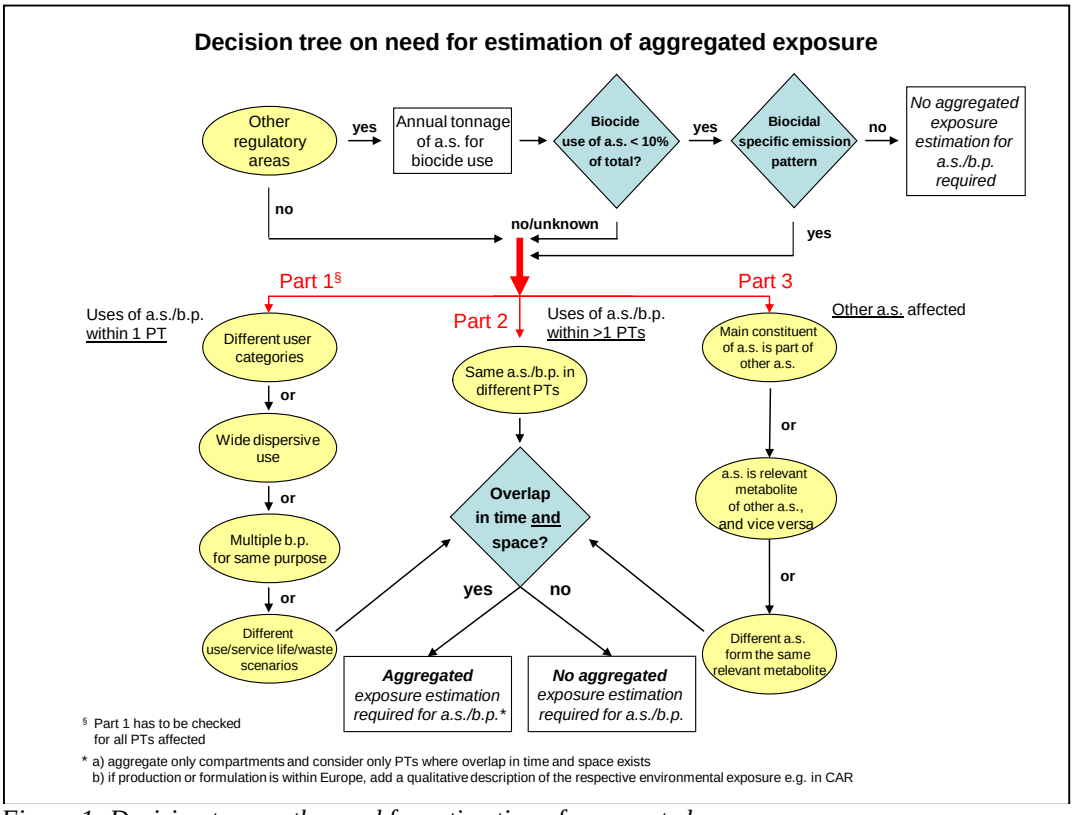


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
The application of the biocidal product FKR-ACQ EXTRA is carried out at industrial sites in closed vessels or autoclaves, and all stages of treating process remain in a closed system.

The application of the biocidal product at industrial sites and storage of treated wood is considered of no concern when risk mitigation measures to avoid releases are taken.

For preventive treatment of wood classes 1 and 2, emissions during service life of treated wood are considered negligible. Therefore, the risks for the service life of treated wood are therefore acceptable for treatment of wood in classes 1 and 2.

The risk characterisation of treated wood in service for wood classes 3 and 4a indicates that the biocidal product FKR-ACQ EXTRA, applied by the industrial processes –dipping/immersion and vacuum impregnation– presents unacceptable risks to the environment for the uses of treated wood in outdoor use classes 3 and 4a except for the Bridge over Pond scenario (UC 3) when the product is applied by dipping immersion at a biocidal product concentration of 0.2 % (retention of 0.26 $g \cdot m^{-2}$).

Therefore, the product FKR-ACQ EXTRA can only be authorized for:

- Treatment of wood classes 1 and 2 when the biocidal product is applied at industrial sites by vacuum impregnation;
- Treatment of green timber of wood classes 1 and 2 when the biocidal product is applied at industrial sites by dipping/immersion;

Treatment of green timber of wood class 3 (NOT timber that, once installed, will affect the soil or groundwater, as it happens in a cladded house, fence, noise barrier, etc.) when the product is applied by dipping/immersion.

2.2.9 Measures to protect man, animals and the environment

Risk mitigation measure to protect man:
Exposure control/PPE accordingly with the mixture classification and the precautionary statements:
Respiratory protection:
Wear protective face mask with cartridge filter type ABEK (EN 141) during product handling phase in case of formation of organic vapors.
Hand protection:
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorization holder within the product information).
Direct contact with the product should always be avoided. Select the appropriate means to prevent splashes or accidental projections
Eye protection:
Wear safety goggles adjustable to eye contour during product handling phase (EN 166).
Trained professionals must wear gloves (90% efficacy), impermeable coverall (95 % efficacy) and protection glasses in industrial use
General measures for protection and hygiene:
Do not drink, eat or smoke during handling. Workplaces should be provided with efficient ventilation, safety showers and eyewash stations.

Particulars of likely direct or indirect effects, first aid instructions
Response precautionary statements related to first aid instructions in point 3 of this PAR shall apply in this section. In adition:
IF SWALLOWED: Call a POISON CENTER/doctor/… if you feel unwell.
Rinse mouth.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER
Phone 91 562 04 20
To incorporate this phone into the label you must make the corresponding notification to the INTCF according to the procedure established in Order JUS/909/2017

Conditions of storage and shelf-life of the product
Shelf-life: 2 years.
Protect from frost.
Storage in fresh and well ventilated place.
Keep the product in the original packaging, well closed.
Due to its alkalinity, keep away from acids or acid formers.
Accordingly to the Spanish Storage Regulation for Chemicals (MIE-APQ), keep away from strong oxidisers and peroxides.
It is recommended to avoid temperatures above 40ºC

2.2.10 Assessment of a combination of biocidal products

Not relevant

2.2.11 Comparative assessment

Not relevant.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
2.1.2	Anonymous	2016	Title: Certificado de composición del producto FKR-ACQ EXTRA. Test Facility: FKR Química S. L.; Crta. Morella, km 1.7, Nave 2, Vinaroz, Castellón.
2.1.2	Anonymous	2016	Title: Declaración de composición del formulado FKR-ACQ EXTRA. Test Facility: FKR Química S. L.; Crta. Morella, km 1.7, Nave 2, Vinaroz, Castellón.
2.1.2	Anonymous	2018	Title: Declaración de composición del formulado FKR-ACQ EXTRA. Test Facility: FKR Química S. L.; Crta. Morella, km 1.7, Nave 2, Vinaroz, Castellón.
2.1.2	Anonymous	2017	MSDS of FKR-ACQ-EXTRA Sheet Facility: FKR Química S. L.; Crta. Morella, km 0.7, Nave 2, Vinaroz, Castellón.
2.1.2	Anonymous	2017	MSDS of Hidróxido de cobre calidad química (Copper (II) hydroxide) Sheet Facility: Spiess-UYrania Chemicals GmbH, Frankenstrasse 18 b, 20097, Hamburg, Germany
2.1.2	Anonymous	2017	MSDS of Didecyldimethylammonium chloride (>25 % w/w) Sheet Facility: Thor Especialidades S. A.; Polígono Industrial EL PLA, Avenida de la Industria, 1, 08297, Castellgali, Barcelona, Spain
2.1.2	See confidential annex.	2017	Certificado analítico - Sheet Facility: Thor Especialidades S. A.; Polígono Industrial EL PLA, Avenida de la Industria, 1, 08297, Castellgali, Barcelona, Spain
2.1.2	See confidential annex.	2018	Composición cualitativa / cuantitativa al 100% del ingrediente activo técnico Sheet Facility: Thor Especialidades S. A.; Polígono Industrial EL PLA, Avenida de la Industria, 1, 08297, Castellgali, Barcelona, Spain
2.1.2	Anonymous	2015	MSDS of coformulant 1 Sheet Facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3, Aptdo.Correos 278, E-28760 TRES CANTOS –MADRID, Spain

2.1.2	Anonymous	2016	MSDS of Monoetanolamina Sheet Facility: ADIEGO Hnos, S. A.; Crta. Valencia, Km. 5.900, 50410, Cuarte de huerva, Zaragoza, Spain
2.2.2	See confidential annex.	2016	Title: Determinación de pH segun guia OECD, apariencia, estado físico, color y olor a t = 0 meses. Test facility: Laboratorio Micro-Bios, C/ Jacint Verdaguer 62, Pol. Ind. Fontsanta 08970 Sant Joan Despí, Barcelona (España) Study code: 16-0168.01 GLP compliance → No Data protection claimed → Yes
2.2.2	See confidential annex.	2015	Title: Determinación de densidad, viscosidad y alcalinidad. Test facility: Laboratorio Micro-Bios, C/ Jacint Verdaguer 62, Pol. Ind. Fontsanta 08970 Sant Joan Despí, Barcelona (España) Study code: 15-0412.01 GLP compliance → No Data protection claimed → Yes
2.2.2	See confidential annex.	2015	Title: Determinación de la tensión superficial. Test facility: **PEINUSA,** Via Augusta, 390, 08017, Barcelona, Spain Study code: 15/0749 GLP compliance → No Data protection claimed → Yes
2.2.2	See confidential annex.	2015	Title: Estudio de estabilidad. Test facility: Laboratorio Micro-Bios, C/ Jacint Verdaguer 62, Pol. Ind. Fontsanta 08970 Sant Joan Despí, Barcelona (España) Study code: 15-0435.01m GLP compliance → No Data protection claimed → Yes
2.2.2	See confidential annex.	2017	Title: Estudio de estabilidad de FKR-ACQ EXTRA. Test facility: Laboratorio Micro-Bios, S.L.; C/ Jacint Verdaguer 62; 08970 Sant Joan Despí, Barcelona (España) Study code: 15-0435.01 GLP compliance → No Data protection claimed → Yes

2.2.3	See confidential annex.	2015	Title: Ensayos de corrosión sobre acero S275J2 en FKR ACG diluido 3%. Test facility: **PEINUSA,** Via Augusta, 390, 08017, Barcelona, Spain Study code: 15/0769.B GLP compliance → No Data protection claimed → Yes
2.2.3	See confidential annex.	2015	Title: Ensayos de corrosión sobre acero S275J2 en FKR ACG concentrado. Test facility: **PEINUSA,** Via Augusta, 390, 08017, Barcelona, Spain Study code: 15/0769.A GLP compliance → No Data protection claimed → Yes
2.2.4	See confidential annex.	2015	Title: Determinación de hidróxido de cobre y materia activa catiónica en el producto FKR-ACQ EXTRA. Test facility: Laboratorio Micro-Bios, C/ Jacint Verdaguer 62, Pol. Ind. Fontsanta 08970 Sant Joan Despí, Barcelona (España) Study code: 15-0435.01 GLP compliance → No Data protection claimed → Yes
2.2.5	See confidential annex.	2012	Title: Determinacion de la eficacia preventiva contra hongos del azulado y mohos en madera recién aserrada según la norma CEN/TS 15082:2005. Test facility: Tecnalia Sponsor: FKR QUIMICA. S.L. Nº Report: 29734
2.2.5	See confidential annex.	2015	Title: Determination of toxic values against *Reticulitermes species* according to EN 117:2012.(EN73) Test facility: Tecnalia Sponsor: FKR QUIMICA. S.L. Nº Report: 15-09007-1-a
2.2.5	See confidential annex.	2015	Title: Determination of toxic values against *Reticulitermes* species according to EN 117:2012. Test facility: Tecnalia, Spain Report no. 15-09007-2-a

2.2.5	See confidential annex.	2015	Title: Determination of toxic values against *Reticulitermes* species according to EN 117:2012.(EN84) Test facility: Tecnalia Sponsor: FKR QUIMICA. S.L. Nº Report: 15-09007-2-(M1)
2.2.5	See confidential annex.	2007	Title: - Test facility: Instituto Nacional de Investigación y Tecnologia Agraria y Alimentaria. Sponsor: FKR QUIMICA. S.L. Nº Report: MTF/6/07
2.2.5	See confidential annex.	2008	Title: Determination of efficacy threshold of FKR ACQ against wood destroying basidiomycetes according to UNE 56,412, corresponding to EN 113, in combination with EN 73 and EN 84. Test facility: Instituto Nacional de Investigación y Tecnologia Agraria y Alimentaria. Sponsor: FKR QUIMICA. S.L. Nº Report: MTF/ACQ-2/08
2.2.5	See confidential annex.	2019	Title: Addendum to Report no. MTF/ACQ-2/08 (10th September 2019) Test facility: INIA-CIFOR, Spain
2.2.5.	See confidential annex.	2008	Title: Determination of efficacy threshold of FKR ACQ against soft rot fungi and other soil microorganisms according to ENV 807 and EN 84.- Test facility: Instituto Nacional de Investigación y Tecnologia Agraria y Alimentaria. Sponsor: FKR QUIMICA. S.L. Nº Report: MTF/ACQ/08
2.2.5	See confidential annex.	2019	Title: Addendum to Report no. MTF/ACQ/08. (10th September 2019) Test facility: INIA-CIFOR, Spain
2.2.5.	See confidential annex.	2014	Title: Realización de ensayos de penetración y retención sobre muestras de madera tratadas con sales de cobre. Test facility: Tecnalia. Sponsor: FKR QUIMICA. S.L. Nº Report: 14_08515
	ECHA	2011	Competent Authority Report and Assessment Report of Copper (II) hydroxide.
	ECHA	2015	Competent Authority Report and Assessment Report of Didecyldimethylammonium chloride (DDAC).

	Official Journal of the European Union	2012	COMMISSION DIRECTIVE 2012/2/EU
	Official Journal of the European Union	2013	COMMISSION DIRECTIVE 2013/4/EU

3.2 New information on the active substance

No new information is provided on the active substance.

3.3 Residue behaviour

No new information is provided about residue behaviour.

3.4 Summaries of the efficacy studies

Please see table on Efficacy data on section 2.2.1.5.