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 APPLICATION

(submitted by the competent authority)

Sinesto XT

Product type

PT 08 (Wood preservatives)

K-HDO and ATMAC/TMAC as included in the Union list of approved active substances of Regulation (EU) No 528/2012

Case Number in R4BP: BC-GS070167-22

Competent Authority: DE (BAuA)

Date: 11.12.2023

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Changes history table

Application type	refMS /eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	DE	BC-GS070167-22	11.12.2023	Initial assessment	p. 7

1 Conclusion

Sinesto XT is a soluble concentrate biocidal product containing K-HDO and ATMAC/TMAC as active substances. The product is used as a wood preservative (product-type 08) by industrial and professional users for the control of wood discolouring fungi (Sapstain fungi, bluestain fungi, mould fungi).

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the uses "Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi_Dipping" (Industrial and professional users) and "Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi_Spraying" (Industrial and professional users), as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended uses of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

The biocidal product contains the following non-active substances (so called "co-formulants") which are considered as substances of concern:

- 2-Ethylhexanoic acid (for human health)
- Potassium hydroxide (for human health)

More detailed information on the substances of concern is provided in chapter 3.6.3 and in the confidential annex.

The biocidal product contains the active substances K-HDO and ATMAC/TMAC, which have not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More information is available in section 2.7 and 3.8.1.4 of the PAR and in the confidential annex.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.3 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturers of the active substances are listed in section 1.4 of the SPC.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substances and of one substance of concern are available. More information on the analytical methods for the active substance(s) is available in section 3.4 of the PAR.

Methods for the detection of ATMAC/TMAC and K-HDO in soil, air and water were provided and deemed acceptable at EU level. No other data are required.
The product is not intended to be used on surfaces in contact with food/feed of plant and animal origin; therefore, analytical methods for the determination of the active substances in food/feed of plant and animal origin are not required.

Analytical methods for the determination of residues of substances of concern are not necessary.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against wood discolouring fungi (Sapstain fungi, bluestain fungi, mould fungi) for all intended uses (Minimum application rate raised to 3.6 g/m^2). However, protection depends on factors like wood type, storage duration and storage mode of the treated wood. A minimum dose of 3.6 g/m² is effective only on loosely packed wood for 8-12 weeks. Closely packed wood requires a dose of 4.4 g/m² or higher and at this dose is protected only for 4-8 weeks. For these reasons, users of the biocidal product should determine which dosage within the authorised dose range is required in their specific circumstances.

More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.

Since 2-Ethylhexanoic acid and potassium hydroxide have been identified as substances of concern, the human health risk assessment is based on the active substances K-HDO and ATMAC/TMAC and on 2-Ethylhexanoic acid and potassium hydroxide.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable acute or chronic risk to industrial and professional users, professional bystanders and non-professional bystanders/general public, if the directions for use, as specified in the SPC, are followed.

Dietary risk assessment

Considering the uses, food, or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substances is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

Considering the uses, exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

Since no substance of concern for the environment has been identified, the risk assessment for the environment is based on K-HDO and ATMAC/TMAC.

Based on the risk assessment it is unlikely that the intended uses cause any unacceptable risk for the environment, if the risk mitigation measures and directions for use, as specified in the SPC, are followed.

2 Information on the biocidal product

2.1 Product type and type of formulation

Table 2.1 Product type and type of formulation

Product type	PT 08 (Wood preservatives)
Type of formulation	SL (soluble concentrate)

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number	Use description	PT	Target organisms	Application method	Application rate (min-max)	User category	Conclusion (eCA/ refMS)	Comment (eCA/refMS)
1	Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi_Dipping	PT 08	Wood discolouring fungi	Fully automated dipping Application by fully automated dipping processes where all steps in the treatment and drying processes are mechanised and no manual handling takes place; including when the treated articles are transported through the dip tank to draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry.	Dipping 3.6 – 9 g Sinesto XT / m² wood (usual range); up to 13.5 g/m² in special cases like very high infestation pressure. Dilution (%): 2.4% - 6% w/w usual range; up to 9% w/w for dipping in special cases like very high infestation pressure (average solution uptake of treated wood: 150 mL/m^2).	Industrial Professional[1]	R	• Minimum application rate raised (efficacy)
2	Preventive, temporary protection of freshly sawn	PT 08	Wood discolouring fungi	Spraying Application by spraying occurs only in a closed	Spraying 3.6 – 8.50 g Sinesto XT / m² wood	Industrial Professional[1]	R	• Minimum application rate raised

1 In Germany only: Professional (Generally, training according to § 15c of the Hazardous Substances Ordinance (GefStoffV) is required.

	timber and wooden pallets against wood discolouring fungi_Spraying			deluge/flow coat/spray-tunnel	Dilution (%): 3.6% - 8.50% w/w (average solution uptake 50-100 ml/m²)			(efficacy)

2.3 Identity and composition

The identity and composition of the biocidal product are

identical ☐
not identical ☒

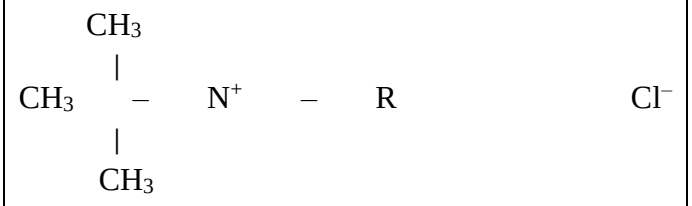
to the identity and composition of the product(s) evaluated in connection with the approval for listing of the active substances on the Union list of approved active substances under Regulation (EU) No 528/2012.

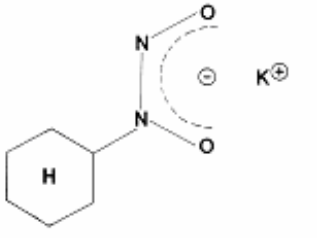
The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.

2.4 Identity of the active substances

Table 2.3 Identity of the active substances

Main constituent	
Common name	Coco alkyltrimethylammonium chloride (ATMAC/TMAC)
Chemical name	Quaternary ammonium compounds, coco alkyltrimethyl, chlorides
EC number	263-038-9
CAS number	61789-18-2
Index number in Annex VI of CLP	-
Minimum purity / content	35% w/w (TK / aqueous solution as manufactured) 96.6% w/w (dry weight)
*	 R = alkyl C8-18 (even-numbered) and C18 (unsaturated)

Main constituent	
Common name	K-HDO
Chemical name	Cyclohexylhydroxydiazene 1-oxide, potassium salt
EC number	-
CAS number	66603-10-9
Index number in Annex VI of CLP	611-181-00-6
Minimum purity / content	30% w/w (TK / aqueous solution as manufactured) 97.7% w/w (dry weight)
Structural formula	

2.5 Information on the sources of the active substances

Is the source of K-HDO and ATMAC/TMAC the same as the ones evaluated in connection with the approval for listing of the actives substances on the Union list of approved active substances under Regulation (EU) No 528/2012?

☒ Yes
☐ No

2.6 Candidate(s) for substitution

No candidate for substitution has been identified.

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product contains the active substances K-HDO and ATMAC/TMAC. According to the CAR for K-HDO (eCA: AT, 2008) and ATMAC/TMAC (eCA: IT, 2016), there are no indications for endocrine disrupting properties of these active substances. However, a comprehensive ED-assessment for the active substances according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More detailed information is available in the confidential annex of the PAR.

2.8 Classification and labelling

Besides the active substances K-HDO and ATMAC/TMAC and the substances of concern 2-Ethylhexanoic acid and potassium hydroxide, the other components do not affect the classification of the biocidal product.

A harmonised classification for the active substance ATMAC/TMAC does not exist. Instead, the following classification from the assessment report (Assessment report ATMAC/TMAC PT 08, 14/04/2016, Italy) was taken into account:

- Aquatic acute 1 (H400), M factor 10
- Acute Tox. 3, H301
- Acute Tox. 3, H311
- Skin Corr. 1B, H314
- EUH071

Additionally, based on a NOEC of 0.008 mg/L for algae, ATMAC/TMAC needs to be considered as H410 based on table 4.1.0 b) ii) of the 2nd ATP to the CLP Regulation. The following classification was concluded:

- Aquatic chronic 1 (H410), M factor 1

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

- Aquatic chronic 2 (H411)
- Acute Tox. 3, H301
- Skin Irrit. 2, H315
- Eye Dam. 1, H318
- STOT RE 2, H373 (liver)

Classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is required. Please, also refer to the confidential annex to this assessment report.

Table 2.4 Classification and labelling of the biocidal product

	Classification			**Labelling**		
Hazard Class and Category code	Aquatic acute Cat 1 (H400) Aquatic chronic Cat 2 (H411) Acute Tox. 4 Skin Corr. 1 Eye Dam. 1 Repr. 1B			Aquatic chronic Cat 1 (H410) Acute Tox. 4 Skin Corr. 1 Repr. 1B		
Hazard Pictograms		 GHS05			 GHS05	
	 GHS07	 GHS08	 GHS09	 GHS07	 GHS08	 GHS09
Signal word(s)	Danger			Danger		
Hazard statements	H302 - Harmful if swallowed. H314 - Causes severe skin burns and eye damage. H318 – Causes serious eye damage H360D - May damage the unborn child. H400 – Very toxic to aquatic life. H411 – Toxic to aquatic life with long-lasting effects.			H302 - Harmful if swallowed. H314 - Causes severe skin burns and eye damage. H360D - May damage the unborn child. H410 – Very toxic to aquatic life with long-lasting effects.		
Precautionary statements*	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe spray. P264: Wash hands thoroughly after handling.			The authorisation holder is responsible to choose the relevant P-statements to be included on the label.		

	P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301 + P312: IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell. P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313: IF exposed or concerned: Get medical advice/attention. P310: Immediately call a POISON CENTRE or doctor. P321: Specific treatment (see information on this label). P330: Rinse mouth. P363: Wash contaminated clothing before reuse. P391: Collect spillage. P405: Store locked up. P501: Dispose of contents/container to appropriate hazardous waste collection point	
Supplemental hazard statements	EUH071 - Corrosive to the respiratory tract.	
Notes		

All P-statements listed under the first column have also been listed in the SPC

2.9 Letter of access

The applicant provided a letters of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[2]) of the active substances ATMAC/TMAC and K-HDO for use in wood preservatives (product-type 08). Please, refer to the corresponding Assessment Report for a reference list.

2.10 Data submitted in relation to product authorisation

Not relevant (no new data on the active substance(s) was submitted).

2.11 Similar conditions of use across the Union

Not relevant (national authorisation).

2 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
Jerrycan	30 L	HDPE		Industrial Professional	Yes
Drum	60 L	HDPE		Industrial Professional	Yes
IBC	600 L	HDPE		Industrial Professional	Yes
IBC	1000 L	HDPE		Industrial Professional	Yes

3.2 Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa				
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	liquid	anonymous, 2020 Study-No. 20-WD-001
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual		clear, slightly lutescent	
3.1.3.	Odour at 20 °C and 101.3 kPa	Olfactory / OPPTS 830.6304		lye-like	
3.2.	Acidity, alkalinity and pH value	CIPAC MT 75.3 CIPAC MT 191	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	pH at 25 °C, undiluted: 14.42 pH at 25 °C, 1% aqueous solution: 11.47 Alkalinity of undiluted product at 25 °C: 1.35% (w/w NaOH)	anonymous, 2020 Study-No. 20-WD-001 anonymous, 2020 Study-No. 20-WD-009
3.3.	Relative density / bulk density	OECD 109/ DIN EN ISO2811-3:2001 (oscillation densimeter))	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	Density at 20 °C: 1.0587 g/cm^3	anonymous, 2020 Study-No. 20-WD-002
3.4.1.1.	Storage stability test – **accelerated storage**	CIPAC MT 46.3 (54 °C, 14 days) CIPAC MT 75.3 (pH) OECD 109 /	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	The samples were stored in 100 ml brown glass bottles with screw caps at 54 ±2 °C for 14 days . K-HDO content (%	anonymous, 2021 Study-No. 20-WD-007

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		DIN EN ISO2811-3:2001 (density) Potentiometric titration (TMAC determination) UPLC-PDA (K-HDO determination)		w/w): T_0: 0.739 T_{end}: 0.728 (-1.5%) TMAC content (% w/w): T_0: 13.94 T_{end}: 14.10 (+1.1%) pH (25 °C, undiluted): T_0: 14.42 T_{end}: 14.39 Density (20 °C): T_0: 1.0587 g/cm^3 T_{end}: 1.0592 g/cm^3	
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	Storage at room temperature for 24 months CIPAC MT 75.3 (pH) OECD 109 / DIN EN ISO2811-3:2001 (density) CIPAC MT 47 (Persisent foaming) CIPAC MT 41 (Dilution	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	The samples were stored in 5 L white HDPE canisters with screw caps in a storage room with glass windows. The temperature during storage varied between 8 °C and 30 °C. Weight loss after 24 months: < 0.1% No change in appearance of the product and packaging. No sedimentation or other deviation	anonymous, 2021 Study-No. 21-WR-001

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		stability) Potentiometric titration (TMAC determination) UPLC-PDA (K-HDO determination)		observerd. K-HDO content (% w/w): T_0: 0.739 T_{end}: 0.735 (-0.5%) TMAC content (% w/w): T_0: 13.94 T_{end}: 13.77 (-1.2%) pH (25 °C, undiluted): T_0: 14.42 T_{end}: 14.29 Density (20 °C): T_0: 1.0587 g/cm^3 T_{end}: 1.0586 g/cm^3 Persistent foaming 2.25% aqueous solution: T_0: 29 ml T_{end}: 19 ml 27.0% aqueous solution: T_0: 26 ml T_{end}: 10 ml Dilution stability (2.25% and 27.0% aqueous solutions): T_0: stable immediately and after 18 h	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				T_{end}: stable immediately and after 18 h	
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	No change in appearance of the product and no precipitation was observed after storage at 0 °C for 7 days.	anonymous, 2020 Study-No. 20-WD-006
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Exposure to daylight during long-term-storage.	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	The product was exposed to daylight during the long-term storage stability study on a regular basis over a timespan of 24 months. As no effect was observed, the product is considered stable against daylight.	anonymous, 2021 Study-No. 21-WR-001
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	CIPAC MT 46.3 (54 °C, 14 days)	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	No degradation or change to the product was observed after storage at 54 °C for 14 days, so the product can be considered stable at higher temperatures. As the product is an aqueous concentrate and effect of humidity	anonymous, 2021 Study-No. 20-WD-007

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				can be excluded.	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT 46.3 (54 °C, 14 days)	-	Storage stability test – **accelerated storage** Results: No changes in active ingredient or product observed; no reaction with container material observed	Wolman Wood and Fire Protection GmbH, 2019, Study-No: 20-WD-007
		GIFAP, OPPTS 830.6317	-	Storage stability test – **long-term storage at ambient temperature** Result: No changes in active ingredient or product observed; no reaction with container material observed	Wolman Wood and Fire Protection GmbH, 2021, Study-No: 21-WR-001
3.5.1.	Wettability [indicate the concentration tested]	Data waiving		Not applicable. Product is a SL liquid formulation.	
3.5.2.	Suspensibility, spontaneity, and dispersion stability [indicate the concentration tested]	Data waiving		Not applicable. Product is a SL liquid formulation.	
3.5.3.	Wet sieve analysis and dry sieve test [indicate the concentration tested]	Data waiving		Not applicable. Product is a SL liquid formulation.	
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability [indicate the concentration tested]	Data waiving		Not applicable. Product is a SL liquid formulation.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.5.	Disintegration time	Data waiving		Not applicable. Product is a SL liquid formulation.	
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability [the particle size distribution of droplets (MMAD) should be reported for RTU products if sprayed.]	Data waiving		Not applicable. Product is a SL liquid formulation and not placed on the market with a spraying device.	
3.5.7.	Persistent foaming [indicate the concentration tested]	CIPAC MT 47	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	Foam after indicated time at 21 °C (ml) 2.25% aqueous solution: 10 s: 13 ml 1 min: 10 ml 3 min: 9 ml 12 min: 7 ml 27.0% aqueous solution: 10 s: 15 ml 1 min: 12 ml 3 min: 5 ml 12 min: 2 ml	anonymous, 2020 Study-No. 20-WD-005
3.5.8.	Flowability/pourability/dustability	Data waiving		Not applicable. Product is a SL liquid formulation.	
3.5.9.	Burning rate — smoke generators	Data waiving		Not applicable. Product is a SL liquid formulation.	
3.5.10.	Burning completeness — smoke generators	Data waiving		Not applicable. Product is a SL liquid formulation.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.11.	Composition of smoke — smoke generators	Data waiving		Not applicable. Product is a SL liquid formulation.	
3.5.12.	Spraying pattern — aerosols / spray	Data waiving		Not applicable. Product is a SL liquid formulation and not placed on the market with a spraying device.	
3.6.1.	Physical compatibility	Data waiving		Not applicable. Product is not intended to be used in combination with other products.	
3.6.2.	Chemical compatibility	Data waiving		Not applicable. Product is not intended to be used in combination with other products.	
3.7.	Degree of dissolution and dilution stability (indicate the concentration tested)	CIPAC MT 41	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	All measurements carried out at 20 °C. 2.25% aqueous solution: T_0: Clear solution and no precipitation T_{18h}: Cloudy phase on the bottom, slightly opaque solution after inversion. 27.0% aqueous solution: T_0: Clear solution and no precipitation T_{18h}: Cloudy phase on the bottom, slightly opaque solution after inversion.	anonymous, 2020 Study-No. 20-WD-004

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				No cloudy phase or opaque solution was observed when demineralised water was used. Sinesto XT is considered stable after dilution in water.	
3.8.	Surface tension [indicate the conditions of the test and the concentration tested]	OECD 115 / EC A.5 (ring method)	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	Surface tension of a 27.0% aqueous solution at 20 °C: 33.32 mN/m Sinesto XT is considered surface-active.	anonymous, 2020 Report No. 200130BT / CPT18943
3.9.	Viscosity [indicate the shear rate and the temperature tested]	OECD 114 (rotation viscosimeter)	Sinesto XT (14.00% TMAC, 0.75% K-HDO) Internal sample No: TH 4101	Dynamic viscosity at 20 °C: 20.1 mPa·s Dynamic viscosity at 40 °C: 10.1 mPa·s	anonymous, 2020 Study-No. 20-WD-003

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
Sinesto XT is a soluble concentrate (SL). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. **Implications for labelling:** **-** Shelf-life: 24 months.

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	UN Manual of Tests and Criteria: Part I: Classification procedures, test methods and criteria relating to explosives of Class 1 EU Method A.14 (Explosive properties) EPA OPPTS 830.6316 (Explodability)	TH 4101 13.86% Quaternary ammonium compound (TMAC) 0.74% N-cyclohexyl-diazeniumdioxy-potassium (K-HDO)	The DSC measurements in the closed crucibles (no mass loss) up to 500 °C showed an exothermic effect starting at a temperature of 140 °C with an average energy release of -60 J/g. The overall decomposition energy does not go beyond the threshold of -500 J/g. Therefore, explosive properties can be excluded.
4.2.	Flammable gases	Data waiving		Not applicable for liquids
4.3.	Flammable aerosols	Data waiving		Not applicable for non-aerosols
4.4.	Oxidising gases	Data waiving		Not applicable for liquids
4.5.	Gases under pressure	Data waiving		Not applicable for liquids
4.6.	Flammable liquids	EU Method A.9 (Flashpoint) DIN EN ISO 2719 (2016): Determination of Flash Point - Pensky Martens EPA OPPTS 830.6315 (Flammability)	TH 4101 13.86% Quaternary ammonium compound (TMAC) 0.74% N-cyclohexyl-diazeniumdioxy-potassium (K-HDO)	TH 4101 has no flash point up to a temperature of 105.0 °C according to Regulation EC No. 440/2008 Method A.9. Flash Point and DIN EN ISO 2719 (2016)
4.7.	Flammable solids	Data waiving		Not applicable for liquids
4.8.	Self-reactive substances and mixtures	UN Manual of Tests and Criteria: Part II, Test Series A to H	TH 4101 13.86% Quaternary ammonium compound (TMAC) 0.74% N-cyclohexyl-diazeniumdioxy-potassium (K-HDO)	The decomposition energy of the exothermic effect is < 300 J/g (see DSC measurement conducted under 4.1). Therefore, Sinesto XT does not need to be classified as a self-reactive substance.
4.9.	Pyrophoric liquids	Data waiving		Sinesto XT is stable at room temperature

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				under air for a longer time period (at least one day), therefore the test on pyrophoric properties does not need to be performed.
4.10.	Pyrophoric solids	Data waiving		Not applicable for liquids
4.11.	Self-heating substances and mixtures	Data waiving		The test for self-heating substances and mixtures is not applicable for this product. No reaction with air has been observed during the test for determination of the flashpoint. The vapour-air mixtures of the product did not ignite. In addition, the product is a liquid where based on the small surface area self-heating is not expected.
4.12.	Substances and mixtures which in contact with water emit flammable gases	Data waiving		The study does not need to be performed because the product is a water-based formulation which does not emit flammable gases in contact with water.
4.13.	Oxidising liquids	Data waiving		Neither K-HDO nor TMAC have oxidizing properties. Likewise, the non-active ingredients are considered non-oxidising due to their chemical structure. It is therefore concluded that oxidizing properties of Sinesto XT can be excluded according to UN Transport Regulation and GHS.
4.14.	Oxidising solids	Data waiving		Not applicable for liquids
4.15.	Organic peroxides	Data waiving		Sinesto XT does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.
4.16.	Corrosive to metals	UN Manual of Tests and Criteria: Part III, 37.4: Test methods for corrosion to metals	TH 4101 13.86% Quaternary ammonium compound (TMAC)	Test duration 28 days: Uniform Corrosion: Steel: (weight loss) Fully immersed: < 0.01 wt%

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
			0.74% N-cyclohexyl-diazeniumdioxy-potassium (K-HDO)	Half immersed: 0.04 wt% Gas phase: 0.73 wt% Aluminium: (weight loss) Fully immersed: 43.04 wt% Half immersed: 11.51 wt% Gas phase: 0.13 wt% Localized Corrosion: Steel: (Max Intrusion Depth [µm]) Fully immersed: No intrusion depths could be found microscopically Half immersed: 108.2 (gas phase part) Gas phase: 65.3 Aluminium: (Max Intrusion Depth [µm]) Fully immersed; Half immersed; Gas phase: No intrusion depths could be found microscopically for all specimens. The criteria for classification as corrosive to metals are not met.
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Regulation EC No. 440/2008 Method A.15. Auto-Ignition Temperature (Liquids and Gases), German Standard DIN 51794 (2003): Determination of Ignition Temperature, DIN EN 14522 (2005): Determination of the Ignition Temperature of gases and liquids	TH 4101 13.86% Quaternary ammonium compound (TMAC) 0.74% N-cyclohexyl-diazeniumdioxy-potassium (K-HDO)	Based on results of the main test series, the lowest auto-ignition temperature was 591 °C. Regulation EC No. 440/2008 and DIN 51794: The auto-ignition temperature rounded down to the nearest multiple of 5 °C was determined as 590 °C. For information: DIN EN 14522: The auto-ignition temperature reduced by 1.5% and rounded to the nearest integer temperature was determined as 582 °C.
4.17.2.	Relative self-ignition temperature for	Data waiving		Not applicable for liquids

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
	solids			
4.17.3.	Dust explosion hazard	Data waiving		Not applicable for liquids

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is not classified for physical hazards.

3.4 Methods for detection and identification

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Principle of the method **TMAC** (Potetiometric Titration): 1 g product sample are diluted to 200 ml with demineralised water. 20 ml of this solution are transferred to a 250 ml beaker and ~ 100 ml demineralised waterre added. Potentiometric titration is carried out using 0.005 M sodium tetraphenylborate solution after addition of an acetic acid solution containing Hyamine 1622. **K-HDO** (UPLC-UV): 0.6 g product sample are diluted to 100 ml with ultra-pure water. The solution is filtered through a 0.20 µm-PTFE-Filter into a LC vial. Analysis is done via UPLC with PDA detector on a Acquity UPLC BEH Shield RP18 1.7 µm column (150 mm x 2.1 mm). Eluent: 55% 0.05 M KH_2PO_4 – solution / 45% Methanol, 0.30 ml/min; Column temperature 40 °C, Injection volume 5 µl, detection wavelength 229 nm. **2-Ethylhexanoic Acid** (UPLC-UV): 0.25 g product sample are diluted to 50 ml with methanol. The solution is filtered through a 0.20 µm-PTFE-Filter into a LC vial. Analysis is done via UPLC with TUV detector on a Acquity BEH C18 (1.7 µm) column (100 mm x 2.1 mm). Eluent: 65% 0.01 M KH_2PO_4 – solution / 35% Acetonitrile,; Column temperature 35 °C, Injection volume 3 µl, detection wavelength 205 nm.										
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
TMAC (active substance)	R^2 = 0.99998 5 samples containing 0.40 - 2.51% TMAC, corresponding to	Matrix of Sinesto XT without TMAC did not lead to additional consumption of the tite - no matrix intereferen	80% 100% 120%	10 10 10	97.9 – 98.8 97.9 – 99.6 100.0 – 100.7	98.3 98.7 100.3	0.32 0.61 0.24	13.77% 13.82% 14.05%	10 (RSD = 0.32) 10 (RSD = 0.57) 10 (RSD = 0.23)	-	Study no. 20-WD-017, 2021

	0.3 – 1.8 g Sinesto XT taken for analysis.	ce detected.									
K-HDO (active substance)	R^2 = 0.99995 5 standard samples containing 9.8 – 153 mg/L K-HDO	Comparison with matrix chromatogram shows no significant interference at retention time of K-HDO.	38.2 mg/L 47.7 mg/L 57.3 mg/L	5 5 5	98.2 – 99.2 98.7-99.4 98.6 – 99.0	98.9 98.9 98.9	0.45 0.31 0.18	38.2 mg/L 47.7 mg/L 57.3 mg/L	5 (RSD = 0.48) 5 (RSD = 0.28) 5 (RSD = 0.16)	-	Study no. 20-WD-016, 2021
2-Ethylhexanoic acid (SoC)	R^2 = 0.99981 3 standard samples containing 500 – 2000 mg/L	Comparison with matrix chromatogram shows no additional peak at retention time of 2-EHA.	902 mg/L 1102 mg/L 1302 mg/L	5 5 5	100.0 – 102.0 100.1 – 106.1 99.2 – 103.4	100.6 101.9 100.7	0.8 2.5 1.6	907.4 mg/L 1123 mg/L 1311 mg/L	5 (RSD = 0.79) 5 (RSD = 2.46) 5 (RSD = 1.58)	16 mg/L	Study no. 20-WD-019, 2021

There is no validated method for the analysis of Potassium hydroxide available, because Sinesto XT contains different sources for Potassium ions and alkalinity (forming hydroxide ions in water). As Potassium Hydroxide is not formed during storage, which is confirmed by the long-term storage stability study with regard to pH value and other properties, a validated analytica method is considered not necessary.

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Analytical methods for the determination of K-HDO, ATMAC/TMAC and 2-Ethylhexanoic acid in the biocidal product are available. Specificity, linearity, accuracy and precision were checked and found acceptable. Analytical methods for air An analytical method for the a.s. is required only for the deluge treatment application - no aerosol exposure is expected for the application by fully automated dipping. For the SoC, inhalation exposure is expected for both application methods. However, the exposure assessment has shown that inhalation exposure is below the reference value. Therefore the reference member state did not request an analytical method air for the a.s. and SoC. Methods for the detection of K-HDO and ATMAC/TMAC in air were provided in the CAR of the a.s. and deemed acceptable at EU level. No other data is required. Methods for the detection of ATMAC/TMAC and K-HDO in soil and water were provided and deemed acceptable at EU level. No other data are required. The product is not intended to be used on surfaces in contact with food/feed of plant and animal origin; therefore, analytical methods for the determination of the active substances in food/feed of plant and animal origin are not required. Analytical methods for the determination of residues of substances of concern are not necessary.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

Sinesto XT is a wood preservative for preventive treatment for temporary control of sapstain (temporary blue stain) and wood-discolouring fungi including mould on wood after it has been freshly cut, during the short storage phase e.g at the saw mill or for transport. Treated wood is to be protected from weathering, this corresponds to Use Class (UC) 2. Sinesto XT is applied to the surface of freshly cut wood only once by fully automated dipping or by spraying.

It must be assured that treated wood is not exposed to weathering (Use Class 3 conditions or higher) at any time.

The category of users is designated as industrial and professional users.

Sinesto XT is a concentrated formulation which will be diluted with water on site to achieve a 2.4-9% treatment solution depending on application method. The application rate is envisaged to be 50-150 g of treatment solution per m² wood, which corresponds to 3.6-9 g Sinesto XT / m² wood. Sinesto XT is effective against discolouring mould fungi and sapstain (e.g. *Aureobasidium pullulans*, *Aspergillus niger*, *Penicillium funiculosum, Trichoderma viride, Sclerophoma pityophila, a.o.*). The product is for use on freshly cut wood and wooden pallets. The product is applied only once for temporary protection during a short storage phase or for transport.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

Growth of discolouring mould and sapstain fungi including the formation of fruiting bodies and spores is suppressed either completely or to the level of insignificantly stained, the most. The issue of unacceptable suffering does not apply.

ATMAC/TMAC
ATMAC/TMAC is a quaternary ammonium compound which acts by disruption and leakage of the membranes, leading to cell damage or lysis of the cell content.

K-HDO
The fungicidal effect of K-HDO is caused by the inhibition of cell metabolism.

3.5.3 Efficacy data

Table 3.8 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
PT 8 UC 2	Sinesto XT (TH 4101)	fungicidal temporary protection against sapstain (temporary blue stain) and mould discolouring fungi on wood	EN/TS 15082:2005 on spruce with closely and loosely packed wood Product retention rates: 3.6; 4.4; 7.2; 9.8 g/m² Concentrations tested: 2,25%, 3.0%, 4.5%, and 6.0% (w/w) Dipping time: 15 seconds Retention approx. 146 to to 164 ml/m² Evaluation times: 4, 8, 12 weeks	For closely packed wood 4.4 g/m² is effective for up to 4 weeks. After 8 weeks effective protection was shown only for 9.8 g/m². After 12 weeks no effective protection was shown. For loosely packed wood 3.6 g/m² is effective for up to 8 weeks. 4.4 g/m² were effective also after 12 weeks. Validity criteria for test results, as given in chapter 8 of EN/TS 15082:2005 , fulfilled.	BASF Test Report B2875_Sinesto XT_Fichte (2020) Updated by B2875_Sinesto XT_Fichte_Rev.1 _Nachtrag (2022)	6.7 Field test_spruce_ Sinesto XT
PT 8 UC 2	Sinesto XT (TH 4101)	fungicidal temporary protection against sapstain (temporary blue stain) and mould discolouring	EN/TS 15082:2005 on pine with closely and loosely packed wood Product retention rates: 3.8; 4.4; 6.2; 8.2 g/m² Concentrations tested: 2,25%, 3.0%, 4.5%, and 6.0% (w/w) Dipping time: 15 seconds	For closely packed wood 4.4 g/m² is effective for up to 4 weeks. After 4 weeks no effective protection was shown. For loosely packed wood protection 3.8	BASF Test Report B2875_Sinesto XT_Kiefer (2020) Updated B2875_Sinesto	6.7 Field test_ pine_ Sinesto XT

		fungi on wood	Retention approx. 137 to to 167 ml/m² Evaluation times: 4, 8, 12 weeks	g/m² is effective for up to 12 weeks. Validity criteria for test results, as given in chapter 8 of EN/TS 15082:2005 , fulfilled.	XT_Kiefer_Rev.2_Nachtrag (2022)	

3.5.4 Efficacy assessment

The applicant provided two efficacy study reports according to CEN/TS 15082:2005 that were performed with Sinesto XT. The applicant also provided two additional study reports for the reference product including untreated controls from previous efficacy tests according to CEN/TS 15082:2005. Results from these tests provide sufficient information about the general virulence of naturally occurring wood-discolouring fungi including mould at the test site and were used to evaluate the overall validity of the tests.
CEN/TS 15082:2005 does not provide information of the effective biological reference rating, nor does EN 599-1 or the ECHA Document of Guidance Efficacy Volume II Assessment and Evaluation. Therefore the reference rating for effectiveness was applied according to EN 152-1 for each individual test specimens (with ratings of "0" or "1" being considered as effective and acceptable).

In both studies, Sinesto XT was tested at 2.25%, 3.0%, 4.5%, and 6.0% and applied through dipping for 15 sec., resulting in an average retention of 136.7 to 166.8 ml/m² (mean: 152 ml/m²) with 3.6 to 3.8 g/m², 4.4 g/m², 6.2 to 7.2 g/m², and 8.2 to 9.8 g of Sinesto XT/m² of treated wood, respectively for each tested concentration. Treated wood was exposed either closely packed (non slatted) or loosely packed on stickers (slatted). Growth of mould and stain was evaluated in regular interval using a rating scheme according to CEN/TS 15082:2005 from "0" no staining visible on specimen to "4" staining of over 50% on the specimen.

In the first report (BASF B 2875_Sinesto XT_Fichte) Sinesto XT was tested on spruce. For closely packed wood a retention of 4.4 g/m² is regarded as effective protection against temporary stain and mould for up to 8 weeks (the few individual ratings of ">1" can be regarded as outliers). After 8 weeks no effective protection was given with any of the tested concentrations on closely packed wood.
For loosely packed wood a retention of 3.6 g/m² is regarded as effective protection against temporary stain and mould for up to 8 weeks, and 4.4 g/m² is regarded as effective for 12 weeks.

In the second report (BASF B 2875_Sinesto XT_Kiefer), Sinesto XT was tested on pine. For closely packed wood a retention of 4.4 g/m² is regarded as effective protection against temporary stain and mould for up to 4 weeks. After 4 weeks no effective protection was given with any of the tested concentrations on closely packed wood.
For loosely packed wood protection was sufficient with 3.8 g/m² for up to 12 weeks.

The tests are valid according to EN/TS 15082:2205 because untreated control wood specimens were heavily stained in all cases after 4 weeks, and closely packed wood treated with a reference preservative (Cu-8 Reference) were stained after 4 weeks when treated with 1.5 g/m².

3.5.5 Conclusion on efficacy

The woods used in the test reports are representative for softwood. In conclusion, Sinesto XT provides adequate protection against temporary blue stain (sapstain) and mould on freshly cut wood within the envisaged retention range of this application.

However, protection depends on factors like wood type, storage duration and storage mode of the treated wood. A minimum dose of 3.6 g/m² is effective only on loosely packed wood for 8-12 weeks. Closely packed wood requires a dose of 4.4 g/m² or higher and at this dose is protected only for 4-8 weeks. For these reasons, users of the biocidal product should

determine which dosage within the authorised dose range is required in their specific circumstances.

3.5.6 Occurrence of resistance and resistance management

ATMAC/TMAC and K-HDO are the active substances in the biocidal product Sinesto XT. The product has characteristics that suppress the risk of resistance development by using a combination of active compounds with differing, unspecific mode of actions. In addition, the intended use with a single application will also constrain the development of resistance.
No reports on the development of resistance in fungi to ATMAC/TMAC or K-HDO are available in the scientific literature including development of resistance by mutation and selection, by horizontal gene transfer and selection of inherently resistant organisms within complex fungal communities. In addition, there is a long history of use for K-HDO without obvious development of resistance during application.
The efficacy data shows fungal growth as slight discoloration (rating 1) over time at the claimed application rate and within the tested storage period. This means that the test strains can grow on the treated wood, with the possibility to evolve resistance by mutation and selection. Hence, it is also possible that certain environmental fungal strains resistant to ATMAC/TMAC or K-HDO could selectively grow on treated wood. In turn, this could lead to the spread of resistant fungal strains in the environment. However, the hazard of such spread is low because it is neither likely to impact the efficacy of other wood preservatives, nor will it impact human health because decreased susceptibility of fungi to ATMAC/TMAC or K-HDO is not known to be associated to cross-resistance to medically important fungicides.
Therefore, the overall risk of resistance development for Sinesto XT is considered to be low.

3.5.7 Known limitations

Protection of closely packed soft wood is given for only 4-8 weeks with approx. 4.4-10 g/m² of Sinesto XT. For longer testing times proof of efficacy was insufficient.

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

Not relevant.

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

There are no human health data available for the product. The assessment, and classification and labelling are based on the agreed endpoints for the active substances and available information for the non-active substances.

3.6.1.1 Skin corrosion and irritation

Table 3.9 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Corrosive to the skin
Justification for the value/conclusion	The biocidal product has a pH value ≥ 11.5, therefore, classification and labelling with Skin corr. 1, H314 is necessary. For further information please refer to the confidential annex.
Classification of the product according to CLP	Skin corrosion, Category 1 - H314 – causes severe skin burns and eye damage (according to Regulation (EC) No 1272/2008)

Table 3.10 Data waiving

Data waiving	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Additionally, information on the physico-chemical properties of the biocidal product (e.g. pH) are available. Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

3.6.1.2 Eye irritation

Table 3.11 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye damage.
Justification for the value/conclusion	The biocidal product has a pH value ≥ 11.5, therefore, classification with Eye Dam. 1 is required. An additional labelling with H318 is not required since the biocidal product is already labelled with H314.
Classification of the product according to CLP	Eye Dam. 1

Table 3.12 Data waiving

Data waiving	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) No 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Additionally, information on the physico-chemical properties of the biocidal product (e.g. pH) are available. Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

3.6.1.3 Respiratory tract irritation

Table 3.13 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value / Conclusion	EUH071 - Corrosive to the respiratory tract.
Justification for the conclusion	The biocidal product is classified with Skin Corr. 1, H314 and as a respiratory exposure cannot be avoided, labelling with EUH071 is necessary. Furthermore, according to the Assessment Report for ATMAC/TMAC (PT 08, 14/04/2016, Italy) labelling with EUH071 is required for the active substance.
Classification of the product according to CLP	Labelling with EUH071 - Corrosive to the respiratory tract is required according to Regulation (EC) No. 1272/2008.

Table 3.14 Data waiving

Data waiving	
Information requirement	8.10. Other tests
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation.

3.6.1.4 Skin sensitization

Table 3.15 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Skin-sensitising properties are not expected.
Justification for the value/conclusion	The biocidal product family does not contain components classified as skin sensitisers in relevant concentrations.
Classification of the product according to	Not required.

CLP	

Table 3.16 Data waiving

Data waiving	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the biocidal product are not available and not required. According to Annex III of the BPR (Regulation (EU) No 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018) "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product, data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

3.6.1.5 Respiratory sensitization

Table 3.17 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Respiratory sensitisation is not assumed.
Justification for the value/conclusion	The biocidal product does not contain components classified for respiratory sensitisation.
Classification of the product according to CLP	Not required.

Table 3.18 Data waiving

Data waiving	
Information requirement	8.4 Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or their components are not available.

3.6.1.6 Acute oral toxicity

Table 3.19 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	ATE: > 300 - < 2000 mg/kg bw
Justification for the selected value	The biocidal product contains the active substances ATMAC/TMAC and K-HDO which are both classified as acute toxic via the oral route. Furthermore, according to Regulation (EC) No 1272/2008, all other components classified for acute toxicity (oral) at a concentration >1% are taken into account. For further information, please refer to the confidential annex.
Classification of the product according	Acute toxicity, Category 4 - H302 Harmful if swallowed

to CLP	

Table 3.20 Data waiving

Data waiving	
Information requirement	8.5.1. By oral route
Justification	Studies on potential acute toxicity by oral route of the biocidal product are not available and are not required. Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

3.6.1.7 Acute inhalation toxicity

Table 3.21 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} (inhalation): > 5 mg/L air
Justification for the selected value	None of the active substances or co-formulants is classified for acute inhalation toxicity. The LC_{50} (inhalation) is calculated from the acute inhalation toxicity data of the single components.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

Table 3.22 Data waiving

Data waiving	
Information requirement	8.5.2. By inhalation
Justification	Studies on potential acute toxicity by inhalation route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) No 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

3.6.1.8 Acute dermal toxicity

Table 3.23 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	ATE: > 2000 mg/kg bw
Justification for the selected value	The biocidal product contains the active substance ATMAC/TMAC that is classified with Acute Tox. 3, H311. The product does not contain any other ingredients, which are classified for acute dermal toxicity. Therefore, calculations are based on the active substance. For further information please refer to the confidential annex.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

Table 3.24 Data waiving

Data waiving	
Information requirement	8.5.3. By dermal route
Justification	Studies on potential acute toxicity by dermal route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal products, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

3.6.2 Information on dermal absorption

Table 3.25 Value(s) used in the Risk Assessment – Dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substances	K-HDO, TMAC and 2-ethylhexanoic acid
Value(s)	100% dermal absorption for concentrate and dilution (Default for corrosive substances (BPC-WG-III-2016, TAB, version 2.0, 2018 – TOX 21)
Justification for the selected value(s)	For TMAC no systemic exposure calculations are required, therefore, dermal absorption is not relevant for the human health risk assessment of this substance. For K-HDO and 2-ethylhexanoic acid 100% dermal absorption is assumed for the concentrate and the dilutions as for both corrosive properties to the skin are expected. The concentrate has a pH value ≥ 11.5, therefore, classification and labelling with Skin corr. 1, H314 is necessary. For the dilutions the pH is also assumed to be ≥ 11.5 as for a 1% dilution a pH of 11.47 was measured and the minimal dilution of the biocidal product is 2.25% w/w. Therefore, corrosive properties cannot be excluded and 100% dermal absorption need to be considered as a worst case.

Table 3.26 Data waiving

Data waiving	
Information requirement	8.6 Dermal absorption
Justification	In the absence of reliable dermal absorption data, default values according to EFSA Guidance on Dermal Absorption (2017) can be applied.

3.6.3 Available toxicological data relating to substances of concern

According to the criteria as set in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)), the following substances need to be considered as substances of concern regarding human health:

Table 3.27 Available toxicological data relating to substances of concern

Substance of concern	Criterion for the identification as a substance of concern	Band	Type of risk assessment performed
2-Ethylhexanoic acid (max. 22.45% w/w)	BPR, Art. 3 (f) – classification of the product with Repr. 1B, H360D	Band C: Fully quantitative risk assessment by using EU IOELVs (when available), DNELs or other reference values (e.g. AELs, AECs)	Quantitative assessment using DNEL values of 2-ethylhexanoic acid
Potassium hydroxide (max. 10.6% w/w)	BPR, Art. 3 (f) – classification of the product with Acute Tox. 4, H302 and Skin Corr. 1, H314	Band A and B: Application of P-statements normally associated with H statements and Qualitative exposure and risk assessment to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied	Local risk assessment

3.6.4 Other

The biocidal product contains the non-active substance 2-ethylhexanoic acid which is classified for Repr. 1B, H360D according to the 18th ATP of Regulation (EC) No 1272/2008 and present above the generic concentration limit of 0.3%. Therefore, according to Regulation (EC) No 1272/2008 a classification and labelling of the product with Repr. 1B, H360D is required. The 18th ATP applies from 1st December 2023.

3.6.4.1 Food and feeding stuffs studies

-

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

-

3.6.4.3 Other test(s) related to the exposure to humans

-

3.6.5 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

Relevant guidance documents consulted for human health risk assessment

Please, consider chapter 4.4.1.

Relevant exposure models or exposure studies used for human health risk assessment

Professional user:
The related harmonised model data are described in the Biocides Human Health Exposure Methodology Document Version 1 (October 2015) in detail.

- TNsG 2002 (Technical Notes for Guidance) Handling model 1
- TNsG 2002 (Technical Notes for Guidance) Dipping model 1
- RISKOFDERM Toolkit (according to HEEG opinion 1)
- ConsExpo Web tool

Strategy for human health risk assessment
Professional user:
Systemic quantitative risk assessment for the active substance K-HDO via the dermal and inhalation route was performed with the $AEL_{chronic}$ of 0.021 mg/kg bw/d and local semi-quantitative risk assessment for the active substance ATMAC/TMAC via the dermal route was performed with the $NOAEC_{dermal}$ of 0.3%.
Moreover, a local risk assessment of the biocidal product as well as cumulative risk characterisation from combined exposure to the active substance K-HDO and the substance of concern (SoC) 2-Ethylhexanoic acid was performed.

Considerations on volatility of the active substances and substances of concern
Inhalation exposure to vapour is only relevant for the SoC 2-Ethylhexanoic acid and therefore assessed.

Strategy for livestock exposure and/or dietary risk assessment
Exposure of food, feed and livestock is excluded by RMMs.

Strategy for the assessment of substance(s) of concern
Professional user:
Systemic quantitative risk assessment for the SoC 2-Ethylhexanoic acid via the dermal and inhalation route was performed with the $DNEL_{inhalative}$ of 14 mg/m³ and the $DNEL_{dermal}$ of 2 mg/kg bw/d.
Note: Both DNEL values were derived within a substance evaluation and thus can be considered validated on EU-level (ES 2012).

General public/bystander, secondary exposure
For the substance of concern 2-ethylhexanoic acid, a full quantitative systemic risk assessment is required. A DNEL of 1 mg/kg bw/d is applied for the general public.

Strategy for disinfectant by-products assessment
Not relevant.

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

Table 3.28 Summary table: main paths of human exposure

Summary table: main paths of human exposure					
Exposure path	**Primary (direct) exposure**		**Secondary (indirect) exposure**		
	Professional users (including industrial users and trained professional users)	**Non-professional users**	**Professional users** (including industrial users and trained professional users)	**Non-professional bystanders/ General public**	**Via food**
Oral	n/a	n.a.	n/a	yes	no
Dermal	Yes	n.a.	Yes	yes	n/a
Inhalation	Yes	n.a.	Yes	yes	n/a

3.6.6.3 List of exposure scenarios

Table 3.29 Summary table: exposure scenarios

Summary table: exposure scenarios			
Scenario and task number	**Description of scenario and tasks**	**Use No.**	**Exposed group**
Primary exposure			
1	Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi [(Fully) automated dipping (indoor)]		
1_M&L-1	Mixing & Loading: Connecting transfer lines (automated M&L)	1	Industrial professional
1-2	Application: (Fully) automated dipping (indoor) (fully automated)	1	Industrial professional
1-3	Post-Application: Cleaning of the dip tank	1	Industrial professional

2	Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi [Deluge treatment]		
2_M&L-1	Mixing & Loading: Connecting transfer lines (automated M&L)	2	Industrial professional
2-2	Application: deluge treatment (automated)	2	Industrial professional
2-3	Post-Application: included in 2-2	2	Industrial professional
M&L	Mixing & Loading [Connecting transfer lines]		
M&L-1	Mixing & Loading: Connecting transfer lines (automated M&L)	1 2	Industrial professional
Secondary exposure			
sec. expo	Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi Mechanical processing of freshly treated wood		
sec. expo-1	Application: Mechanical processing of treated wood secondary exposure	1 2	Industrial Professional
sec. expo-2	Secondary acute exposure, adult - sanding treated wood, inhalation and dermal exposure		General public
sec. expo-3	Secondary acute exposure, toddler – chewing/mouthing treated wood off-cut, oral exposure		General public
sec. expo-4	Secondary long-term exposure, toddler - inhalation of volatilised residues indoors, inhalation exposure		General public
sec. expo-5	Secondary long-term exposure, toddler - playing on treated structure and mouthing of hands, dermal and oral exposure		General public

3.6.6.4 Reference values to be used in risk characterisation

Table 3.30 Reference values to be used in risk characterisation

ATMAC/TMAC

Reference	Value	Study	AF
AEL long-term	Not relevant	Assessment Report (RMS Italy (2016))	-
AEL medium-term	Not relevant	Assessment Report (RMS Italy (2016))	-
AEL acute	Not relevant	Assessment Report (RMS Italy (2016))	-
Dermal NOAEC	0.3%	2-week skin irritation study with rats, ATMAC/TMAC Assessment Report (RMS Italy (2016))	-
Oral NOAEC	0.03%	52-week oral gavage study in dogs, ATMAC/TMAC Assessment Report (RMS Italy (2016))	-

K-HDO

Reference	Value	Study	AF
AEL long-term	0.021 mg/kg bw/d [1,2,3]	2-year oral carcinogenicity study in rat; read-across from Cu-HDO, adjusted to equimolar dose of K-HDO Mellert (1996)	300
AEL medium-term	0.034 mg/kg bw/d [2,4]	Developmental toxicity study in rabbit (gavage); read-across from Cu-HDO, adjusted to equimolar dose of K-HDO Hellwig (1994)	300
AEL acute	0.102 mg/kg bw/d [1,2]	Developmental toxicity study in rabbit (gavage); read-across from Cu-HDO, adjusted to equimolar dose of K-HDO Hellwig (1994)	100
Inhalative absorption	Not established [1,2]	Default value: 100%	
Oral absorption	100% [1,2]	Hoffmann (1993)	

[1] Based on CAR, Austria (2007)
[2] Based on Assessment-Report, Austria (2008)
[3] Since the absence of alerts for fertility effects was only deduced from the available repeated dose and developmental studies, but no 2-generation study was submitted, a safety factor of 300 to the chronic NOAEL was considered necessary by the RMS to define an acceptable risk.
[4] The RMS proposed to apply a safety factor of 300 to account for the fact that the absence of alerts for fertility effects was only deduced from the available repeated dose and developmental studies, but no 2-generation study was submitted.

2-ethylhexanoic acid

Reference	Value	Study	AF
Acute toxicity: Dermal: LD50	> 2000 mg/kg bw	Species: Rat	-
Acute toxicity: Inhalation: LC50	0.11 mg/L air	Species: Rat	-
Acute toxicity: Oral: LD50	2043 mg/kg bw	Species: Rat	-
Eye irritation	Not irritant		-
Skin irritation	Not irritant	Species: Rabbit	-
Skin sensitization	Non sensitising	Species: Guinea Pig	-

Potassium hydroxide

Reference	Value	Study	AF
Acute toxicity: Oral: LD50	333 mg/kg bw	Species: Rat	-
Eye irritation	Corrosive Irritant	Species: Rabbit	-
Skin irritation	Corrosive Irritant	Species: Rabbit	-
Skin sensitization	Non sensitising	Species: Guinea Pig	

3.6.6.5 Specific reference value for groundwater

No specific references values four groundwater were derived.

3.6.6.6 Professional users (including industrial users and trained professional users)

Sinesto XT is a water-based liquid wood preservative. It is applied for deluge treatment, immersion (fully automated dipping) for the preventive treatment of wooden structures. In addition, secondary exposure of workers resulting from mechanical processing of treated wood, i.e. sawing or sanding treated wood, has to be considered for risk assessment.

Sinesto XT is a concentrate wood preservative containing the active substances (a.s.) ATMAC/TMAC (CAS-No.: 61789-18-2, 14.00% w/w) and K-HDO (CAS-No.: 66603-10-9, 0.75% w/w) as well as the substance of concern (SoC) 2-Ethylhexanoic acid (CAS-No.: 149-57-5, 22.45% w/w)

The exposure to the a.s./SoC are assessed separately for the different application techniques and will thus be described in individual subsections of the current section. It is usually based on the harmonised document "Biocides Human Health Exposure methodology (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.
In the separate Excel file "Output_table_professional-Sinesto_XT.xlsx", the details of the exposure calculations to the a.s./SoC for the professional user are laid out.

Scenario 1: Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi [(Fully) automated dipping (indoor)]

Description and input parameters

Table 3.31 Description and input parameters

Description of Scenario 1
A harmonised approach for exposure assessment of automated dipping and fully automated dipping is described in the *Biocides Human Health Exposure Methodology* document (October 2015, version 1). The assessment laid out in this PAR follows this approach considering in Tier 1 the automated dipping and in Tier 3 the fully automated dipping. As Tier 2 approch the changing of protective gloves after each cycle is assumed. The immersion/automated dipping process is a batch process using industrial scale treatment units. The treatment itself is carried out in open dip tanks. The wood is lowered by forklift truck into the dipping tank. Alternatively, for fully automated dipping the dip tank unit is featured with a hydraulic lifting equipment. Application includes all stages in preservation, from loading the dip tanks to stacking the treated wood to dry. The task entails a cycle of loading, waiting, unloading and removal of treated timber to storage. Since Sinesto XT is a concentrated wood preservative, it has to be diluted prior to application. Therefore, the operator has to transfer the concentrate into the dipping tank or the treatment liquid is prepared in a mixing tank and is later pumped into the dipping

tank. In both cases, the operator has to connect the transfer lines only; the dilution process itself is an automated procedure

The application phase consists of immersing the wood piles with a forklift truck (automated dipping) or hydraulic lifting equipment (fully automated dipping) into the application liquid. The degree of penetration varies by time schedule (minutes to hours). When the immersion process is completed, the operator lifts the piles with a forklift truck or hydraulic lifting equipment to allow drip off of treatment liquid. After drip off time, the wood is removed and placed on the storage yard.

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

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

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

For the application phase, exposure to hands and body is assessed using "Handling model 1" for water-based liquid formulations (TNsG on Human Exposure). There is no generic model data available for the immersion process. However, according to the Human Exposure Expert Group (HEEG) opinions on "HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT8)" as well as "HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping", Handling model 1" reflects the procedures listed above most accurately. As a reasonable default value a number of 4 cycles is used for the assessment of the application phase for the automated dipping in Tier 1.

As Tier 2 approch the changing of protective gloves after each cycle and the wearing of an impermeable coverall (type 4) is assumed. The indicative values for hands are reduced when using new gloves every cycle according to the revision of HEAdhoc Recommendation 6: 540 mg/cycle (inside new gloves) instead of 1080 mg/cycle (inside used gloves) can be summarised in a factor for new gloves of 2.

Since the applicant requested a "fully automated dipping process" the HEEG opinion 18 - in line with the *Biocides Human Health Exposure Methodology document (October 2015, version 1)* – additional is used for the Tier 3 assessment.

"The biocidal product must only be used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place including when the treated articles are transported through the dip tank to the draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until the treated articles are surface dry."
The untreated wood may only be lowered by a separate lifting unit into the dipping tank. The latter statement excludes the use of forklift trucks for lowering the wood into the dipping tank.
Due to HEEG opinion 18 the exposure is decreased by a factor of 4 for a fully automated dipping process (in Tier 2).

Professional post-application exposure constitutes system maintenance and is not considered a daily, but rather a weekly process (expert judgement). Therefore, the indicative value of "Handling model 1" for one cycle (TNsG on Human Exposure, part 3) is used to assess weekly dermal exposure.

Exposure by inhalation
According to the Human Exposure Expert Group (HEEG) opinion mentioned above, inhalation exposure to aerosols can be considered negligible. Inhalation exposure to the volatile SoC was assessed using the ConsExpo evaporation model.

Exposure to the eyes
During the application of the b.p. by fully automated dipping splashes are likely to occur. Eye contact in consequence of splashes cannot be excluded.

Calculations
The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 3.34, Table 3.35 and Table 3.36,. Values for long term (daily) and short term (weekly) exposure are disclosed separately.
For details of the calculation of dermal and inhalation exposure, please refer to the separate Excel file "Output_table_professional-Sinesto_XT.xlsx".

Further information and considerations
The classification of the b.p. and the application liquid require additional assessment of local risks (see Table 3.37). Local risk assessment has indicated a risk for eye damages, thus eye protection is required.
Furthermore, the quantitative exposure assessment has indicated significant exposure of hands and body. Due to the identified risk in Tier 1 refined exposure assessments (Tier 2 and Tier 3) are performed.

Input parameters for Scenario 1			
Input parameters for task M&L			
Dermal			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Density of product [g/cm³]	1.0587	Product specification
	Concentration of ATMAC/TMAC in b.p.	14%	Product specification
	Concentration of K-HDO in b.p.	0.75%	Product specification
	Concentration of 2-	22.45%	Product specification

	Ethylhexanoic acid in b.p.		
	Application duration [min]	10	Expert judgement
	Number of events [1/day]	1	Expert judgement
	Frequency	daily	Expert judgement
	Indicative value (75th percentile) [mg/min]	0.92	HEEG Opinion 1 *RISKOFDERM Toolkit*
Tier 2	Protective gloves (Default protection factor)	90%	HEEG opinion 9
Inhalation			
Not expected, negligible			
Input parameters for task 1-2			
Dermal			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Concentration of b.p. in application solution	9%	Applicant information
	Density of product [g/cm³]	1.0587	Product specification
	Concentration of ATMAC/TMAC in b.p.	14%	Product specification
	Concentration of K-HDO in b.p.	0.75%	Product specification
	Concentration of 2-Ethylhexanoic acid in b.p.	22.45%	Product specification
	Application duration [min]	30	Expert judgement
	Number of events [1/day]	4	HEEG Opinion 8
	Frequency	daily	Expert judgement
	Indicative value, actual hand exposure (75th percentile) [mg/event]	1080	Handling Model 1 (WB liquid formulation), TNsG Human Exposure User Guidance 2002
	Indicative value, potential body exposure (75th percentile) [mg/event]	8570	Handling Model 1 (WB liquid formulation), TNsG Human Exposure User Guidance 2002
Tier 2	Technical factor "new gloves every"	2	revision of HEAdhoc Recommendation 6
	Protective coverall type 4 (impermeable c.) (Default protection factor)	95%	HEEG opinion 9
Tier 3	Technical factor "fully automated immersion system"	4	HEEG opinion 18
Inhalation			
	Parameters[1]	Value	Reference and justification[3]

Tier 1 (no PPE)	Application duration [min]	30	Expert judgement
	Exposure duration [min]	30	Expert judgement
	Room volume [m³]	1500	Outdoor/industrial area
	Ventilation rate [h^{-1}]	10	Outdoor/industrial area
	Release area [m²]	1000	Expert judgement
	Does emmision area increase?	No	
	Application temperature [°C]	25	Room temperature
	vapour pressure (2-Ethylhexanoic acid) [Pa]	4	
	Total amount of application solution used [kg]	150	150 ml/m² * 1000 m² *solution uptake * release area*
Input parameters for task 1-3			
Dermal			
	Parameters	Value	Reference and justification[3]
Tier 1 (no PPE)	Concentration of b.p. in application solution	9%	Applicant information
	Density of product [g/cm³]	1.0587	Product specification
	Concentration of ATMAC/TMAC in b.p.	14%	Product specification
	Concentration of K-HDO in b.p.	0.75%	Product specification
	Concentration of 2-Ethylhexanoic acid in b.p.	22.45%	Product specification
	Application duration [min]	30	Expert judgement
	Number of events [1/day]	1	HEEG Opinion 8
	Frequency	weekly	Expert judgement
	Indicative value, actual hand exposure (75th percentile) [mg/event]	1080	Handling Model 1 (WB liquid formulation), TNsG Human Exposure User Guidance 2002
	Indicative value, potential body exposure (75th percentile) [mg/event]	8570	Handling Model 1 (WB liquid formulation), TNsG Human Exposure User Guidance 2002
Tier 2	Technical factor "new gloves every"	2	revision of HEAdhoc Recommendation 6
	Protective coverall type 4 (impermeable c.) (Default protection factor)	95%	HEEG opinion 9
Inhalation			
	Parameters[1]	Value	Reference and justification[3]

Tier 1 (no PPE)	Application duration [min]	30	Expert judgement
	Exposure duration [min]	30	Expert judgement
	Room volume [m³]	1500	Outdoor/industrial area
	Ventilation rate [h^{-1}]	10	Outdoor/industrial area
	Release area [m²]	1000	Expert judgement
	Does emmision area increase?	No	
	Application temperature [°C]	25	Room temperature
	vapour pressure (2-Ethylhexanoic acid) [Pa]	4	

Scenario 2: Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi

[Deluge treatment]

Description and input parameters

Table 3.32 Description and input parameters

Description of Scenario 2
A harmonised approach for exposure assessment of deluge treatment is described in the *Biocides Human Health Exposure Methodology* document (October 2015, version 1). The assessment laid out in this PAR follows this approach. Sinesto XT is a concentrated wood preservative which has to be diluted prior to application. For deluge treatment, Sinesto XT is pumped into the deluge tunnel throughout the application process. The operator connects the transfer lines to the mixing tank/dosing system. During application, timber is passed through a tunnel (on a conveyor) in which the wood preservative is applied from various types of spray jets. On the exit conveyor, the freshly treated wood leaves the tunnel, is automatically piled up and transported to storage using forklift trucks. Since the tunnel may be used with different types of wood preservatives on one day and to prevent jamming of the spray jets, extensive cleaning procedures have to be carried out after each pass and each working day, respectively. *Dermal exposure* Exposure to skin is considered to occur during all phases of handling. Exposure to hands is expected for the loading phase during connecting transfer lines to the automatic dosing system. An appropriate model is recommended by Human Exposure Expert Group (HEEG) and is used to calculate the hand exposure. This phase has a minor impact on the total dermal exposure. There is no generic model data available for the deluge treatment, however "Dipping model 1" (TNsG on Human Exposure) is used because the tasks described in this model most accurately reflect the procedures occurred. The model provides measurement data of potential body and actual hand exposure (measurements of hand exposure inside gloves). Even if the timber is automatically piled up and transported to storage using a forklift truck, manual handling may occasionally occur. Based on the information according to User Guidance Document (2002, page 46) 30 min are used to assess the contact to treated timber. *Exposure by inhalation* Due to the construction type of the deluge tunnel, exposure to aerosols cannot be excluded for the worker operating next to the tunnel unit. Therefore, inhalation exposure to aerosols has been calculated for the application phase using indicative values of "Dipping model 1". Exposure to aerosols during mixing/loading and post-application are not expected to occur. *Exposure to the eyes* During the application of the b.p. by deluge treatment splashes are likely to occur. Eye contact in consequence of splashes cannot be excluded.

Calculations
The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 3.34, Table 3.35 and Table 3.36. Values for long term (daily) and short term (weekly) exposure are disclosed separately.
For details of the calculation of dermal and inhalation exposure, please refer to the separate Excel file "Output_table_professional-Sinesto_XT.xlsx".

Further information and considerations
The classification of the b.p. and the application liquid require additional assessment of local risks (see Table 3.37). Local risk assessment has indicated a risk for eye damages, thus eye protection is required.
Furthermore, the quantitative exposure assessment has indicated significant exposure of hands and body. Due to the identified risk in Tier 1 a refined exposure assessment (Tier 2) is performed.

Input parameters for Scenario 2

Input parameters for task M&L

Dermal

	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Density of product [g/cm³]	1.0587	Product specification
	Concentration of ATMAC/TMAC in b.p.	14%	Product specification
	Concentration of K-HDO in b.p.	0.75%	Product specification
	Concentration of 2-Ethylhexanoic acid in b.p.	22.45%	Product specification
	Application duration [min]	10	Expert judgement
	Number of events [1/day]	1	Expert judgement
	Frequency	daily	Expert judgement
	Indicative value (75th percentile) [mg/min]	0.92	HEEG Opinion 1 *RISKOFDERM Toolkit*
Tier 2	Protective gloves (Default protection factor)	90%	HEEG opinion 9

Inhalation

Not expected, negligible

Input parameters for task 1-2

Dermal

	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Concentration of b.p. in application solution	8.5%	Applicant information
	Density of product [g/cm³]	1.0587	Product specification
	Concentration of ATMAC/TMAC in b.p.	14%	Product specification
	Concentration of K-HDO in b.p.	0.75%	Product specification

	Concentration of 2-Ethylhexanoic acid in b.p.	22.45%	Product specification
	Application duration [min]	30	CAR boric acid, NL June 2008, DOC IIB:
	Number of events [1/day]	2	CAR boric acid, NL June 2008, DOC IIB:
	Frequency	daily	Expert judgement
	Indicative value, actual hand exposure (max.) [mg/min]	25.7	Dipping Model 1, TNsG Human Exposure User Guidance 2002
	Indicative value, potential body exposure (75th percentile) [mg/min]	178	Dipping Model 1, TNsG Human Exposure User Guidance 2002
Tier 2	Technical factor "automatically piled up, transportation by forklift truck"	2	Expert judgement
	Protective coverall type 4 (impermeable c.) (Default protection factor)	95%	HEEG opinion 9
Inhalation			
	Parameters[1]	Value	Reference and justification[3]
Tier 1 (no PPE)	Indicative value, aerosol inhalation exposure (75th percentile) [mg/m³]	1	Dipping Model 1, TNsG Human Exposure User Guidance 2002
	Exposure duration (aerosol) [min]	2 x 30	CAR boric acid, NL June 2008, DOC IIB:
	Application duration [min]	480	Expert judgement
	Exposure duration (vapour) [min]	480	Expert judgement
	Room volume [m³]	1500	Outdoor/industrial area
	Ventilation rate [h^{-1}]	5	cross ventilation
	Release area [m²]	500	Expert judgement
	Does emmision area increase?	Yes	
	Application temperature [°C]	25	Room temperature
	vapour pressure (2-Ethylhexanoic acid) [Pa]	4	
	Total amount of application solution used [kg]	50	100 ml/m² * 500 m² *solution uptake * release area*
Tier 2	Ventilation rate [h^{-1}]	10	Outdoor/industrial area
	Technical factor "automatically piled up,	2	Expert judgement

	transportation by forklift truck"		
Input parameters for task 1-3			
included in application phase			

Scenario Sec. expo-1: Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi

Mechanical processing of freshly treated wood

Description and input parameters

Table 3.33 Description and input parameters

Description of Scenario Sec. expo-1
Secondary exposure due to mechanical processing of freshly treated wood after application via deluge treatment, immersion (fully automated and automated dipping) cannot be excluded. Therefore, the inhalation exposure to wood dust and dermal exposure during handling of treated wood and resulting from transfer of wood preservative to the skin are estimated here. Inhalation exposure for mechanical processing of treated wood is assessed taking the limit value for wood dust concentration of 2 mg/m^3 into account - according to the German Hazardous Substances Ordinance "Gefahrstoffverordnung" and the Technical Rules for Hazardous Substances (TRGS 553). For calculation of the concentration of the a.s. within the wood dust, it is assumed that the applied application liquid is distributed within a thin layer at the wood surface. Sanding, as a worst case, releases wood dust created entirely from this layer. The density of the wood is taken from the Technical Agreements for Biocides (TAB, August 2021). Since the a.s. are not chemically fixed to the wood it cannot be ruled out that the substances can be released when the surface is wet, for instance. Therefore, it is reasonable that during the mechanical processing of treated wood dermal exposure could occur due to transfer of wood preservative to the hand. For exposure assessment, it is assumed that 20% of both palms are exposed. *Exposure to the eyes* Significant eye contact to the b.p. or wood dust containing the treated wood is expected to be unlikely if the general rules of occupational hygiene are followed. **Calculations** The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 3.34, Table 3.35 and Table 3.36. Values for long term (daily) and short term (weekly) exposure are disclosed separately. For details of the calculation of dermal and inhalation exposure, please refer to the separate Excel file "Output_table_professional-Sinesto_XT.xlsx". **Further information and considerations** The classification of the b.p. and the application liquid requires additional assessment of local risks (see Table 3.37). Local risk assessment has indicated a risk to the skin of the hands, thus protective gloves are required.

Input parameters for Scenario Sec. expo-1			
Input parameters for task Sec. expo-1			
Dermal			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Conc b.p. in treated wood surface	4.5 kg/m³	assumed penetration depth (outer layer): 0.002 m Expert judgement product uptake: 9 g/m² Applicant information
	Density of wood (soft wood)	400 kg/m³	TM III/2008 MOTA
	Exposed skin area [cm²]:	410	palm of both hands
	contaminated hand surface	20%	Expert judgement
	Application rate [g/m²]:	9	Applicant information
	Indicative value, potential hand exposure [mg/event]	73,8	Application amount of b.p. * exposed hand area (20% of palm of both hands)
	Number of events [1/day]	1	Expert judgement
	Concentration of b.p. in wood dust	1,1%	Conc b.p.in wood surface / Density of soft wood
	Concentration of ATMAC/TMAC in b.p.	14%	Product specification
	Concentration of K-HDO in b.p.	0.75%	Product specification
	Concentration of 2-Ethylhexanoic acid in b.p.	22.45%	Product specification
Inhalation			
	Parameters[1]	Value	Reference and justification[3]
Tier 1 (no PPE)	Limit value for dust concentration [mg/m³]	2	limit value for dust concentration according to TRGS 553: 2mg/m³
	Conc b.p. in treated wood surface	4.5 kg/m³	assumed penetration depth (outer layer): 0.002 m Expert judgement product uptake: 9 g/m² Applicant information
	Density of wood (soft wood)	400 kg/m³	TM III/2008 MOTA

Outcome of systemic exposure and risk characterisation

Table 3.34 Summary table: estimated systemic exposure and risk characterisation for K-HDO for professional users

Summary table: estimated systemic exposure and risk characterisation for K-HDO for professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.021 mg/kg bw/d	**Acceptable (Yes/No)**
M&L	1/no PPE	n.a.	$1.22x10^{-3}$	Not expected	$1.22x10^{-3}$	5.80	**Yes**
M&L + 1-2	1/ *gloves during application phase*	n.a.	0.44	Not expected	0.44	2074	No
	2/ *new gloves for every phase and cycle and impermeable coverall (type 4)*	n.a.	0.04	Not expected	0.04	208	No
	3/ *new gloves for every phase and cycle, impermeable coverall (type 4) and fully automated system*	n.a.	0.01	Not expected	0.01	52	**Yes**

1-3	1/ *gloves during post-application phase*	n.a.	0.11	Not expected	0.11	517	No
	2/ *new gloves and coated coverall (type 6)*	n.a.	0.02	Not expected	0.02	75	**Yes**
2	1/ *gloves during application phase*	n.a.	0.13	$2.66x10^{-5}$	0.13	624	No
	2/ *gloves for every phase, coated coverall (type 6), automatically pile up & transportation by forklift and improved ventilation*	n.a.	0.01	$1.33x10^{-5}$	0.01	67	**Yes**

n.a.: not applicable

Table 3.35 Summary table: estimated systemic exposure and risk characterisation for 2-Ethylhexanoic acid for professional users

Summary table: estimated systemic exposure and risk characterisation for 2-Ethylhexanoic acid for professional users								
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal exposure [mg/kg bw/day]**	**Estimated inhalation exposure [mg/m³]**	**Estimated dermal exposure/ $DNEL_{dermal}$ (%)** $DNEL_{dermal}$ = 2 mg/kg bw/d	**Estimated inhalation exposure/ $DNEL_{inhalative}$ (%)** $DNEL_{inhalative}$ = 14 mg/m³	**Estimated dermal exposure/ $DNEL_{dermal}$ (%) + Estimated inhalation exposure/ $DNEL_{inhalative}$ (%)**	**Acceptable (Yes/No)**
M&L	1/no PPE	n.a.	0.04	No aerosol exposure	1.82	0	1.82	**Yes**
M&L + 1-2	1/ *gloves during application phase*	n.a.	13.03	0.05	652	0.38	652	No
	2/ *new gloves for every phase and cycle and impermeable coverall (type 4)*	n.a.	1.31	0.05	65	0.38	66	**Yes**
	3/ *new gloves for every phase and cycle, impermeable coverall (type 4) and fully automated system*	n.a.	0.33	0.01	16	0.10	17	Yes

1-3	1/ *gloves during post-application phase*	n.a.	3.25	No aerosol exposure	162	0	162	No
	2/ *new gloves and coated coverall (type 6)*	n.a.	0.47	No aerosol exposure	24	0	24	**Yes**
2	1/ *gloves during application phase*	n.a.	3.92	0.26	196	1.88	198	No
	2/ *gloves for every phase, coated coverall (type 6), automatically pile up & transportation by forklift and improved ventilation*	n.a.	0.42	0.08	21	0.56	0.21	**Yes**

n.a.: not applicable

Combined scenarios

Not applicable.

Outcome of (semi-)quantitative local exposure and risk characterisation

ATMAC/TMAC:

Table 3.36 Summary table: estimated local exposure and risk characterisation for ATMAC/TMAC for professional users

Summary table: estimated local exposure and risk characterisation for ATMAC/TMAC for professional users				
Exposure scenario	**Dermal NOAEC [%]**	**Concentration ATMAC/TMAC (max.) in application solution [%]**	**Concentration ATMAC/TMAC higher/lower than dermal NOAEC?**	**RMM**
M&L	0.3	14	higher	Skin protection needed; see section Local risks
M&L + 1-2	0.3	1.26	higher	Skin protection needed; see section Local risks
1-3	0.3	1.26	higher	Skin protection needed; see section Local risks
2	0.3	1.19	higher	Skin protection needed; see section Local risks

Outcome of qualitative local risk assessment

Table 3.37 Outcome of qualitative local risk assessment

Hazard			Exposure information						Risk	
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMMs & PPE**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
High	Acute Tox. 4, H302 Skin Corr. 1, H314 Eye Dam. 1, H318 Repr. 2, H361d EUH071		PT08	Mixing & Loading: Connecting transfer lines (automated M&L)	SKIN (Hands):		frequently	**Technical measure:** - Automatic dosing system **PPE:** Protective gloves (EN 374), Protective coverall, Eye protection (face Shield),	**Acceptable**	+ Professionals using appropriate PPE
					SKIN (Body):		cannot be excluded			
					EYES:		rarely			
					RESPIRATORY SYSTEM:		not expected			
					FEET:		cannot be excluded			
High	Skin Corr. 1 , H314 Eye Dam. 1, H318 EUH071		PT08	Application: (Fully) automated dipping (indoor) (fully automated)	SKIN (Hands):		frequently	**Technical measure:** - fully automated immersion system **Organisational measure:** - new gloves every cycle are required - Avoid hand to eye/body	**Acceptable**	+ Professionals using appropriate PPE
					SKIN (Body):		frequently			
					EYES:		frequently			
					RESPIRATORY SYSTEM:		not expected			
					FEET:		cannot be excluded			

								contact **PPE:** Protective gloves (EN 374), Protective coverall, Eye protection (face Shield),		
High	Skin Corr. 1 , H314 Eye Dam. 1, H318 EUH071		PT08	Post-Application: Cleaning of the dip tank	SKIN (Hands):		rarely	**PPE:** Protective gloves (EN 374), Protective coverall, Eye protection (face Shield), Water-resissantant footwear/chemical protective footwear (EN 13832),	**Acceptable**	+ Professionals using appropriate PPE
					SKIN (Body):		rarely			
					EYES:		rarely			
					RESPIRATORY SYSTEM:		not expected			
					FEET:		frequently			
High	Skin Corr. 1 , H314 Eye Dam. 1, H318 EUH071		PT08	Application: deluge treatment (automated)	SKIN (Hands):		frequently	**Technical measure:** - Improved ventilation (outdoors or industrial ventilation) **PPE:** Protective coverall, Full mask with appropiate Respiratory protection,	**Acceptable**	+ Professionals using appropriate PPE
					SKIN (Body):		frequently			
					EYES:		frequently			
					RESPIRATORY SYSTEM:		frequently			
					FEET:		cannot be excluded			
High	Skin Corr. 1 , H314 Eye Dam. 1, H318		PT08	Post-Application: included in 2-2	SKIN (Hands):		rarely	**PPE:** Protective gloves (EN 374), Protective	**Acceptable**	+ Professionals using appropriate
					SKIN (Body):		rarely			

	EUH071				EYES:		rarely	coverall, Full mask with appropiate Respiratory protection,		PPE
					RESPIRATORY SYSTEM:		rarely			
					FEET:		cannot be excluded			
High	Skin Corr. 1 , H314 Eye Dam. 1, H318 EUH071		PT08	Application: Mechanical processing of treated wood secundary exposure	SKIN (Hands):		cannot be excluded	**PPE:** Protective gloves (EN 374), Protective coverall, Full mask with appropiate Respiratory protection,	**Acceptable**	+ Professionals using appropriate PPE
					SKIN (Body):		cannot be excluded			
					EYES:		rarely			
					RESPIRATORY SYSTEM:		rarely			
					FEET:		cannot be excluded			

Conclusion

Based on the individual systemic risk assessment of the active substance K-HDO and the SoC 2-Ethylhexanoic acid via the inhalation and dermal route, and a semi-quantitative local risk assessment of the active substance ATMAC/TMAC via the dermal route, a risk for professional users resulting from the scenarios, as well as from secondary exposure of the biocidal product Sinesto XT is unlikely at the latest after TIER 3 consideration. For risk characterisation from combined exposure to the active substance K-HDO and the SoC 2-Ethylhexanoic acid within the biocidal product, please refer to chapter 3.6.10. In summary, regarding occupational safety, there are no objections against the uses taking into account the provisions described in chapter 3.6.11 of this PAR.

3.6.6.7 Non-professional users

Not relevant. The biocidal product is for industrial/professional use only.

3.6.6.8 Secondary exposure to professional bystanders and non-professional bystanders/general public

Scenario Sec. expo-1: Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi

Please refer to Table 3.33 for the description of mechanical processing of freshly treated wood by the professional user.

Scenario Sec. expo-2: Secondary acute exposure, adult - sanding treated wood, inhalation and dermal exposure

Table 3.38 Description

Description of Scenario Sec. expo-2
Secondary acute exposure, adult - sanding treated wood, inhalation and dermal exposure Exposure scenario Sec. expo-1 for professional users represents also a worst case for users without a professional background. Hence, exposure values for the secondary exposure of the general public are transfered from scenario Sec. expo-1 (refer to Table 3.42, Table 3.43 and Table 3.47 in section 3.6.6.8).

Calculations for Scenario Sec. expo-2, refer to scenario Sec. expo-1

K-HDO
$Exposure_{dermal}$ = 0.000104 mg a.s./kg bw

$Exposure_{inhalation}$ = 0.000028 mg a.s./kg bw

Total systemic exposure = 0.000132 mg a.s./kg bw

2-Ethylhexanoic acid
$Exposure_{dermal}$ = 0.00311 mg SoC/kg bw

$Exposure_{inhalation}$ = 0.00505 mg SoC/m^3
$Exposure_{inhalation}$ = 0.00084 mg SoC/kg bw

Total systemic exposure = 0.00395 mg SoC/kg bw

Scenario Sec. expo-3: Secondary acute exposure, toddler – chewing/mouthing treated wood off-cut, oral exposure

Table 3.39 Description and input parameters

Description of Scenario Sec. expo-3			
Secondary acute exposure, toddler - chewing treated wood off-cut, oral exposure The exposure estimates are based on the recommendations of the TNsG on Human Exposure (2002) Part 3. It is based on the assumption that a toddler mouthes and chews a piece of wood of 4 cm x 4 cm x 1 cm, which can be considered as 1 cm-off-cut of a wooden post.			
Input parameters for Scenario Sec. expo-3			
Oral exposure			
	Parameters	Value	Reference and justification
Tier 1	Application rate	13.5 g/m^2	Applicant
	Concentration a.s. and SoC (applicant)	K-HDO: 0.75% (w/w) 2-Ethylhexanoic acid: 22.45% (w/w)	Applicant
	Concentration a.s. and SoC on the treated wood	K-HDO: 0.010125 mg a.s./cm^2 2-Ethylhexanoic acid: 0.303075 mg SoC/cm^2	Application rate x density x concentration a.s. or SoC in the b.p.
	Dimension of the wood off-cut	4 cm x 4 cm x 1 cm = 16 cm^3	TNsG Human Exposure to Biocidal Products (2002) Part 3, Infant acute, Chewing wood off-cut
	Total amount a.s. and SoC in the treated wood off-cut	K-HDO: 0.162 mg a.s. 2-Ethylhexanoic acid: 4.849 mg SoC	= a.s. or SoC in the treated wood x volume of wood off-cut[1)]
	Extraction coefficient	10%	TNsG Human Exposure to Biocidal Products (2002) Part 3
	Oral absorption	100%	CAR/AR, default for a.s.
	Body weight, toddler	10 kg	HEAdhoc Recommendation No.14, 2017

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

Calculations for Scenario Sec. expo-3

Systemic exposure

$Exposure_{oral}$ = Total amount a.s. or SoC in the treated wood off-cut x extraction coefficient x oral absorption / body weight toddler

K-HDO

$Exposure_{oral}$ = 0.162 mg a.s. x 10% x 100% / 10 kg
= 0.00162 mg a.s./kg bw

2-Ethylhexanoic acid

$Exposure_{oral}$ = 4.849 mg SoC x 10% x 100% / 10 kg
= 0.0485 mg SoC/kg bw

Scenario Sec. expo-4: Secondary long-term exposure, toddler - inhalation of volatilised residues indoors, inhalation exposure

Table 3.40 Description and input parameters

Description of Scenario Sec. expo-4			
Secondary long-term exposure, toddler - inhalation of volatilised residues indoors, inhalation exposure This scenario is based on a proposal from the TNsG on Human exposure (2002) and the more specified recommendations in the HEEG opinion No. 13 "Assessment of Inhalation Exposure of Volatilised Biocide Active Substance". The estimation of air concentrations by saturated vapour pressure is a conservative but very simple approach. This exposure assessment for toddlers represents also a worst case for other members of the general public.			
Input parameters for Scenario Sec. expo-4			
Inhalation exposure			
	Parameters	Value	Reference and justification
Tier 1	Molecular weight K-HDO	182.3 g/mol	CAR/AR, 2008
	Vapour pressure K-HDO (20 °C)	0.000001 Pa	CAR/AR, 2008
	Molecular weight 2-Ethylhexanoic acid	144.21 g/mol	ECHA registration dossier
	Vapour pressure sodium salt of 2-Ethylhexanoic acid (20 °C)	0.000001 Pa	ECHA registration dossier, considering the pH of the product and its dilution, the SoC is present in ionic form, hence the value for the sodium salt of this acid is considered as appropriate
	Gas constant	8.31451 J/mol/K	Atkins Physical Chemistry, 5th Edition, HEEG opinion No 13, 2011
	Temperature	293 K	Assumed room temperature = 20 °C, HEEG opinion No 13, 2011
	Saturated vapour pressure	K-HDO: 0.000075 mg/m³ 2-Ethylhexanoic acid: 0.000059 mg/m³	Calculated acc. to HEEG opinion No. 13, 2011
	Exposure duration	24 h	Worst case, HEEG opinion No. 13, 2011
	Inhalation rate, toddler	8 m³/24 h	HEAdhoc Recommendation No.14, 2017, long-term exposure
	Inhalation absorption	100%	CAR/AR, 2008, default

	Body weight, toddler	10 kg	HEAdhoc Recommendation No.14, 2017

Calculations for Scenario Sec. expo-4

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

K-HDO
$Exposure_{inhalation}$ = 7.48 x 10^{-5} mg/m^3 x 8 m^3/d x 1 d x 100% / 10 kg
= 0.000060 mg a.s./kg bw/d

2-Ethylhexanoic acid
$Exposure_{inhalation}$ = 5.92 x 10^{-5} mg/m^3 x 8 m^3/d x 1 d x 100% / 10 kg
= 0.000047 mg SoC/kg bw/d

Scenario Sec. expo-5: Secondary long-term exposure, toddler - playing on treated structure and mouthing of hands, dermal and oral exposure

Table 3.41 Description and input parameters

Description of Scenario Sec. expo-5			
Secondary long-term exposure, toddler - playing on treated structure and mouthing, dermal and oral exposure A first recommendation for assessment of secondary long-term exposure of a toddler playing on treated structures is provided in the TNsG on Human Exposure (2002). This exposure assessment was amended in accordance to the Recommendation No. 5 of the BPC Ad hoc Working Group on Human Exposure (HEAdhoc) "Non-professional use of antifouling paints: exposure assessment for a toddler" (2015). It is assumed that dried wood preservatives and antifoulings have similar properties in this context. This exposure assessment for toddlers represents also a worst case for other members of the general public. Please note that exposure of the general public to wet, freshly treated wood is not expected and not assessed since the biocidal product is used only in industrial settings. Access of the general public to such areas is not expected.			
Input parameters for Scenario Sec. expo-5			
Dermal and oral exposure			
	Parameters	Value	Reference and justification
Tier 1	Application rate	13.5 g/m^2	Applicant
	Concentration a.s. and SoC	K-HDO: 0.75% (w/w) 2-Ethylhexanoic acid: 22.45% (w/w)	Applicant
	Amount a.s. and SoC available on wood surface for transfer to skin	K-HDO: 0.010125 mg a.s./cm^2	Application rate x concentration a.s. or SoC

		2-Ethylhexanoic acid: 0.303075 mg SoC/cm²	
	Hand surface (toddler, palms of both hands)	115.2 cm²	HEAdhoc Recommendation No.14, 2017
	Proportion of palms of hand in contact with the b.p., percentage contaminated skin	40%	HEAdhoc Recommendation No. 5, 2015
	Transfer coefficient of biocidal product from dried b.p. to hand	3%	HEAdhoc Recommendation No. 5, 2015
	Transfer coefficient of paint from hand to mouth for dried paint	50%	HEAdhoc Recommendation No. 5, 2015, based on Pest Control Products Fact Sheet, 2.2.7, 2006
	Dermal absorption for K-HDO, 2-Ethylhexanoic acid	100%	TAB TOX21, 2018
	Oral absorption	100%	CAR/AR, 2008, default
	Body weight, toddler	10 kg	HEAdhoc Recommendation No.14, 2017

Calculations for Scenario Sec. expo-5

Systemic exposure

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

$Exposure_{oral}$ = Concentration a.s. or SoC on the surface x hand inner surface of both hands x transfer coefficient x percentage contaminated skin x transfer coefficient hand to mouth x oral absorption / body weight

K-HDO

$Exposure_{dermal}$ = 0.010125 mg a.s./cm² x 115.2 cm² x 3% x 40% x 100% / 10 kg
= 0.00140 mg a.s./kg bw/d

$Exposure_{oral}$ = 0.010125 mg a.s./cm² x 115.2 cm² x 3% x 40% x 50% x 100% / 10 kg
= 0.00070 mg a.s./kg bw/d

Total systemic exposure = 0.00210 mg a.s./kg bw/d

2-Ethylhexanoic acid

$Exposure_{dermal}$ = 0.303075 mg SoC/cm² x 115.2 cm² x 3% x 40% x 100% / 10 kg
= 0.04190 mg SoC/kg bw/d

$Exposure_{oral}$ = 0.303075 mg SoC/cm² x 115.2 cm² x 3% x 40% x 50% x 100% / 10 kg
= 0.02095 mg SoC/kg bw/d

Total systemic exposure = 0.06285 mg SoC/kg bw/d

Local Exposure Assessment for ATMAC/TMAC

Description of Scenario Sec. expo-2
Secondary acute exposure, adult - sanding treated wood, inhalation and dermal exposure Exposure scenario 4 for professional users represents also a worst case for users without a professional background. Hence, exposure values for the secondary exposure of the general public are transfered from scenario Sec. expo-1 (refer to section Table 3.42 and Table 3.43 in section 3.6.6.8).

Description of Scenario Sec. expo-3
Secondary acute exposure, toddler - chewing treated wood off-cut, oral exposure The assessment was adopted from the CAR. The biocidal product in the CAR was applied in an amount of 0.168 mg ATMAC/TMAC/cm^2. The application rate of the biocidal product Sinesto XT is similar (0.189 mg ATMAC/TMAC/cm^2). Extract from the CAR: *'Secondary exposure: Infants chewing wood off-cut - ingestion route* *Watanabe et al (1995) informs that in 15 boys and 15 girls of five years old, the mean flow of unstimulated saliva was 0.26 (+0.16 SD) ml/min and that of saliva while chewing was 3.6 (+0.8 SD) ml/min. The Watanabe study measured saliva flow when chewing foodstuffs. It can be assumed that this stimulated saliva flow would be similar for any chewing action. Dawes (2008) found that taste also stimulated saliva flow. In adults infusion of 5% citric acid into the mouth elicited a flow rate of 7.07 ml/min compared to 4.94 ml/min. Thus, the taste of the active substance could also add to the rate of saliva flow. Information taken from a study on leachability of ATMAC/TMAC in the fate and behaviour data supporting the assessment of this substance can be used to determine the amount of active substance released from a treated wood off-cut. Section 3.3.2 of Doc IIB gives details of a study in which wooden blocks (19 x 19 x 19 mm) were vacuum pressure treated at 3 different concentrations. The ATMAC/TMAC retention levels were calculated to be 3.5, 7.0 and 14.0 kg/m^3. The blocks were then suspended in water and measurements of ATMAC/TMAC concentration in the leachate water were taken at various time points up to 14 days after initiation of leaching. The shortest interval was 6 hours after initiation of leaching. For the 6 hour time-point the level of leaching, expressed as a percentage of the original amount, was 0.63%, 1.08% and 1.97% for the 3.5, 7.0 and 14.0 kg/m^3 respectively. Whilst there appears to be some uncertainty over the value derived for the highest concentration, these data suggest less than 2.0% of ATMAC/TMAC was removed from the treated wood after soaking in water for 6 hours. Considering a retention rate of 150 g treatment solution/m^2 and an in-use treatment solution with a maximum active substance content of 1.12%, the worst case loading is 0.168 mg a.s./cm^2 (150g b.p./m^2 x 1.12/100 = 1.68 g a.s./m^2 = 0.168 mg a.s./cm^2). The total surface area of wood off-cut is 48 cm^2 (= 2 x [4cm x 4cm + 4cm x 1cm + 4cm x 1cm]) with a volume of 16 cm^3 (4 cm x 4 cm x 1 cm). Using an extraction factor of 2.0% for human health risk assessment, the concentration of active substance in saliva of an infant chewing/mouthing a 4 x 4 x 1 cm wood off-cut treated by dipping application can be calculated as follows.* *Estimation of exposure to infant mouthing wood off-cut treated by dipping application* *Concentration of a.s. in treated wood* — *0.168 mg a.s./cm^2 (TMAC dossier)* *total surface of wood off- cut* — *48 cm^2* *Amount of a.s. released from off-cut – assuming 2.0% extraction* — *0.16 mg*

Amount of saliva produced by an infant (stimulated saliva flow)	*3.6 ml/minute*
Duration of chewing of off-cut	*1 minute*
Concentration of a.s. in saliva	*0.04 mg a.s./ml*

For wood treated by dipping application, the predicted exposure concentration is 0.04 mg a.s./ml.

Extrapolating the environmental fate data to an infant mouthing treated wood involves a degree of uncertainty, as the treated wooden blocks used were soaked and not sucked or chewed. However, it is of note that the blocks were soaked for 360 minutes compared to 1 minute for the infant mouthing the off-cut.'

For inhalation exposure:
Not applicable. An AEC for inhalation has not been derived for active substance approval.

For dermal exposure:
Concentration of ATMAC/TMAC in the treated wood = 0.16%

Using the same approach for the biocidal product with the slilghtly increased application rate of 0.189 mg ATMAC/TMAC/cm^2, the following active substance concentration in saliva is expected for the bicodal product (assuming a linear relation):

Concentration of ATMAC/TMAC in saliva = 0.05 mg/ml = 0.0005%

Description of Scenario Sec. expo-4
Secondary long-term exposure, toddler - inhalation of volatilised residues indoors, inhalation exposure The air concentration of volatilised residues is determined by the calculation of the saturated vapour concentration (SVC). This is a conservative but very simple approach to estimate the potential concentration of a substance in the air. This estimate is based on parameters laid down in the HEEG opinion No. 13 "Assessment of Inhalation Exposure of Volatilised Biocide Active Substance".

Input parameters for Scenario Sec. expo-4			
Inhalation exposure			
	Parameters	Value	Reference and justification
Tier 1	Molecular weight ATMAC/TMAC	273 g/mol (273000 mg/mol)	(CAR/AR, 2016)
	Vapour pressure ATMAC/TMAC (20°C, CAR/AR, 2016)	0.0000018 Pa	(CAR/AR, 2016)
	Gas constant	8.31451 J/mol/K	(Atkins Physical Chemistry, 5th Edition), HEEG opinion No. 13, 2011
	Temperature, assumed room temperature = 20°C	293 J/mol/K	HEEG opinion No. 13, 2011

Saturated vapour concentration = molecular weight x vapour pressure / (gas constant x temperature)
= 273 g/mol x 0.0000018 Pa / (8.31451 J/mol/K x 293 K)
= 0.000202 mg/m³

Description of Scenario Sec. expo-5
Secondary long-term exposure, toddler - playing on treated structure and mouthing, dermal and oral exposure. With respect to dermal exposure of toddlers playing on weathered structures the following statement from the CAR is adopted: *"The handling of treated wet wood, where exposure was to the diluted product, posed only a "low" hazard. When the treated wood has dried, the release of the active substance is not expected to reach a concentration that could lead to irritative effects during dermal exposure. Therefore, the potential of local effects during child playing on weathered structure is negligible. No risk to the child playing on weathered structure is identified."* Considering this statement from the CAR, an exposure by this scenario is considered not relevant.

Dermal and oral exposure from contact to treated surfaces = not relevant

Outcome of systemic exposure and risk characterisation

K-HDO

Table 3.42 Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

Summary table: estimated systemic exposure and risk characterisation for K-HDO for professional bystanders and non-professional bystanders/general public							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day**	**Estimated total uptake [mg/kg bw/day]**	**Estimated total uptake/ AEL (%)** Sec. expo-1: AEL = 0.021 mg/kg bw/d Sec. expo-2 and 3: AELshort-term: 0.1 mg/kg bw/d Sec. expo-4 and 5: AELlong-term: 0.021 mg/kg bw/d	**Acceptable (Yes/No)**
Sec. expo-1	1/no PPE	n.a.	$1.04x10^{-4}$	$2.81x10^{-5}$	$1.32x10^{-4}$	0.63	**Yes**
Scenario Sec. expo-2	1	-	$1.04x10^{-4}$	$2.81x10^{-5}$	$1.32\ x10^{-4}$	0.1	Yes
Scenario Sec. expo-3	1	$1.62x10^{-3}$	-	-	$1.62x10^{-3}$	1.6	Yes
Scenario Sec. expo-4	1	-	-	$6.0x10^{-5}$	$6.0x10^{-5}$	0.3	Yes
Scenario Sec. expo-5	1	$7.0x10^{-4}$	$1.40x10^{-3}$	-	$2.10\ x\ 10^{-3}$	10	Yes

n.a.: not applicable

2-Ethylhexanoic acid

Table 3.43 Summary table: estimated systemic exposure and risk characterisation for 2-Ethylhexanoic acid for professional bystanders - Sec. expo-1

Summary table: estimated systemic exposure and risk characterisation for 2-Ethylhexanoic acid for professional bystanders and non-professional bystanders/general public								
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal exposure [mg/kg bw/day]**	**Estimated inhalation exposure [mg/m³]**	**Estimated dermal exposure/ $DNEL_{dermal}$ (%)** $DNEL_{dermal}$ = 2 mg/kg bw/d	**Estimated inhalation exposure/ $DNEL_{inhalative}$ (%)** $DNEL_{inhalative}$ = 14 mg/m³	**Estimated dermal exposure/ $DNEL_{dermal}$ (%) + Estimated inhalation exposure/ $DNEL_{inhalative}$ (%)**	**Acceptable (Yes/No)**
Sec. expo-1	1/no PPE	n.a.	$3.11x10^{-3}$	$5.05x10^{-3}$	0.16	0.04	0.19	**Yes**

n.a.: not applicable

Table 3.44 Summary table: estimated systemic exposure and risk characterisation for 2-Ethylhexanoic acid for professional bystanders and non-professional bystanders/general public – Scenario Sec. expo-2-5

Summary table: estimated systemic exposure and risk characterisation for 2-Ethylhexanoic for professional bystanders and non-professional bystanders/general public							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** DNEL: 1 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario Sec. expo-2	1	-	$3.11x10^{-3}$	$8.4x10^{-4}$	$3.95x10^{-3}$	0.4	Yes
Scenario Sec. expo-3	1	$4.85x10^{-2}$	-	-	$4.85x10^{-2}$	4.8	Yes
Scenario Sec. expo-4	1	-	-	$5.0x10^{-5}$	$5.0x10^{-5}$	0.005	Yes
sec. expo-5	1	$2.095x10^{-2}$	$4.190x10^{-2}$	-	$6.285x10^{-2}$	6.3	Yes

Combined scenarios

For professional user a combined exposure is not relevant.

Outcome of combined systemic exposure and risk characterisation

K-HDO

Table 3.45 Summary table: combined systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

Summary table: combined systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public							
Scenarios combined	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.021 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario Sec. expo-4 + Scenario Sec. expo-5	1	0.00070	0.00140	0.00006	0.00216	10.3	Yes

2-Ethylhexanoic acid

Table 3.46 Summary table: combined systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

Summary table: combined systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public							
Scenarios combined	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** DNEL: 1 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario Sec. expo-4 + Scenario Sec. expo-5	1	0.02095	0.04190	0.00005	0.06290	6.3	Yes

Outcome of (semi-)quantitative local exposure and risk characterisation

ATMAC/TMAC

Table 3.47 Summary table: estimated local exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

Summary table: estimated local exposure and risk characterisation for professional bystanders and non-professional bystanders/general public							
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated oral exposure [%]**	**Estimated inhalation exposure [mg/m³]**	**Estimated total exposure [mg/m³ or %]**	**Estimated exposure / AEC (%)** NOAECdermal = 0.3% NOAECoral: 0.03%	**Acceptable (yes/no)**
Sec. expo-1	1	0.16	n.a.	$3.15x10^{-3}$	-	Dermal: 53	Yes
Scenario Sec. expo-2	1	0.16	-	-	-	Dermal: 53	Yes
Scenario Sec. expo-3	1	-	0.0005	-	-	Oral: 1.7	Yes
Scenario Sec. expo-4	1	-	-	0.000202	-	n.a.	n.a.
Scenario Sec. expo-5	1	Not relevant					

n.a.: not applicable

Outcome of qualitative local risk assessment

A qualitative local assessment for the general public is considered not relevant. Local effects from treated wood resulting from the biocidal product are not expected or covered by the (semi-)quantitative assessment

Conclusion

Professional user:
Based on the individual systemic risk assessment of the active substance K-HDO and the SoC 2-Ethylhexanoic acid via the inhalation and dermal route, a risk for professional bystanders resulting from secondary exposure to the biocidal product Sinesto XT is unlikely at the latest after Tier 2 consideration. For risk characterisation from combined secondary exposure to the active substance K-HDO and the SoC 2-Ethylhexanoic acid within the biocidal product, please refer to chapter 3.6.10. In summary, regarding occupational safety for bystanders, there are no objections against the uses taking into account the provisions described in chapter 3.6.11 of this PAR.
General public:
Systemic exposure to the active substance K-HDO and the substance of concern 2-Ethylhexanoic acid does not exceed the corresponding AEL. No risk is identified for the combined and cumulative assessment.
No risk from local exposure to the active substance ATMAC/TMAC was identified. A qualitative local risk assessment is considered not necessary.
In conclusion, exposure of the general public is considered acceptable without further risk mitigation measures.

3.6.7 Monitoring data

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3.6.8 Dietary risk assessment

The intended use descriptions of the biocidal product are not relevant in terms of residues in food and feed. The product is to be used for control of wood discolouring fungi by professional or industrial application on wood that does not come in direct contact with food, feed or livestock (contact excluded by appropriate RMM).

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

3.6.9 Aggregated exposure and risk characterisation

Not applicable.

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

Tier 1 and tier 2
Professional user

Table 3.48 Tier 1 and tier 2

M&L	**K-HDO**	**2-Ethylhexanoic acid**	**Conclusions**
without PPE			
Tier 1[a]	6% AEL	1.82% AEL	Acceptable
Tier 2[b]	0.06	0.02	Acceptable
	HI = 0.08		
M&L + 1-2	**K-HDO**	**2-Ethylhexanoic acid**	**Conclusions**

without PPE			
Tier 1[a]	2074% AEL	652% AEL	Not acceptable
Tier 2[b]	20.7	6.52	Not acceptable
	HI = 27.26		
with PPE			
Tier 1[a]	208% AEL	66% AEL	Not acceptable
Tier 2[b]	2.08	0.66	Not acceptable
	HI =2.74		
with PPE and refined exposure assessment			
Tier 1[a]	52% AEL	16.7% AEL	Acceptable
Tier 2[b]	0.52	0.17	Acceptable
	HI =0.69		
1-3	**K-HDO**	**2-Ethylhexanoic acid**	**Conclusions**
without PPE			
Tier 1[a]	517% AEL	162% AEL	Not acceptable
Tier 2[b]	5.17	1.62	Not acceptable
	HI = 6.79		
with PPE			
Tier 1[a]	75% AEL	23.5% AEL	Acceptable
Tier 2[b]	0.75	0.24	Acceptable
	HI = 0.98		
2	**K-HDO**	**2-Ethylhexanoic acid**	**Conclusions**
without PPE			
Tier 1[a]	624% AEL	210% AEL	Not acceptable
Tier 2[b]	6.24	2.1	Not acceptable
	HI = 8.34		
with PPE			
Tier 1[a]	67% AEL	21% AEL	Acceptable
Tier 2[b]	0.67	0.25	Acceptable
	HI = 0.92		
Sec. expo-1	**K-HDO**	**2-Ethylhexanoic acid**	**Conclusions**
without PPE			
Tier 1[a]	1% AEL	0.19% AEL	Acceptable
Tier 2[b]	0.01	0.00	Acceptable
	HI = 0.01		

a: Tier 1 here is an intermediary step to verify risk acceptability for each individual substance with systemic effects (active substance or SoC) used in the product and is followed by
b: Tier 2 to assess the combined exposure/toxixity of the biocidal product

Exposure of the general public

Table 3.49 Tier 1 and tier 2

Scenario Sec. expo-2 Secondary exposure	**K-HDO**	**2-Ethylhexanoic acid**	**Conclusion**
Acute			
Tier 1	0.1% AEL	0.4% AEL	Acceptable
Tier 2	HI: 0.005		Acceptable
Scenario Sec. expo-3 Secondary exposure	**K-HDO**	**2-Ethylhexanoic acid**	**Conclusion**
Acute			
Tier 1	1.6% AEL	4.8% AEL	Acceptable
Tier 2	HI: 0.06		Acceptable
Scenario Sec. expo-4 Secondary exposure	K-HDO	2-Ethylhexanoic acid	Conclusion
Chronic			
Tier 1	0.3% AEL	0.005% AEL	Acceptable
Tier 2	HI: 0.003		Acceptable

Scenario Sec. expo-5 Secondary exposure	K-HDO	2-Ethylhexanoic acid	Conclusion
Chronic			
Tier 1	10.0% AEL	6.3% AEL	Acceptable
Tier 2	HI: 0.16		Acceptable
Scenario Sec. expo-4+5 Secondary exposure	**K-HDO**	**2-Ethylhexanoic acid**	**Conclusion**
Chronic			
Tier 1	10.3% AEL	6.3% AEL	Acceptable
Tier 2	HI: 0.17		Acceptable

3.6.11 Overall conclusion on risk assessment for human health

Table 3.50 Overall conclusion on the risk assessment for human health from systemic and local exposure

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
1	Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi_Dipping	Acceptable with the following risk mitigation measures	- N-9: Wear a protective coverall (at least type 4, EN 14605) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information). - N-78: Wear protective chemical resistant gloves meeting the requirements of European Standard EN 374 during product handling phase (glove material to be specified by the authorisation holder within the product information). Operators must wear new protective gloves for each cycle. - N-182: The process of dilution has to be carried out using an automatic dosing system. - N-79 (modified): Wear suitable protective footwear against chemicals (EN 13832) when cleaning the dipping tank the product. - Use in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
			articles are transported through the dip tank to the draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until the treated articles are surface dry. The untreated wood may only be lowered by a separate lifting unit into the dipping tank.
2	Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi_Spraying	Acceptable with the following risk mitigation measures	- N-10: Wear a protective coverall (at least type 6, EN EN 13034). - N-78: Wear protective chemical resistant gloves meeting the requirements of European Standard EN 374 during product handling phase (glove material to be specified by the authorisation holder within the product information). - N-182: The process of dilution has to be carried out using an automatic dosing system. - N-29: Ensure that application is carried out in areas with a minimum ventilation of 10 h^{-1}. - N-73: Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with particle filter P2 is required. - The product may only be used with spray tunnels featuring an automated onward transport of the

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
			freshly treated wood with automated stacking or into a drier so as to avoid manual contact with the freshly treated wood.

3.7 Risk assessment for animal health

Due to the lack of an appropriate guidance, a specific exposure and risk assessment for pets and domestic animals is not performed.
However, it is expected that animals can be exposed to the active substance after treatment, particularly by contact to treated surfaces. It is assumed that the health risk for these animals is comparable to those of toddlers and children and covered by the corresponding assessment. In addition, the applicant stated that the biocidal product is not intended for wood used for animal housing. Since the human health risk assessment for the general public demonstrates safe use without further risk mitigation measures, there is also no health risk expected for animals. The RMM resulting from the dietary risk assessment (section 3.6.8) is also appropriate to exclude livestock exposure with respect to animal health.

3.7.1 Risk for companion animals

Not relevant.

3.7.2 Risk for livestock animals

Not relevant.

3.8 Risk assessment for the environment

Sinesto XT is a concentrated wood preservative containing the active substances ATMAC/TMAC (14%; CAS: 61789-18-2) and K-HDO (0.75% CAS: 66603-10-9), which is to be diluted with water to reach the final in-use concentration. The product is intended to temporarily prevent wood discoloring fungi on freshly sawn timber and wooden pallets. It is applied industrially by dipping or spraying.
Since no substances of concern were identified for the environment, the environmental risk assessment of Sinesto XT is based on the active substances, only and was conducted according to the Guidance on the BPR: Volume IV Environment Part A (2022) as well as Parts B+C (2017).

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance(s), metabolite(s) and transformation product(s)

No new studies regarding environmental effects or fate and behaviour of the active substances were submitted for this product. Therefore, the assessment is based on the information provided in in the respective CA reports of the active substances:

- ATMAC/TMAC (CAS: 61789-18-2): Assessment report PT 8, April 2016, Italy
- K-HDO (CAS: 66603-10-9): Assessment report PT 8, February 2008, Austria

The assessment reports are available on the ECHA website.
Fate and behaviour of the active substances are summarised briefly below:

ATMAC/TMAC
ATMAC/TMAC is a quaternary ammonium compound with a fungistatic mode of action. It was shown to be readily biodegradable. Hence, according to the Guidance on BPR, Vol IV ENV Parts B+C, a half-life in surface water of 15 d can be assumed. In soil, considering the Kpsoil of 22,000 L/kg it was decided that a DT50 of 30,000 d should be used.
Regarding abiotic degradation, ATMAC/TMAC is hydrolytically stable at pH 5, 7 or 9 at 25 ºC and photolytically stable. Estimation of photodegradation in air via the assessment tool AOPWIN showed a half-life in air of 13.505 hours.
The results of an adsorption/desorption study conducted with a structural analogue substance indicated that ATMAC/TMAC is adsorbed in soil and has little or no potential for mobility in soil. Hence, it should not pose an environmental risk for contamination of groundwater. A Koc value of 562,314 L/Kg was agreed to be used for the risk assessment of the active substance.

K-HDO
According to the CAR, K-HDO is not readily or inherently biodegradable. No degradation rates for soil and water are available.
Regarding abiotic degradation, K-HDO is hydrolytically stable at pH 5 and 9 at 25 ºC. Photolytic degradation was shown for the read-across substance Cu-HDO (80 – 90% after 72 hours of exposure to UV radiation (> 290 nm)) and can be assumed for K-HDO, too. However, the quality of the study is poor.
Estimation of photodegradation in air via the assessment tool AOPWIN showed a half-life in air of 11.2 hours. The mean Koc of K-HDO is 4,296 L/kg.

The endpoints applied in the environmental risk assessment are summarised in the table below.

Table 3.51 Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment

Endpoints and PNEC values for the active substances applied in the environmental risk assessment				
	Value		Unit	Remarks
	ATMAC/ TMAC	K-HDO		
Fate and behaviour in the environment				
Molecular weight	275.35 (mean)	182.3	g/mol	
Melting point	decomposes before melting	163.1	°C	
Vapour pressure (at 20°C)	$1.8*10^{-6}$	10^{-4}	Pa	
Water solubility (at 20°C)	346	452	g/L	
Log Octanol/water partition coefficient (K_{ow})	0	-0.2	Log 10	
Organic carbon/water partition coefficient (K_{oc})	562,314	4,296	L/kg	K-HDO: instead of the arithmetic mean Koc from CAR Doc II A the geometric mean Koc as recommended in GD BPR B+C, ch. 2.3.5.3 is used
Henry's Law Constant	$1.38*10^{-9}$	$4.4*10^{-8}$	$Pa/m^3/mol$	calculated
Characterisation of biodegradability	ready biodegradable, fulfilling 10-day window	Not readily or inherently biodegradable	-	
Rate constant for STP	1	0	h^{-1}	ATMAC:. Default endpoint for readily biodegradable was used.
DT_{50} for biodegradation in surface water	15	no biodegradation	d (at 12 ºC)	ATMAC: acc. BPR, Vol IV ENV Parts B+C, Table 5 K-HDO: no valid experimental data is available. Degradation was therefore not considered.
DT_{50} for hydrolysis in surface water	stable	stable at pH7		
DT_{50} for degradation in soil	30,000	no biodegradation	d (at 12 ºC)	ATMAC: see CAR Doc IIB K-HDO: no valid experimental data is available. Degradation was therefore not considered.
DT_{50} for degradation in air	13.505	3.735	hr	
Distribution in STP - to air - to water - to sludge - degraded	 0 64.97 35.02 0	 0 6.212 85.09 8.695	%	Modelled with Simple Treat 4.0

Predicted no effect concentrations (PNEC)				
Sewage treatment plant	0.122	0.09	mg/L	ATMAC + K-HDO: based on a EC50 for respiration inhibition and an assessment factor of 100.
Surface water	0.0008	0.0094	mg/L	ATMAC: Read-across to DDAC; based on three chronic studies and an assessment factor of 10. Algae are most sensitive. K-HDO: based on NOEC for daphnia and an AF of 50.
Marine water	--	--	mg/L	not relevant
Sediment	2.67	1.24	mg/kg wwt	ATMAC: Read-across to DDAC; based on NOEC for *Chironomus r.* and an AF of 100 K-HDO: calculated from PNECwater.
Marine sediment	--	--	mg/kg wwt	not relevant
Soil	1.05	≥0.36	mg/kg wwt	ATMAC: Read-across to DDAC; microorganisms were most sensitive. An assessment factor of 50 was applied. K-HDO: based on NOEC for microorganisms with an AF of 100.
Bird	0.41		mg/kg food	ATMAC: based on read-across to DDAC K-HDO: no PNECoral has been determined due to low bioaccumulation potential.
Mammals	1.11		mg/kg food	ATMAC: based on 90-d NO(A)C and an AF of 90 no PNECoral has been determined due to low bioaccumulation potential.

3.8.1.2 Endpoints for the product

A semi-field leaching test with the product was performed to estimate the released amounts of the active substances into the environment during service life of treated timber. The submitted study has been evaluated by the Competent Authority:

Semi-field leaching test

The leaching of ATMAC/TMAC and K-HDO from treated timber was investigated in a semi-field study for a period of two years at MPA-Eberswalde (Materialprüfanstalt Brandenburg GmbH). A summary of the test report is included in the IUCLID dossier. The test design is in accordance with NT Build 509, but the exposed wood surface of each test set was 0.8155 m^2 according to DIN CEN/TR 16663:2014. Wood of *Pinus sylvestris* was treated with a solution containing 3.75% of the wood preservative by short-term dipping. The mean retention rate of the product was 6.73 g/m^2, equivalent to a retention rate of 0.94 g TMAC per m^2 and 0.05 g K-HDO per m^2.

One untreated test set and three preservative treated test set-ups were established. The vertically oriented timber panels were exposed to the weather facing the south-west. Run-off leachates were continuously collected and analysed for TMAC and K-HDO after each major rain event. Leachates were collected from 28 May 2019 to 28 May 2021.

The calculated flux rates based on the leaching test are summarised below. The detailed calculations are presented in chapter 4.1.3. A correction factor of 2.006 was applied to calculate leaching rates, since the product retention of 6.73 g product per m² in the study is lower than the maximum intended retention rate of the product of 13.5 g/m².

Table 3.52 Endpoints for leaching behaviour derived with the semi-field leaching test

	Leaching of Sinesto XT		
Active substance	**TIME 1 (30 days)**	**TIME 1b (1 year)**	**TIME 2 (5 years)**
Cumulative leaching $Q^*_{leach,time}$ (mg/m²)			
ATMAC/TMAC	14.94	25.18	31.52
K-HDO	0.098	1.546	2.604
Leaching rate FLUX (mg/(m²*d))			
ATMAC/TMAC	0.498	0.069	0.017
K-HDO	0.003	0.004	0.001

3.8.1.3 Substance(s) of concern

No substances of concern regarding the environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)). Consequently, only the active substances were addressed in the environmental risk assessment.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

The full composition of the product as well as the results of the ED-assessment of the co-formulants are summarised in chapter 3 of the confidential annex.

3.8.1.5 PBT Assessment

The conclusions from the PBT assessment do not differ from the results of the PBT assessment, which was performed within the frame of the evaluation of the active substances. Accordingly, ATMAC/TMAC and K-HDO neither fulfil the PBT- nor the vP/vB-criteria.

3.8.2 Emission estimation

3.8.2.1 General information

The wood-preservative Sinesto XT is applied industrially to freshly sawn timber and pallets via spraying or dipping. The concentrated wood preservative containing the active substances ATMAC/TMAC (14%; CAS: 61789-18-2) and K-HDO (0.75% CAS: 66603-10-9) is to be diluted with water to reach the final in-use concentration. The dilution rate is dependent on the infestation pressure, climate conditions and type of wood. The intended product retention in wood is 3.6-13.5 g/m². The product is supposed to temporarily prevent wood discolouring fungi on freshly sawn timber and pallets.

The environmental exposure assessment is based on the Emission Scenario Document for PT8 (ESD PT8) and on the document "PT8: Assessment of temporary anti-sapstain wood-preservatives"[3] (adopted at WG ENV II 2018, see TAB ENV 199, v.Nov.2021). Predicted Environmental Concentrations (PECs) were calculated according to the relevant exposure scenario document (release to the environment), the Guidance on the BPR: Volume IV Environment (Parts B+C) (distribution in the environment), the Technical Agreement on Biocides (TAB) and the model SimpleTreat (concentrations for micro-organisms in the sewage treatment plant (STP) the STP's effluent) by using the default values for parameters, unless otherwise noted. Distribution in the STP has been calculated using SimpleTreat version 4.0 in which the concentration of suspended solids in the effluent has been increased to 30 mg/L in accordance with the TAB. Distribution in the STP and the environment is calculated based on the physical-chemical properties as listed in section 3.2.
Emission to groundwater was assessed based on the substance's mobility in soils (K_{oc}) as described in the guidance. No higher tier modelling was deemed necessary.

Following life cycle steps of the product were assessed:

Production and formulation: No
Use (application) and storage of treated wood: Yes (qualitative)
Storage: Yes (qualitative)
Service life: Yes (quantitative)

Emission of Sinesto XT or single product components to the environment could generally occur during application of the product and storage and service life of treated wood.
Release of active substances during the waste phase of the end-products is not assessed, because it is assumed that these are disposed as solid waste and usually incinerated.

The table below summarises the receiving environmental compartments that have been identified as potentially exposed during the use and service life of the product. Compartments highlighted in bold are directly exposed.

[3] https://webgate.ec.europa.eu/s-circabc/w/browse/6f4c1846-184f-4158-b381-969e23975afd

Table 3.53 Environmental risk assessment

Environmental risk assessment				
Use number	**Scenario assessed**	**Assessment approach**	**Maximum in-use concentration of the active substances**	**Receiving compartments**
Use [1] and Use [2] (the different application techniques (fully automated spraying or dipping) have no impact on the environmental risk assessment	Scenario 1 – Production, formulation and application of the product and storage of treated wood	Qualitative assessment		
	Scenario 2 – House	Quantitative assessment according to "OECD Emission Scenario Documents, Number 2, Revised Emission Scenario Document for Wood Preservatives, September 2013"	Maximum retention rate: 13.5 g Sinesto XT / m² wood Corresponding to: ATMAC/TMAC: 1.89 g/m² K-HDO: 0.101 g/m²	**soil** groundwater
	Scenario 3 – Noise barrier			**STP** freshwater freshwater sediment **soil** groundwater
	Scenario 4 – Bridge over pond			**freshwater** freshwater sediment

3.8.2.2 Emission estimation for the scenario(s)

3.8.2.2.1 Formulation, industrial application and storage

Scenario 1- Production, formulation and application of the product and storage of treated wood

Sinesto XT is intended for industrial application, only. The product is to be diluted with water to reach the final use-concentration. The dilution rate is dependent on the infestation pressure, climate conditions and type of wood. Application takes place automatically in an industrial treatment plant by spraying or dipping.

The following qualitative assessment evaluates potential emission of Sinesto XT or single product components to the environment during the life cycle steps formulation, production and application of the product and storage of freshly treated wood:

Formulation/ production of the biocidal product
Environmental emission estimation for production of the active substances and formulation of the biocidal product has not been performed as the active substances as well as the product are manufactured in a closed system and unacceptable emissions to the environment are not expected. Furthermore, other EU legislation already cover this step.

Industrial application of the biocidal product
The product is used for the industrial treatment of wood by automated dipping or spraying. It is diluted with water to reach the use concentration.

In ESD PT8, sentences 100 and 101, following is stated for automated spraying: "The treatment apparatus is typically established in a contained or bunded area fabricated from materials resistant to the wood preservative product. Provision is made for the collection, recycling and reuse of wood preservative collected from the conveyor or drip dry area. The release of wood preservatives from the treating installation or where the treated timber is stored into a surface water drain or drain connected to a Sewage Treatment Plant (STP) is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process." and "Even though release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, the corresponding emission pathway (facility drain to STP to surface water) is nevertheless a worst case the assessment of which can be of relevance outside the EU.". Equivalent information is stated in sentences 125 and 126 for dipping.

Authorisation of Sinesto XT within the EU member state countries is sought after in this application process. Since emissions from the treatment process of wood to the environment are not allowed within the EU, a quantitative emission estimation is not needed. The design and safe operation of timber treatment installations are regulated by national laws which implement EU directives and correspond to the current state of technique and scientific knowledge, e.g. as given in the European Code of Practice EWPM (2011[4]).

Safety measures regarding the application process are also demanded in the

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

Implementation Directive (IR) of the active substance ATMAC/TMAC (2016) and apply to the application of Sinesto XT as well. Following risk mitigation measure (RMM) has to be added to the SPC:

- *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).*

In addition, the following instruction for use is required to ensure the safe use of Sinesto XT and is part of the authorisation:

- *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.*

Storage of freshly treated wood

Emissions to the environment could potentially occur during storage of wood or pallets after industrial application of Sinesto XT.

In ESD PT8, sentence 90, following is stated "On European level, where the industrial application of wood preservatives is regulated by local authorities, it can be assumed that most storage places are sealed to prevent any direct release to soil. In the case that the storage place is sealed and run-off from storage places will be collected and disposed of by save means, the storage place scenario does not need to be considered."

As stated in the Inclusion Directive on ATMAC/TMAC, storage of treated timber exposed to wetting poses a risk to the environment unless RMM (storage under shelter or on impermeable hard standing) are undertaken. Taking into account this RMM, only not relevant emissions to the environment are expected. Therefore, according to the Inclusion Directive, the following RMM is part of the authorisation of Sinesto XT:

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

Because of the information provided and the required RMM, no quantitative emission and exposure calculation and risk assessment is performed for the storage of wood after industrial application.

3.8.2.2.2 Service life of treated wood

Emissions to the environment may take place due to leaching from constructions built from industrially treated wood. The following assessment focusses on the use of treated wood in UC3.

During the Arona Leaching Workshop in June 2005 (EC, 2005[5]), it was agreed that besides a short-term assessment (30 days) a long-term assessment should be carried out which is linked to the service life of the treated wood. For wood treated industrially by spraying and dipping a service life of 15 years should be taken into account.

However, as the product is intended to temporarily protect wood from wood-discolouring

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

fungi, following amendments according to the agreements of WG ENV II 2018 (see TAB ENV 199, v.Nov.2021) regarding the assessment of temporary anti-sapstain wood-preservatives[6] were made:

- an additional removal rate of the active substances via sawing or sanding of 50% ($F_{removal}$ = 0.5) is considered
- a service life of 5 years is assessed

According to the applicant, freshly sawn timber is treated with Sinesto XT to protect the wood from bluestain during drying, transport and storage. During further processing of the treated wood, it can be assumed that a large proportion of the product is removed due to sawing and sanding of the wood. Therefore, $F_{removal}$ = 0.5 is applied.
Regarding pallets, the sawn timber is treated with the product and further surface treatments like sawing or sanding do not take place. Therefore, no removal rate is applied in this case.
However, the UC3 scenarios represent the worst-case assessment regarding the emissions to the environment, also if $F_{removal}$ = 0 is considered for the pallet scenario. Therefore, the pallet scenario is not considered further in the following assessment.
The following assessment is based on the highest intended product retention (13.5 g/m² for cases with high infestation pressure). All other product retention rates are covered by this assessment.

Scenario 2- House

With the "House"-Scenario, direct emissions to soil are assessed. The following input parameters were applied:

Table 3.54 Input parameters for calculating the local emission

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2: House				
Leachable wood area	$AREA_{house}$	125	m²	D
Duration of the initial assessment period	TIME1	30	d	D
Duration of the intermediate assessment period	TIME1b	365	d	D
Duration of the long-term assessment period	TIME2	1825	d	see TAB ENV 199
Cumulative quantity of substance leached out of 1 m² of treated wood over TIME1	$Q^*_{leach,time1}$	ATMAC/TMAC: 14.94 K-HDO: 0.098	mg m^{-2}	S
Cumulative quantity of substance leached out of 1 m² of treated wood over TIME1b	$Q^*_{leach,time1b}$	ATMAC/TMAC: 25.18 K-HDO: 1.546	mg m^{-2}	S
Cumulative quantity of substance leached out of 1 m²	$Q^*_{leach,time2}$	ATMAC/TMAC: 31.52	mg m^{-2}	S

[6] https://webgate.ec.europa.eu/s-circabc/faces/jsp/extension/wai/navigation/container.jsp

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2: House				
of treated wood over TIME2		K-HDO: 2.604		
Removal rate of the active substances via sawing or sanding	$F_{removal}$	0.5	-	see TAB ENV 199
Soil volume (wet)	V_{soil}	13	m^3	D
Bulk density of wet soil	RHO_{soil}	1700	$kg_{wwt}\ m^{-3}$	D

Calculations for Scenario 2:

Table 3.55 Resulting local emission to relevant environmental compartments

Resulting local emission to relevant environmental compartments

Compartment	Substance	Time	Local emission ($Elocal_{compartment}$) [mg/d]	Remarks
Soil	ATMAC/TMAC	Time 1	31.13	
		Time 1b	4.312	
		Time 2	1.079	
	K-HDO	Time 1	0.204	
		Time 1b	0.265	
		Time 2	0.089	

Scenario 3- Noise barrier

With the scenario "Noise barrier", direct emissions to soil and emissions to the sewer system are assessed. The following input parameters were applied:

Table 3.56 Input parameters for calculating the local emission

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 3: Noise barrier				
Leachable wood area	$AREA_{noise\text{-}barrier}$	3000	m^2	D
Duration of the initial assessment period	TIME1	30	d	D
Duration of the intermediate assessment period	TIME1b	365	d	D
Duration of the long-term assessment period	TIME2	1825	d	see TAB ENV 199
Cumulative quantity of substance leached out of 1 m^2 of treated wood over TIME1	$Q^*_{leach,time1}$	ATMAC/TMAC: 14.94 K-HDO: 0.098	$mg\ m^{-2}$	S
Cumulative quantity of	$Q^*_{leach,time1b}$	ATMAC/TMAC:	$mg\ m^{-2}$	S

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 3: Noise barrier				
substance leached out of 1 m^2 of treated wood over TIME1b		25.18 K-HDO: 1.546		
Cumulative quantity of substance leached out of 1 m^2 of treated wood over TIME2	$Q^*_{leach,time2}$	ATMAC/TMAC: 31.52 K-HDO: 2.604	mg m^{-2}	S
Removal rate of the active substances via sawing or sanding	$F_{removal}$	0.5	-	see TAB ENV 199
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

Calculations for Scenario 3:

Table 3.57 Resulting local emission to relevant environmental compartments

Resulting local emission to relevant environmental compartments

Compartment	**Substance**	**Time**	**Local emission ($Elocal_{compartment}$) [mg/d]**	**Remarks**
STP	ATMAC/TMAC	Time 1	522.9	
		Time 1b	72.44	
		Time 2	18.14	
	K-HDO	Time 1	3.43	
		Time 1b	4.447	
		Time 2	1.498	
Soil	ATMAC/TMAC	Time 1	224.1	
		Time 1b	31.04	
		Time 2	7.772	
	K-HDO	Time 1	1.47	
		Time 1b	1.906	
		Time 2	0.642	

Scenario 4- Bridge over pond

The scenario "Bridge over pond" is representative for direct emissions to the surface water compartment from wood treated with Sinesto XT. The following input parameters were applied:

Table 3.58 Input parameters for calculating the local emission

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2: Bridge over pond				
Leachable wood area	$AREA_{bridge}$	10	m²	D
Duration of the initial assessment period	TIME1	30	d	D
Duration of the intermediate assessment period	TIME1b	365	d	D
Duration of the long-term assessment period	TIME2	1825	d	see TAB ENV 199
Cumulative quantity of substance leached out of 1 m^2 of treated wood over TIME1	$Q^*_{leach,time1}$	ATMAC/TMAC: 14.94 K-HDO: 0.098	mg m^{-2}	S
Cumulative quantity of substance leached out of 1 m^2 of treated wood over TIME1b	$Q^*_{leach,time1b}$	ATMAC/TMAC: 25.18 K-HDO: 1.546	mg m^{-2}	S
Cumulative quantity of substance leached out of 1 m^2 of treated wood over TIME2	$Q^*_{leach,time2}$	ATMAC/TMAC: 31.52 K-HDO: 2.604	mg m^{-2}	S
Removal rate of the active substances via sawing or sanding	$F_{removal}$	0.5	-	see TAB ENV 199
Water volume under bridge	V_{water}	1000	m³	D

Calculations for Scenario 4:

Table 3.59 Resulting local emission to relevant environmental compartments

Resulting local emission to relevant environmental compartments

Compartment	**Substance**	**Time**	**Local emission ($Elocal_{compartment}$) [mg/d]**	**Remarks**
Freshwater	ATMAC/TMAC	Time 1	2.49	
		Time 1b	0.345	
		Time 2	0.086	
	K-HDO	Time 1	0.016	
		Time 1b	0.021	
		Time 2	0.007	

3.8.3 Exposure calculation and risk characterisation

The PECs in the environmental compartments are calculated on the basis of the emission scenarios available for Product Type 8, taking into account degradation processes and/or dilution (where applicable). The PECs and resulting PEC/PNEC for service life of Sinesto XT are presented in the following table:

Table 3.60 Summary table of PNEC, PEC and PEC:PNEC values

Summary table of PNEC, PEC and PEC:PNEC values				
	Time period	**ATMAC/TMAC**	**K-HDO**	
PNEC values				
PNECstp (µg/L)		122	90	
PNECwater (µg/L)		0.8	9.4	
PNECsed (µg/kg wwt)		2670	1240	
PNECsoil (mg/kg wwt)		1.05	≥0.36	
SCENARIO 2 - House				
		PEC values		
PECsoil (mg/kg wwt)	Time 1	0.042*	2.771E-04	
	Time 1b	0.071*	0.004	
	Time 2	0.087*	0.007	
PECgw (µg/L)	Time 1	0.004**	0.004	
	Time 1b	0.007**	0.058	
	Time 2	0.009**	0.097	
		PEC/PNEC values		**Mixture toxicity**
PEC/PNECsoil	Time 1	0.040	0.001	0.041
	Time 1b	0.068	0.012	0.080
	Time 2	0.083	0.020	0.103
SCENARIO 3 – Noise barrier				
		PEC values		
PECstp (µg/L)	Time 1	0.016	0.001	
	Time 1b	0.002	0.001	
	Time 2	5.631E-04	4.866E-04	
PECwater (µg/L)	Time 1	8.812E-04	1.107E-04	
	Time 1b	1.213E-04	1.435E-04	
	Time 2	3.055E-05	4.835E-05	
PECsed (µg/kg wwt)	Time 1	10.77	0.010	
	Time 1b	1.483	0.014	
	Time 2	0.374	0.005	
PECsoil (mg/kg wwt)	Time 1	0.016*	1.038E-04	
	Time 1b	0.027*	0.002	
	Time 2	0.033*	0.003	
PECgw (µg/L)	Time 1	0.002**	0.001	
	Time 1b	0.003**	0.022	
	Time 2	0.003**	0.036	
		PEC/PNEC values		**Mixture toxicity**
PEC/PNECstp	Time 1	1.102E-03	1.238E-05	1.455E-04
	Time 1b	1.833E-05	1.606E-05	3.438E-05
	Time 2	4.616E-06	5.407E-06	1.002E-05
PEC/PNECwater	Time 1	0.001	1.178E-05	0.001
	Time 1b	1.516E-04	1.527E-05	1.669E-04
	Time 2	3.819E-05	5.144E-06	4.333E-05
PEC/PNECsed	Time 1	0.004	8.411E-06	0.004
	Time 1b	5.554E-04	1.090E-05	5.663E-04
	Time 2	1.399E-04	3.672E-06	1.436E-04
PEC/PNECsoil	Time 1	0.015	2.883E-04	0.016
	Time 1b	0.026	0.005	0.030
	Time 2	0.031	0.008	0.039
SCENARIO 3 – Bridge over pond				

		PEC values		
PECwater (µg/L)	Time 1	0.025*	2.573E-04	
	Time 1b	0.007*	0.004	
	Time 2	0.002*	0.007	
PECsed (µg/kg wwt)	Time 1	302.0**	0.024	
	Time 1b	85.85**	0.364	
	Time 2	55.58**	0.613	
		PEC/PNEC values		**Mixture toxicity**
PEC/PNECwater	Time 1	0.031	2.737E-05	0.031
	Time 1b	0.009	4.114E-04	0.009
	Time 2	0.002	6.926E-04	0.003
PEC/PNECsed	Time 1	0.113	1.954E-05	0.113
	Time 1b	0.032	2.937E-04	0.032
	Time 2	0.021	4.944E-04	0.021

*including degradation
**including degradation in previous compartment

The results of the risk assessment for service life of Sinesto XT are summarized below. The mixture toxicity assessment is shown in chapter 3.8.5.

Atmosphere

Exposure of the atmosphere is not considered relevant for the active substances of Sinesto XT due to their fate and behaviour in air. Therefore, the calculation of PEC values for the atmosphere (PEC_{air}) is of no relevance and air is not regarded as a compartment of concern for this product type and proposed use patterns. Consequently, the risk to the air compartment is considered acceptable.

Sewage treatment plant (STP)

The requirements for acceptable risks are met for the STP for the representative "Noise barrier" scenario with PEC/PNEC ratios < 1 for each active substance of Sinesto XT.

Aquatic compartment

The risk to the aquatic compartment was assessed for direct exposure with the "bridge over pond" scenario and for indirect exposure via the STP with the "noise barrier" scenario. Both scenarios yield PEC/PNEC ratios below one for surface water for both active substances, indicating an acceptable risk for surface water organisms.
Acceptable risks for the sediment compartment were found for the "noise barrier" scenario and the "bridge over pond" scenarios as well.

Terrestrial compartment

Exposure of the soil compartment was assessed with the scenarios "House" and "Noise barrier". Acceptable risks for the soil compartment were identified for the active substances of Sinesto XT.

Groundwater

The predicted concentration in groundwater is represented by the porewater concentration as a first tier approach. The maximum permissible concentration for biocides and their metabolites in groundwater is 0.1 µg/L according to Directive 2006/118/EC.

The calculated porewater concentrations of ATMAC/TMAC and K-HDO for the scenarios "House" and "Noise barrier" are below this trigger value. Consequently, no unacceptable emissions to groundwater are expected for service life of wood treated with Sinesto XT and no further refinement of groundwater concentrations is needed.

3.8.4 Primary and secondary poisoning

3.8.4.1 Primary poisoning

Not relevant for PT 8.

3.8.4.2 Secondary poisoning

The active substances ATMAC/TMAC and K-HDO do not pose a risk of secondary poisoning via the food chain as it can be concluded from the respective Assessment Reports.

3.8.5 Mixture toxicity

Mixture toxicity assessment was conducted according to the Guidance on the BPR: Volume IV Environment (Part B; Part II).

3.8.5.1 Screening step

Screening Step 1: Identification of the concerned environmental compartments

Significant release to the aquatic and terrestrial environment will occur during the application of the product. For further information on the release pathway and the relevant compartments for the assessment of the product, see the respective chapters.

Screening Step 2: Identification of relevant substances

Besides the two active substances no substance of concern (SoC) for the environment is contained in the biocdal product.

Screening Step 3: Screen on synergistic interactions

There is no indication of synergistic interactions for the product or its constituents.

Table 3.61 Screening step

Screening step	
1	Significant exposure of environmental compartments? (Y)
2	Number of relevant substances >1? (Y)
3	Indication for synergistic effects for the product or its constituents in the literature? (N)

Mixture toxicity assessment is required, as two ecotoxicologically relevant components/ active substances were identified.

3.8.5.2 Tiered approach

In Tier 1 summation of PEC/PNEC quotients of both active substances in the environmental compartments was conducted and the overall result is shown in the following table. The detailed results of the PEC/PNEC summation are shown in Table 3.60.

Tier 1. PEC/PNEC summation

Table 3.62 Tier 1

Tier 1		
RQ product	Acceptable risk for the environment? (Y/N)	Remarks
<1	Y	See Table 3.60

Conclusion: No unacceptable risk for the environment was identified by conducting Tier1-mixture toxicity assessment.

3.8.6 Aggregated exposure (combined for relevant emission sources)

As there is no current guidance available, no quantitative aggregated exposure assessment was conducted for "Sinesto XT".

3.8.7 Overall conclusion on the risk assessment for the environment

As shown above, unacceptable risks for the environment from use of the product Sinesto XT are only to be expected from the industrial application and the storage of freshly treated timber. These can be mitigated if RMMs and instructions for use are followed.
The overall conclusion is shown in the following table:

Table 3.63 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
1	Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi_Dipping	Acceptable with the following risk mitigation measures and instruction for use	**RMM**: 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). **RMM:** Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal. **Instruction for use:** Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer.
2	Preventive, temporary protection of freshly sawn timber and wooden pallets against wood discolouring fungi_Spraying	see use #1	see use #1

3.9 Assessment of a combination of biocidal products

Not relevant (a use with other biocidal products is not intended).

3.10 Comparative assessment

Not relevant (no candidate for substitution was identified).

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Professional user: calculation sheets for exposure and risk assessment are available in the document "Output_table_professional-Sinesto_XT.xlsx"

Output_table_professional-Sinesto_XT.x

4.1.2 Dietary assessment

Not relevant.

4.1.3 Environment

Derivation of the leaching rates used for the environmental risk assessment
The detailed results of the semi-field leaching study described in chapter 3.8.1.2 are shown in the table below. Concentrations of ATMAC/TMAC refer to the sum of measured compounds (TMAC-C_8/C_{10}/C_{12}/C_{14}/C_{16}/C_{18}).

Table 4.1 Results of leaching study for ATMAC/TMAC and K-HDO

Leaching values (mean values of three test set-ups) for ATMAC/TMAC and K-HDO					
Exposure period (days)	Cumulated precipitation (mm)	Concentration in leachate			
		ATMAC/TMAC		K-HDO	
		mg/m² wood	% of applied	mg/m² wood	% of applied
28/05/2019 - 07/06/2019 (10 days)	54	7.248	0.769	0.041	0.081
07/06/2019 – 12/06/2019 (5 days)	97	2.222	0.236	0.086	0.171
12/06/2019 – 27/09/2019 (107 days)	200	0.0122	0.0013	<0.003*	<0.007
27/09/2019 – 06/01/2020 (101 days)	405	1.964	0.208	0.503	0.996
06/01/2020 – 28/05/2020 (143 days)	585	0.456	0.048	0.076	0.151
28/05/2020 – 11/09/2020 (106 days)	814	1.337	0.142	0.140	0.277

11/09/2020 – 05/11/2020 (55 days)	951	0.085	0.009	0.071	0.140
05/11/2020 – 28/05/2021 (204 days)	1265	0.252	0.027	0.047	0.092

*measured concentration below LOD, 0.003 mg/m² was considered as a worst case.
Limits of quantification (LOQ) and Limits of detection (LOD) of active substances:
- TMAC: LOQ - 5 µg/L per compound (TMAC-C_8/C_{10}/C_{12}/C_{14}/C_{16}/C_{18}); LOD : 2.5 µg/L per compound
- K-HDO: LOQ - 6.9 µg/L; LOD: 2.6 µg/L

For determination of the leaching rates used for the risk assessment, the experimental leaching rate was normalized to a yearly precipitation of 700 mm as recommended in the revised ESD for PT8 (OECD, 2013). The normalized FLUX is presented in Table 4.2.

Table 4.2 FLUX values for ATMAC/TMAC and K-HDO

FLUX values (mg/m²/d) normalized to a precipitation of 700 mm / year				
Cumulative sampling time (d)	Cumulative precipitation (mm)	Cumulative normalized sampling time (d)	Normalized FLUX ATMAC/TMAC (mg/m²/d)	Normalized FLUX K-HDO (mg/m²/d)
10	54	28	0.257	0.001
15	97	51	0.099	0.004
122	200	104	0.000	0.000
223	405	211	0.018	0.005
366	585	305	0.005	0.001
472	814	424	0.011	0.001
527	951	496	0.001	0.001
731	1265	660	0.002	0.000

The experimental data of each active substance were fitted by a polynomial regression of second order:

$$Log_{10}FLUX(t) = a + b \cdot Log_{10}(t) + c \cdot Log_{10}(t)^2$$

The trend lines with the corresponding regression equations and coefficients of variation are shown in the following figures:

Figure 1

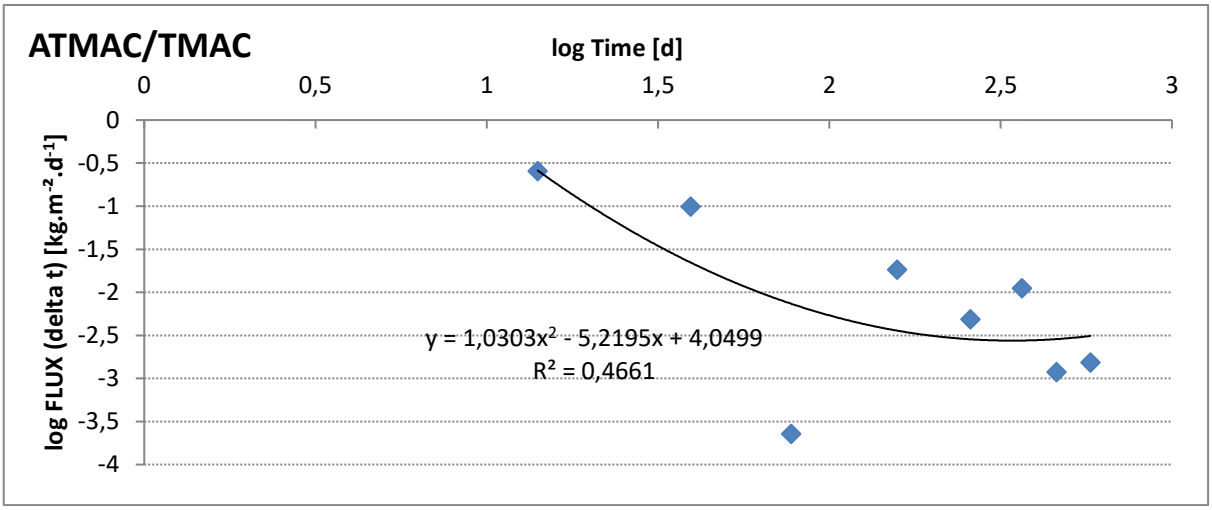
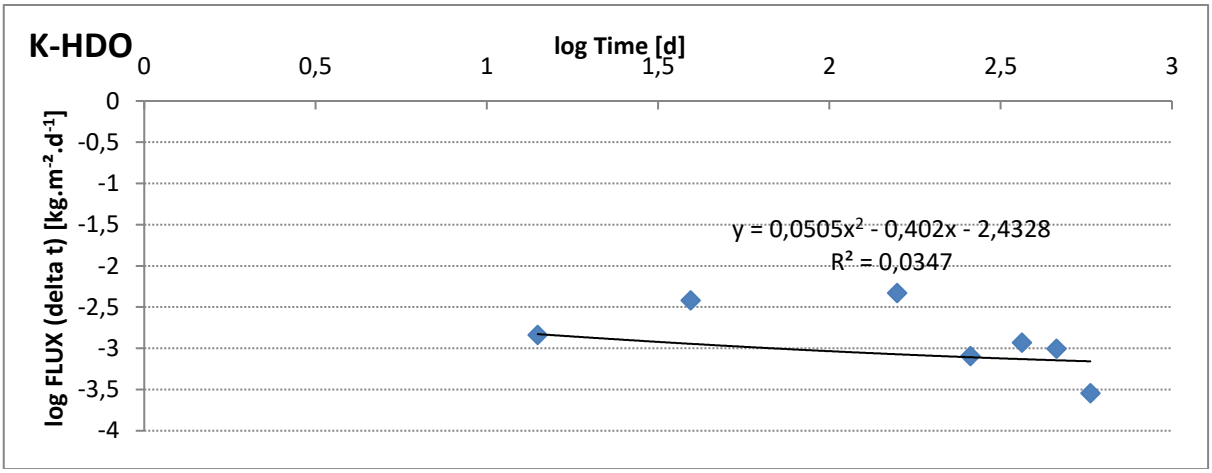


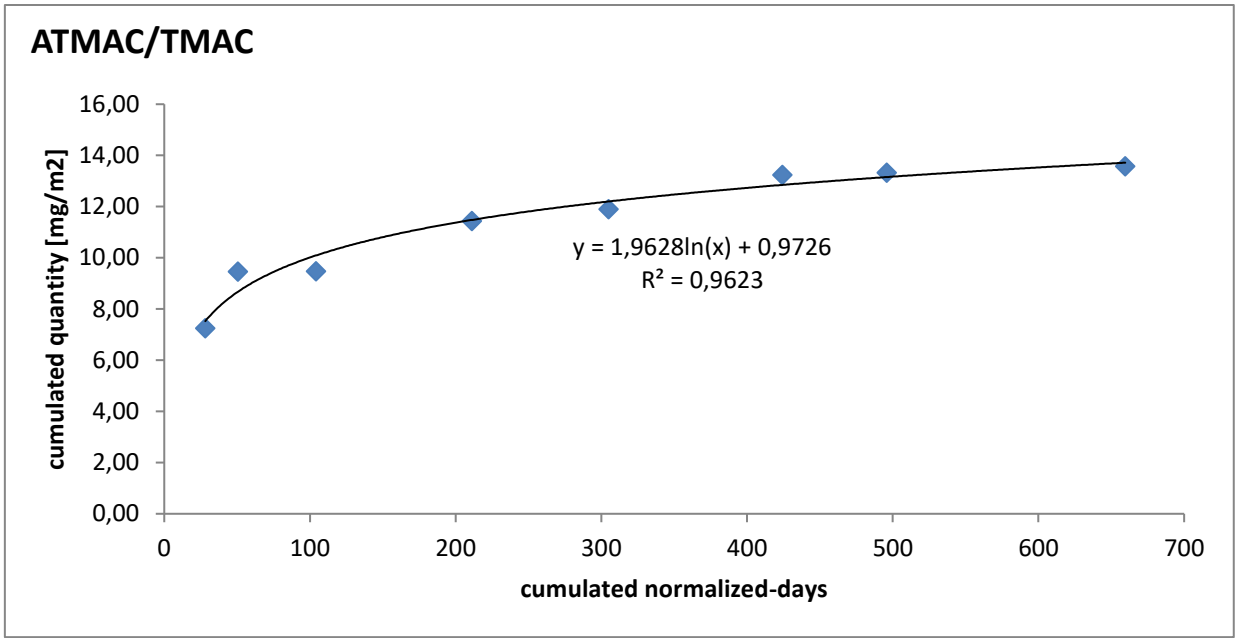
Figure 2



For both active substances, the fitting is very poor, which is underlined by a $R^2<0.5$.

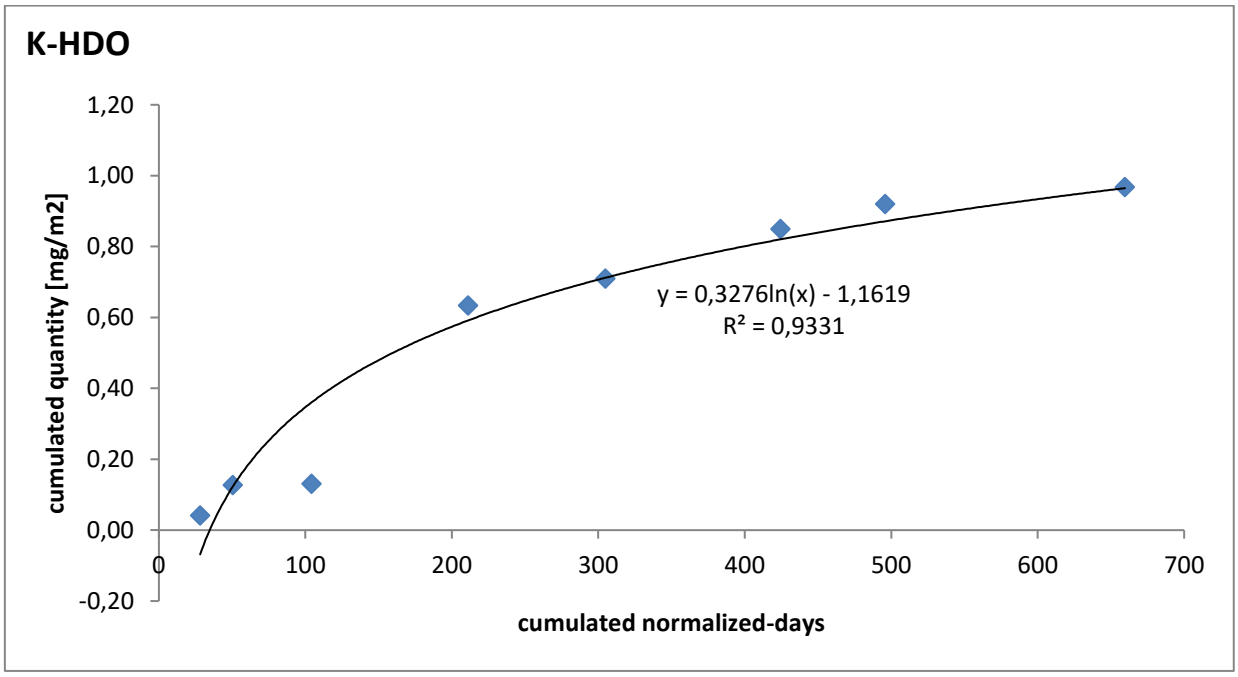
Therefore, the approach in Appendix 2 point 519 of the ESD for PT 8 (OECD, 2013) was chosen for both active substances, instead. The cumulative quantities leached [Qc(t)], normalized to 700 mm precipitation, were plotted in a diagram. All points are fitted with one logarithmic curve. This curve is used to derive TIME 1b and TIME 2 leaching rates. The long-term leaching rates for the service life of 5 years are calculated by extrapolation.
Derivation of leaching at TIME 1 with this curve results in a negative value for K-HDO. Therefore, for both active substances, leaching at TIME 1 was calculated from the measured leaching at the first 2 two sampling points.

Figure 3



For ATMAC/TMAC the following rates are derived:
30 days: (cumulative quantity at first data point (after 28 normalized days) + (30 d – 28 d) * FLUX of second sampling period)/30 d = ((7.25+ (30-28)*0.099)/30 = 0.248 mg/m²/d
1 year: (1.9628 x Ln(365) + 0.9726) / (365) days = 0.034 mg/m²/d
5 years: (1.9628 x Ln(1825) + 0.9726) / (1825) days = 0.009 mg/m²/d

Figure 4



For K-HDO the following rates are derived:
30 days: (cumulative quantity at first data point (after 28 normalized days) + (30 d – 28 d)

* FLUX of second sampling period)/30 d = ((0.04 + (30-28)*0.004)/30 = 0.002 mg/m^2/d
1 year: (0.3276 x Ln(365) – 1.1619) / (365) days = 0.002 mg/m^2/d
5 years: (0.3276 x Ln(1825) – 1.1619) / (1825) days = 0.001 mg/m^2/d

A correction factor of 2.006 needs to be applied to calculate the cumulative leaching and leaching rates used for the environmental risk assessment, since the product retention of 6.73 g product per m² in the study is lower than the maximum intended retention rate of the product of 13.5 g/m². The corrected values are shown in chapter 3.8.1.2.

4.2 New information on the active substances and substances of concern

Not relevant (no new information on the active substances and the substances of concern is available).

4.3 List of studies for the biocidal product

Table 4.3 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
anonymous	2020	3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour)	3.1_Appearance (at 20°C and 101.3 kPa)	Odour, physical state and pH value of Sinesto® XT Report No.: Project-No: U 20341 ; Study No.: 20-WD-001	Study report	BASF Wolman GmbH	no - Sample prepared following Good Laboratory Practice	yes
		3.2 Acidity, alkalinity (pH)	3.2_Acidity, alkalinity_01				no - Sample prepared following Good Laboratory Practice	yes
anonymous	2020	3.2 Acidity, alkalinity (acidity / alkalinity)	3.2_Acidity, alkalinity.02	Alkalinity of Sinesto® XT Report No.: Project No. U 20341 ; Study No.: 20-WD-009	Study report	BASF Wolman GmbH	no - Sample prepared following Good Laboratory Practice	yes
anonymous	2020	3.3 Relative density (liquids) and bulk, tap density (solids) (relative density)	3.3_Relative density (liquids) and bulk, tap density (solids)	Density of Sinesto® XT Report No.: Project No. U 20341 ; Study No.: 20-WD-002	Study report	BASF Wolman GmbH	no - Sample prepared following Good Laboratory Practice	yes
anonymous	2021	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	3.4.1.1_Accelerated storage test	Accelerated storage test by heating of Sinesto® XT Report No.: Project-No: U 20341 ; Study	Study report	BASF Wolman GmbH	no	yes

				No.: 20-WD-007				
anonymous	2021	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	3.4.1.2_Long term storage test at ambient temperature	Stability of Sinesto® XT Report No.: - ; Study No.: 21-WR-001	Study report	Wolman Wood & Fire GmbH	no	yes
anonymous	2020	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	3.4.1.3_Low temperature storage stability test	Low temperature stability of Sinesto ® XT Study No.: 20-WD-006	Study report	BASF Wolman GmbH	no	yes
anonymous	2020	3.5 Technical characteristics of the biocidal product (persistent of foaming)	3.5.7 Persistent foaming	Determination of the persistence of foaming of Sinesto® XT Report No.: Project-No: TH 4101 ; Study No.: 20-WD-005	Study report	BASF Wolman GmbH	no - GLP is not required for this kind of study but the preparation of the test sample follows the Good Laboratory Practice.	yes
anonymous	2020	3.7 Degree of dissolution and dilution stability (dilution stability)	3.7_Degree of dissolution and dilution stability	Dilution stability of Sinesto® XT Study No.: 20-WD-004	Study report	BASF Wolman GmbH	no	yes
anonymous	2020	3.8 Surface tension (surface tension)	3.8_Surface tension	TH 4101 Determination of Surface Tension Report No.: 200130BT / CPT18943 ; Study No.: -	Study report	NOACK LABORATORIEN BASF Wolman GmbH	yes (incl. QA statement)	yes

anonymous	2020	3.9 Viscosity (viscosity)	Viscosity	Viscosity of Sinesto® XT Report No.: Project No.: U 20341 ; Study No.: 20-WD-003	Study report	BASF Wolman GmbH	no - Sample prepared following Good Laboratory Practice	yes
anonymous	2020	4.1 Explosiveness (explosiveness, other)	4.1_Explosiveness	Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) Report No.: CSL-20-0074.01	Study report	Consilab BASF Wolman GmbH	yes (incl. QA statement)	yes
		4.4 Oxidising properties (oxidising liquids)	4.13_Oxidising liquids				yes (incl. QA statement)	yes
		4.6 Flammable liquids (flash point, other)	4.6_Flammable liquids_flash point				yes (incl. QA statement)	yes
		4.17.1 Auto-ignition temperature (liquids and gases) (auto-ignition temperature (liquids))	4.17.1_Auto-ignition temperature (liquids and gases)				yes (incl. QA statement)	yes
anonymous	2020	4.8 Self-reactive substances and mixtures (self-reactive substances)	4.8_Self-reactive substances and mixtures	Determination of the self reactive properties according to UN transport regulation Report No.: CSL-20-0074.03 ; Study No.: CSL-20-0074.03	Study report	Consilab BASF Wolman GmbH	yes (incl. QA statement)	yes
anonymous	2020	4.16 Corrosive to metals (corrosive to metals)	4.16_Corrosive to metals	Determination of physico-chemical properties Corrosive Properties of Liquids (UN Test	Study report	Consilab BASF Wolman GmbH	yes (incl. QA statement)	yes

				C.1) Report No.: CSL-20-0074.02 ; Study No.: CSL-20-0074.02				
anonymous	2020	5 Methods of detection and identification (analytical methods)	5.1-01_Methods of detection and identification_TMAC	Validation of a Potentiometric Titration Method for the Determination of TMAC in Sinesto® XT Report No.: 20-WD-017 ; Study No.: 20-WD-017	Study report	Wolman Wood and Fire Protection GmbH	no	yes
anonymous	2021	5 Methods of detection and identification (analytical methods)	5.1-02_Methods of detection and identification_K-HDO	UPLC method for the determination of N-cyclohexyl-diazeniumdioxy-potassium K(HDO) in Sinesto® XT Report No.: - ; Study No.: 20-WD-016	Study report	Wolman Wood and Fire Protection GmbH WR - Wood Protection R&D and Regulatory Affairs Dr.-Wolman-Str. 31-33, 76547 Sinzheim, Germany BASF Wolman GmbH	no	yes
anonymous	2021	5 Methods of detection and identification (analytical methods)	5.1-04_Methods of detection and identification_2-EHA	UPLC method for the determination of 2-Ethylhexanoic Acid (2-EHA) in Sinesto® XT Report No.: - ; Study No.: 20-WD-019	Study report	Wolman Wood and Fire Protection GmbH	no	yes
anonymous	2021	5 Methods of detection and identification (analytical methods)	5.1-05_Methods of detection and identification_TMAC	Qualitative Analysis of TMAC in Sinesto XT by Gas Chromatography (GC-FID) Report No.: 21-	Study report	Wolman Wood and Fire GmbH	no	yes

				WR-002 ; Study No.: Ref. 5.1-05				
anonymous	2020	6.7 Efficacy data to support these claims (efficacy data)	Field test_pine_Sinesto XT	Determination of the preventive effectiveness of wood preservatives against sapstain fungi and mould fungi on freshly sawn timber - Field test according DIN CEN/TS 15082:2005-10 Report No.: B 2875_Sinesto XT_Kiefer_Rev.2 ; Study No.: -	Study report	BASF Wolman GmbH	no	yes
			Field test_spruce_Sinesto XT				no	yes
anonymous	2020	8.10 Other test(s) related to the exposure to humans (expected exposure and proposed acceptable residues)	Other test(s) related to the exposure to humans	Prüfbericht Nr. 31/20/4065/01 Report No.: 31/20/4065/01 ; Study No.: 31/20/4065/01	Study report	MPA Eberswalde Materialprüfanstalt Brandenburg GmbH - Holz and Holzschutz Wolman Wood and Fire GmbH	no	yes
anonymous	2021	10.3 Leaching behaviour (emissions from preservative-treated wood)	Emissions from preservative-treated wood.001	Test Report No. 31/19/3594/02 (NT BUILD 509 “Leaching of active ingredients from preservative-treated timber — Semi-field testing” - first year of exposure) Report No.: 31/19/3594/02 ;	Study report	MPA Eberswalde Wolman Wood and Fire GmbH	no	yes

				Study No.: -				
anonymous	2022	10.3 Leaching behaviour (emissions from preservative-treated wood)	Emissions from preservative-treated wood.001	Test Report No. 31/19/3594/02A (NT BUILD 509 “Leaching of active ingredients from preservative-treated timber – Semi-field testing” - Second year of exposure) Report No.: 31/19/3594/02A ; Study No.: -	Study report	MPA Eberswalde Wolman Wood and Fire GmbH	no	yes

4.4 References

4.4.1 Guidance documents

Packaging
- Guidance on the Biocidal Products, Volume I, Parts A+B+C, Version 2.1, March 2022
- Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2, March 2021
- ADR 2023 - Agreement concerning the International Carriage of Dangerous Goods by Road | UNECE

Physical, chemical, and technical properties
- Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/ physico-chemical properties/ analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C; Version 2.1, March 2022 (https://echa.europa.eu/documents/10162/2672387/vol_i_part_abc_v2-0_superseded_en.pdf/530ec0db-326b-1388-bafa-4cdb32563d73?t=1648538881142)
- Technical Agreements for Biocides – APCP; Version 3.0, Semptember 2022 (https://webgate.ec.europa.eu/s-circabc/sd/d/e4a2ab28-050b-4a58-b41b-3921794a65c8/TAB%20APCP_Version%203.0(1).pdf)

Physical hazards and respective characteristics
- Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/ physico-chemical properties/ analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C; Version 2.1, March 2022 (https://echa.europa.eu/documents/10162/2672387/vol_i_part_abc_v2-0_superseded_en.pdf/530ec0db-326b-1388-bafa-4cdb32563d73?t=1648538881142)
- Guidance on the Application of the CLP Criteria: Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. Version 5.0, July 2017 (https://echa.europa.eu/documents/10162/2324906/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5?t=1499091929578)
- Technical Agreements for Biocides – APCP; Version 3.0, Semptember 2022 (https://webgate.ec.europa.eu/s-circabc/sd/d/e4a2ab28-050b-4a58-b41b-3921794a65c8/TAB%20APCP_Version%203.0(1).pdf)

Methods for detection and identification
- Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/ physico-chemical properties/ analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C; Version 2.1, March 2022 (https://echa.europa.eu/documents/10162/2672387/vol_i_part_abc_v2-0_superseded_en.pdf/530ec0db-326b-1388-bafa-4cdb32563d73?t=1648538881142)
- Technical Agreements for Biocides – APCP; Version 3.0, Semptember 2022 (https://webgate.ec.europa.eu/s-circabc/sd/d/e4a2ab28-050b-4a58-b41b-3921794a65c8/TAB%20APCP_Version%203.0(1).pdf)

Efficacy
- Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0, April 2018

Human health
- Guidance on the Biocidal Products RegulationVolume III Human Health - Assessment& Evaluation (Parts B+C), Version 4.0

- Biocides Human Health Exposure Methodology, Version 1, 2015
- 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
- Frequently used sentences spc translations, updated 12.07.2022
- Guidance on the Biocidal Products Regulation, Parts B, C Volume III, Human Health (Version 1.2, May 2018)
- Guidance on the Application of the CLP Criteria, 2017
- Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, 2021
- Biocides Human Health Exposure Methodology, 2015
- EFSA guidance on dermal absorption, 2017

Animal health
No guidance agreed yet.
- However, consider Doc. no. CG-30-2018-09-vf

Environment
- Guidance on the BPR: Volume IV Environment Part A (2022) as well as Parts B+C (2017)
  - https://echa.europa.eu/documents/10162/2324906/bpr_guidance_ra_vol_iv_part_b-c_en.pdf/e2622aea-0b93-493f-85a3-f9cb42be16ae
  - https://echa.europa.eu/documents/10162/23036412/bpr_guidance_vol_iv_part_a_en.pdf/4a70aa9e-7491-7fc5-0734-6777ade10b02
- Revised Emission Scenario Document for Wood Preservatives (2013): https://echa.europa.eu/documents/10162/983773/pt8_esd_wood_preservatives_en.ppt/c9ae395d-db98-46f1-8d3b-93b11e391a2b
- Technical Agreements for Biocides - Environment (ENV) (2021)
  - https://webgate.ec.europa.eu/s-circabc/sd/d/54366e74-6aa9-4bef-9c4e-c152dd4dee38/ENV-TAB_DB_2021_11_09.pdf

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.