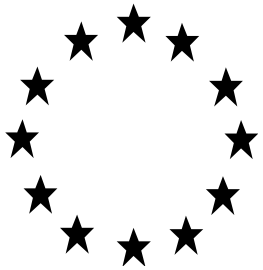
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product dentifier in R4BP	Sinesto B
Product type(s):	08 (Wood preservatives)
Active ingredient(s):	Coco alkyltrimethylammonium chloride (ATMAC/TMAC) (CAS-Nr. 61789-18-2) Disodium tetraborate pentahydrate (CAS-Nr. 12179-04-3)
Case No. in R4BP	BC-YC039250-48
Asset No. in R4BP	DE-0031919-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/08.00020 710-05-08-00020-00-00-00-0000
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1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks for the uses surface treatment by fully automated dipping and surface treatment in spraytunnel, if the soluable concentrate Sinesto B with the active substances ATMAC/TAMC and disodium tetraborate pentahydrate is used as wood preservative (product-type 08) for the temporary, preventive protection of fresh sawn timber against wood discolouring fungi, blue-stain fungi, and mould fungi by industrial users.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] (BPR) for the aforementioned use are fulfilled.

In the course of evaluation of applications for active substance approval according to the BPR, active substances are assessed against the exclusion criteria according to Article 5 (1) BPR. An active substance meeting the exclusion criteria shall not be approved unless at least one of the conditions for derogation set out under Article 5(2) BPR is met. During active substance approval, the applicant, the Member States and the stakeholders have the opportunity to submit to the Commission elements to demonstrate whether one or several of the conditions for derogation set out under Article 5(2) are met, or are not.[2]. On the basis of the information received, if any, the Commission will decide whether or not to propose to derogate to the principle that the substance shall not be approved[2]. Biocidal Products containing an active substance meeting the exclusion criteria according to Article 5 (1) BPR but approved in accordance with Article 5 (2) BPR are to be authorised only in Member States where the derogation conditions identified at active substance approval stage are met.

The product Sinesto B contains among others the active substance disodium tetraborate pentahydrate. Disodium tetraborate pentahydrate was approved according to Directive 98/8/EC (BPD). The active substance disodium tetraborate pentahydrate is classified as toxic for reproduction category 1B, H360D and therefore meets the exclusion criteria according to Article 5 (1) c) BPR. The decision whether the conditions for derogation set out under Article 5 (2) BPR are met will be taken during the on-going renewal of approval of the active substance. Since it has not yet been decided whether the approval of disodium tetraborate pentahydrate is renewed and if one or more of the conditions for derogation set out under Article 5(2) will be met, it is not possible to assess whether a biocidal product containing disodium

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

[2] CA-Nov14-Doc.4.5 – Final: Further Guidance on the Procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2)

tetraborate pentahydrate fulfils the derogation conditions. This can only be done after the decision on the renewal of the approval of disodium tetraborate pentahydrate and a derogation according to one or more conditions according Article 5 (2) BPR is finalised.
However, the active substance is already classified with a criterium given in Article 5 (1) BPR and this classification is not expected to change. The extension of the active substance approval is therefore possible for a maximum of 7 years (Art. 10 (4) BPR) and the active substance itself will then be considered as candidate for substitution (Art. 10 BPR). When deciding about the duration of the requested authorisation the longest possible approval period of the active substance and the expected classification as candidate for substitution has to be taken into account. The requested authorisation for the biocidal product Sinesto B shall therefore only be granted for 5 years. This applies all the more as the authorisation according to Art. 23 BPR would only allow a maximum authorisation period of 5 years. Therefore, the maximum possible authorisation period of 10 years according to Art. 17 (4) BPR shall not be exhausted but limited to a period of 5 years.

The intended use of Sinesto B by automated dipping systems leads to unacceptable risks for industrial users and the conditions for granting an authorisation according to Article 19 (1) b) iii) BPR are therefore not fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.
General directions for use of the product are summarised in chapter 2.5.

A classification according to Regulation (EC) No 1272/2008[3] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the BPC opinion for the approval of the active substance ATMAC/TMAC including the “elements to be taken into account by Member States when authorising products” as requested by the Italian CA.
2. The conclusions and recommendations of the Dutch Assessment Report for the approval of the active substance disodium tetraborate pentahydrate including the “elements to be taken into account by Member States when authorising products” as requested by the Dutch CA.
3. The specific provisions from the Commission Implementing Regulation for the active substance ATMAC/TAMAC (Commission Implementing Regulation (EU) 2016/1934).

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

4. The specific provisions from the Inclusion Directive for the active substance disodium tetraborate pentahydrate (Commission Directive 2009/91/EC).

Approval of the active substances

The active substances ATMAC/TMAC and disodium tetraborate pentahydrate are included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- ATMAC/TMAC
    - The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.
    - In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: (a) industrial and professional users; (b) soil and groundwater for wood in service that will be exposed to frequent weathering.
    - In view of the risks identified for soil, surface and ground water, labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
- Disodium tetraborate pentahydrate
    - When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment.
    - When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks.
    - Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.
    - Member States shall ensure that authorisations are subject to the following conditions:
        1. Products authorised for industrial and professional use must be used with appro priate personal protective equipment, unless it can be demonstrated in the appli cation for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other mean.
        2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the

application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products au thorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

Composition and formulation

The liquid Sinesto B contains the active substances ATMAC/TMAC and disodium tetraborate pentahydrate.

The substances Sodium hydroxide (CAS No 1310-73-2) and 2-Ethylhexanoic acid sodium salt (CAS No 19766-89-3) have been identified as substance of concern for human health. Please refer to chapter 2.2.3 for further information.

Please refer to chapter 2.2 (Composition and formulation) and the confidential annex for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

Physical-chemical hazard(s) were not identified (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.3. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.4. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

The substances Sodium hydroxide (CAS No 1310-73-2) and 2-Ethylhexanoic acid sodium salt (CAS No 19766-89-3) have been identified as substances of concern.

The human health risk assessment for this product is based on the active substance and substances of concern.

A human health risk assessment has been carried out for industrial/professional use of the product (see chapter 3.5) for all intended uses (see chapter 3.1). Based on the risk assessment it is unlikely that the

intended uses 1 (surface treatment - Fully automated dipping) and 3 (surface treatment – Spraytunnel application (closed spray-tunnel)) causes any acute or chronic unacceptable risk to industrial users, bystanders or residents. However, the intended use 2 (surface treatment - Automated dipping) leads to unacceptable risks for industrial/professional user and is therefore not appropriate for authorisation. Regarding industrial/professional users health protection, there are no objections against uses 1 (surface treatment - Fully automated dipping) and 2 (surface treatment – Spraytunnel application (closed spray-tunnel)) if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

Since no relevant substance of concern has been identified the risk assessment for the environment for this product is based on the active substances.

A risk assessment for the environment has been carried out for industrial application, storage of treated wood and use of treated wood in use class 3 (see chapter 3.8) according to the intended uses (see chapter 3.1).

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 according to chapter 2.5 are followed.

Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore, no corresponding regulatory measures are required.

Comparative Assessment

The active substance disodium tetraborate pentahydrate meets the criteria for substitution (see also chapter 2.2.4), but was not identified as a candidate for substitution during approval. Please see chapter 3.10 for more information.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Sinesto B

2.1.2 Manufacturer(s) of the product

Name of manufacturer	Wolman Wood and Fire Protection GmbH
Address of manufacturer	Dr.-Wolman-Strasse 31-33 76547 Sinzheim Germany
Location of manufacturing sites	Dr.-Wolman-Strasse 31-33 76547 Sinzheim Germany

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

Active substance	Coco alkyltrimethylammonium chloride (ATMAC/TMAC)
Name of manufacturer	Nouryon Surface Chemistry A
Address of manufacturer	Stenunge Alle 3 SE 444 85 Stenungsund Sweden
Location of manufacturing sites	Stockviksverken85013 Sundsvall Sweden

Active substance	Coco alkyltrimethylammonium chloride (ATMAC/TMAC)
Name of manufacturer	You Solution Germany GmbH”
Address of manufacturer	Nattermannallee 1 50829 Cologne Germany
Location of manufacturing sites	84508 Burgkirchen

	Germany

Active substance	Disodiumtetraborate, pentahydrate
Name of manufacturer	Rio Tinto Iron & Titanium GmbH (acting for Borax Europe Limited (UK)
Address of manufacturer	Alfred-Herrhausen-Allee 3-5, 65760 Eschborn, Germany
Location of manufacturing sites	US Borax Inc, 14486 Borax Road, Boron, CA 93516-2000, USA
	Eti maden isletmeleri g.m.; Bandirma bor ve asit fab. Islt. Müdürlügü 10200 Bandirma/Balikesir Turkey
	Eti maden isletmeleri g.m.; Emet kolemanit Islt. Müdürlügü 43700 Emet/Kütahya Turkey

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
ATMAC/TMAC, 100%	Coco alkyltrimethyl-ammonium chloride	active substance	61789-18-2	263-038-9	14
Disodium tetraborate pentahydrate, 100 %	Disodium tetraborate, pentahydrate	active substance	12179-04-3	215-540-4	3.97
Sodium hydroxide	Sodium hydroxide	Non-active substance	1310-73-2	215-185-5	0.8
2-Ethylhexanoic acid sodium salt	Sodium 2-ethylhexanoate	Non-active substance	19766-89-3	243-283-8	26

- Information on the full composition is provided in the confidential[4] annex.

[4] Access level: “Restricted” to applicant and authority

- Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substances on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☐
  No ☒

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

2.2.2 Information on technical equivalence

- Is the source of the active substances the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☒
  No ☐

2.2.3 Information on the substance(s) of concern

The following substances of concern for human health were identified:

- Sodium-2-ethylhexanoate (CAS No 19766-89-3)
- Sodium hydoxide (CAS No 1310-73-2)

➢ (Further) information on the substance(s) of concern is provided in chapter 3.6.2.8.and in the confidential annex.

2.2.4 Candidate(s) for substitution

For Disodium tetraborate pentahydrate, the following criteria for substitution are met:

- Toxic to reproduction category 1B
- Very persistent and toxic,

Additionally, disodium tetraborate pentahydrate is meeting the exclusion criteria according to Article 5(1) BPR.

2.2.5 Type of formulation

SL – Soluble concentrate

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[5]

Besides the active substances ATMAC/TMAC (CAS No 61789-18-2) and Disodium tetraborate pentahydrate (CAS No 12179-04-3) and the substance of concern Sodium-2-ethylhexanoate (CAS No 19766-89-3) and Sodium hydoxide (CAS No 1310-73-2), 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 CA report (RMS Italy, April 2016) was taken into account:

- Acute Tox. 3 (H301)
- Acute Tox. 3 (H311)
- Skin Corr. 1B (H314)
- Aquatic Acute 1 (H400), M factor 10
- (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 Disodium tetraborate pentahydrate is based Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):[6] in connection with Comission Regulation (EU) 2021/849 (17th ATP)

Repr. 1B (H360FD)

Therefore, a classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is required.

The classification for the biocidal product Sinesto B is based on the classification of the active substances, and on information on other components of the biocidal product (CLP classifications and Safety Data Sheets).
Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.
It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

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5 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
6 See: https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/85475

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.5 and if applicable to chapter 2.4.

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Acute Tox. 4 (oral)	H302
Skin Corr. 1	H314
Eye Dam. 1	H318
STOT SE 3	H335
Repr. 1B	H360FD
Aquatic Acute 1	H400 – Very toxic to aquatic life.
Aquatic chronic 2	H411 – Toxic to aquatic life with long lasting effects.

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS05	
	GHS07	
	GHS08	
	GHS09	
Signal word	-	Danger
Hazard statements	H302	Harmful if swallowed.
	H314	Causes severe skin burns and eye damage.
	EUH071	Corrosive to the respiratory tract.
	H360FD	May damage fertility. May damage the unborn child
	H410	Very toxic to aquatic life with long lasting effects.
Supplemental hazard information		

Supplemental label elements		
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 dust or mist.
	P264	Wash hands thoroughly after handling.
	P270	Do no eat, drink or smoke when using this product.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301 + P312	IF SWALLOWED: Call a POISON CENTRE/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 CENTER ordoctor/physician
	P312	Call a POISON CENTRE/doctor/… if you feel unwell.
	P321	Specific treatment (see … on this label).
	P330	Rinse mouth.
	P363	Wash contaminated clothing before reuse.
	P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
	P405	Store locked up.
	P501	Dispose of contents/container to appropriate hazardous waste collection point
	P273	Avoid release to the environment.
	P391	Collect spillage.
Note	-	

2.4 Use(s) appropriate for authorisation[7]

2.4.1 Use 1 appropriate for authorisation – surface treatment – Fully automated dipping

Product Type(s)	08
Where relevant, an exact description of the use	5 - 8 % w/w application concentration (corresponding to 5 – 12 g product /m²; solution uptake: 100 - 150 ml /m²), depending upon duration of the required protection as well as on timber species and local climatic conditions.
Target organism(s) (including development stage)	Wood discolouring fungi Blue-stain fungi Mould fungi
Field(s) of use	Indoor use Preventive treatment For the temporary, preventive protection of fresh sawn timber and wooden pallets against wood discolouring fungi, blue-stain fungi and mould in areas with temperate or tropical climate, during seasoning, storage and transport.
Application method(s)	Fully automated dipping Recommended dipping time: minimum 3-5 seconds
Application rate(s) and frequency	Application rate 5 – 12 g product /m² depending upon duration of the required protection as well as on timber species and local conditions. Soluble concentrate for dilution in water to be applied as a diluted treatment solution.Dilution: 5 - 8% w/w 100 – 150 ml treatment solution /m² Frequency: single preventive treatment
Category(ies) of users	Industrial[8]

7 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

8 The active substance "disodium tetraborate pentahydrate " is classified as Repr 1B and fulfils the exclusion criteria of Article 5 of Regulation (EU) No 528/2012 (Biocidal Products Regulation). According to § 15 of the Ordinance on the Notification and Distribution of Biocidal Products and on the Implementation of Regulation (EU) No 528/2012 (Biocidal Products Implementation Ordinance - ChemBiozidDV) biocidal products containing active substances with exclusion criteria may only be approved in Germany for trained professionals. For the use of the products, the provisions according to § 15 c Hazardous Substances Ordinance (Gefahrstoffverordnung – GefStoffV) apply. Accordingly the category of users in Germany is defined as "trained professional user according to § 15 c GefStoffV".

Pack sizes and packaging material	1000 L IBC (HDPE), Screw cap (HDPE) 600 L IBC (HDPE), Screw cap (HDPE) 30 L Jerrycan (HDPE), Screw cap (HDPE)

2.4.1.1 Use-specific instructions for use

1) Use in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to the draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until the treated articles are surface dry. The untreated wood may only be lowered by a separate lifting unit into the dipping tank.
2) The product may only be loaded with an automatic dosing system.
3) The product may only be used in the following maximum use concentrations in solution:8 % (w/w) biocidal product.
4) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Wear a protective coverall (at least type 6, EN 13034) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information). The use of eye protection during handling of the product is mandatory. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.4.2 Use 2 appropriate for authorisation – surface treatment – Spraytunnel application (closed spray-tunnel)

Product Type(s)	08
Where relevant, an exact description of the use	Spray application (stationary, closed and automated spraytunnel): 5 - 20 % w/w application concentration (corresponding to 5 – 12 g product /m²; solution uptake: 50 - 100 g treatment solution /m²), depending upon duration of the required protection as well as on timber species and local conditions.
Target organism(s) (including development stage)	Wood discolouring fungi Blue stain fungi Mould fungi
Field(s) of use	Indoor use Preventive treatment For the temporary, preventive protection of fresh sawn timber and wooden pallets against wood discolouring fungi, blue-stain fungi and mould in areas with temperate or tropical climate, during seasoning, storage and transport.
Application method(s)	Spraytunnel application (stationary, closed and automated spraytunnel)
Application rate(s) and frequency	Application rate 5 – 12 g product /m² depending upon duration of the required protection as well as on timber species and local conditions. Soluble concentrate for dilution in water to be applied as a diluted treatment solution. Dilution: 5 - 20% w/w Spraying: 50 – 100 ml treatment solution /m² Frequency: single preventive treatment
Category(ies) of users	Industrial[9]
Pack sizes and packaging material	1000 L IBC (HDPE), Screw cap (HDPE) 600 L IBC (HDPE), Screw cap (HDPE) 30 L Jerrycan (HDPE), Screw cap (HDPE)

[9] The active substance "disodium tetraborate pentahydrate " is classified as Repr 1B and fulfils the exclusion criteria of Article 5 of Regulation (EU) No 528/2012 (Biocidal Products Regulation). According to § 15 of the Ordinance on the Notification and Distribution of Biocidal Products and on the Implementation of Regulation (EU) No 528/2012 (Biocidal Products Implementation Ordinance - ChemBiozidDV) biocidal products containing active substances with exclusion criteria may only be approved in Germany for trained professionals. For the use of the products, the provisions according to § 15 c Hazardous Substances Ordinance (Gefahrstoffverordnung – GefStoffV) apply. Accordingly the category of users in Germany is defined as "trained professional user according to § 15 c GefStoffV".

2.4.2.1 Use-specific instructions for use

1) The product may only be used with spray tunnels featuring an automated onward transport of the freshly treated wood with automated stacking or into a drier so as to avoid manual contact with the freshly treated wood. 2) The product may only be loaded with an automatic dosing system. 3) The product may only be used in the following maximum use concentrations in solution: 20 % (w/w) biocidal product 4) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Wear a protective coverall (at least type 6, EN 13034) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).The use of eye protection during handling of the product is mandatory. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

2.4.2.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.5 General directions for use

2.5.1 Instructions for use

1) 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) Do not treat wood intended for the use in animal housing or fencing
3) The necessary product uptake depends upon the duration of the required protection as well as on timber species and local conditions. Therefore, the user should determine dosage requirements within the authorised range for their specific situation. If needed, consult the manufacturer of the preservative product.
4) Inform the authorisation holder if the treatment is ineffective.

2.5.2 Risk mitigation measures

1) 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).
2) 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.
3) Do not apply the product on wood which will be exposed to weathering.
4) Wood must be dry before manual further processing (e.g., unloading, repositioning) is performed.
5) Wear protective chemical resistant gloves for subsequent manual processing of treated wood (glove material to be specified by the authorisation holder within the product information). This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.
6) Do not use on wood which may come in direct contact with food, feed and livestock.

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

1) IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.
2) IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

3) IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.
4) IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
5) IF EXPOSED OR CONCERNED: Get medical advice/attention.

2.5.4 Instructions for safe disposal of the product and its packaging

1. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
2. Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Shelf-life: 24 months

2.5.6 Other information

-

2.6 Packaging

Table 4

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of the closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials**
Jerrycan	30 L	HDPE	Screw cap HDPE	Professional	Yes
IBC	600 L, 1000 L	HDPE	Screw cap HDPE	Professional	Yes

3 Assessment of the product

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

3.1.1 Intended use 1 – surface treatment - Fully automated dipping

Product Type(s)	08
Where relevant, an exact description of the use	Dipping application: 5 - 8 % (corresponding to 5 – 12 g product /m²; solution uptake: 100 - 150 ml /m²), depending upon duration of the required protection as well as on timber species and local conditions.
Target organism(s) (including development stage)	Wood discolouring fungi Sapstain fungi (hyphae) Mould fungi (hyphae)
Field(s) of use	For the temporary, preventive protection of fresh sawn timber and wooden pallets against blue-stain and wood discolouring fungi in areas with temperate or tropical climate, during seasoning, storage and transport.
Application method(s)	Fully automated dipping
Application rate(s) and frequency	Application rate - Dipping: 100 – 150 ml treatment solution /m² Dilution: 5.0 - 8.0% product uptake: 5 – 12 g product /m² depending upon duration of the required protection as well as on timber species and local conditions non-recurring treatment
Category(ies) of users	Industrial
Pack sizes and packaging material	1000 L IBC (HDPE), Screw cap (HDPE) 600 L IBC (HDPE), Screw cap (HDPE) 30 L Jerrycan (HDPE), Screw cap (HDPE) 24000 L bulk container for transport by road (stainless steel)

3.1.1 Intended use 2 – surface treatment - automated dipping

Product Type(s)	08
Where relevant, an exact description of the use	Dipping application: 5 - 8 % (corresponding to 5 – 12 g product /m²; solution uptake: 100 - 150 ml /m²), depending upon duration of the required protection as well as on timber species and local conditions.
Target organism(s) (including development stage)	Wood discolouring fungi Sapstain fungi (hyphae) Mould fungi (hyphae)

Field(s) of use	For the temporary, preventive protection of fresh sawn timber and wooden pallets against blue-stain and wood discolouring fungi in areas with temperate or tropical climate, during seasoning, storage and transport.
Application method(s)	automated dipping
Application rate(s) and frequency	Application rate - Dipping: 100 – 150 ml treatment solution /m² Dilution: 5.0 - 8.0% product uptake: 5 – 12 g product /m² depending upon duration of the required protection as well as on timber species and local conditions non-recurring treatment
Category(ies) of users	Industrial
Pack sizes and packaging material	1000 L IBC (HDPE), Screw cap (HDPE) 600 L IBC (HDPE), Screw cap (HDPE) 30 L Jerrycan (HDPE), Screw cap (HDPE) 24000 L bulk container for transport by road (stainless steel)

3.1.2 Intended use 3 – surface treatment - Spraytunnel application (closed spray-tunnel)

Product Type(s)	08
Where relevant, an exact description of the use	Spray application: 5 - 20 % (corresponding to 5 – 12 g product /m²; solution uptake: 50 - 100 ml /m²), depending upon duration of the required protection as well as on timber species and local conditions.
Target organism(s) (including development stage)	Wood discolouring fungi Sapstain fungi (hyphae) Mould fungi (hyphae)
Field(s) of use	For the temporary, preventive protection of fresh sawn timber and wooden pallets against blue-stain and wood discolouring fungi in areas with temperate or tropical climate, during seasoning, storage and transport.
Application method(s)	Spraying Industrial spraying application occurs only in closed, automated spraytunnel
Application rate(s) and frequency	Application rate - Spraying: 50 – 100 ml treatment solution /m² Dilution: 5.0 - 20.0% product uptake: 5 – 12 g product /m² depending upon duration of the required protection as well as on timber species and local conditions non-recurring treatment
Category(ies) of users	Industrial
Pack sizes and packaging material	1000 L IBC (HDPE), Screw cap (HDPE) 600 L IBC (HDPE), Screw cap (HDPE) 30 L Jerrycan (HDPE), Screw cap (HDPE) 24000 L bulk container for transport by road (stainless steel)

3.2 Physical, chemical and technical properties

Table 5: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	Sinesto B, batch: TH 3702; ATMAC/TMAC: 14.63 Boron: 0.617	homogeneous liquid	BASF Wolman GmbH (2016): Odour, physical state and pH value of Sinesto B (Report No. 16-WD-022-R0)
Colour at 20 °C and 101.3 kPa	Visual inspection		clear, slightly lutescent	
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304 (Odor)		faint specific odour	
Acidity / alkalinity	CIPAC Handbook MT 75.3 “Determination of pH values”	Sinesto B, batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	Mean values of three repeated measurements: pH (at 25°C) Concentrate of Sinesto® B: 13.98 pH (at 25°C) Solution of Sinesto® B (1 % w/w): 11.54	BASF Wolman GmbH (2016): Odour, physical state and pH value of Sinesto B (Report No. 16-WD-022-R0)
	CIPAC method MT 191 (acidity or alkalinity of formulations)	Sinesto B, batch: TH 3702-1417162; batch 0020210466	alkalinity of Sinesto® B: - TH 3702: 3.21 % calculated as NaOH - production batch 0020210466: 3.23 % calculated as NaOH.	BASF Wolman GmbH (2019): Alkalinity of Sinesto B (Report No. 19-WD-001)
Density	OECD Guideline 109 (Density of Liquids and Solids); DIN EN ISO 2811-3 "Paints and varnishes - Determination of density - Part 3:	Sinesto B, batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	Density: 1.0758 g/cm³ at 20.0°C	BASF Wolman GmbH (2016): Density of Sinesto B (Report No. 16-WD-027)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	Oscillation method (DIN EN ISO2811-3:2001); EPA OPPTS 830.7300			
Storage stability test – **accelerated storage**	CIPAC-MT 46.3; CIPAC Handbook MT 75.3 (Determination of pH values); DIN EN ISO 2811-3 (Paints and varnishes – Determination of density – Part 3: Oscillation method (DIN EN ISO2811-3:2001)) CIPAC MT 191 "Acidity or Alkalinity of Formulations" CIPAC MT 41 "Dilution stability of herbicide aqueous solutions"	Sinesto B, batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	Accelerated storage: 14 days at 54°C ± 2°C (test conducted in 100 ml brown glass bottle, fitted with screw caps) **pH (Sinesto B; 25°C):** start: 13.98 end: 13.65 **pH (1% w/w; 25°C):** start: 11.54 end: 10.90 **Density (20°C) [g/cm³]:** start: 1.0758 end: 1.0774 **TMAC/ATMAC [%]:** start: 14.63 end: 14.65 **Boron [%]:** start: 0.617 end: 0.615 **Alkalinity as NaOH [%]:** start: 3.21 end: 3.17 **Dilution stability :**	BASF Wolman GmbH (2016): Accelerated storage test by heating of Sinesto B (Report No. 16-WD-067)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			start: Slightly opaque but stable solution of 20 % and 3 % Sinesto B in water end: Slightly opaque but stable solution of 20 % and 3 % Sinesto B in water No significant degradation of the active ingredients TMAC/ATMAC and boron within the testing period. The product is stable under accelerated storage conditions.	
Storage stability test – **long term storage at ambient temperature**	OPPTS 830.6317; CIPAC Handbook MT 75.3 (Determination of pH values)	Sinesto B, batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	Description of the storage stability test (24 months): ▫ 5L test sample in a HDPE container ▫ ambient conditions ▫ storage in a non-air conditioned storage room equipped with a glass window ▫ storage temperature ranges between 4 °C and 30 °C; average test temperature: 18°C Results: **pH (Sinesto B; 25°C):** start: 13.98 end: 13.65 **pH (1% w/w; 25°C):** start: 11.54 end: 11.22	BASF Wolman GmbH (2017): Stability of Sinesto B (Report No. 17-WD-025)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Density (20°C) [g/cm³]: start: 1.0759 end: 1.0759 **Dilution stability:** start: Slightly opaque but stable solution of 20.00 % and 3% Sinesto® B in water. end: Slightly opaque but stable solution of 20.00 % and 3% Sinesto® B in water. **Persistent foaming:** start: 12 ml foam of 20.00 % Sinesto® B in water. end: 17 ml foam of 20.00 % Sinesto® B in water. **TMAC/ATMAC [%]:** start: 14.63 end: 14.33 (-2.05%) **Boron [%]:** start: 0.617 end: 0.610 (-1.13%) No significant changes of pH, density, appearance properties and technical properties have been observed. No relevant changes in the content of the active ingredients have been observed.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Based on the given results from the long-term (and the accelerated) storage stability test a shelf-life of 24 months is assumed. Remark: Since there was no significant decrease in the content of the active substances (neither in the long-term storage test not in the accelerated storage test, max. a.s. decrease after 24 months: 2.05%), we decided to accept the aspect that the weight change was not documented in the shelf-life study.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT-39 - Stability of liquid formulations at 0°C; CIPAC MT 39.1	Sinesto B, batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	After 7 days storage at 0°C +/- 1°C: Sinesto B is homogenous, clear, slightly lutescent and shows no precipitation after storage at 0°C. Warming up to room temperature and once inverted results in a homogenous, clear, slightly lutescent liquid concentrate without any precipitation. (No changes observed.)	BASF Wolman GmbH (2016): Low temperature stability of Sinesto B (Report No. 16-WD-062-R0)
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	Sinesto B, batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	The effects of light on the content of the active substances and technical characteristics of the biocidal product were tested within the long term storage test at ambient temperature. No effect on technical properties (dilution stability, persistence of foam)	BASF Wolman GmbH (2017): Stability of Sinesto B (Report No. 17-WD-025)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			during long-term storage observed; no change of appearance properties of the formulation; no effect of daylight exposure.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	Sinesto B, batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	The effects of temperature and humidity on the content of the active substances and technical characteristics of the biocidal product were tested within the long term and accelerated storage test at ambient temperature. No effect during accelerated storage and long-term storage observed; no effect of the temperature within the range of 4 to 30 °C; humidity is of no concern because the product is based on water.	BASF Wolman GmbH (2017): Stability of Sinesto B (Report No. 17-WD-025); BASF Wolman GmbH (2016): Accelerated storage test by heating of Sinesto B (Report No. 16-WD-067)
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The data about the packaging material jerrycan, IBC and tank container is sufficient.	
Wettability	-	-	Data waiving acceptable (data not required for soluble concentrates/liquid formulations).	waiving[10]
Suspensibility, spontaneity and dispersion stability	-	-	Data waiving acceptable (data not required for soluble concentrates).	waiving[10]

[10] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Wet sieve analysis and dry sieve test	-	-	Data waiving acceptable (data not required for soluble concentrates/liquid formulations).	waiving[10]
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Data waiving acceptable (data not required for soluble concentrates).	waiving[10]
Disintegration time	-	-	Data waiving acceptable (data not required for soluble concentrates/liquid formulations).	waiving[10]
Particle size distribution, content of dust/fines, attrition, friability	-	-	Data waiving acceptable (data not required for soluble concentrates/liquid formulations).	waiving[10]
Mass medium aerodynamic diameter (MMAD)	-	-	According to the APCP-TAB, the determination of the MMAD can be waived under the following conditions: *"All of the following criteria must be fulfilled if the determination of the MMAD will be waived:* *1. The product is not sold together with a spraying device, applicable for solid and liquid* *products;* *2. The MMAD is not required as an input parameter for the human exposure assessment;* *3. The MMAD is not relevant to demonstrate efficacy."* With regard to these aspects: The product Sinesto B is not sold together with a spraying device.	waiving[10]

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Furthermore, the MMAD was not required as an input parameter for human exposure and it was not relevant to demonstrate efficacy.	
Persistent foaming	CIPAC MT 47.1	20.0 % water solution of Sinesto B; batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	The 20.0 % water solution carried out a maximum of 12.2 ml corresponding to a maximum of 2.44 cm foam. Results: **Initial foam volume after 10 s:** 2.44 cm/12.2 mL **Foam formation after 1 min:** 0.88 cm/4.4 mL **Foam formation after 3 min:** 0.44 cm/2.2 mL **Foam formation after 12 min:** 0.14 cm/0.7 mL	BASF Wolman GmbH (2016): Determination of the persistende of foaming of Sinesto B (Report No. 16-WD-052-R0)
Flowability/Pourability/Dustability	-	-	Data waiving acceptable (data not required for soluble concentrates).	waiving[10]
Burning rate — smoke generators	-	-	Data waiving acceptable (not applicable since Sinesto B is not a smoke generator).	waiving[10]
Burning completeness — smoke generators	-	-	Data waiving acceptable (not applicable since Sinesto B is not a smoke generator).	waiving[10]
Composition of smoke — smoke generators	-	-	Data waiving acceptable (not applicable since Sinesto B is not a smoke generator).	waiving[10]

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Spraying pattern — aerosols	-	-	Data waiving acceptable (not applicable since Sinesto B is not applied as an aerosol).	waiving[10]
Physical compatibility	-	-	Data waiving acceptable (not applicable; use with other products is not intended).	waiving[10]
Chemical compatibility	-	-	Data waiving acceptable (not applicable; use with other products is not intended).	waiving[10]
Degree of dissolution and dilution stability	CIPAC MT 41	min. (3 %) and max. (20 %) application solution of Sinesto B; batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	No separated material, no precipitation has been observed neither directly after dilution nor after the storage period of 18 h. Sinesto B has therefore been shown to be stable after dilution in water.	BASF Wolman GmbH (2016): Dilution stability of Sinesto B (Report No. 16-WD-042-R0)
Surface tension	EU Method A.5 (Surface Tension); OECD Guideline 115 (Surface Tension of Aqueous Solutions)	10 % application solution of Sinesto B, batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	The surface tension of a 10 %w/w aqueous solution of Sinesto B is determined to 29.5 mN/m at 20 °C. Therefore, the product is considered as surface active.	BioChem GmbH (2016): Determination of the surface tension of Sinesto B (Report No. R_PB_W24_16.09_596527.02)
Viscosity	OECD Test Guideline 114 (Viscosity of Liquids); DIN 53019 Part 1; EPA OPPTS 830.7100 (Viscosity)	Sinesto B, batch: TH 3702-1417162; ATMAC/TMAC: 14.63 Boron: 0.617	The dynamic viscosity of the product Sinesto® B is determined to 33.3 mPa.s at 20 °C and to 15.9 mPa.s at 40 °C.	BASF Wolman GmbH (2016): Viscosity of Sinesto B (Report No. 16-WD-032)

Table 6

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. Sinesto B is a clear, slightly lutescent homogeneous liquid with a faint specific odour. The density of Sinesto B is 1.0758 g/cm³ at 20.0°C. The pH value of the undiluted product is 13.98 and the corresponding value of a 1% w/w solution is 11.54 (both at 25°C). Furthermore, Sinesto B is stable after dilution in water. The surface tension of a 10 %w/w aqueous solution of Sinesto B is 29.5 mN/m at 20 °C, therefore, the product is considered as surface active.The dynamic viscosity of the product is 33.3 mPa.s at 20 °C and 15.9 mPa.s at 40 °C. The product respectively its active substance concentrations, pH value and density are stable under accelerated storage conditions (14 days at 54°C ± 2°C). Sinesto B shows no precipitation after storage for 7 days at 0°C. Based on the results of the long-term storage test, the product has a shelf-life of 24 months.

3.3 Physical hazards and respective characteristics

Table 7: Physical hazards and respective characteristics of the product

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Conclusions of evaluation
Explosives	UN Transport Regulation Class 1 and CLP Regulation EC 1272/2008: Annex 1: 2.1. Differential Scanning Calorimetry (DSC) according to OECD Guideline 113	100 % Sinesto B; Batch: TH 3702; ATMAC/TMAC: 14.63 Boron: 0.617	**DSC-Measurements:** ***Up to 450°C*** Sample-amount: 3.28 mg & 3.19 mg Crucible: closed gold plated stainless steel crucibles, closed under N_2 Heating rate: 3 K/min Temperature range: 0-500°C Atmosphere: inert gas Mass loss: 0.00 mg ***Up to 500°C*** Sample-amount: 3.19 mg Crucible: closed gold plated stainless steel crucibles, closed under N_2 Heating rate: 3 K/min	Ref. 4.1 (consilab Gesellschaft für Analagensicherheit mbH, Report No. CSL-16-1839.01 (**2017**))	Acceptable. The study does not need to be conducted, because the substance is an organic substance or mixture containing chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500°C. The product is not explosive.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Conclusions of evaluation
			Temperature range: 0-500°C Atmosphere: inert gas Mass loss: 0.00 mg **Results:** In the DSC measurements test item Sinesto B showed no exothermic effects up to the maximum test temperature of 450 °C and 500 °C, meaning the decomposition energy is below the threshold of -500 J/g to exclude explosive properties. Due to this, the test item has no explosive properties.		
Flammable gases	Not applicable for liquids, Sinesto B is a liquid formulation				
Flammable aerosols	Not applicable for liquids, Sinesto B is a liquid formulation				
Oxidising gases	Not applicable for liquids, Sinesto B is a liquid formulation				
Gases under	Not applicable for liquids, Sinesto B is a liquid formulation				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Conclusions of evaluation
pressure					
Flammable liquids	EC No. 440/2008 Method A.9 OCSPP 830.6315 CIPAC MT12	100 % Sinesto B; Batch: TH 3702; ATMAC/TMAC: 14.63 Boron: 0.617	The vapour / air-mixtures did not ignite; the test substance is therefore regarded as non-flammable. The test item Sinesto B has no flash point up to a temperature of 76 °C by using Pensky-Martens closed cup method (DIN EN ISO 2719).	Ref. 4.1 (consilab Gesellschaft für Analagensicherheit mbH, Report No. CSL-16-1839.01 (**2017**))	Acceptable. Sinesto B does not have to be classified as flammable liquid.
Flammable solids	Not applicable for liquids, Sinesto B is a liquid formulation				
Self-reactive substances and mixtures	UN Transport Regulation Class 1 and CLP Regulation EC 1272/2008: Annex 1: 2.1. Differential Scanning Calorimetry (DSC)	100 % Sinesto B; Batch: TH 3702; ATMAC/TMAC: 14.63 Boron: 0.617	In the DSC measurements test item Sinesto B showed no exothermic effects up to the maximum test temperature of 450 °C and 500 °C, meaning the decomposition energy is below the threshold of -300 J/g to exclude self-reactive properties. Due to this, the test item has no self-reactive properties. (Please also refer to the endpoint “Explosives”.)	Ref. 4.1 (consilab Gesellschaft für Analagensicherheit mbH, Report No. CSL-16-1839.01 (**2017**))	Acceptable. The exothermic decomposition energy is less than 300 J/g. The test item has no self-reactive properties.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Conclusions of evaluation
	according to OECD Guideline 113				
Pyrophoric liquids	UN Transport Regulation, N.3	-	Sinesto B is stable at room temperature under air for a longer time-period (at least one day), therefore the test on pyrophoric properties does not need to be performed.	Ref. 4.1 (consilab Gesellschaft für Analagensicherheit mbH, Report No. CSL-16-1839.01 (**2017**))	Acceptable. The study does not need to be conducted, because the product is known to be stable in contact with air at room temperature for prolonged periods of time (days).
Pyrophoric solids	Not applicable for liquids, Sinesto B is a liquid formulation				
Self-heating substances and mixtures	Not applicable for liquids, Sinesto B is a liquid formulation				
Substances and mixtures which in contact with water emit flammable gases	Not applicable. Sinesto B is a water-dilutable product, which does not emit flammable gases in contact with water.				Acceptable. The study does not need to be conducted because the product is known to be soluble in water to form a stable mixture.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Conclusions of evaluation
Oxidising liquids	UN Transport Regulation, Division 5.1, Test Series O.2 EC-No. 440/2008 Method A.21 Oxidizing Properties of Liquids	-	Expert statement: Based on the chemical composition of the components of the test item Sinesto B has no oxidizing properties according to the UN Transport Regulation, Division 5.1. and Regulation EC No. 440/2008 Method A.21. Oxidizing Properties of Liquids.	Ref. 4.1 (consilab Gesellschaft für Analagensicherheit mbH, Report No. CSL-16-1839.01 (**2017**))	Acceptable. No test is necessary to be performed because oxidizing properties of the test item can be excluded by an evaluation of the chemical structures of the components of the test item: All compounds of the test item (besides the active substance Disodium tetraborate pentahydrate), which could be chemically relevant, contain oxygens chemically bonded only to carbon and hydrogen. With regard to the active substance Disodium tetraborate pentahydrate (content: 3.97% w/w), which contains oxygen bonded to boron, the “Guidance on the Application of the CLP” states

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Conclusions of evaluation
					in section 2.13.4.1.1. amongst others: *“In case a mixture of an oxidising substance and a non-hazardous inert substance is offered for classification, the following should be taken into account: […]* *• The determination of the oxidising properties of an aqueous solution of solid oxidising substances and the classification as an oxidising mixture is not necessary provided that the total concentration of all solid oxidisers in the aqueous solution is less than or equal to 20 % (w/w).”*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Conclusions of evaluation
					For this case the testing procedure for oxidizing substances needs not to be applied (in accordance with section 2.13.4 of Annex I to Regulation (EC) No 1272/2008).
Oxidising solids	Not applicable for liquids, Sinesto B is a liquid formulation				
Organic peroxides	Not applicable. Sinesto B is thermally stable and cannot undergo exothermic selfaccelerating decomposition				The study does not need to be conducted because the product does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.
Corrosive to metals	UN Test C.1	100 % Sinesto B; Batch: 0020436068; ATMAC/TMAC: 14.0 Boron: 0.605	Materials: Steel Plates: type S235JR+CR (size: 50x20x2 mm); Aluminium Plates: type 7075-T6 (size: 50x20x2 mm);	Ref. 4.16-02 (consilab Gesellschaft für Analagensicherheit mbH, Report No.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Conclusions of evaluation
			Expose time: 28 days (672±1 h); 55°C; **Results:** <u>Uniform corrosion:</u> *Weight loss [% w/w]; Steel:* Fully immersed: <0.01 after 28 d Half immersed: 0.03 after 28 d Gas phase: 0.57 after 28 d *Weight loss [% w/w]; Aluminium:* Fully immersed: 46.76 after 28 d Half immersed: 23.90 after 28 d Gas phase: >0.01 after 28 d <u>Localized corrosion:</u> *Max. Intrusion Depth [µm]; Steel:* Fully immersed: ---[1)] after 28 d Half immersed: 124.2[2)] after 28 d Gas phase: 230.6 after 28 d *Max. Intrusion Depth [µm]; Al:* Fully immersed: ---[1)] after 28 d Half immersed: 28.0[2)] after 28 d	CSL-19-1538.01 (**2020**))	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Conclusions of evaluation
			Gas phase: ---[1)] after 28 d [1)] No intrusion depths could be found microscopically. [2)] Intrusion depths found on the part in the gas phase. Sinesto B is not corrosive to metals according to the UN Transport Regulation, Test C.1 and DIN 52 168 part 1.		
Auto-ignition temperatures of products (liquids and gases)	(EC) No. 440/2008 Method A.15 DIN 51794 (2003)	100 % Sinesto B; Batch: TH 3702; ATMAC/TMAC: 14.63 Boron: 0.617	620 °C	Ref. 4.1 (consilab Gesellschaft für Analagensicherheit mbH, Report No. CSL-16-1839.01 (**2017**))	Acceptable.
Relative self-ignition temperature for solids	Not applicable for liquids, Sinesto B is a liquid formulation				
Dust explosion	Not applicable for liquids, Sinesto B is a liquid formulation				

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

Conclusion on the physical hazards and respective characteristics of the product
For the biocidal product Sinesto B no flash point was observed up to a temperature of 76 °C, at which the flame extinguished by evaporating of water. Sinesto B does not have to be classified as flammable liquid. Explosive or oxidising properties can be excluded. The auto-ignition temperature of the biocidal product Sinesto B is 620 °C. The product is a water-based soluble concentrate and the co-formulants are not expected to be hazardous according to the available data. On the basis of data/information provided by applicant of the product, Sinesto B has not to be classified with regard to physical hazards according to Regulation (EC) No 1272/2008.

3.4 Methods for detection and identification

Table 8

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
TMAC/ ATMAC	Potentio-metric Titration method	Quantitative (non-specific) method, biocidal product composition without ATMAC/ TMAC showed no additonal titer consumption	Range: 175 – 1050 mg/L TMAC (0.35 – 2.08 % TMAC) (4 concentration levels, 3 measurements per level; linearity equals to a range of 25 % to 150 % a.s. referring to the nominal content in the biocidal product) Correlation coefficient: 0.99998	Level A: 560 mg/L TMAC	99.8 – 100.2	100.0	0.18	LOQ: 0.1 % TMAC LOD: 0.03 % TMAC	BASF Wolman GmbH (2018): Validation of a Potentiometric Titration Method for the Determination of TMAC in Sinesto B; (Report No. 17-WD-034)
				Level B: 700 mg/L TMAC	99.7 – 100.3	100.1	0.32		
				Level C: 840 mg/L TMAC (5 measurements per level)	100.1 – 100.6	100.3	0.22		
	Gas chromato-graphy (GC-FID)	The validated potentiometric titration above facilitates the quantitative ATMAC/TMAC determination. However, the titration method does not provide qualitative evidence for ATMAC/TMAC (non-specific method). The additional method by gas chromatography (GC-FID) is suitable for the qualitative determination of ATMAC/TMAC in the biocidal product (specific method).							BASF Wolman GmbH (2020): Qualitative Analysis of TMAC in Sinesto B by Gas Chromatography (GC-FID); (Report No. 20-WD-012)
		Identification: The chromatograms of an actual batch of the ATMAC/TMAC raw material as well as of Sinesto B (Batch TH3702) and of a ATMAC/TMAC-free Sinesto B formulation were compared. The comparison showed that all peaks of the Sinesto B (Batch TH3702) occur in the chromatogram of the raw material, too. No (significant) additional peak is observed. Specificity: The influence of the matrix of Sinesto B on the determination of ATMAC/TMAC was investigated. A comparison of the chromatograms of the raw material (ATMAC/TMAC), Sinesto B formulation without ATMAC/TMAC and a Sinesto B solution (made of Sinesto B, batch TH 3702) shows no additional peaks and thus no interference from the matrix.							

Disodiumtetraborate pentahydrate – expressed as Boron	Atom Absorption Spectro-meter method (AAS)	specific	Range: 50 – 500 mg Boron/L (4 concentration levels, three measurements per level) Correlation coefficient: 0.999	Level A: 170 mg/L	95.9 – 98.5	97.0	1.38	LOD: 16 mg Boron/L LOQ: 25 mg Boron/L	BASF Wolman GmbH (2018): Validation of an Atom Absorption Spectrometer Method for the Determination of Boron in Sinesto® B; (Report No. 17-WD-033)
				Level B: 220 mg/L	96.6 – 99.3	98.0	1.08		
				Level C: 280 mg/L (five measurements per level)	104.5 – 109.7	107.6	1.76		
NaOH (SoC)	Waiving (The content of sodium hydroxide in Sinesto B does not increase after manufacturing and/or during storage. An analytical method for determination of the content of this substance is considered not to be necessary.)								
Sodium 2-ethyl-hexanoate [Na-2-EH] (SoC)	Ultrahigh pressure liquid chromato-graphy (UPLC-UV)	specific	Range: 513 – 2052 mg Na-2-EH/L (three-point calibration) Correlation coefficient: 0.99994	Level 1: 1398 mg/L	99.5 – 100.2	99.9	0.5	LOQ: 11 mg Na-2-EH/L	BASF Wolman GmbH (2020): UPLC method for the determination of Sodium 2-ethyl-hexanoate in Sinesto® B; (Report No. 20-WD-014)
				Level 2: 1683 mg/L (five measurements per level)	100.4 – 100.8	100.6	0.7		
	Since it is assumed that the content of Sodium 2-ethyl-hexanoate in Sinesto B does not increase after manufacturing and/or during storage, the given data are deemed sufficient.								

Table 9

Relevant residue definitions for monitoring of ATMAC/TMAC and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	ATMAC/TMAC	0.05 mg/kg	common limit (since $PNEC_{soil}$> 0.05 mg/kg) combined AR for ATMAC and TMAC, PT8 chapter 2.2.2.2

Relevant residue definitions for monitoring of ATMAC/TMAC and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Drinking water	ATMAC/TMAC	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	ATMAC TMAC	0.57 µg/L 0.11 µg/L	$PNEC_{water}$ =0.00057 mg/L based on read across to DDAC and correction for MW $PNEC_{water}$ =0.00011 mg/L based on read across to C_{12-16}-BKC and correction for MW combined AR for ATMAC and TMAC, PT8 chapter 2.2.2.2
Air	no relevant residues expected		combined AR for ATMAC and TMAC, PT8 chapter 2.1.1 and LoEP, 11/2014
Animal and human body fluids and tissues	no relevant residues expected		combined AR for ATMAC and TMAC, PT8 chapter 2.1.1 and LoEP, 11/2014
Food of plant origin	no relevant residues expected		combined AR for ATMAC and TMAC, PT8 chapter 2.1.1 and LoEP, 11/2014
Food of animal origin	no relevant residues expected		combined AR for ATMAC and TMAC, PT8 chapter 2.1.1 and LoEP, 11/2014

Table 10

Relevant residue definitions for monitoring of Disodiumtetraborate pentahydrate and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	boron	Boron is naturally occuring from 5 mg/kg (basalt) to 100 mg/kg (shale)	EFSA Journal (2004) 80, 1-22

Relevant residue definitions for monitoring of Disodiumtetraborate pentahydrate and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Drinking water	boron	1 mg/L	Council Directive 80/778/EEC and Drinking Water Act (Trinkwasser-VO), appendix 2, chemical parameter
Surface water	boron	180 µg/L	PNEC based on NOEC *Bachydanio rerio*, AR; List of endpoints, chapter 5, 2009-02-20, AR Disodium tetraborate
Air	no relevant residues expected		vapour pressure $<10^{-5}$ Pa
Animal and human body fluids[1]	boron	0.5 mg/L	classified as toxic
Food of plant origin	no relevant residues expected		List of endpoints, chapter 2, 2009-02-20, AR Disodium tetraborate
Food of animal origin	no relevant residues expected		List of endpoints, chapter 2, 2009-02-20, AR Disodium tetraborate

[1] No accumulation in tissues (AR Disodium tetraborate, Doc IIA, chapter 3.1; 06/2008), therefore monitoring of blood or urine level is more suitable.

Table 11

Analytical methods for ATMAC/TMAC in drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
TMAC (active substance) determined as C8, C10, C12, C14, C16, C18,	LC-MS/MS, C18, ESI+ C8 m/z 172→60; m/z 172→57 C10	included by second MS/MS transition	0.01 – 1.04 µg/L (total C8-C18un) R^2: 0.999068 – 0.999961	<u>Primary method</u> <u>groundwater</u> C8 0.014/5 0.14/5	C8 $<LOQ_{C8}$ 84-94 C10	C8 $<LOQ_{C8}$ 90 C10	C8 - 4.1 C10	0.1 µg/L (lowest fortification level as total TMAC) For individual constituents	Combined CAR ATMAC-TMAC Doc IIA, Water, 04/2016

Analytical methods for ATMAC/TMAC in drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
unsaturated C18	m/z 200→60; m/z 200→57 C12 m/z 228→60; m/z 228→57 C14 m/z 256→60; m/z 256→57 C16 m/z 284→60; m/z 284→57 C18 m/z 312→60; m/z 312→57 C18un m/z 310→60; m/z 310→69			C10 0.014/5 0.14/5 C12 0.014/5 0.14/5 C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5 <u>tap water</u> C8 0.014/5 0.14/5 C10	<LOQ_{C10} 90-95 C12 79-87 89-96 C14 75-83 89-97 C16 <LOQ_{C16} 72-81 C18 <LOQ_{C18} 63-77 C18un <LOQ_{C18un} 65-76 C8 <LOQ_{C8} 84-92 C10 <LOQ_{C10}	<LOQ_{C10} 93 C12 83 93 C14 81 94 C16 <LOQ_{C16} 79 C18 <LOQ_{C18} 72 C18un <LOQ_{C18un} 71 C8 <LOQ_{C8} 88 C10 <LOQ_{C10}	- 2.2 C12 4.1 3.0 C14 4.1 3.5 C16 - 5.5 C18 - 9.6 C18un - 5.8 C8 - 4.5 C10 -	LOQ_{C8}, LOQ_{C10}, LOQ_{C12}, LOQ_{C14}, LOQ_{C16}, LOQ_{C18} and LOQ_{C18un} = 0.014 µg/L	

Analytical methods for ATMAC/TMAC in drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				0.014/5 0.14/5 C12 0.014/5 0.14/5 C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5 <u>Confirmatory method</u> <u>groundwater</u> C8 0.014/5 0.14/5	91-94 C12 74-84 89-97 C14 79-84 91-98 C16 <LOQ$_{C16}$ 81-88 C18 <LOQ$_{C18}$ 82-89 C18un <LOQ$_{C18un}$ 73-79 C8 <LOQ$_{C8}$ 86-100	93 C12 81 94 C14 82 95 C16 <LOQ$_{C16}$ 85 C18 <LOQ$_{C18}$ 85 C18un <LOQ$_{C18un}$ 76 C8 <LOQ$_{C8}$ 93	1.6 C12 3.6 3.2 C14 2.3 2.7 C16 - 3.5 C18 - 3.4 C18un - 3.3 C8 - 6.5		

Analytical methods for ATMAC/TMAC in drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				C10 0.014/5 0.14/5 C12 0.014/5 0.14/5 C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5 tap water C8 0.014/5 0.14/5	C10 <LOQ_{C10} 88-94 C12 81-90 90-96 C14 79-88 87-96 C16 <LOQ_{C16} 73-84 C18 <LOQ_{C18} 71-85 C18un <LOQ_{C18un} 66-75 C8 <LOQ_{C8} 89-95 C10	C10 <LOQ_{C10} 91 C12 86 95 C14 84 92 C16 <LOQ_{C16} 81 C18 <LOQ_{C18} 80 C18un <LOQ_{C18un} 71 C8 <LOQ_{C8} 94 C10	C10 - 2.5 C12 3.9 2.9 C14 4.0 3.9 C16 - 6.1 C18 - 5.1 C18un - 4.7 C8 - 3.1 C10		

Analytical methods for ATMAC/TMAC in drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				C10 0.014/5 0.14/5 C12 0.014/5 0.14/5 C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5	<LOQ_{C10} 85-103 C12 77-90 90-97 C14 77-92 88-98 C16 <LOQ_{C16} 79-88 C18 <LOQ_{C18} 96-103 C18un <LOQ_{C18un} 73-80	<LOQ_{C10} 93 C12 84 94 C14 85 94 C16 <LOQ_{C16} 84 C18 <LOQ_{C18} 99 C18un <LOQ_{C18un} 78	- 6.9 C12 5.9 2.9 C14 6.9 4.5 C16 - 4.8 C18 - 3.3 C18un - 4.5		
ATMAC (active substance) determined as C12	LC-MS, ESI+, m/z 228.3	no confirmation included, since validation data for a single fragment ion	0.01 – 0.5 µg/L R^2 = 0.9986	<u>drinking water</u> C12 0.01/5 0.1/5 <u>groundwater</u> C12	 94-109 77-86	 103 80	 5.5 4.5	0.1 µg/L	CAR DocIIIA ATMAC, 4.2c(1); 01/2014 Brewin, 2004

Analytical methods for ATMAC/TMAC in drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				0.01/5 0.1/5	71-103 79-95	87 82	14.5 9.0		

Table 12

Analytical methods for Disodiumtetraborate pentahydrate in drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Disodiumtetraborate pentahydrate (active substance) determined as Boron	ICP-AES, 249.678 nm	no interfering substances reported, but emission lines show apparently interference from Fe	Linear graph R^2>0.995	0.1 and 0.4 mg/L (background level in water 0.023 -0.063 mg/L)	97-111	-	-	Method detection limit: 5 µg/L (aqueous samples)	CAR, Doc IIIA, 4.2a/(03), Martin (1994), US EPA method 200.7 revision 4.4

Table 13

Analytical methods for ATMAC/TMAC in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
TMAC (active substance) determined as C8, C10, C12, C14, C16, C18, unsaturated C18	LC-MS/MS, C18, ESI+ C8 m/z 172→60; m/z 172→57 C10 m/z 200→60; m/z 200→57 C12 m/z 228→60; m/z 228→57 C14 m/z 256→60; m/z 256→57 C16 m/z 284→60; m/z 284→57 C18 m/z 312→60; m/z 312→57 C18un m/z 310→60; m/z 310→69	included by second MS/MS transition	0.01 – 1.04 µg/L (total C8-C18un) R^2: 0.999068 – 0.999961	Primary method C8 0.00714/5 0.0714/5 C10 0.00714/5 0.0714/5 C12 0.00714/5 0.0714/5 C14 0.00714/5 0.0714/5 C16 0.00714/5 0.0714/5 C18 0.00714/5 0.0714/5 C18un 0.00714/5 0.0714/5	C8 <LOQ_{C8} 93-98 C10 <LOQ_{C10} 93-101 C12 97-99 97-101 C14 89-99 94-103 C16 <LOQ_{C16} 78-87 C18 <LOQ_{C18} 75-88 C18un <LOQ_{C18un} 87-93	C8 <LOQ_{C8} 95 C10 <LOQ_{C10} 96 C12 98 99 C14 93 96 C16 <LOQ_{C16} 82 C18 <LOQ_{C18} 82 C18un <LOQ_{C18un} 90	C8 - 2.0 C10 - 3.1 C12 1.0 1.4 C14 4.1 4.0 C16 - 3.9 C18 - 5.9 C18un - 2.0	0.05 mg/kg (lowest fortification level as total TMAC) For individual constituents LOQ_{C8}, LOQ_{C10}, LOQ_{C12}, LOQ_{C14}, LOQ_{C16}, LOQ_{C18} and LOQ_{C18un} = 0.00714 mg/kg	Combined CAR ATMAC-TMAC Doc IIA, Soil, 04/2016

Analytical methods for ATMAC/TMAC in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				Confirmatory method C8 0.00714/5 0.0714/5 C10 0.00714/5 0.0714/5 C12 0.00714/5 0.0714/5 C14 0.00714/5 0.0714/5 C16 0.00714/5 0.0714/5 C18 0.00714/5 0.0714/5 C18un 0.00714/5 0.0714/5	C8 $<LOQ_{C8}$ 90-103 C10 $<LOQ_{C10}$ 94-102 C12 92-100 98-100 C14 92-98 93-101 C16 $<LOQ_{C16}$ 81-88 C18 $<LOQ_{C18}$ 76-92 C18un $<LOQ_{C18un}$ 88-95	C8 $<LOQ_{C8}$ 95 C10 $<LOQ_{C10}$ 98 C12 95 99 C14 95 95 C16 $<LOQ_{C16}$ 85 C18 $<LOQ_{C18}$ 81 C18un $<LOQ_{C18un}$ 90	C8 - 5.3 C10 - 3.2 C12 3.5 1.0 C14 2.5 3.8 C16 - 3.8 C18 - 8.0 C18un - 3.0		

Analytical methods for ATMAC/TMAC in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
ATMAC (active substance) determined as C12	LC-MS, ESI+, m/z 228.3	no confirmation included, since validation data for a single fragment ion	0.002 – 0.2 mg/kg R^2 = 0.9997	clay loam 0.01/5 0.1/5 sandy loam 0.01/5 0.1/5	 81-93 77-99 82-98 80-101	 85 86 90 88	 5.9 9.5 8.1 10.7	0.1 mg/kg	CAR DocIIIA ATMAC, 4.2a(1); 01/2014 Brewin, 2004

Table 14:

Analytical methods for Disodiumtetraborate pentahydrate in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Disodiumtetra-borate pentahydrate (active substance) determined as Boron	ICP-AES, 249.678 nm	no interfering substances reported, but emission lines show apparently interference from Fe	linear graph R^2>0.995	100 and 400 mg/kg (background level in soil: 20.4 – 31.9 mg/kg)	93-113	-	-	method detection limit: 5 µg/L (aqueous samples) corresponds to 0.5 mg/kg (soil samples)	CAR, Doc IIIA, 4.2a/(03), Martin (1994), US EPA method 200.7 revision 4.4

Table 15

Analytical methods for ATMAC/TMAC in surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
TMAC (active substance) determined as C8, C10, C12, C14, C16, C18, unsaturated C18	LC-MS/MS, C18, ESI+ C8 m/z 172→60; m/z 172→57 C10 m/z 200→60; m/z 200→57 C12 m/z 228→60; m/z 228→57 C14 m/z 256→60; m/z 256→57 C16 m/z 284→60; m/z 284→57 C18 m/z 312→60; m/z 312→57 C18un m/z 310→60; m/z 310→69	included by second MS/MS transition	0.01 – 1.04 µg/L (total C8-C18un) R^2: 0.999068 – 0.999961	<u>Primary method</u> C8 0.014/5 0.14/5 C10 0.014/5 0.14/5 C12 0.014/5 0.14/5 C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5	C8 <LOQ_{C8} 76-84 C10 <LOQ_{C10} 80-89 C12 81-82 84-94 C14 80-82 83-94 C16 <LOQ_{C16} 73-80 C18 <LOQ_{C18} 68-79 C18un <LOQ_{C18un} 67-78	C8 <LOQ_{C8} 81 C10 <LOQ_{C10} 85 C12 82 89 C14 81 88 C16 <LOQ_{C16} 77 C18 <LOQ_{C18} 72 C18un <LOQ_{C18un} 71	C8 - 5.0 C10 - 4.8 C12 0.8 4.8 C14 1.0 5.1 C16 - 3.6 C18 - 7.2 C18un - 6.4	0.1 µg/L (lowest fortification level as total TMAC) For individual constituents LOQC8, LOQC10, LOQC12, LOQC14, LOQC16, LOQC18 and LOQC18un = 0.014 µg/L	Combined CAR ATMAC-TMAC Doc IIA, Water, 04/2016

Analytical methods for ATMAC/TMAC in surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				<u>Confirmatory method</u> C8 0.014/5 0.14/5 C10 0.014/5 0.14/5 C12 0.014/5 0.14/5 C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5	C8 <LOQ_{C8} 76-85 C10 <LOQ_{C10} 78-90 C12 79-83 84-95 C14 79-83 83-93 C16 <LOQ_{C16} 75-82 C18 <LOQ_{C18} 68-79 C18un <LOQ_{C18un} 69-77	C8 <LOQ_{C8} 82 C10 <LOQ_{C10} 84 C12 82 89 C14 94 88 C16 <LOQ_{C16} 79 C18 <LOQ_{C18} 74 C18un <LOQ_{C18un} 73	C8 - 4.2 C10 - 5.3 C12 2.1 5.2 C14 2.4 4.7 C16 - 3.8 C18 - 7.2 C18un - 4.6		

Analytical methods for ATMAC/TMAC in surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
ATMAC (active substance) determined as C12	LC-MS, ESI+, m/z 228.3	no confirmation included, since validation data for a single fragment ion	0.01 – 0.5 µg/L R^2 = 0.9986	surface water C12 0.01/5 0.1/5	 75-106 81-107	 97 92	 13.0 13.9	0.1 µg/L	CAR DocIIIA ATMAC, 4.2c(1); 01/2014 Brewin, 2004

Table 16

Analytical methods for Disodiumtetraborate pentahydrate in surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Disodiumtetraborate pentahydrate (active substance) determined as Boron	ICP-AES, 249.678 nm	no interfering substances reported, but emission lines show apparently interference from Fe	Linear graph R^2>0.995	0.1 and 0.4 mg/L (background level in water 0.023 -0.063 mg/L)	97-111	-	-	Method detection limit: 5 µg/L (aqueous samples)	CAR, Doc IIIA, 4.2a/(03), Martin (1994), US EPA method 200.7 revision 4.4

Table 17

Analytical methods for Disodiumtetraborate pentahydrate in animal and human body fluids									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Disodiumtetraborate pentahydrate (active substance) determined as Boron	method for soil is applicable								List of endpoints, chapter 2, 2009-02-20, AR Disodium tetraborate

Table 18

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.1. Analytical method including validation parameters for determining the concentration of the substance of concern sodium hydroxide in the biocidal product: The content of the SoC sodium hydroxide in Sinesto B does not increase after manufacturing and/or during storage. An analytical method for determination of the content of this substance is considered not to be necessary. 2. 5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product An analytical method for the a.s./SoC is required only for the deluge treatment application - no inhalation exposure is expected for other applications. However, for deluge treatment, the exposure assessment has shown that inhalation exposure is far below the reference value (less than 10% of the limit value). Therefore the reference member state did not requested an analytical method air for the active substances and SoC. 3. 5.2.4. Body fluids and tissues for ATMAC/TMAC 4. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant[11] for both active substances.
Justification	See above

Table 19

Conclusion on the methods for detection and identification
The methods provided regarding the active substances and substances of concern were acceptable The methods provided regarding the residues of the active substances were acceptable. Methods regarding residues of substances of concern were not necessary.

[11] *Not necessary if neither the active substance nor the material treated with it come into contact with food- producing animals, food of plant and animal origin or feeding stuffs*

3.5 Efficacy against target organisms

3.5.1 Function and field of use

Sinesto B is a wood preservative for preventive treatment for temporary control of sapstain (temporary blue stain) and mould discolouring fungi 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 B is applied to the surface of freshly cut wood only once by fully automated dipping, by automated dipping or by spraying in closed spray-tunnels.

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 users.

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

Sinesto B is a concentrated formulation which will be diluted with water on site. The intended application rate is 5 – 12 g Sinesto B /m² wood. This is achieved in practice by dilution rates of 5 – 8% (m/m) with 100 – 150 ml/m² uptake of the treatment solution (uses 1 and 2) or by dilution rates of 5 – 20% (m/m) with 50 – 100 ml/m² uptake (use 3). Sinesto B 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.

3.5.3 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 insignificant stain, the most. The issue of unacceptable suffering does not apply.

3.5.4 Mode of action, including time delay

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.

Disodium tetraborate pentahydrate

All boron formulations inhibit proper cell functions. Boron compounds penetrate cell walls causing the protoplasma to swell with depressive effects on the metabolism.

3.5.5 Efficacy data

The applicant provided four efficacy study reports of different value.

Best indication of effectiveness can be taken from two reports of semi-field tests carried out according to prCEN/TS 15082:2005. In all cases the test product was Sinesto B.. In the first report (BASF Wolman GmbH, B 2742 A), Sinesto B was tested at 6.0% and applied through dipping for 3 to 5 sec. resulting in an average retention of 10.1 g of Sinesto B/m². Treated wood was tested either closely packed or loosely packed on stickers. Growth of mould and stain was evaluated in regular intervals using a rating scheme from “0” (no staining visible on specimen) to “4” (staining of over 50 % on the specimen). Ratings of “0” or “1” (insignificant staining) are considered as acceptable in line with the acceptance criteria for EN 152. Protection against temporary stain and mould was sufficient for closely packed wood up to 8 weeks and for loosely packed wood up to 10 weeks. Untreated control wood was heavily stained in all cases, so the test is valid.

In the second report (Latvian State Institute of Wood Chemistry 274/234 Bio) Sinesto B was tested at 2.0%, 3.0%, and 4.0% and applied through dipping for 30 sec. resulting in an average retention of 3.4 g of Sinesto B/m², 6.4 g of Sinesto B/m², and 8.1 g of Sinesto B/m². Treated wood was tested closely packed. Growth of mould and stain was evaluated using the same rating scheme as above in an interval of 2, 4, 6, and 8 weeks. The test duration was shorter than foreseen in the standard, but can be used to gain relevant information about short protection times. Protection against temporary stain and mould was sufficient for closely packed wood up to 6 weeks at 3.4 g of Sinesto B/m², demonstrating efficacy of the lowest intended dosage for a relevant timeframe. Although no NaPCP reference control was used, this is accepted in the specific case, as infestation pressure in the untreated and water controls was higher than in the abovementioned B 2742 A test report, which contained a valid NaPCP reference control in addition. This comparison indicates that infestation pressure was sufficient to yield valid data.

Untreated control wood was heavily stained in all cases.

In the third report (Field test report from Portugal, two independent test locations) Sinesto B was tested at 6.0%, and 8.0% and applied through dipping for 15-30 sec. resulting in an estimated average retention of 12 g of Sinesto B/m², and 16 g of Sinesto B/m². Treated wood was tested in a combination of closely and loosely packed. Growth of mould and stain was evaluated using a similarrating scheme as above. Protection against temporary stain and mould was sufficient for up to 22 weeks for both tested retentions in one of the two tested locations. Efficacy in the second test location was insufficient, but still slightly higher than efficacy of the reference product 3% NaPCP.Untreated control wood was heavily stained in all cases.

The fourth report (BAM 8.1/6536) was on a laboratory study dated 17.02.1995 which followed a standardized testing protocol according to RAL GZ 830 for efficacy against temporary blue stain and mould fungi. Sinesto B was tested in a range of concentrations from 0% to 10%. The highest effective average retention of Sinesto B was 6,85 g/m² resulting in sufficient protection of pine sapwood against temporary blue stain for 6 weeks. Protection against mould was insufficient after 6 weeks.
Untreated control wood was heavily stained in all cases.

In conclusion, Sinesto B provides adequate protection against temporary blue stain (sapstain) and mould on freshly cut wood and wooden pallets for up to 22 weeks when applied at the higher end of the envisioned application range. In cases of closely packed wood and lower retentions the time of sufficient effectiveness decreases to 6 weeks. Effective protection time in practice will depend on the applied dosage as well as on other factors, such as climatical conditions at the place of use (especially temperature and humidity), local infestation pressure, predominant fungal species in the local microbial community, way of packing, and the type and humidity of the treated wood, among others.

Table 20

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Fungicide; Preventive temporary effectiveness against discolouring mould fungi and sapstain	Wood preservative	Sinesto B ATMAC/TMAC 14%; Disodium tetraborate pentahydrate 4.0%	Natural exposure to mould and sapstain	prCEN/TS 15082	Semifield test Scots pine wood (*Pinus sylvestris*) 6% Sinesto B, dipping for 3-5 sec., retention 10.1 g/m² ca. 19 weeks of testing	Control of fungal growth in closely stacked wood for 8 weeks Control in loosely staged wood for 10 weeks	BASF Wolman GmbH 2016 Report B 2742 A Key study
Fungicide; Preventive temporary effectiveness against discolouring mould fungi and sapstain	Wood preservative	Sinesto B	Natural exposure to mould and sapstain	Adapted prCEN/TS 15082	Semifield test Scots pine wood 2%, 3%, 4% Sinesto B, dipping for 30 sec., retentions 3.4 g/m², 6.4 g/m², 8.1 g/m²	Control of fungal growth in closely stacked wood for 6 weeks	Latvian State Institute of Wood Chemistry, 2016 Report 274/234 Bio Key study

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					8 weeks of testing		
Fungicide; Preventive temporary effectiveness against discolouring mould fungi and sapstain	Wood preservative	Sinesto B	Natural exposure to mould and sapstain	similar to prCEN/TS 15082 Rating system comparable to EN 152	Field test Maritime pine wood (*Pinus pinaster*) 6%, 8% Sinesto B, dipping for 15-30 sec., retentions 12 g/m², 16 g/m² ca. 22 weeks of testing two field locations	Control of fungal growth in a combination of closely stacked wood for 22 weeks at 12 g/m² in one of the two test locations At the second test location, Sinesto B showed insufficient efficacy, despite still being slightly more effective than the reference formulation 3% NaPCP	APCIM (Portugal), 1990 No report number Supporting study
Fungicide; Preventive temporary effectiveness against discolouring mould fungi and sapstain	Wood preservative	Sinesto B	Mixture of nine different mould and stain fungi	RAL GZ 830 temporary blue stain Rating system comparable to CEN/TS 15082	Laboratory test Scots pine wood 0%, 4%, 7%, 10%, Dipping for 30 s, highest retention 6.85 g/m²	Control of fungal (temporary blue stain) growth for 6 weeks at 6.85 g/m²	BAM, 1995 Report 8.1/6536 Supporting study

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Reference product: 3% NaPCP Replicates: n=6 6 weeks of testing in humidity chambers		

3.5.6 Occurrence of resistance and resistance management

Trimethylcocoammonium chloride and Disodiumtetraborate pentahydrate are the active substances in the biocidal product Sinesto B. No reports on the development of resistance in fungi are available in the scientific literature including development of resistance by mutation and selection, by horizontal gene transfer and selection of inherently resistant organisms with complex fungal communities. In addition, there is a long history of use for the active substances without obvious development of resistance during application.

However, the efficacy data show slow fungal growth occurring over time at the claimed application rate and within the tested storage period. This shows that exposed fungi are growing in the presence of sub-inhibitory concentrations of the active substance and that selection processes can occur in principle. Therefore, resistance development should be observed, and any instance of resistance development should be reported to the authorisation holder. To avoid an increased risk of resistance development, it must be assured that treated wood is not exposed to weathering at any time, thus avoiding leaching of the active substances.

3.5.7 Known limitations

None.

3.5.8 Evaluation of the label claims

Sinesto B temporary controls mould and sapstain growth on freshly cut wood and wooden pallets for up to 22 weeks as demonstrated by efficacy tests. The range of application with 5 to 12 g Sinesto B / m² wood is justified. Sinesto B as a concentrate is to be diluted with water to 5-8% with applications of 100

to 150 ml/m² (uses 1 and 2) or to be diluted 5 – 20% (m/m) with applications of 50 – 100 g/m² in order to reach the intended application rates of 5 – 12 g/m² Sinesto B.

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

The product is not intended to be used with other biocidal products.

3.5.10 Data waiving and conclusion

Efficacy tests of Sinesto B in combination with ageing procedures are not required. Temporary protection against sapstain and mould has been demonstrated for up to 22 weeks by test reports. This is covered by the test reports. Additional evaporation or leaching prior the test according to EN 73 or EN 84 is not relevant.

Table 21

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.

Table 22

Conclusion on the efficacy
Sinesto B temporary controls mould and sapstain growth on freshly cut wood and wooden pallets. The range of application with 5 – 12 g Sinesto B / m² wood is justified. Sinesto B as a concentrate is either to be diluted with water to 5 – 8% (m/m) with applications of 100 – 150 ml/m² (uses 1 and 2) or to be diluted 5 – 20% (m/m) with applications of 50 – 100 ml/m² in order to reach the intended application rates of 5 – 12 g/m² Sinesto B.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 23

ATMAC/TMAC	Value	Study	Safety factor
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))	
ADI	Not applicable	Assessment Report (RMS Italy (2016))	
ARfD	Not applicable	Assessment Report (RMS Italy (2016))	

Table 24

ATMAC/TMAC	Value	Reference
Inhalative absorption	no need to perform inhalation studies	Assessment Report (RMS Italy (2016))
Oral absorption	It is expected that its oral absorption is limited (around 10 % at non-corrosive concentrations) and that the majority (90 %) of orally administered a.s. is excreted unabsorbed via the faeces.	**ATMAC** Assessment Report (RMS Italy (2016))
Oral absorption	TMAC: ≥ 3.3 % (based on 1.22 excreted by urine and 2 % in bile). Supporting data. DDAC & C12-16-BKC: 10 %, based the urinary and biliary excretion mean values (3-4 % with a single peak value = 8.3 % and 3.7-4.6 %, respectively as worst case values), in the absence of residues in the carcass. The oral absorption value of 10 % at non-corrosive concentrations.	**TMAC** Assessment Report (RMS Italy (2016))
Dermal absorption	see Chapter 3.6.2.7	

Table 25

Disodium tetraborate pentahydrate	Value	Study	Safety factor
AEL long-term	0.1 mg/kg bw/day*	Developmental toxicity, rat (Price et al., 1994; based on fetal effects), supported by 2-yr	100

Disodium tetraborate pentahydrate	Value	Study	Safety factor
		feeding, rat (Weir, 1966)	
AEL medium-term	0.1 mg/kg bw/day*	Developmental toxicity, rat (Price et al., 1994; based on fetal effects)	100
AEL acute	0.1 mg/kg bw*	Developmental toxicity, rat (Price et al., 1994; based on fetal effects)	100
ADI	Not relevant	Assessment Report (RMS NL (2009))**	
ARfD	Not relevant	Assessment Report (RMS NL (2009))**	

* All threshold limits are given as boron. In the EU evaluation under Directive 98/8/EC, no AELs were established but a (rounded) AOEL of 0.1 mg/kg bw/day was set [see Assessment Report (NL, 2009) on Disodium tetraborate, Product-type 8, as finalised in the "Standing Committee on Biocidal Products" on 20 February 2009].

** The borates will be used in wood preservatives. The borates are not used on wood products that are used for food preparation or feeding stuff. Furthermore finished wood products containing borates and manufactured for structural and building material are not appropriate to be used and would not be used to make products that would come into contact with food or feeding stuff. Therefore the derivation of an ADI and ARfD is considered not necessary.

Table 26

Disodium tetraborate pentahydrate	Value	Reference
Inhalative absorption	100 %**	default
Oral absorption	100 %**	default
Dermal absorption	see Chapter 3.6.2.7	

** See Assessment Report (NL (2009)

3.6.2 Assessment of effects of the product on human health

Studies with the biocidal product were performed in the 1980s. From a national assessment of a wood preservative with the same name in 2002 we have an identity, which is slightly different from the one submitted for this biocidal product authorisation. Therefore, it must be expected that the identity of the biocidal product and the test formulation are different. However, the actual formulation and the previous product from 2002 would be comparable with respect to human toxicological studies (for details refer also to the Confidential Annex). No statement on the identity of the test formulations was provided by the applicant.

3.6.2.1 Skin corrosion and irritation

Table 27

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose level, Exposure duration**	**Results (average scores 24, 48, 72 h of each animal), Other observations, Reversibility**	**Remarks**	**Reference**
OECD 404 GLP: No information Reliability: 2	New Zealand white rabbit, Male, 3 animals / group	Sinesto B No vehicle, Undiluted, 0.5 mL Exposure duration: 4 h	Erythema: 2 / 4 / 1.7 Oedema: 2 / 2 / 2 Necrotic lesions in the second animal with the highest scores. All effects were non-reversible in all animals within 14 days.	-	Report No.: 83614D/KKM 6/SE (G)

Table 28

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Corrosive to the skin
Justification for the value/conclusion	Based on an *in vivo* study with a comparable formulation and confirmed by the additivity approach according to Regulation (EC) No. 1272/2008. According to the CAR for ATMAC (2016) and the corresponding discussion in an adhoc follow-up, MS agreed that the dilutions of Sinesto B (reference product of the CAR) up to 8 % are classified as Skin Irrit. 2, H315. However, the biocidal product will also be used in a dilution of 20 %, which is not covered by the agreement during active substance evaluation. For this dilution, the classification is based on the high pH above 11.5 resulting in a classification as Skin Corr. 1, H314.
Classification of the product according to CLP	Skin Corr. 1 (undiluted product, 20 % dilution) Skin Irrit. 2 (8 % dilution)

3.6.2.2 Eye irritation

Table 29

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	In accordance to Regulation (EC) No 1272/2008 a study is not required because the biocidal product is a strong base (pH approx. 14) and is alraedy classified as corrosive to the skin. This implies eye damaging properties. Also classification based on the properties of the individual components would lead to classification with Eye Dam. 1.

Table 30

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye Dam. 1
Justification for the value/conclusion	Based on the skin-corrosive properties of the biocidal product (documented in a valid study) and its pH of 14. According to the CAR for ATMAC (2016) and the corresponding discussion in an adhoc follow-up, MS agreed that the dilutions of Sinesto B (reference product of the CAR) up to 8 % are classified as Eye Irrit. 2, H319. However, the biocidal product will also be used in a dilution of 20 %, which is not covered by the agreement during active substance evaluation. For this dilution, the classification is based on the high pH of ≥ 11.5 resulting in a classification as Eye Dam. 1, H318.
Classification of the product according to CLP	Eye Dam. 1 (undiluted product, 20 % dilution) Eye Irrit. 2 (8 % dilution)

3.6.2.3 Respiratory tract irritation

Table 31

Data waiving was acceptable for the following information requirements	
Information requirement	8.10. Other tests
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008.

Table 32

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Irritating to the respiratory tract
Justification for the value/conclusion	The biocdal product contains a co-formulant (sodium 2-ethylhexanoic acid) classified with STOT SE 3, H335 in a concentration relevant for classification. For details refer to the Confdential Annex. However, the biocidal product is classified as Skin Corr. 1, H314. An acute inhalation toxicity study with the biocidal product is not available and exposure by inhalation cannot be excluded. Therefore, labelling with EUH071 is appropriate and will overrule the labelling with H335. Since the 20 % in-use dilution of Sinesto B is classified as Skin Corr. 1 based on a pH ≥ 11.5, labelling with EUH071 would also be required for this dilution.
Classification of the product according to CLP	STOT SE 3 EUH071

3.6.2.4 Skin sensitisation

Table 33

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Exposure duration, Route of exposure**	**Results, Proportion of sensitised animals at induction dose, Evidence for local or systemic toxicity**	**Remarks**	**Reference**
OECD 406 (GPMT) GLP: No information Reliability: 2	Guinea Pig Hartley/Dunkin Female Test group: 20 animals Control group: 20 animals	Sinesto B Vehicle: water Induction: Intradermal 0.25 % Topical: 5 % Challenge: 0.5 %; 1 %	Test group 0.5 % 24 h: 1 / 20 animals 48 h: 1 / 20 animals 1 % 24 h: 3 / 20 animals 48 h: 4 / 20 animals Control group 0.5 % 24 h: 1 / 20 animals 48 h: 2 / 20 animals 1 % 24 h: 1 / 20 animals 48 h: 4 / 20 animals According to the study report the observed effects are localised dermal reactions restricted to a small area of the challenge site and are not considerd to be related to an allergic reaction.	-	Report No.: 871692D/KKM 9/SS

Table 34

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin
Justification for the value/conclusion	Based on an *in vivo* study and confirmed by the known toxicological properties of the single components.
Classification of the product according to CLP	Classification is not required.

3.6.2.5 Respiratory sensitisation (ADS)

Table 35

Data waiving was acceptable for the following information requirements	
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 products or their components are not available.

Table 36

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract
Justification for the value/conclusion	The biocidal product does not contain any components that are known to have sensitising properties for the respiratory tract. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 37

Summary table of animal studies on acute oral toxicity						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Type of administration**	**Signs of toxicity**	**LD_{50}**	**Remarks**	**Reference**
OECD 401 GLP: No information Reliability: 2	Rat HC/CFY Remote Sprague-Dawley M / F 5 per per sex per group	Sinesto B No vehicle, undiluted 1.26 g/kg 1.60 g/kg 2.0 g/kg 3.2 g/kg 5.0 g/kg gavage	Mortality (m / f): 1.26 g/kg: 0 / 2 1.60 g/kg: 2 / 4 2.0 g/kg: 4 / 4 3.2 g/kg: 5 / 5 5.0 g/kg: 5 / 5 Signs of reaction (most common signs in all dose levels): pilo erection, abnormal body carriage, abnormal gait, lethargy, decreased respiratory rate, pallor of extremities, increased salivation	Male 1.7 g/kg bw Female: 1.4 g/kg bw Combined: 1.5 g/kg bw	-	Report No.: 83635D/KKM 5/AC

Table 38

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} (oral): 1500 mg/kg bw
Justification for the selected value	Based on an *in vivo* study.
Classification of the product according to CLP	Acute Tox. 4, H302

3.6.2.6.2 Acute toxicity by inhalation

Table 39

Data waiving was acceptable for the following information requirements	
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) 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 mixture 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.

Table 40

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} (inhalation): > 5 mg/L
Justification for the selected value	None of the components is classified for acute inhalation toxicity.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

3.6.2.6.3 Acute toxicity by dermal route

Table 41

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area,**	**Signs of toxicity**	**LD_{50}**	**Remarks**	**Reference**
OECD 402 GLP: No information Reliability: 2	CD-Rat M / F 5 per per sex and per group	Sinesto B No vehicle, undiluted Occlusive dressing 2000 mg/kg bw 1/10 of total body surface	No mortality No clinical signs of systemic reaction Dermal changes: Skin irritation reactions in all animals, reversible in male rats latest until day 6, in female rats latest until day 12	> 2000 mg/kg bw	-	Report No.: 87734D/KKM 8/AC

Table 42

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} (dermal): > 2000 mg/kg bw
Justification for the selected value	Based on an *in vivo* study. and confirmed by the additivity approach according to Regulation (EC) No. 1272/2008.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.6.2.7 Information on dermal absorption

Table 43

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	Studies with the biocidal product or comparable formulations are not available. In accordance to Regulation (EU) No 528/2012 and the corresponding guidance documents experimental data on dermal absorption is not required if default values can be applied.

Table 44

Value(s) used in the Risk Assessment – Dermal absorption		
Substance exposure scenarios	Undiluted corrosive product and corrosive in-use dilutions	Non-corrosive dilutions, dried residues
Value(s)	100 %	50 %

Value(s) used in the Risk Assessment – Dermal absorption		
Justification for the selected value(s)	Default for corrosive substances (TAB, version 2.0, 2018 – TOX 21)	Default for aqueous dilutions and solids according to EFSA Guidance on Dermal Absorption (2017)
Note	According to the CAR of ATMAC/TMAC (2016), based on a read-across approach from 1.85 % DDAC in water, estimated worst-case dermal absorption of 10 % at non-corrosive concentrations have been agreed for the representative product. The biocidal product Sinesto B and its in-use dilutions are classified for either skin corrosion or irritation. However, since no systemic risk characterisation for ATMAC/TMAC is required, dermal absorption of the active substance is not relevant.	

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

3.6.2.8.1 Sodium hydroxide (CAS-Nr. 1310-73-2)

Classification	
According to Annex VI of Regulation (EC) No 1272/2008	Skin Corr. 1A, H314 Eye Damage 1 SCL: Skin Corr.1A for concentration of NaOH: ≥ 5 % and Skin Corr. 1B for concentration range of NaOH: ≥ 2 % - < 5 %) Skin Irrit. 2, H315 for concentration range of NaOH: ≥ 0.5 %- < 2 %) Eye Irrit. 2, H319 for concentration range of NaOH: ≥ 0.5 %-< 2 %)

3.6.2.8.2 Sodium 2-ethylhexanoate (CAS-Nr. 19766-89-3)

Classification	
According to RAC opinion CLH-O-0000006817-63-01/F	Repr. 1B, H360D
According to the SDS submitted by the applicant	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Please note that the classification of the SoC changed during assessment. The biocidal product is classified as Repro 1B already due to the active substance concentration. Nevertheless, we asked the applicant to give further information on the necessity of the SoC in the formulation. Please find further information in the confidential annex, chapter 2.2

Threshold Limits and other Values for Human Health Risk Assessment

Summary			
	Value	**Source**	**AF**
Workers, systemic effect **inhalation route, long-term**	14 mg/m³	Reach Registration dossier: 01-2119972937-17 01-2119979083-31	12.5
Workers, systemic effects **dermal route, long-term**	2 mg/kg bw/day	Reach Registration dossier: 01-2119972937-17 01-2119979083-31	50
General Population, systemic effect **inhalation route, long-term**	3.5 mg/m³	Reach Registration dossier: 01-2119972937-17 01-2119979083-31	25
General Population, systemic effects **dermal route, long-term**	1 mg/kg bw/day	Reach Registration dossier: 01-2119972937-17 01-2119979083-31	100
General Population, systemic effects **oral route, long-term**	1 mg/kg bw/day	Reach Registration dossier: 01-2119972937-17 01-2119979083-31	100

DNELs are based on experimental data obtained with 2-ethylhexanoic acid rather than its sodium salt and default assessment factors in accordance with REACH Guidance were applied. Read-across of this information to the sodium salt as performed in the REACH dossier is supported and in agreement with the read-across assessment framework, RAAF (ECHA 2017). Scenario 1: „(bio)transformation to common compound(s), analogue approach“ is considered applicable as both the acid and the salt will lead to the same acid/base ratio at a given pH. DNEL values for 2-ethylhexanoic acid were confirmed during substance evaluation by Spain

Remark: DNEL dermal values were derived from toxicity studies performed through the oral route. No reduction of the default route-to-route extrapolation factor of 1 was applied in the absence of suitable toxicokinetic data. Nevertheless, it appears likely that the dermal absorption is not higher than the oral absorption and may even be less.

Refer to the Confidential Annex.

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

According to Annex VI of Regulation (EC) No 1272/2008 (17th ATP), the active substance disodium tetraborate pentahydrate is classified as Repr. 1B, H360FD. The substance of concern sodium 2-

ethylhexanoate is classified as Repr. 1B, H360D according to RAC opinion CLH-O-0000006817-63-01/F. Based on these classifications, the corresponding generic concentration limit of 0.3 % for mixtures and the respective substance concentrations of 3.97 % and 26 % in the biocidal product, classification of the product as Repr. 1B, H360FD is required.

3.6.2.11 Endocrine disrupting properties

No component of the biocidal product was identified as an ED in accordance with Article 57(f) and Article 59 (1) REACH or in any EU decision.

There are no data indicating that any component of the biocidal product may have endocrine disrupting properties based on the existing knowledge and the available scientific information (SDS, ECHA). The biocidal product contains sodium 2-ethylhexanoate classified as Repr. 1B, H360D. The corresponding acid has been evaluated in context of the CoRAP by ES. The substance evaluation report concludes that the substance has CMR properties. However, it does not contain any specific information on potential endocrine-disrupting properties. Therefore, the co-formulants are not considered to have endocrine disrupting properties. For details refer to the Confidential Annex section 3.

3.6.2.12 Summary of effects assessment

Table 45

Endpoint	Brief description
Skin corrosion and irritation	Based on an in vivo study and confirmed on available toxicological information for the single components the biocidal product is classified with Skin Corr. 1, H314.
Eye irritation	Based on the in vivo skin corrosion study and confirmed on available toxicological information for the single components the biocidal product is classified with Eye Dam. 1.
Respiratory tract irritation	Based on the available toxicological information for the single components the biocidal product is classified with STOT SE 3. However, based on the classification of the biocidal product as Skin Corr.1, H314 and potential inhalation exposure, labelling with EUH071 is required.
Skin sensitisation	Based on an in vivo study and confirmed by available toxicological information for the single components the biocidal product is not classified for skin sensitisation.
Respiratory sensitization (ADS)	Based on the available toxicological information for the single components the biocidal product is not classified for respiratory sensitisation.
Acute toxicity by oral route	Based on an in vivo study and confirmed on available toxicological information for the single components the biocidal product is classified with Acute Tox. 4, H302.
Acute toxicity by inhalation	Based on the available toxicological information for the single components the biocidal product is not classified for acute inhalation toxicity.
Acute toxicity by dermal route	Based on an in vivo study and confirmed by available toxicological information for the single components the biocidal product is not classified for acute dermal toxicity.
Information on dermal absorption	Corrosive undiluted formulation: 100 % (Default for corrosive substances)

Endpoint	Brief description
	Non-corrosive dilutions of the formulation: 50 % (EFSA Guidance, 2017)
Available toxicological data relating to non-active substances	Refer to the Confidential Annex.
Available toxicological data relating to a mixture	Not relevant.
Other relevant information	Based on the concentration and the classification of disodium tetraborate pentahydrate (Repr. 1B, H360FD) and the SoC sodium 2-ethylhexanoate (Repr. 1B, H360D), the biocidal product, has to be classified as Repr. 1B, H360FD.

3.6.3 Exposure assessment

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

Table 46

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	Yes	Yes	n.a.	Yes	Yes	Yes	n.a.
Dermal	Yes	Yes	n.a.	Yes	Yes	Yes	n.a.
Oral	N.a.	N.a.	n.a.	N.a.	N.a.	Yes	Yes

List of scenarios

Table 47

Summary table: scenarios				
Use	**Scenario number**	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1	1	Immersion (fully automated dipping)	Primary exposure of workers resulting from mixing and loading, fully automated dipping processes in industrial scale treatment units entailing cycles of loading, waiting, unloading and removal of treated timber to storage and maintenance work.	Professional user Industrial user
2	2	Immersion (automated dipping)	Primary exposure of workers resulting from mixing and loading, automated dipping processes in industrial scale treatment units entailing cycles of loading, waiting, unloading and removal of treated timber to storage and maintenance work.	Professional user Industrial user
3	3	Deluge treatment	Primary exposure of workers resulting from mixing and loading, deluge processes in industrial scale treatment units entailing loading, waiting, unloading and removal of treated timber to storage and maintenance work.	Professional user Industrial user
1-3	All applications/ 4	Secondary exposure: Mechanical processing of preventively treated wood	Secondary exposure of workers resulting from mechanical processing of treated wood, i.e. sawing or sanding preventively treated wood.	Professional user

	5	Post application	Secondary acute exposure, adult - sanding treated wood, inhalation and dermal exposure	General public
	6	Post application	Secondary acute exposure, toddler – chewing/mouthing treated wood off-cut, oral exposure	General public
	7	Post application	Secondary long-term exposure, toddler - inhalation of volatilised residues indoors, inhalation exposure	General public
	8	Post application	Secondary long-term exposure, toddler - playing on treated structure and mouthing of hands, dermal and oral exposure	General public

3.6.3.1.1 Industrial exposure

The exposure assessments for industrial uses are described in chapter 3.6.3.1.2

3.6.3.1.2 Professional exposure

Sinesto B is a water-based liquid wood preservative. It is applied for deluge treatment, immersion (fully automated and 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 B is a concentrate wood preservative containing the active substances “Disodium tetraborate pentahydrate” (CAS-No.: 12179-04-3, 3.97 % w/w) (calculated as boron) and “Quaternary ammonium compounds, coco alkyltrimethyl, chlorides” (CAS-No.: 61789-18-2, 14.00 % w/w).

The biocidal product also contains the SoC Sodium 2-ethylhexanoat (CAS-No.: 19766-89-3, 26.00 % w/w) and the SoC sodium hydroxide (CAS-No.: 1310-73-2, 0.8 % w/w).

The biocidal product is marketed in different package sizes: 1000 L IBC (HDPE), 600 L IBC (HDPE), 30 L canister (HDPE)

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 Annex 4.3.1, the details of the exposure calculations to the a.s./SoC for the professional user are laid out.

All of the results for the a.s. containing boron are expressed as boron equivalents, using conversion factors for disodium tetraborate pentahydrate of 0.148 (see CAR disodium tetraborates, Doc. IIB, RMS NL, June 2008).

- **Scenario 1 – Immersion (fully automated dipping)**

Description

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 2 the fully automated dipping.

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 job entails a cycle of loading, waiting, unloading and removal of treated timber to storage.

Since Sinesto B 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 B. 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.

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)* – is used for the Tier 2 assessment.
“The biocidal product mus 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.
It can be assumed that the post-application phase is not carried out daily and also cannot be carried out if the normal number of application cycles are carried out. For the reasons the exposure is not to be considered combined.

Exposure by inhalation

According to the Human Exposure Expert Group (HEEG) opinion mentioned above, inhalation exposure to aerosols can be considered negligible.

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.

Table 48

Details of Scenario 1 – Immersion (fully automated dipping)		
	Parameters	Value
Tier 1 (automated dipping)	Concentration of a.s. Disodium tetraborate pentahydrate in b.p.	3.97 %
	Concentration of a.s. "Quaternary ammonium compounds, coco alkyltrimethyl, chlorides" in b.p.	14.00 %
	Concentration of SoC Sodium 2-ethylhexanoat in b.p.	26.00 %
	Concentration of b.p. in application liquid	8 %
	Density of the b.p.	1.0758 g/cm³ (20 °C)
	Number of dipping cycles performed per day	4
	Application duration per cycle	30 min
	Indicative value hand exposure (actual)	1080 mg/event
	Indicative value body exposure (potential)	8570 mg/event
	Protective gloves (EN 374, only during application and post-application phase)	Actual exposure values
Tier 2 (fully automated dipping)	Technical protection factor	4
	Protective gloves (EN 374)	10% penetration
	Protective coverall (type 6, EN 13034)	10% penetration

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 52.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR.
For risk characterisation, see chapter 3.6.4.

Further information and considerations

The classification of the b.p. and the application liquid require additional assessment of local risks (see chapter 3.6.4.5 Risk for professional users). 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.

- **Scenario 2 – Immersion (automated dipping)**

Description

Please refer to scenario 1 "Fully automated dipping". This scenario is basically identical to scenario 2 "Automated dipping", but in scenario 2 there is no reduction of exposure by factor 4 (Tier 2), as the process is not fully automated.

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., hHowever 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.

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.
It can be assumed that the post-application phase is not carried out daily and also cannot be carried out if the normal number of application cycles are carried out. For the reasons the exposure is not to be considered combined.

Exposure by inhalation

According to the Human Exposure Expert Group (HEEG) opinion mentioned above, inhalation exposure to aerosols can be considered negligible.

Exposure to the eyes

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

Table 49

Details of Scenario 2 – Immersion (automated dipping)		
	Parameters	Value
Tier 1 (automated dipping)	Concentration of a.s. Disodium tetraborate pentahydrate in b.p.	3.97 %
	Concentration of a.s. "Quaternary ammonium compounds, coco alkyltrimethyl, chlorides" in b.p.	14.00 %
	Concentration of SoC Sodium 2-ethylhexanoat in b.p.	26.00 %
	Concentration of b.p. in application liquid	8 %
	Density of the b.p.	1.0758 g/cm³ (20 °C)
	Number of dipping cycles performed per day	4
	Application duration per cycle	30 min
	Indicative value hand exposure (actual)	1080 mg/event
	Indicative value body exposure (potential)	8570 mg/event
	Protective gloves (EN 374, only during application and post-application phase)	Actual exposure values
Tier 2 (automated dipping)	Protective gloves (EN 374)	10% penetration
	Protective coverall (type 6, EN 13034)	10% penetration

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 52.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR.
For risk characterisation, see chapter 3.6.4.

Further information and considerations

The classification of the b.p. and the application liquid require additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). 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.

- **Scenario 3 – Deluge treatment**

Description

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 B is a concentrated wood preservative which has to be diluted prior to application.

For deluge treatment, Sinesto B 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.

Table 50

Details of Scenario 3 – Deluge treatment		
	Parameters	Value
Tier 1	Concentration of a.s. Disodium tetraborate pentahydrate in b.p.	3.97 %
	Concentration of a.s. "Quaternary ammonium compounds, coco alkyltrimethyl, chlorides" in b.p.	14.00 %
	Concentration of SoC Sodium 2-ethylhexanoat in b.p.	26.00 %
	Concentration of b.p. in application liquid	20 %
	Density of the b.p.	1.0758 g/cm³ (20 °C)
	Number of dipping cycles performed per day	2
	Application duration per cycle	30 min
	Indicative value hand exposure (actual)	25.7 mg/min
	Indicative value body exposure (potential)	178 mg/min
	Protective gloves (EN 374, only during application and post-application phase)	Actual exposure values
Tier 2	Technical protection factor	2 (treated wood automatically piled up, transportation by forklift truck)
	Protective gloves (EN 374)	10% penetration
	Protective coverall (type 6, EN 13034)	10% penetration

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 52.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR.
For risk characterisation, see chapter 3.6.4.

Further information and considerations

The classification of the b.p. and the application liquid require additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). 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.

- **Scenario 4 – Secondary exposure of professionals**

Description
Secondary exposure due to mechanical processing of treated wood produced by 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.

Table 51

Details of Scenario 4 – Secondary exposure of professionals		
	Parameters	Value
Tier 1	Concentration of a.s. Disodium tetraborate pentahydrate in b.p.	3.97 %
	Concentration of a.s. "Quaternary ammonium compounds, coco alkyltrimethyl, chlorides" in b.p.	14.00 %
	Concentration of SoC Sodium 2-ethylhexanoat in b.p.	26.00 %
	Application amount b.p.	12 g/m^2
	Concentration b.p. in treated wood surface*	6 kg/m^3
	Hand area: palms of both hands	410 cm^2
	Contaminated hand surface**	40 %
	Exposed hand area	164 cm²
	Transfer coeffizient	1**
Tier 2	-/-	-/-

* assumed penetration depth (outer layer): 0.002 m; expert judgement
** No specific transfer coefficient has been included in the calculation

Calculations
The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 52.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR.
For risk characterisation, see chapter 3.6.4.

Further information and considerations
The classification of the b.p. and the application liquid requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). Local risk assessment has indicated a risk to the skin of the hands, thus protective gloves are required.

- **Summary of professional exposure**

For the active substance disodium tetraborate pentahydrate and the SoC Sodium 2-ethylhexanoate, the scenarios described here include all phases of application (mixing and loading, application and post-application).

Table 52

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.					
Exposure scenario	**Tier/RMM**	**Disodium tetraborate pentahydrate**		**Sodium 2-ethylhexanoate**	
		Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**	**Estimated external inhalation exposure [mg/m³]**	**Estimated external dermal exposure [mg/day]**
Scenario 1[3)]: Fully automated dipping (use 1)	Tier 1: • Automatic dosing system • Protective gloves (EN 374; application and post-application)	Not expected, no aerosol	Daily: 18.25[4)] Weekly: 4.55[4)]	Not expected, no aerosol	Daily: 805.45 Weekly: 200.72
	Tier 2: • Protective gloves (EN 374; mixing & loading) • Protective coverall (type 6, EN 13034 • Fully automated immersion system	Not expected, no aerosol	Daily: 0.92[4)] Weekly: 0.91[4)]	Not expected, no aerosol	Daily: 40.55 Weekly: 40.29
Scenario 2[3)]: Automated dipping (use 2)	Tier 1: • Automatic dosing system • Protective gloves (EN 374; application and post-application)	Not expected, no aerosol	Daily: 18.25[4)] Weekly: 4.55[4)]	Not expected, no aerosol	Daily: 805.45 Weekly: 200.72
	Tier 2: • Protective gloves (EN 374; mixing & loading) • Protective coverall (type 6, EN 13034	Not expected, no aerosol	Daily: 3.66[4)] Weekly: 0.91[4)]	Not expected, no aerosol	Daily: 161.42 Weekly: 40.29
Scenario 3[3)]: Deluge treatment (use 3)	Tier 1: • Automatic dosing system • Protective gloves (EN 374; application and post-application)	1.47×10^{-4} [4)]	14.46[4)]	6.50×10^{-3}	638.12
	Tier 2: • Protective gloves (EN 374; mixing & loading) • Protective coverall (type 6, EN 13034 • Treated wood gets automatically piled up;	1.47×10^{-4} [4)]	1.54[4)]	6.50×10^{-3}	68.12

	transportation by forklift truck [1)]				
Scenario 4[2, 3)]: Mechanical processing of treated wood (all uses)	Tier 1: No RMM	$1.77x10^{-4}$ [4)]	1.16[4)]	$7.80x10^{-3}$	51.17
	Tier 2: No RMM	$1.77x10^{-4}$ [4)]	1.16[4)]	$7.80x10^{-3}$	51.17

1) Since the intensive dermal contact during the manual handling of treated wood significantly contributes to the total dermal exposure, it is assumed that the timber is automatically piled up and transported to storage by installed technical devices where manual handling only occasionally occur. Consequently, a reduced dermal exposure is expected for the application phase.

2) According to the calculation performed in Tier 1, additional protective equipment is not necessary; a risk for professional users is unlikely.

3) For all relevant RMM (based on the local and systemic risk assessment) see chapter 2.5.2.

4) Expressed as boron

- **Combined scenarios**

The product is intended for industrial use. It is therefore considered that the further processing of the treated wood is not carried out by the same worker or bystander. A combination of the scenarios is consequently not necessary.

3.6.3.1.3 Non-professional exposure

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

3.6.3.1.4 Secondary exposure of the general public

The biocidal product Sinesto B is used with a maximum application rates of 12 g/m^2, which is considered as the worst-case for the risk assessment of the general public.

The concentration of 3.97 % disodium tetraborate pentahydrate is equivalent to 0.59 % boron. Exposure values are reported as boron.

For sodium 2-ethylhexanoate, the estimated exposure was compared to a DNEL. DNELs are external exposure values, for which dermal absorption is not relevant. In the dermal exposure estimates, it is therefore set to 100 %.

A systemic exposure and risk assessment is performed for the active substance disodium tetraborate pentahydrate and the substance of concern sodium 2-ethylhexanoate. For the active substance ATMAC/TMAC, systemic reference values are not available. The observed systemic effects can be considered secondary in comparison to the local ones. Therefore, the AEL approach is not performed for this substance. A local exposure assessment for ATMAC/TMAC, based on the same scenarios as for systemic exposure assessment, is performed and included after the section on systemic exposure assessment.

- **Scenario 5**

Table 53

Description of Scenario 5
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 4 (refer to Table 77 and Table 78 in section 3.6.4.5).

Calculations for Scenario 5

refer to scenario 4

Disodium tetraborate pentahydrate as boron

$Exposure_{dermal}$ = 0.00483 mg a.s./kg bw

$Exposure_{inhalation}$ = 0.00003 mg a.s./kg bw

Total systemic exposure = 0.00486 mg a.s./kg bw

Sodium 2-ethylhexanoate

$Exposure_{dermal}$ = 0.40 mg SoC/kg bw

$Exposure_{inhalation}$ = 0.0006 mg SoC/kg bw

Total systemic exposure = 0.40 mg SoC/kg bw

- **Scenario 6**

Table 54

Description of Scenario 6		
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.		
	Parameters	Value
Tier 1	Application rate (applicant)	12 g/m^2
	Concentration a.s. and SoC (applicant)	Disodium tetraborate penta-hydrate as boron: 0.59 % (w/w) Sodium 2-ethylhexanoate: 26 % (w/w)

	Concentration a.s. and SoC on the treated wood (application rate x density x concentration a.s. or SoC in the b.p.)	Disodium tetraborate penta-hydrate as boron: 0.00708 mg a.s./cm^2 Sodium 2-ethylhexanoate: 0.312 mg a.s./cm^2
	Dimension of the wood off-cut (TNsG Human Exposure to Biocidal Products (2002) Part 3, Infant acute, Chewing wood off-cut)	4 cm x 4 cm x 1 cm = 16 cm^3
	Total amount a.s. and SoC in the treated wood off-cut (= a.s. or SoC in the treated wood x volume of wood off-cut)[1)]	Disodium tetraborate penta-hydrate as boron: 0.11328 mg a.s. Sodium 2-ethylhexanoate: 4.992 mg
	Extraction coefficient (TNsG Human Exposure to Biocidal Products (2002) Part 3)	10 %
	Oral absorption (CAR/AR, default for a.s.)	100 %
	Body weight, toddler (HEAdhoc Recommendation No.14, 2017)	10 kg

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

Calculations for Scenario 6

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

Disodium tetraborate pentahydrate as boron

$Exposure_{oral}$ = 0.11328 mg a.s. x 10 % x 100 % / 10 kg

= 0.00113 mg a.s./kg bw

Sodium 2-ethylhexanoate

$Exposure_{oral}$ = 4.992 mg SoC x 10 % x 100 % / 10 kg

= 0.04992 mg SoC/kg bw

- **Scenario 7**

Table 55

Description of Scenario 7		
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.		
Tier 1	Parameters	Value
	Molecular weight Disodium tetraborate pentahydrate (CAR/AR, 2009)	291.3 g/mol
	Vapour pressure Disodium tetraborate pentahydrate (20 °C, CAR/AR, 2009)	> 0.00001 Pa
	Molecular weight Sodium 2-ethylhexanoate (ECHA registration dossier)	167.2 g/mol
	Vapour pressure Sodium 2-ethylhexanoate (20 °C, ECHA registration dossier)	0.000001 Pa
	Gas constant (Atkins Physical Chemistry, 5th Edition)	8.31451 J/mol/K
	Temperature (assumed room temperature = 20 °C HEEG opinion No. 13, 2011)	293 K
	Saturated vapour pressure (calculated acc. to HEEG opinion No. 13, 2011)	Disodium tetraborate penta-hydrate: < 1.196×10^{-3} mg/m³ Sodium 2-ethylhexanoate: 6.863×10^{-5} mg/m³
	Exposure duration (worst case, HEEG opinion No. 13, 2011)	24 h
	Inhalation rate, toddler (HEAdhoc Recommendation No.14, 2017, long-term exposure)	8 m³/24 h
	Inhalation absorption (CAR/AR of all a.s., default)	100 %
	Body weight, toddler (HEAdhoc Recommendation No.14, 2017)	10 kg

Calculations for Scenario 7

Systemic exposure

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

Disodium tetraborate pentahydrate

$Exposure_{inhalation}$ = 1.196×10^{-3} mg/m³ x 8 m³/d x 1 d x 100 % / 10 kg

= 0.000957 mg a.s./kg bw/d

As boron:

= 0.000142 mg a.s./kg bw/d

Sodium 2-ethylhexanoate

$Exposure_{inhalation}$ = 6.863 x 10^{-5} mg/m^3 x 8 m^3/d x 1 d x 100 % / 10 kg

= 0.000055 mg SoC/kg bw/d

- **Scenario 8**

Table 71

Description of Scenario 8		
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.		
	Parameters	Value
Tier 1	Application rate (applicant)	12 g/m^2
	Concentration a.s. and SoC (applicant)	Disodium tetraborate pentahydrate as boron: 0.59 % (w/w) Sodium 2-ethylhexanoate: 26 % (w/w)
	Amount a.s. available on wood surface for transfer to skin (Application rate x concentration a.s. or SoC)	Disodium tetraborate pentahydrate as boron: 0.00708 mg a.s./cm^2 Sodium 2-ethylhexanoate: 0.312 mg SoC/cm^2
	Hand surface (toddler, palms of both hands, HEAdhoc Recommendation No. 5, 2015)	115.2 cm^2
	Proportion of palms of hand in contact with the b.p., percentage contaminated skin (HEAdhoc Recommendation No. 5, 2015)	40 %
	Transfer coefficient of biocidal product from dried b.p. to hand (HEAdhoc recommendation No. 5, 2015)	3 %
	Transfer coefficient of paint from hand to mouth for dried paint (HEAdhoc Recommendation No. 5, 2015, based on Pest Control Products Fact Sheet, 2.2.7, 2006)	50 %
	Dermal absorption for disodium tetraborate pentahydrate (default for a.s., EFSA Guidance on Dermal Absorption, 2017)	50 %
	Dermal absorption for sodium 2-ethylhexanoate (see above)	100 %

	Oral absorption (CAR/AR)	100 %
	Body weight, toddler (HEAdhoc Recommendation No.14, 2017)	10 kg

Calculations for Scenario 8

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

Disodium tetraborate pentahydrate as boron

$Exposure_{dermal}$ = 0.00708 mg a.s./cm^2 x 115.2 cm^2 x 3 % x 40 % x 50 % / 10 kg
= 0.000489 mg a.s./kg bw/d

$Exposure_{oral}$ = 0.00708 mg a.s./cm^2 x 115.2 cm^2 x 3 % x 40 % x 50 % x 100 % / 10 kg
= 0.000489 mg a.s./kg bw/d

Total systemic exposure = 0.000979 mg a.s./kg bw/d

Sodium 2-ethylhexanoate

$Exposure_{dermal}$ = 0.312 mg SoC/cm^2 x 115.2 cm^2 x 3 % x 40 % x 100 % / 10 kg
= 0.04313 mg SoC/kg bw/d

$Exposure_{oral}$ = 0.312 mg SoC/cm^2 x 115.2 cm^2 x 3 % x 40 % x 50 % x 100 % / 10 kg
= 0.02157 mg SoC/kg bw/d

Total systemic exposure = 0.06470 mg SoC/kg bw/d

Table 56 Disodium tetraborate pentahydrate as boron

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw(/d)]**	**Estimated dermal uptake [mg/kg bw(/d)]**	**Estimated oral uptake [mg/kg bw(/d)]**	**Estimated total uptake [mg/kg bw(/d)]**
Scenario [5]	1	0.00003	0.00483	-	0.00486
Scenario [6]	1	-	-	0.001133	0.001133
Scenario [7]	1	0.000142	-	-	0.000142
Scenario [8]	1	-	0.000489	0.000489	0.000979

Table 57 Sodium 2-ethylhexanoate

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw(/d)]**	**Estimated dermal uptake [mg/kg bw(/d)]**	**Estimated oral uptake [mg/kg bw(/d)]**	**Estimated total uptake [mg/kg bw(/d)]**
Scenario [5]	1	0.0006	0.40	-	0.40
Scenario [6]	1	-	-	0.04992	0.04992
Scenario [7]	1	0.00005	-	-	0.00005
Scenario [8]	1	-	0.04313	0.02157	0.06470

Local Exposure Assessment for ATMAC/TMAC

- **Scenario 5**

Table 58

Description of Scenario 5
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 4 (refer to Table 79 in section 3.6.4.5

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 = 0.21 %

- **Scenario 6**

Table 59

Description of Scenario 6
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 B is identical. 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.'*

Using the same approach for the biocidal product, the same active substance concentration in saliva is expected for the bicodal product:

Concentration of ATMAC/TMAC in saliva =0.04 mg/ml = 0.004 %

- **Scenario 7**

Table 60

Description of Scenario 7		
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”.		
Tier 1	Parameters	Value
	Molecular weight ATMAC/TMAC (CAR/AR, 2016)	273 g/mol (273000 mg/mol)
	Vapour pressure ATMAC/TMAC (20°C, CAR/AR, 2016)	0.0000018 Pa
	Gas constant (Atkins Physical Chemistry, 5th Edition)	8.31451 J/mol/K
	Temperature (assumed room temperature = 20°C HEEG opinion No. 13, 2011)	293 J/mol/K

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/m^3

- **Scenario 8**

Table 61

Description of Scenario 8
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

- **Combined scenarios**

Table 62 Disodium tetraborate pentahydrate as boron

Summary table: combined systemic exposure of the general public				
Scenarios combined	**Estimated inhalation uptake [mg/kg bw(/d)]**	**Estimated dermal uptake [mg/kg bw(/d)]**	**Estimated oral uptake [mg/kg bw(/d)]**	**Estimated total uptake [mg/kg bw(/d)]**
Scenarios 7 + 8	0.000142	0.000489	0.000489	0.00112

Table 63 Sodium 2-ethylhexanoate

Summary table: combined systemic exposure of the general public				
Scenarios combined	**Estimated inhalation uptake [mg/kg bw(/d)]**	**Estimated dermal uptake [mg/kg bw(/d)]**	**Estimated oral uptake [mg/kg bw(/d)]**	**Estimated total uptake [mg/kg bw(/d)]**
Scenarios 7 + 8	0.00005	0.04313	0.02157	0.06475

3.6.3.2 Dietary exposure

Table 64

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	Coco alkyltrimethylammonium chloride (ATMAC/TMAC) Disodiumtetraborate pentahydrate
Type of formulation	soluble concentrate
Substance(s) of concern	Natrium-2-ethylhexanoat (CAS-Nr. 19766-89-3) Natriumhydroxid (CAS-Nr. 1310-73-2)
Field(s) of use	Temporary preventive protection of fresh timber, fresh sawn timber and timber used for wooden pallets in areas with temperate or tropical climate, during seasoning, storage and transport
Target organism(s)	Wood discolouring fungi Sapstain fungi (hyphae) Mould fungi (hyphae)
Application rate(s) and frequency	one-time dipping or spray application at application rate of 5 - 12 g biocidal product/m^2 depending upon duration of the required protection as well as on timber species and local conditions maximal application rate of 12 g /m^2 corresponds to ▪ ATMAC/TMAC: 1.680 g a.s./m^2 = 0.168 mg a.s./cm^2 ▪ disodium tetraborate pentahydrate: 0.476 g/m^2 = 0.048 mg a.s./cm^2 (corresponding to 0.071 g boron /m^2

Intended use(s) (critical application with regard to dietary exposure)	
	= 0.007 mg boron /cm^2); ▪ sodium 2-ethylhexanoat: 3.12 g /m^2 = 0.312 mg /cm^2
Category(ies) of users	industrial
Waiting periods after treatment	none
Further information	Applicants dossier - Proposed risk mitigation measure in section 2.1.6.2 (p. 14): Timber destined to direct contact with food and feeding stuffs must not be treated with the preservative. - Information given in section 2.2.5.2.2.1 (p. 80): The product Sinesto B will not be used for impregnation of animal stables despite of constructional wood like roof beams. The treatment of animal boxes is excluded. ... The only problem sometimes experienced in use is chewing on wood used for paddocks.

Representative dietary exposure scenarios

Critical scenarios with respect to consumer dietary intake for the biocidal product Sinesto B are presented in the following table. They have been selected based on the information on the intended uses given in Table 64.

Table 65

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
Livestock exposure			
1.	animal husbandry	chewing on wood used for paddocks*	livestock species that are kept on paddocks and may engage in chewing on wood, e.g. horses, goats**
Transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)			
2.	food storage and transport	residue transfer into food from wooden pallets intended for transport and storage of packaged food	packaged food

* Note: This use is not explicitly mentioned in the intended uses. However in his dossier the applicant indicated that treatment of wood used for animal boxes is excluded, but “the only problem sometimes experienced is chewing on wood used for paddocks”. Therefore, the applicant provided an assessment for this scenario in his dossier and an evaluation of the scenario is included in this PAR.

** Relevant animal species for this scenario are not detailed in the Guidance on BPR Vol III Parts B+C. For the calculation model default values are only provided for horses and rabbits. The paddock scenario has therefore only been calculated for horses, while rabbits are considered less relevant.

3.6.3.2.1 General information on active substance(s)

Table 66

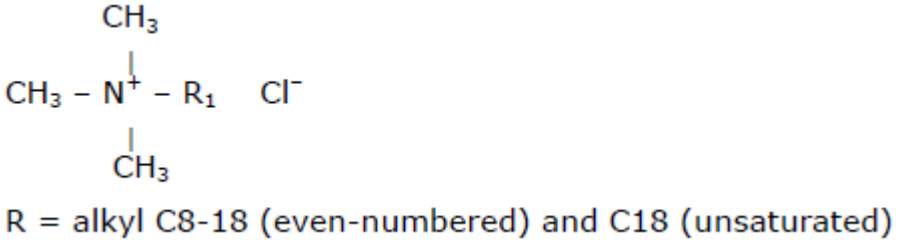
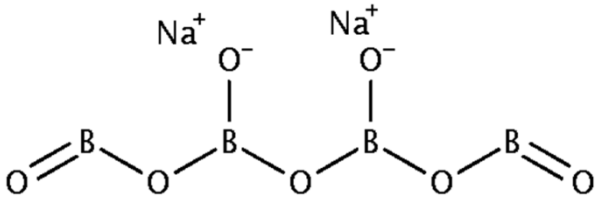
Active substance (Common Name)	Coco alkyltrimethylammonium chloride (ATMAC/TMAC)
CAS number	61789-18-2
Chemical structure	 R = alkyl C8-18 (even-numbered) and C18 (unsaturated)
Molecular formular	$C_{(n+3)}H_{(2n+10)}N.Cl$ (n = 8, 10, 12, 14, 16, 18) and $C_{21}H_{44}N.Cl$ (unsaturated C18)
Molar mass	207.8 – 348.1 g/mol (range corresponding to C8/C18)
Log Po/w	TMAC-Akzo Nobel Surface Chemistry AB: -0.17 (calculated, CAR)
Active substance approval	PT: 08; RMS: IT
Restrictions	BPC-Opinion (PT 8, 2016) Where use of the product may lead to contamination of food and feeding stuffs, an assessment of the risk in food and feed areas may be required at product authorisation. Analytical methods for residues in/on food and/or feedstuffs may be required, too.
Current regulations on MRLs	see Section 3.7.4.2. Maximum residue limits or equivalent

Table 67

Active substance (Common Name)	Disodiumtetraborate pentahydrate
CAS number	12179-04-3
Chemical structure	 (representing the anhydrous form)

Molecular formular	$Na_2B_4O_7.5H_2O$
Molar mass	291.296 g/mol
Log Po/w	n.a.
Active substance approval	PT: 08; RMS: NL
Restrictions	AR (PT8, 2009) (section 2.2.1.2., p. 11) The borates will be used as wood preservatives. The borates are not used on wood products that are used for food preparation or feeding stuff. Furthermore, finished wood products containing borates and manufactured for structural and building material are not appropriate to be used and would not be used to make products that would come in to contact with food or feeding stuff.
Current regulations on MRLs	see Section 3.7.4.2. Maximum residue limits or equivalent

3.6.3.2.1.1 Information of non-biocidal use of the active substance

- Information on the residue definitions is provided in chapter 3.6.4.2 (Maximum residue limits or equivalent).

Table 68

Summary table of other (non-biocidal) uses: ATMAC/TMAC			
	Sector of use	**Intended use**	**Reference value(s)**
1.	plant protection products	not approved for use in plant protection products Reg (EC) No. 2002/2076	default MRL of 0.01 mg/kg acc. to Art 18(1)(b) Reg 396 / 2005 (Alkyltrimethyl ammonium chloride)
2.	cosmetics	preservative in cosmetic products	Reg (EC) No. 1223/2009, Annex V, No. 44 preservative allowed in cosmetic products at maximum concentration in ready-for-use preparation: 0.1 % (Alkyl (C12-22) trimethyl ammonioum bromide and chloride)

Table 69

Summary table of other (non-biocidal) uses: Disodiumtetraborate pentahydrate			
	Sector of use	**Intended use**	**Reference value(s)**
1.	plant protection products	not approved for use in plant protection products COM Decision No. 2004/129/EC	default MRL of 0.01 mg/kg acc. to Art 18(1)(b) Reg 396 / 2005 (Sodium tetraborate) co-formulant not accepted for inclusion in plant protection products Reg 1107/2009/EC, as amended by Regulation 2021/383/EU, 4 March 2021 Annex III No. 27
2.	veterinary medicine	preservative, antiseptic, water softener, pH adjuster, emulsifier, neutralizer, stabilizer, buffer or viscosifier	„No MRL required" entry in Reg. (EU) No. 37/2010
3.	food contact materials	not allowed for use in components of active and intelligent materials	Reg (EC) No. 450/2009/EC
4.	cosmetics	banned from use in any cosmetic products	Reg (EC) No. 1223/2009, Annex II, No. 1396
5.	Food additive	Authorised food additive E 285: use only on sturgeons´eggs (caviar)	Maximum limit 4 g/kg sturgeons´ eggs (caviar) Reg. (EC) No. 1129/2011

3.6.3.2.2 Nature of residues

- **Other information on active substance (degradation, metabolism, potential for accumulation etc)**

The applicant has provided a study analysing migration of Sinesto B constituents from treated wood into foods (summarized in the confidential Annex). In this context, also degradation of the active substances ATMAC/TMAC and disodium tetraborate pentahydrat under food storage conditions has been assessed.

In brief, wood splints spiked with the biocidal product Sinesto B were incubated under defined test conditions similar to those used in the framework of food contact materials. One set of two spiked wood samples was incubated at 60 °C for 10 days covering "long term storage above 6 months at room temperature and below" according to Reg. (EU) Nr. 10/2011. A second set of two spiked wood samples was incubated at 20 °C for 30 days which represented modified conditions following a preliminary test to represent 6 month storage at refrigerated and frozen conditions (see also explanations in the confidential Annex). After the indicated incubation time the spiked wood was extracted and ATMAC/TMAC residues were determined by LC-MS/MS, while sodium tetraborate pentahydrat was determined as boron via ICP-OES. Residue levels of ATMAC/TMAC and boron in unincubated control samples and in incubated

samples were then compared to conclude on degradation of the substances. An overview of degradation study results is given in the tables below.

Results of degradation study: ATMAC/TMAC (µg/g wood)					
Storage conditions	**Sample 1**	**Sample 2**	**Mean**	**st dev**	
day 0 (control)	2620	2962	2791	171	
10 days, 60°C	2701	3000	2851	150	
30 days, 60°C	2716	2695	2706	11	
RMS´ conclusion					
The study results indicate that no significant degradation of ATMAC/TMAC is observed during incubation at 20 °C for 30 days, while only minor degradation of ATMAC/TMAC on wood is observed at 60 °C for 10 days. Therefore, analysis of degradation products is not considered necessary for residues studies performed under the same conditions.					

Results of degradation study: Disodiumtetraborate pentahydrate (measured as boron in µg/g wood)					
Storage conditions	Sample 1	Sample 2	Mean	st dev	
day 0 (control)	139.8	133.2	136.5	3,30	
10 days, 60°C	119.1	123.1	121.1	2,00	
30 days, 60°C	137.8	130.6	134.2	3,60	
RMS´ conclusion					
In the degradation study the active substance disodiumtetraborate pentahydrate was analysed as boron. The study results indicate that boron levels on wood stored at 60 °C for 10 days and at 20 °C for 30 days do not significantly differ from boron levels in control wood samples without incubation. Therefore, analysis of degradation products is not required for residues studies performed under the same conditions.					

- **Conclusion and summary on nature of residues**

Table 70

Summary on the nature of residues: ATMAC/TMAC	
Hydrolytic stability (DT50) (state pH and temperature) as reported in AR Coco alkyltrimethylammonium chloride, PT8, eCA: IT, 2016	**ATMAC-Lonza Cologne GmbH**: No significant degradation was observed during the 33 day evaluation period. **TMAC-Akzo Nobel Surface Chemistry AB**: Hydrolytically stable
Photostability (DT50) (aqueous, sunlight, state pH) as reported in AR Coco alkyltrimethylammonium chloride, PT8, eCA: IT, 2016	**ATMAC-Lonza Cologne GmbH**: >30 days pH 7 **TMAC-Akzo Nobel Surface Chemistry AB**: Not applicable, no absorbance above 290 nm in UV spectrum

Summary on the nature of residues: ATMAC/TMAC	
Stability under food storage conditions (degradation study, confidential Annex)	The study results indicate that no significant degradation of ATMAC/TMAC on wood occurs at 60 °C for 10 days and at 20 °C for 30 days. Therefore analysis of degradation products is not required for residues studies performed under the same conditions.
Stability under standard hydrolysis conditions (Processed commodities)	not analysed
Animal metabolism	no information on livestock metabolism available
Existing plant residue definitions	not available
Existing animal residue definitions	not available
Conclusion on degradation of active substance under use conditions	Based on the results of the degradation study no significant degradation of the active substance ATMAC/TMAC under food storage conditions (relevant for food stored in wooden boxes and on wooden pallets) is expected.

Table 71

Summary on the nature of residues: Disodiumtetraborate pentahydrate	
Hydrolytic stability (DT50) (state pH and temperature) as reported in AR Disodiumtetraborate pentahydrate, PT8, eCA: NL, 2009	not determined as disodiumtetraborate pentahydrate is converted into boric acid upon dissolution in water
Photostability (DT50) (aqueous, sunlight, state pH) as reported in AR Disodiumtetraborate pentahydrate, PT8, eCA: NL, 2009	not determined
Stability under food storage conditions (degradation study, confidential Annex)	In the degradation study the active substance disodiumtetraborate pentahydrate was analysed as boron. The study results indicate that boron levels on wood treated with wood preservative and stored at 60 °C for 10 days and at 20 °C for 30 days do not significantly differ from boron levels in control wood samples not incubated. Therefore analysis of degradation products is not required for residues studies performed under the same conditions.
Stability under standard hydrolysis conditions (Processed commodities)	not analysed
Animal metabolism	no information on livestock metabolism available
Existing plant residue definitions	not available
Existing animal residue definitions	not available
Conclusion on degradation of active substance under use conditions	Based on the results of the degradation study no significant degradation of the active substance Disodiumtetraborate pentahydrate under food storage conditions (relevant for food in wooden boxes and on wooden pallets) is expected.

3.6.3.2.3 Estimating Livestock Exposure to Active Substances used in Biocidal Products

Description of scenarios

Wood (used as pasture fencepost) is treated with the biocidal product. Livestock animals (e.g. horses, goats) can be exposed orally by chewing on the wood.

Calculations for estimating external livestock exposure

- **Tier 1** (External exposure assessment for livestock animals (Calculations according to DRAWG Draft Proposal Guidance on Estimating Livestock Exposure to Biocidal Active Substances)

Table 72

Tier 1: Estimation of livestock exposure: Oral exposure by chewing wood		
In the absence of default values for other livestock species kept on paddocks livestock exposure is estimated for horses (Guidance on BPR, Vol. III Parts B+C, section 6.5.3.1). Parameters $c_{a.s., wood}$ Amount of active substance per m^3 calculated following the recommendations for human secondary exposure (wooden post with volume = 0.04 x 0.04 x 2.5 m^3 and assumption that all applied a.s. is located in the outer 1 cm layer)[e]: $c_{a.s., wood}$ (mg/m^3) = $c_{a.s., wood}$ (g/m^2) x 0.4032 m^2 / 0.003 m^3 maximal application rate of 12 g bp/m^2 corresponds to ATMAC/TMAC: 1.680 g a.s./m^2 = 225.792 g a.s./m^3 Disodium tetraborate pentahydrate (calculated as boron): 0.071 g a.s./m^2 = 9.542 g/m^3 I_{wood} Amount of wood consumed by horse: 1.9 x 10^{-5} m^3/d (ARTFood Guidance: wood consumption value based on one study only, not a confirmed default value) TF fraction of surface residues transferred from treated wood into/onto animal, transfer factor: 100 % (default) Abs_{oral} 100 % oral absorption (default) bw body weight: 400 kg (default horse) Calculation $Exp_{livestock} = c_{a.s., wood}$ [g/m^3] x 1000 mg/g x I_{wood} x TF x Abs_{oral}/ bw		
	ATMAC/TMAC	**Disodium tetraborate pentahydrate** (calculated as boron)
$c_{a.s., wood}$ [g a.s./cm^2]	1.680	0.071
$c_{a.s., wood}$ [g a.s./m^3]	225.792	9.542
Tier 1		
$Exp_{livestock}$ [mg a.s./kg bw]	0.0197	0.0005

Conclusion
ATMAC/TMAC The estimated external livestock exposure exceeds the trigger value of 0.004 mg/kg bw. Therefore a refined external exposure estimation is performed in Tier 2. **Disodium tetraborate pentahydrate** The trigger value of 0.004 mg/kg bw is not exceeded. Therefore no significant residues are expected in food of animal origin.

[e] TNsG Human Exposure to Biocidal Products, 2002; consideration of a wooden post of 2.5 m x 0.04 m x 0.04 m with a surface area of 0.4032 m^2 (=4x (2.5 m x 0.04 m) + 2x (0.04m x 0.04 m)) and the volume of the outer 1 cm layer of 0.003 m^3 (= 2x (2.5 m x 0.04m x 0.01m) + 2x (2.5 m x 0.02 m x 0.01 m) + 2x (0.02m x 0.02 m x 0.01 m)). Conversion of the application rate: $c_{a.s., wood}$ [g/m^3] = $c_{a.s., wood}$ [g/m^2] x 0.4032 m^2 / 0.003 m^3

- **Tier 2** (Refined external exposure estimate for livestock animals)

Table 73

Tier 2: Estimation of livestock exposure: Oral exposure by chewing wood		
External livestock exposure calculated as described in Tier 1. <u>Refinement</u> For refinement of the livestock exposure estimate for ATMAC/TMAC an oral absorption of Abs_{oral}/ = 10 % is applied for ATMAC/TMAC (AR, PT8, eCA: IT, 2016).		
	ATMAC/TMAC	**Disodium tetraborate pentahydrate** (calculated as boron)
$c_{a.s., wood}$ [g a.s./cm^2]	1.680	0.071
$c_{a.s., wood}$ [g a.s./m^3]	225.792	9.542
<u>Tier 1</u>		
$Exp_{livestock}$ [mg a.s./kg bw]	0.0197	0.0005
Tier 2		
Refined $Exp_{livestock}$ [mg a.s./kg bw] considering oral absorption	0.0020	no refinement necessary
Conclusion		
ATMAC/TMAC In Tier 2 the estimated external livestock exposure does not exceed the trigger value of 0.004 mg/kg bw. Considering the low oral absorption of ATMAC/TMAC (around 10 %)[a] and its rapid excretion, significant residues in food of animal origin from the application of the biocidal product Sinesto B on wooden materials used in animal husbandry are not expected. Accumulation in edible tissues and milk is not expected due to a Log Po/w below 3.		

[a] AR, ATMAC/TMAC PT8, eCA: IT, 2016

Conclusion on "Livestock chewing wood scenario"

External livestock exposure was estimated for the scenario "Oral exposure by chewing wood" resulting in values below the trigger value of 0.004 mg/kg bw for both active substances ATMAC/TMAC (Tier 2 calculation) and disodium tetraborate pentahydrate (calculated as boron, Tier 1 calculation). Consequently, significant residues of both active substances in food of animal origin are not expected. No further MRL assessment is considered necessary with regard to the application of the biocidal product Sinestro B on wooden materials used in animal husbandry.

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

Note: To date no finalised guidance on dietary exposure assessment for professional uses is available. In the dossier submitted by the applicant the scenario "storage and transport of fruits and vegetables in wooden boxes" has been evaluated using a calculation model previously used in the CAR for propiconazole (Doc IIIA 6.15, 2007, eCA: FI). However, as direct contact of food with treated wood is excluded via risk mitigation measures, the scenario of storage and transport of fruits and vegetables in wooden boxes is not relevant for the intended use of Sinesto B. Instead, the scenario "storage/transport of packaged food on wooden pallets" is more suitable as treatment of wooden pallets with Sinesto B is intended. This scenario is described in the ARTFood Draft Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses (https://echa.europa.eu/documents/10162/1094048/artfood_draft_prof_uses_en.pdf/77fef4bd-93b2-3407-3507-18db2b26b8ce?t=1646641163003). Even though this guidance has not been finalised yet, the RMS applied this approach in the absence of other guidance.

Description of scenarios

The biocidal product is a wood preservative for industrial use. In the intended use it is specified that treated wood may be used to manufacture pallets. In case treated pallets are used for transport and storage of food and feeding stuff indirect contact of treated wood with packaged food and/or feeding stuff may occur.

Calculations for estimating residue levels in food and consumer exposure

Wooden pallets: Estimation of residue transfer into food
Evaluation according to ARTFood Draft Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses Parameters $C_{a.s., surface}$ active substance concentration on wood surface [mg a.s./cm^2]

derived from maximal application rate of 12 g biocidal product/m^2
containing 14 % (w/w) ATMAC/TMAC, 3.97 % (w/w) disodium tetraborate pentahydrate (corresponding to 0.59 % (w/w) boron); 26 % (w/w) sodium 2-ethylhexanoat (SoC)
corresponding to
ATMAC/TMAC: 1.680 g a.s./m^2 = 0.168 mg a.s./cm^2
disodium tetraborate pentahydrate: 0.476 g/m^2 = 0.048 mg a.s./cm^2
(corresponding to 0.071 g boron /m^2 = 0.007 mg boron /cm^2);

TF fraction of surface residues transferred onto food, transfer factor: 10 % (default)

$A_{contact}$ contact surface of food with wooden pallet: 300 cm^2/kg food
(default assuming a food layer of 3.3 cm height)

I_{food} Consumption of packaged food: 1 kg/ person per day

bw human body weight, adult: 60 kg, toddler 10 kg

Calculation of residue concentration in food

$R_{food} = c_{a.s., surface} \times TF \times A_{contact}$

Calculation of consumer exposure

$Exp_{cons} = R_{food} \times I_{food} / bw$

	ATMAC/TMAC	Disodium tetraborate pentahydrate
$c_{a.s., surface}$ [mg a.s./cm^2]	0.168	disodium tetraborate pentahydrate 0.048 calculated as boron 0.007
R_{food} [mg a.s./kg]	5.040	disodium tetraborate pentahydrate 1.440 calculated as boron 0.213
Dietary exposure assessment		
Estimation of consumer exposure [mg/kg bw/d]	adult: 0.08400 toddler: 0.50400	disodium-tetraborate pentahydrate adult: 0.024 toddler: 0.144 calculated as boron adult: 0.00355 toddler: 0.02130
Tox. reference value	no reference value derived as no relevant systemic effect occurs[a]	Oral AOEL[b]: 0.1 mg/kg bw/d boron
Estimation of acute consumer exposure [% tox ref value]	/	calculated as boron adult: 3.6 toddler: 21

Conclusion

ATMAC/TMAC

Residues in food from the intended use of Sinesto B on wooden pallets were estimated as 5.04 mg/kg leading to a consumer exposure of 0.084 mg/kg bw/d for adults and 0.504 mg/kg bw/d for toddlers.

Disodium tetraborate pentahydrate

Residues in food from the intended use of Sinesto B on wooden pallets were estimated as 1.440 disodium tetraborate pentahydrate mg/kg corresponding to 0.995 mg disodium tetraborate, anh. /kg or 0.213 mg boron/kg. Consumer exposure to boron was 0.0035 mg /kg bw/d for adults and 0.0213 mg /kg bw/d for toddlers.

[a] AR, ATMAC/TMAC PT8, eCA: IT, 2016
[b] AR, Disodium tetraborate pentahydrate, PT8, eCA: NL, 2009

Dietary exposure assssment based on residue data

The applicant has performed a study analysing the migration of constituents of the wood preservative Sinesto B from treated wood onto food (Reprt No.: 31/21/4373/01, for study summary see the confidential Annex). The study protocol included conditions for storage and transport of packaged foods on wooden pallets as well as storage and transport of fruits and vegetables in wooden boxes. As application of Sinesto B is only intended on wooden pallets scenario the results for the wooden box scenario are not further discussed in this section of the PAR.

For the experiment, wooden boards were pre-treated with Sinesto B at the maximal application rate of 12 g /m^2 and let dry. Next, packaged food items (flour, sugar, tea, cocoa, egg powder, milk powder) were placed on the boards ensuring maximum contact of the food item with wood. Subsequently the set-up was wrapped twice with stretch film. Food commodities were chosen to cover food of plant and animal origin with varying chemical composition and large surface area. Foods were packaged in paper or cardboard, i.e. materials with high permeability. For each food commodity the set-up was prepared in triplicate, plus one additional negative control using an untreated wooden board.

The wooden boards in contact with the packaged foods were then incubated at 60 °C for 10 days. These test conditions are similar to those used in the framework of food contact materials covering “long-term storage above 6 months at room temperature and below” according to Reg. (EU) Nr. 10/2011. A default contact duraction of 6 months for food in contact with treated wood is also proposed in the ARTFood Draft Guidance on Estimating Transfer of Biocidal Active Substances into foods – Professional Uses. At the end of the incubation time stored food items were completely homogenized. Aliquots of the homogenates were used for extraction and subsequent analysis. ATMAC/TMAC residues were determined by LC-MS/MS, while sodium tetraborate pentahydrat was determined as boron via ICP-OES. In a preliminary experiment no degradation of ATMAC/TMAC or disodiumtetraborate pentahydrate was observed under the test conditions (see PAR section on Nature of residues). Therefore, no analysis of degradation products was considered necessary.

The results of the migration study for are summariswed in the following tables.

Results of migration study: ATMAC/TMAC (mg/kg food)				
	untreated control	**sample 1**	**sample 2**	**sample 3**
Wooden pallet scenario				

flour	<0.10	<0.10	<0.10	<0.10
sugar	<0.10	<0.10	<0.10	<0.10
tea	<0.10	<0.10	<0.10	<0.10
cocoa	<0.10	<0.10	<0.10	<0.10
egg powder	<0.10	<0.10	<0.10	<0.10
milk powder	<0.10	<0.10	<0.10	<0.10

RMS´ conclusion

For all packaged food commodities measured ATMAC/TMAC levels were below the LOQ of 0.1 mg/kg in all samples in contact with treated wood. In addition, ATMAC/TMAC levels in the respective negative controls on untreated wood were below the LOQ of 0.1 mg/kg. Therefore, no migration of ATMAC/TMAC has been observed from the treated wood into food items.

In the study report, it was reported that TMAC residues in foods relevant for the wooden pallet scenario (flour, sugar, tea, cocoa, egg powder, milk powder) were analysed by LC-MS/MS with an overall LOQ of 0.1 mg/kg. Nevertheless the information provided in the report indicates that the individual components of TMAC have been analysed separately, i.e. components with varying alkyl chain lengths TMA-C8, TMA-C10, TMA-C12, TMA-C14, TMA-C16 and TMA-C18. However, the LOQs for the individual substances are not reported in the study report.

Results of migration study:
Disodiumtetraborate pentahydrate determined as boron (mg/kg food)

	untreated control	**sample 1**	**sample 2**	**sample 3**
Wooden pallet scenario				
flour	0.804	0.590	0.547	1.026
sugar	0.049	0.059	0.069	0.048
tea	12.493	12.343	12.503	13.336
cocoa	23.860	23.955	24.21	25.2
egg powder	0.853	0.729	0.662	0.621
milk powder	0.796	0.782	0.792	0.754
RMS´ conclusion				

To conclude on potential transfer of disodiumtetraborate pentahydrate residues boron levels have been analysed in samples of food items stored on Sinesto B treated wood. As expected, high natural boron levels have been detected in the untreated control samples of the various foods. This in line with published information on natural boron levels in food, e.g. 16.0 mg boron/kg black tea, 22 mg boron/ kg cocoa powder, 3.3 mg boron/kg milk powder(*). Comparing treated (food in contact with treated wood) and untreated samples (food in contact with untreated wood) there is no indication that boron levels in food are elevated due to application of Sinesto B on the wood.

(*) acc. to Souci Fachmann Kraut Online, Food Composition and Nutrition Tables, https://www.sfk.online, Kreissl J, Mall V, Steinhaus P, Steinhaus M. Leibniz-LSB@TUM Odorant Database, Version 1.2. Leibniz Institute for Food Systems Biology at the Technical University of Munich: Freising, Germany, 2022 (https://www.leibniz-lsb.de/en/databases/leibniz-lsbtum-odorant-database).

Conclusion on "Wooden pallet scenario"

Residue levels of ATMAC/TMAC and disodium tetraborate pentahydrate transferred from Sinesto B treated wood onto packaged food have been estimated using a calculation model described in the ARTFood Draft Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses. Considering the maximal application rate of Sinesto B of 12 g/m^2 residue levels of 5.04 mg ATMAC/TMAC /kg food and 1.44 mg disodium tetraborate pentahydrate (= 0.21 mg boron /kg food) were calculated. Consumption of 1 kg of this contaminated food leads to consumer exposure of 0.084 mg ATMAC/TMAC /kg bw/d for adults and 0.504 mg ATMAC/TMAC /kg bw/d for toddlers. For disodium-tetraborate pentahydrate consumer exposure was estimated as 0.024 mg /kg bw/d for adults (= 0.0036 mg boron /kg bw/d) and 0.144 mg/kg bw /d for toddlers (= 0.0213 mg boron/kg bw/d).

In addition, the applicant provided a migration study analysing potential transfer of wood preservative constituents from treated wood onto packaged food. The experimental set-up mimicking storage and transport of packaged food on wooden pallets is considered reasonable. The study results indicate that no migration of TMAC (measured residues in all samples and untreated controls below the LOQ of 0.1 mg/kg food) and disodiumtetraborate pentahydrate (no elevated boron levels compared to naural boron levels of food) is detected. Based on this study data no relevant consumer exposure to both active substances is expected from the intended use of Sinesto B on wooden pallets.

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

not relevant

3.6.3.2.6 Dietary exposure to substances of concern

Two substances of concern have been identified for the biocidal product "Sinesto B". The substances with their required assessment scheme according to the Guidance on BPR are listed in the following table:

Summary table on substances of concern (SoC)			
SoC Name (CAS-No.)	**Classification of BP due to classified SoC**	**Band (acc. to Guidance on BPR[a])**	**Dietary exposure evaluation of SoC**
Natrium-2-ethylhexanoat (CAS-Nr. 19766-89-3)	STOT SE 3, H335 Repr. 1B, H3660D	A D	**Full quantitative assessment of SoC** see below
Natriumhydroxid (CAS-Nr. 1310-73-2)	Skin Corr 1B, H314 Eye Dam 1	B	**Qualitative assessment of SoC** Substance induces local effects like skin corrosion. It is not considered to be systemically available after dermal or oral

			exposure and therefore no accumulation in animal tissues is expected. For the naturally occurring ions sodium (Na^+) and hydroxide (OH^-) no further assessment is considered necessary.

[a] Guidance on the BPR: Vol. III Parts B+C, Version 4.0, December 2017, Annex A: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products

Dietary exposure assessment for Natrium-2-ethylhexanoat

Note: Scenarios (see Table 59) and evaluation approaches for dietary exposure assessment are identical to the ones described for the active substances.

Calculations for estimating external livestock exposure

- Estimating Livestock Exposure to Active Substances used in Biocidal Products

Tier 1: Estimation of livestock exposure: Oral exposure by chewing wood

Description of scenario

Wood used as pasture fencepost is treated with the biocidal product. Livestock animals can be exposed orally by chewing on the wood (e.g. horses, goats). Below livestock exposure is estimated for a horse as Guidance on BPR, Vol III, Parts B+C, section 6 only contains default values for horses.

Parameters

$c_{a.s., wood}$	Amount of active substance per m^3 calculated following the recommendations for human secondary exposure (wooden post with volume = 0.04 x 0.04 x 2.5 m^3 and assumption that all applied a.s. is located in the outer 1 cm layer)[a]: $c_{a.s., wood}$ (mg/m^3) = $c_{a.s., wood}$ (g/m^2) x 0.4032 m^2 / 0.003 m^3 maximal application rate of 12 g bp/m^2 corresponds to Sodium 2-ethylhexanoat (SoC): 3.12 g SoC/m^2 = 419.328 g a.s./m^3
I_{wood}	Amount of wood consumed by horse: 1.9 x 10^{-5} m^3/d (ARTFood Guidance: wood consumption value based on one study only, not a confirmed default value)
TF	fraction of surface residues transferred from treated wood into/onto animal, transfer factor: 100 % (default)
Abs_{oral}	Oral absorption 100 % (default)
bw	body weight: 400 kg (default horse)

Calculation

$Exp_{livestock} = c_{a.s., wood}$ [g/m^3] x 1000 mg/g x I_{wood} x TF / bw

	Sodium 2-ethylhexanoat (SoC)
$c_{a.s., wood}$ [g a.s./cm^2]	3.120
$c_{a.s., wood}$ [g a.s./m^3]	419.328
$Exp_{livestock}$ [mg a.s./kg bw]	0.0199
RMS´ conclusion	
The estimated external livestock exposure exceeds the trigger value of 0.004 mg/kg bw. In the absence of other refinement options, a worst-case consumer exposure is calculated as described below.	

[a] TNsG Human Exposure to Biocidal Products, 2002; consideration of a wooden post of 2.5 m x 0.04 m x 0.04 m with a surface area of 0.4032 m^2 (=4x (2.5 m x 0.04 m) + 2x (0.04m x 0.04 m)) and the volume of the outer 1 cm layer of

0.003 m^3 (= 2x (2.5 m x 0.04m x 0.01m) + 2x (2.5 m x 0.02 m x 0.01 m) + 2x (0.02m x 0.02 m x 0.01 m)). Conversion of the application rate: $c_{a.s., wood}$ [g/m^3] = $c_{a.s., wood}$ [g/m^2] x 0.4032 m^2 / 0.003 m^3

- Worst-case consumer exposure (WCCE)

Worst-case consumer exposure (WCCE) considering Tier 1 livestock exposure estimate

- worst case consumer estimate (WCCE) according to EMA guideline on risk characterisation and assessment of maximum residue limits (MRL) for biocides.

- external livestock exposure (value estimated for horses only, as wood consumption value was only available for horses). Nevertheless, the estimated exposure value was also applied to consider residues in milk as goats are also a relevant species for this livestock exposure scenario.
$Exp_{livestock, oral}$: horse: 0.0199 mg/kg bw/d

- estimated residues in animal edible tissues calculated as
$R_{tissue} = Exp_{livestock, oral}$ x TF (dermal and inhalative exposure not relevant)
with R_{tissue}: residues in animal edible tissues [mg/kg],
$Exp_{livestock}$: external livestock exposure [mg/kg bw/d], $TF_{tissues}$: transfer factor
Transfer factors ($TF_{tissues}$)[a] were chosen as applicable for sodium 2-ethylhexanoat with an Log Po/w of 1.3 (20 °C)[b]: meat and fat: 0.1; edible offal and milk: 0.2. The factors are applicable for oral uptake only.

- consumer exposure to residues in edible tissue calculated as $WCCE_{tissue} = R_{tissue}$ x I_{tissue} ÷ bw
with $WCCE_{tissue}$: worst case consumer exposure for a specific tissue (mg/kg bw/d), R_{tissue}: residues in animal edible tissues (mg/kg), I_{tissue}: consumer intake of specific edible animal tissue (kg)[c]; consumer body weight (default 60 kg)

WCCE = $WCCE_{meat} + WCCE_{fat} + WCCE_{liver} + WCCE_{kidney} + WCCE_{milk}$
= $(R_{meat}$ x $I_{meat} + R_{fat}$ x $I_{fat} + R_{liver}$ x $I_{liver} + R_{kidney}$ x $I_{kidney} + R_{milk}$ x $I_{milk})$ / bw
= (0.00199 mg/kg x 0.30 kg + 0.00199 mg/kg x 0.05 kg + 0.00398 mg/kg x 0.10 kg
+ 0.00398 mg/kg x 0.05 kg + 0.00398 mg/kg x 1.50 kg) / 60 kg
= 0.00012 mg/kg bw

	Sodium 2-ethylhexanoat (SoC)
$R_{meat} = R_{fat}$ [mg/kg]	0.00199
$R_{liver} = R_{kidney} = R_{milk}$ [mg/kg]	0.00398
Tox. reference value	Oral DNEL[b]: 1 mg /kg bw/d
WCCE [mg/kg bw/d]	0.00012
WCCE [% tox ref value]	0.01

RMS conclusion

Refined calculation of transfer of the SoC into edible animal tissues (based on transfer factors applied to the estimated external livestock exposure) results in residues of 0.002 mg/kg in meat and fat and 0.004 mg/kg in kidney and liver. Accumulation of the SoC in edible tissues and milk is not expected due to a Log Po/w below 3. WCCE was calculated as 0.00012 mg/kg bw/d.

[a] Leeman et al. (2007): Transfer of chemicals from feed to animal products: The use of transfer factors in risk assessment. Food additives and contaminants; 24, 1-13.
[b] ECHA Brief profile, sodium 2-ethylhexanoate, https://echa.europa.eu/brief-profile/-/briefprofile/100.039.334
[c] Worst case consumer exposure: combined estimate of the internal dose with the CVMP standard food basket for a 60 kg adult consuming 300 g muscle, 100 g liver, 50 g fat, 50 g kidney, plus 1500 g milk

Calculations for estimating residue levels in food and consumer exposure (professional uses)

Wooden pallets: Estimation of residue transfer into food

Description of scenario

The biocidal product is a wood preservative for industrial use. In the intended use it is specified that treated wood may be used to manufacture pallets intended for transport and storage of food and feeding stuff. Thus indirect contact of treated wood with food and/or feeding stuff may occur.

Parameters

$c_{a.s., surface}$	active substance concentration on wood surface [mg a.s./cm^2] derived from maximal application rate of 12 g biocidal product/m^2 containing 26 % (w/w) sodium 2-ethylhexanoat (SoC) corresponding to 3.12 g SoC/m^2 = 0.312 mg SoC/cm^2
TF	fraction of surface residues transferred onto food, transfer factor: 10 % (default)
$A_{contact}$	contact surface of food with wooden pallet: 300 cm^2/kg food (default assuming a food layer of 3.3 cm height)
I_{food}	Consumption of packaged food: 1 kg/ person per day
bw	human body weight, adult: 60 kg, toddler 10 kg

Calculation

$R_{food} = c_{a.s., surface} \times TF \times A_{contact}$

Calculation of consumer exposure

$Exp_{cons} = R_{food} \times I_{food} / bw$

	Sodium 2-ethylhexanoat (SoC)
$c_{a.s., surface}$ [mg a.s./cm^2]	0.312
R_{food} [mg a.s./kg]	9.360
Dietary exposure assessment	
Estimation of consumer exposure [mg/kg bw/d]	adult: 0.15600 toddler: 0.93600
Tox. reference value	Oral DNEL[a]: 1 mg /kg bw/d
Estimation of acute consumer exposure [% tox ref value]	adult: 16 toddler: 94
RMS´ conclusion	
Residues in food from the intended use of Sinesto B on wooden pallets were estimated as 9.36 mg/kg. Consumption of 1 kg of this contaminated food leads to consumer exposure of 0.156 mg Sodium-2-ethylhexanoat /kg bw/d for adults and 0.936 mg Sodium-2-ethylhexanoat /kg bw/d for toddlers.	

[a] https://echa.europa.eu/brief-profile/-/briefprofile/100.039.334

3.6.3.2.7 Overall conclusion for dietary exposure

Scenario “Livestock chewing on wood used for paddocks”

Estimated external livestock exposure was below the trigger value of 0.004 mg/kg bw for both active substances ATMAC/TMAC and disodium tetraborate pentahydrate. Consequently, significant residues of both active substances in food of animal origin are not expected.

For the SoC sodium 2-ethylhexanoate refined calculation of transfer of into edible animal tissues (based on transfer factors applied to the estimated external livestock exposure) estimated residues of 0.002 mg/kg in meat and fat and 0.004 mg/kg in kidney and liver. Worst case consumer exposure was calculated as 0.00012 mg/kg bw/d for adults.

“Wooden pallet” scenario

Residue levels of ATMAC/TMAC and disodium tetraborate pentahydrate transferred from Sinesto B treated wood onto packaged food have been estimated using a calculation model described in the ARTFood Draft Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses. Considering the maximal application rate of Sinesto B of 12 g/m^2 residue levels of 5.04 mg ATMAC/TMAC /kg food and 1.44 mg disodium tetraborate pentahydrate (= 0.21 mg boron /kg food) were calculated. Consumption of 1 kg of this contaminated food leads to consumer exposure of 0.084 mg ATMAC/TMAC /kg bw/d for adults and 0.504 mg ATMAC/TMAC /kg bw/d for toddlers. For disodium-tetraborate pentahydrate consumer exposure was estimated as 0.024 mg /kg bw/d for adults (= 0.0036 mg boron /kg bw/d) and 0.144 mg/kg bw /d for toddlers (= 0.0213 mg boron/kg bw/d).

In addition, the applicant provided a migration study analyzing potential transfer of wood preservative constituents from treated wood onto packaged food. The study results indicate that no migration of TMAC (measured residues in all samples and untreated controls below the LOQ of 0.1 mg/kg food) and disodiumtetraborate pentahydrate (no elevated boron levels compared to natural boron levels of food) is detected. Based on this study data no relevant consumer exposure to these substances is expected from the intended use of Sinesto B on wooden pallets.

For the SoC sodium-2-ethylhexanoate an assessment similar to that of the active substances has been performed. Based on the calculation model residues in food were estimated as 9.36 mg/kg leading to a consumer exposure of 0.156 mg sodium-2-ethylhexanoate /kg bw/d for adults and 0.936 mg sodium-2-ethylhexanoate /kg bw/d for toddlers

Regarding both scenarios no dietary exposure assessment was considered necessary for the second SoC Natrium hydroxide as the substance induces local effects and is not systemically available.

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

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

Not relevant for non-professional users and the general public.

3.6.3.4 Aggregated exposure

Not relevant.

3.6.3.5 Summary of exposure assessment

Table 74 Disodium tetraborate pentahydrate as boron

Scenarios and values to be used in risk assessment			
Scenario	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake** [mg B/kg bw/d]
1.: Fully automated dipping (use 1)	Professional user Industrial user	Tier 1 and 2: • Automatic dosing system[1, 2] • Protective gloves (EN 374)[1, 2] • Fully automated immersion system[1, 2] • Protective coverall (type 6, EN 13034[1, 2] • Eye protection[1]	Tier 2: daily 7.66×10^{-3} weekly 7.61×10^{-3}
2.: Automated dipping (use 2)	Professional user Industrial user	Tier 1 and 2: • Automatic dosing system[1, 2] • Protective gloves (EN 374)[1, 2] • Protective coverall (type 6, EN 13034[1, 2] • Eye protection[1]	Tier 2: daily 0.03 weekly 7.61×10^{-3}

3.: Deluge treatment (use 3)	Professional user Industrial user	Tier 1 and 2: • Automatic dosing system[1, 2] • Protective gloves (EN 374)[1, 2] • Treated wood gets automatically piled up; transportation by forklift truck • Protective coverall (type 6, EN 13034[1, 2] • Eye protection[1]	Tier 2: 0.01
4.: Mechanical processing of treated wood (use 1-3)	Professional user	Tier 1: • Protective gloves (EN 374)[1]	Tier 1: 4.86×10^{-3}
5	General public	Tier 1	0.00486
6	General public	Tier 1	0.001133
7	General public	Tier 1	0.000142
8	General public	Tier 1	0.000979

[1] Based on local risk assessment
[2] Based on systemic risk assessment

Table 75 Sodium 2-ethylhexanoate

Scenarios and values to be used in risk assessment			
Scenario	**Exposed group** **(e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake** [µg/kg bw/d]
1.: Fully automated dipping (use 1)	Professional user Industrial user	Tier 1 and 2: • Automatic dosing system[1, 2] • Protective gloves (EN 374)[1, 2] • Fully automated immersion system[1, 2] • Protective coverall (type 6, EN 13034[1, 2] • Eye protection[1]	Tier 2: Daily 0.34 Weekly 0.34
2.: Automated dipping (use 2)	Professional user Industrial user	Tier 1 and 2: • Automatic dosing system[1, 2] • Protective gloves (EN 374)[1, 2]	Tier 2: Daily: 1.35 Weekly: 0.34

Scenarios and values to be used in risk assessment			
		• Protective coverall (type 6, EN 13034[1, 2] • Eye protection[1]	
3.: Deluge treatment (use 3)	Professional user Industrial user	Tier 1 and 2: • Automatic dosing system[1, 2] • Protective gloves (EN 374)[1, 2] • Treated wood gets automatically piled up; transportation by forklift truck • Protective coverall (type 6, EN 13034[1, 2] • Eye protection[1]	Tier 2: 0.57
4.: Mechanical processing of treated wood (use 1-3)	Professional user	Tier 1: • Protective gloves (EN 374)[1]	Tier 1: 0.21
5	General public	Tier 1	0.40
6	General public	Tier 1	0.04992
7	General public	Tier 1	0.00005
8	General public	Tier 1	0.06470

[1] Based on local risk assessment

[2] Based on systemic risk assessment

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) see chapter 3.6.1.

3.6.4.2 Maximum residue limits or equivalent

Table 76

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL (Alkyltrimethyl ammonium chloride)	default MRL acc. to Art 18(1)(b) Reg 396 / 2005. Reg (EC) No. 2002/2076	all food commodities	0.01 mg/kg
MRL (Sodium tetraborate)	default MRL acc. to Art 18(1)(b) Reg 396 / 2005.	all food commodities	0.01 mg/kg
MRL (Boric acid and borates)	Reg. (EU) No.37/2010	Food of animal origin, all food producing species	No MRL required

3.6.4.3 Specific reference value for groundwater

No specific references values for groundwater were derived.

3.6.4.4 Risk for industrial users

The risk characterisation for industrial users is described in chapter 3.6.4.5.

3.6.4.5 Risk for professional users

The occupational risk assessment for the biocidal product Sinesto B takes into account systemic effects of the active substance disodium tetraborate pentahydrate, local effects of the active substance ATMAC/TMAC as well as systemic and local effects of the substances of concern.

In the biocidal product Sinesto B sodium hydroxide (CAS No.: 1310-73-2) and sodium 2-ethylhexanoate (CAS No.: 19766-89-3) are identified as substances of concern based on the classification of the product Sinesto B due to

- **Systemic effects** - quantitative

Active substance disodium tetraborate pentahydrate

The primary toxic effect of the active substance disodium tetraborate pentahydrate is developmental toxicity. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to disodium tetraborate pentahydrate resulting from use of the biocidal product. As reference value the $AEL_{long\text{-}term}$ of 0.1 mg boron/kg bw/day is used.

Details of risk characterisation

Reference values

As systemic reference value the $AEL_{long\text{-}term}$ of 0.1 mg boron/kg bw/d is used.

Calculation of total uptake and AEL exhaustion (%)

For inhalation route 100 % absorption is assumed as default absorption for the active substance disodium tetraborate pentahydrate.

The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Valid data are not available for the diluted product. Therefore, the default value of 50 % for a diluted and water based or dispersed or solid product (according to the EFSA Guidance on Dermal Absorption, 2017) has to be taken into consideration for risk assessment.

Dermal exposure to disodium tetraborate pentahydrate given in mg boron/kg bw/d is calculated from dermal exposure to disodium tetraborate pentahydrate given in mg boron/person/d through division by 60 kg/person.

The inhalation uptake and dermal uptake referring to the active substance disodium tetraborate pentahydrate calculated as boron resulting from use of the biocidal product Sinesto B are determined according to the following equations:

Inhalation uptake (mg boron/kg bw/d) = inhalation exposure to disodium tetraborate pentahydrate calculated as boron (mg/m³) x 10 m³/d breathing volume / 60 kg body weight / 100 % x 100 % inhalation absorption

Dermal uptake (mg boron/kg bw/d) = dermal exposure to disodium tetraborate pentahydrate calculated as boron (mg/kg bw/d) / 100 % x 50 %-dermal absorption

The summation of inhalation uptake and dermal uptake within a scenario gives the total uptake.

The AEL exhaustion is determined by calculating the percentage of the total uptake from the AEL.

A risk for professional users referring to the active substance disodium tetraborate pentahydrate calculated as boron resulting from the use of the biocidal product Sinesto B is unlikely if the AEL exhaustion (%) for each scenario is below the value of 100 %. Table 77 gives a detailed overview of the risk assessment results referring to the active substance disodium tetraborate pentahydrate in the biocidal product Sinesto B. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places in Table 77. However, the underlying calculations are based on unrounded values.

As shown in Table 77 for the scenarios ‘Fully automated dipping – weekly’, ‘Automated dipping – weekly’, ‘Secondary exposure: Mechanical processing of treated wood’ a risk for the professional user is unlikely already in Tier 1. By contrast, for the scenarios ‘Fully automated dipping – daily’, ‘Automated dipping – daily’, ‘Deluge treatment’ inacceptable risks are identified after Tier 1 consideration. However when risk mitigation measures are implemented a risk for the professional user is unlikely in Tier 2.

Table 77 Overview of detailed risk assessment results referring to the active substance disodium tetraborate pentahydrate calculated as boron in the biocidal product Sinesto B

Scenario		**$AEL_{long-term}$** mg B/kg bw/d	**Estimated inhalation uptake** mg B/kg bw/d	**inhalation uptake / AEL** %	**Estimated dermal uptake** mg B/kg bw/d	**dermal uptake / AEL** %	**Estimated total uptake** mg B/kg bw/d	**Estimated total uptake / AEL** AEL exhaustion %	**Acceptable** (yes/no)
Fully automated dipping - daily	Tier 1	0.1	Not expected, no aerosol		0.15	152	0.15	152	no
	Tier 2	0.1			7.66×10^{-3}	7.7	7.66×10^{-3}	7.6	**yes**
Fully automated dipping - weekly	Tier 1	0.1	Not expected, no aerosol		0.04	38	0.04	38	**yes**
	Tier 2	0.1			7.61×10^{-3}	7.6	7.61×10^{-3}	7.6	yes
Automated dipping - daily	Tier 1	0.1	Not expected, no aerosol		0.15	152	0.15	152	no
	Tier 2	0.1			0.02	22	0.02	22	**yes**
Automated dipping - weekly	Tier 1	0.1	Not expected, no aerosol		0.04	38	0.04	38	**yes**
	Tier 2	0.1			15.49×10^{-3}	5.5	15.49×10^{-3}	5.5	yes
Deluge treatment	Tier 1	0.1	2.46×10^{-5}	0.02	0.12	121	0.12	121	no
	Tier 2	0.1	2.46×10^{-5}	0.02	0.01	13	0.01	13	**yes**
Secondary exposure: Mechanical processing of treated wood	Tier 1	0.1	2.95×10^{-5}	0.03	9.66×10^{-3}	9.7	9.69×10^{-3}	9.7	**yes**
	Tier 2	0.1	2.95×10^{-5}	0.03	9.66×10^{-3}	9.7	9.69×10^{-3}	9.7	yes

Conclusion

Based on the risk assessment of the active substance disodium tetraborate pentahydrate via the inhalation and dermal route, a risk for professional users resulting from the scenarios ('Fully automated dipping – weekly', 'Automated dipping – weekly', 'Fully automated dipping – daily', 'Automated dipping – daily', 'Deluge treatment') as well as from secondary exposure ('Mechanical processing of treated wood') with the biocidal product Sinesto B is unlikely at the latest after TIER 2 consideration. Regarding occupational safety, there are no objections against the uses as well as secondary exposure taking into account the provisions described in chapter 2.5.2 of this PAR.

Substance of concern sodium 2-ethylhexanoate

The primary toxic effect of the substance of concern sodium 2-ethylhexanoate is developmental toxicity. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to sodium 2-ethylhexanoate resulting from use of the biocidal product Sinesto B.

Details of risk characterisation

Reference values

As reference values available DNELs for 2-ethylhexanoic acid for the inhalation and the dermal route for workers are used: worker-$DNEL_{long\text{-}term}$ for inhalation route-systemic of 14 mg/m³ and the worker-$DNEL_{long\text{-}term}$ for dermal route-systemic of 2 mg/kg bw/day. The present values are derived by a member state under the European chemicals regulation and are thus validated by an european regulatory authority (substance evaluation report of 2-ethylhexanoic acid, ES 2017).

Calculation of dermal exposure and DNEL exhaustion (%)

Dermal exposure to sodium 2-ethylhexanoate given in mg/kg bw/d is calculated from dermal exposure to sodium 2-ethylhexanoate given in mg/person/d through division by 60 kg/person.

The DNEL exhaustion is estimated by calculating the percentage of the inhalation exposure to sodium 2-ethylhexanoate from the worker-$DNEL_{long\text{-}term}$ for inhalation route-systemic and the percentage of the dermal exposure to sodium 2-ethylhexanoate from the worker-$DNEL_{long\text{-}term}$ for dermal route-systemic. The sum of the two gives the total DNEL exhaustion.

A risk for professional users referring to the substance of concern sodium 2-ethylhexanoate resulting from the use of the biocidal product Sinesto B is unlikely if the DNEL exhaustion (%)is below the value of 100 %. Table 78 gives a detailed overview of the risk assessment results referring to the substance of concern sodium 2-ethylhexanoate in the biocidal product Sinesto B. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places in Table 78. However, the underlying calculations are based on unrounded values.

As shown in Table 78, for the scenarios ‘Secondary exposure: Mechanical processing of treated wood’ a risk for the professional user is unlikely already in Tier 1. By contrast, for the scenarios ‘Fully automated dipping – daily’, ‘Fully automated dipping – weekly’, ‘Automated dipping – weekly’, ‘Deluge treatment’ inacceptable risks are identified after Tier 1 consideration. However when risk mitigation measures are implemented a risk for the professional user is unlikely in Tier 2.

As shown in Table 78, for the scenario ‘Automated dipping – daily’ a risk for the professional user from the dermal route is likely also after Tier 2 consideration. This means, even if risk mitigation measures in the dermal route are implemented a risk for the professional user cannot be excluded.

Table 78 Overview of detailed risk assessment results referring to the substance of concern sodium 2-ethylhexanoate in the biocidal product Sinesto B

Scenario		**$DNEL_{inhalation}$** mg/m³	**Estimated inhalation exposure** mg/m³	**Estimated inhalation exposure / $DNEL_{inhalation}$** DNEL exhaustion inhalation **%**	**$DNEL_{dermal}$** mg/kg bw/d	**Estimated dermal exposure** mg/kg bw/d	**Estimated dermal exposure / $DNEL_{dermal}$** DNEL exhaustion dermal **%**	**HQ (Total)**	**Accep** (yes
Fully automated dipping - daily	Tier 1	14	Not expected, no aerosol		2	13.4	671	6.71	n
	Tier 2	14			2	0.68	34	0.34	**ye**
Fully automated dipping - weekly	Tier 1	14	Not expected, no aerosol		2	3.4	167	1.67	n
	Tier 2	14			2	0.67	34	0.34	**ye**
Automated dipping - daily	Tier 1	14	Not expected, no aerosol		2	13.4	671	6.71	n
	Tier 2	14			2	1.9	97	0.97	**ye**
Automated dipping - weekly	Tier 1	14	Not expected, no aerosol		2	3.4	167	1.67	n
	Tier 2	14			2	0.48	24	0.24	**ye**
Deluge treatment	Tier 1	14	6.50×10^{-3}	0.05	2	10.6	532	5.32	n
	Tier 2	14	6.50×10^{-3}	0.05	2	1.1	57	0.57	**ye**
Secondary exposure: Mechanical processing of treated wood	Tier 1	14	7.80×10^{-3}	0.06	2	0.85	43	0.43	**ye**
	Tier 2	14	7.80×10^{-3}	0.06	2	0.85	43	0.43	ye

Conclusion

Based on the risk assessment of the substance of concern sodium 2-ethylhexanoate via the inhalation and dermal route, a risk for professional users resulting from the scenarios 'Fully automated dipping – daily', 'Fully automated dipping – weekly', 'Automated dipping – weekly', 'Deluge treatment' as well as from secondary exposure ('Mechanical processing of treated wood') with the biocidal product Sinesto B is unlikely at the latest after TIER 2 consideration. Regarding occupational safety, there are no objections against these uses as well as secondary exposure taking into account the provisions described in chapter 2.5.2 of this PAR.

However, based on the risk assessment of the substance of concern sodium 2-ethylhexanoate via the dermal route, a risk for professional users resulting from the 'Automated dipping – daily' with the biocidal product Sinesto B cannot be excluded.

- **Local effects**

Local effects – semi-quantitative

Active substance ATMAC/TMAC

The primary toxic effect of the active substance ATAC/TMAC are dermal local effects. The semi-quantitative risk characterisation for professional users takes into account the dermal exposure concentration of ATMAC/TMAC resulting from use of the biocidal product Sinesto B. For the assessment the dermal 'No observed adverse effect concentration' (NOAEC) of 0.3 % ATMAC/TMAC, is used

Details of risk characterisation

Dermal effect concentration

For the purpose of risk characterisation for professional users the dermal exposure concentration of ATMAC/TMAC is compared with the dermal NOAEC of 0.3 % ATMAC/TMAC.

If the dermal exposure concentration exceeds the NOAEC, appropriate risk mitigation measures (RMMs) have to be applied to avoid skin contact with the biocidal product Sinesto B.

Table 79 gives a detailed overview of the semi-quantitative risk assessment results referring to the active substance ATMAC/TMAC in the biocidal product Sinesto B.

Shown in Table 79 for the scenarios 'Fully automated dipping - mixing and loading', 'Fully automated dipping - application and post-application', 'Automated dipping - mixing and loading', 'Automated dipping - application and post-application', 'Deluge treatment - mixing and loading', 'Deluge treatment - application and post-application' the dermal exposure concentration exceeds the NOAEC. Appropriate RMMs (skin protection) are to be implemented so that a risk for the professional user regarding ATMAC/TMAC is unlikely for these scenarios. Because a qualitative assessment of the product Sinesto B is also carried

out, the appropriate RMMs are listed and assessed in the section “Local effects – qualitative” in this chapter. For the scenario ‘Secondary exposure: Mechanical processing of treated wood’ the NOAEC is not exceeded.

Table 79 Overview of semi-quantitative risk assessment results for dermal route and the active substance ATMAC/TMAC in the biocidal product Sinesto B based on dermal NOAEC 0.3 %

Task/scenario	Dermal NOAEC [%]	Concentration ATMAC/TMAC (max.) in application solution [%]	Concentration ATMAC/TMAC higher/lower than dermal NOAEC?	RMM
Fully automated dipping - mixing and loading	0.3	14.0	higher	Skin protection needed; see section Local risks
Fully automated dipping - application and post-application	0.3	1.12	higher	Skin protection needed; see section Local risks
Automated dipping - mixing and loading	0.3	14.0	higher	Skin protection needed; see section Local risks
Automated dipping - application and post-application	0.3	1.12	higher	Skin protection needed; see section Local risks
Deluge treatment - mixing and loading	0.3	14.0	higher	Skin protection needed; see section Local risks
Deluge treatment - application and post-application	0.3	2.80	higher	Skin protection needed; see section Local risks
Secondary exposure: Mechanical processing of treated wood	0.3	0.21	lower	-

Conclusion

Based on the semi-quantitative risk assessment of the local effects of the active substance ATMAC/TMAC via the dermal route, a risk for professional users resulting from the scenarios ‘Fully automated dipping - mixing and loading’, ‘Fully automated dipping - application and post-application’, ‘Automated dipping - mixing and loading’, ‘Automated dipping - application and post-application’, ‘Deluge treatment - mixing and loading’, ‘Deluge treatment - application and post-application’ is unlikely taking into account the provisions for skin protection described section “Local effects – qualitative” in this chapter.

Local effects – qualitative

The local toxicity profiles of the active substance ATMAC/TMAC as well as the substance of concern sodium hydroxide are considered. These substances contribute to the classification of the biocidal product "Sinesto B" with H314 (Causes severe skin burns and eye damage) and H318 (Causes severe eye damage).

Qualitative risk characterisation of local effects

A qualitative risk assessment for local effects regarding contact with skin and/or eye and/or respiratory tract is necessary.

The qualitative risk assessment of local effects takes into account the concentrated biocidal product as well as the different dilutions thereof. The Table 80 gives an overview of the relevant classifications for the qualitative local risk assessment of biocidal product Sinesto B. Furthermore, the allocated hazard categories according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) are plotted against the respective classification.

Table 80 Relevant classification and resulting hazard categories of the biocidal product Sinesto B

b.p. concentration in application solution [%]	**Resulting classification according to Regulation (EC) No. 1272/2008**	**Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)**
100	Skin Corr. 1B, H314 Eye Dam. 1, H 318	high
20	Skin Corr. 1, H314 Eye Dam. 1, H 318	high
8	Skin Irrit. 2, H315 Eye Irrit. 2, H319	low

For the concentrated biocidal product and the 20% dilution the local risk assessment is triggered by corrosion (Skin Corr. 1B/1, H314; Eye Dam. 1, H318). These classifications are allocated to the hazard category "high". For the b.p. concentration of 8 % in the application solution the local risk assessment is triggered by irritation (Skin Irrit. 2, H315, Eye Irrit. 2, H319). These classifications are allocated to the hazard category "low".

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into

account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) the following tables are prepared to carry out the qualitative risk assessment for local effects regarding contact with the skin and eye of the biocidal product Sinesto B for the intended uses. ‘Fully automated dipping’ (Table 81) ‘Automated dipping’ (Table 82), ‘Deluge treatment’ (Table 83), as well as from Secondary exposure (‘Mechanical processing of treated wood’) (Table 84).

Table 81 Summary of qualitative conclusions for local risk assessment for scenario 'Fully automated dipping'

Tasks, uses, processes	concentration b.p. (max.) in application solution	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing and loading Dilution of b.p. (Automated/Semi-Automated)	100%	Skin Corr. 1B, H314 Eye Dam. 1, H 318	HIGH	10 minutes per day	Skin: Incidental contact to hands likely Eyes: Incidental contact possible	Technical Measure: - Automatic dosing system Organisation: - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE: -Protective coverall (EN 13034) -Protective gloves -Eye protection	Acceptable + Low frequency/used for short duration + Engineering controls: Automatic dosing system + Minimization of manual phases + professionals using appropriate PPE
Fully automated dipping	8%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	LOW	4 cycles per day	Skin: Frequent contact to hands and body expected.	Technical Measure: - Fully automated immersion system (according to HEEG opinion no. 18) Organisation: - Regular cleaning of equipment	Acceptable + Fully automated dipping process + Minimization of manual phases

Tasks, uses, processes	concentration b.p. (max.) in application solution	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
					Eyes: Incidental contact possible	- Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE: -Protective coverall (EN 13034) -Protective gloves -Eye protection	+ Professionals using appropriate PPE
Cleaning of the dipping tank	8%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	LOW	1 cycle per week	Skin: Frequent contact to hands and body expected. Eyes: Incidental contact possible	Technical Measure: - Organisation[1]: - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE:	Acceptable +task expected to be carried out weekly + Professionals using appropriate PPE

Tasks, uses, processes	concentration b.p. (max.) in application solution	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
						-Protective coverall (EN 13034) -Protective gloves -Eye protection	

[1)] Organisational measures include implementation of occupational hygiene standards. In Germany, the provisions of the Hazardous Substances Ordinance are obeyed.

Table 82 Summary of qualitative conclusions for local risk assessment for scenario 'Automated dipping'

Tasks, uses, processes	**concentration b.p. (max.) in application solution**	**Local Effects in terms of C&L**	**Hazard Category**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Acceptability**
Mixing and loading Dilution of b.p. (Automated/Semi-Automated)	100%	Skin Corr. 1B, H314 Eye Dam. 1, H 318	HIGH	10 minutes per day	Skin: Incidental contact to hands likely Eyes: Incidental contact possible	Technical Measure: - Automatic dosing system Organisation: - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE: -Protective coverall (EN 13034) -Protective gloves -Eye protection	Acceptable + Low frequency/used for short duration + Engineering controls: Automatic dosing system + Minimization of manual phases + professionals using appropriate PPE
Automated dipping	8%	Skin Irrit. 2, H315	LOW	4 cycles per day	Skin: Frequent	Technical Measure: - Automated immersion system	Acceptable

Tasks, uses, processes	concentration b.p. (max.) in application solution	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
		Eye Irrit. 2, H319			contact to hands and body expected. Eyes: Incidental contact possible	Organisation: - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE: -Protective coverall (EN 13034) -Protective gloves -Eye protection	+ Automated dipping process + Minimization of manual phases + Professionals using appropriate PPE

Tasks, uses, processes	concentration b.p. (max.) in application solution	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Cleaning of the dipping tank	8%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	LOW	1 cycle per week	Skin: Frequent contact to hands and body expected. Eyes: Incidental contact possible	Technical Measure: - Organisation: - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE: -Protective coverall (EN 13034) -Protective gloves -Eye protection	Acceptable +task expected to be carried out weekly + Professionals using appropriate PPE

[1)] Organisational measures include implementation of occupational hygiene standards. In Germany, the provisions of the Hazardous Substances Ordinance are obeyed.

Table 83 Summary of qualitative conclusions for local risk assessment for scenario 'Deluge treatment'

Tasks, uses, processes	**concentration b.p. (max.) in application solution**	**Local Effects in terms of C&L**	**Hazard Category**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Acceptability**
Mixing and loading Dilution of b.p. (Automated/Semi-Automated)	100%	Skin Corr. 1B, H314 Eye Dam. 1, H 318	HIGH	10 minutes per day	Skin: Incidental contact to hands likely Eyes: Incidental contact possible	Technical Measure: - Automatic dosing system Organisation: - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE: -Protective coverall (EN 13034) -Protective gloves - Eye protection	Acceptable + Low frequency/used for short duration + Engineering controls: automatic dosing system + Minimization of manual phases + Professionals using appropriate PPE

Tasks, uses, processes	concentration b.p. (max.) in application solution	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Deluge treatment (automated spraying)	20%	Skin Corr. 1, H314 Eye Dam. 1, H318	HIGH	60 min per day	Skin: Frequent contact to hands and body expected. Eyes: Incidental contact possible	Technical Measure: - Closed spray tunnel - Treated wood gets automatically piled up; transportation by forklift truck Organisation: - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE: -Protective coverall (EN 13034) -Protective gloves - Eye protection	Acceptable + closed tunnel + Professionals using appropriate PPE

Tasks, uses, processes	concentration b.p. (max.) in application solution	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Cleaning of the spray tunnel	20%	Skin Corr. 1, H314 Eye Dam. 1, H318	HIGH	30 min per day	Skin: Frequent hand contact expected. Eyes: Incidental contact possible	Technical Measure: - Organisation: - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE: -Protective coverall (EN 13034) -Protective gloves -Eye protection	Acceptable + Professionals using appropriate PPE

Table 84 Summary of qualitative conclusions for local risk assessment for scenario ‘Secondary exposure: Mechanical processing of treated wood’

Tasks, uses, processes	**concentration b.p. (max.) in application solution**	**Local Effects in terms of C&L**	**Hazard Category**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Acceptability**
Application (sawing or sanding of treated wood)	20%	Skin Corr. 1, H314 Eye Dam. 1, H318	HIGH	several times per day	Contact to hands likely	Technical Measure: - Automated processing Organisation: - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene - treated wood is dried until it is at least surface dry before further treatment may be carried out PPE: -Protective gloves	Acceptable + Professionals using appropriate PPE

[1)] Organisational measures include implementation of occupational hygiene standards. In Germany, the provisions of the Hazardous Substances Ordinance are obeyed.

Conclusion for local effects

Concerning the irritating/corrosive properties of the biocidal product Sinesto B, exposure should be minimized with RMMs. If the proposed RMMs are implemented, the intended uses ('Fully automated dipping', 'Automated dipping', 'Deluge treatment') as well as secondary exposure resulting from 'Mechanical processing of treated wood' do not lead to concern for professional users.

Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product Sinesto B is unlikely for the intended uses 'Fully automated dipping', 'Automated dipping - weekly', 'Deluge treatment', as well as from secondary exposure ('Mechanical processing of treated wood').
Risk mitigation measures described in chapter 2.5.2 have to be taken into account in order to ensure safe use of the biocidal product Sinesto B.

However, based on the risk assessment of the substance of concern sodium 2-ethylhexanoate via the dermal route, a risk for professional users resulting from the 'Automated dipping – daily' with the biocidal product Sinesto B cannot be excluded.

For details see Table 77, Table 78 and Table 81 to Table 84.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.6 Risk for non-professional users

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

3.6.4.7 Risk for the general public

Table 85: Systemic effects Disodium tetraborate pentahydrate as boron

Task/ Scenario	Tier	Systemic NOAEL [mg/kg bw(/d)]	AEL [mg/kg bw(/d)]	Estimated uptake [mg/kg bw(/d)]	Estimated uptake/ AEL (%)	Acceptable (yes/no)
5	1	9.6	0.1	0.004860	4.9	yes
6	1	9.6	0.1	0.001133	1.1	yes
7	1	9.6	0.1	0.000142	0.1	yes
8	1	9.6	0.1	0.000979	1.0	yes

Table 86: Combined scenarios Disodium tetraborate pentahydrate as boron

Scenarios combined	Tier	Systemic NOAEL [mg/kg bw(/d)]	AEL [mg/kg bw(/d)]	Estimated uptake [mg/kg bw(/d)]	Estimated uptake/ AEL (%)	Acceptable (yes/no)
7 + 8	1	9.6	0.1	0.00112	1.1	yes

Table 87: Systemic effects Sodium 2-ethylhexanoate

Task/ Scenario	Tier	Systemic NOAEL [mg/kg bw(/d)]	DNEL [mg/kg bw(/d)]	Estimated uptake [mg/kg bw(/d)]	Estimated uptake/ AEL (%)	Acceptable (yes/no)
5	1	100	1	0.40	40	yes
6	1	100	1	0.04992	5.0	yes
7	1	100	1	0.00005	0.01	yes
8	1	100	1	0.06470	6.5	yes

For simplification, inhalation exposure was not assessed separately. Instead the DNEL for oral and/or dermal exposure was applied.

Table 88: Combined scenarios Sodium 2-ethylhexanoate

Scenarios combined	Tier	Systemic NOAEL [mg/kg bw(/d)]	DNEL [mg/kg bw(/d)]	Estimated uptake [mg/kg bw(/d)]	Estimated uptake/ AEL (%)	Acceptable (yes/no)
7 + 8	1	100	1	0.06475	6.5	yes

- **Local effects**

Table 89: Local effects ATMAC/TMAC

Task/ Scenario	Tier	NOAEC/DNEL	Exposure concentration	Margin of exposure	Acceptable (yes/no)
5, Sanding treated wood	1	Dermal NOAEC: 0.3 %	0.21 %	1.4	yes
6, Mouthing treated wood	1	Oral NOAEC: 0.03 %	0.004 %	7.5	yes
7, inhalation volatilised residues	1	Inhalation DNEL: 1 mg/m^3 [1)]	0.000202 mg/m^3	4950	yes
8, Contact to treated surfaces	1	Dermal NOAEC: 0.3 % Oral NOAEC: 0.03 %	Not relevant	n.a.	yes

[1)] A NOAEC for inhalation exposure has not been derived during biocidal active substance evaluation to Regulation (EU) 528/2012. However, from the REACH registration report an inhalation DNEL of 1 mg/m^3 is available.

Conclusion

Systemic exposure to the active substance disodium tetraborate pentahydrate and the substance of concern sodium 2-ethylhexanoate does not exceed the corresponding AEL. No risk is identified for the combined assessment.

No risk from local exposure to the active substance ATMAC/TMAC was identified. Considering the assessment in the CAR, MOE of 1.4 after dermal exposure (scenario 5) and of 7.5 after oral exposure (scenario 6) are considered safe. Regarding scenario 5 with a MoE of 1.4, exposure is considered safe since the AEC is based on a 14-d-dermal irritation study, whereas exposure of the general public occurs only occasionally. Repeated exposure is not expected. In addition, the active substance is bound in the wood dust and will not be available like the liquid dilution used in the dermal irritation study.

Risk mitigation measures to protect the general public are not required.

3.6.4.8 Risk for consumers via residues in food

Dietary risk assessment					
Scenario	**Tier**	**Tox. ref. value** mg/kg bw/d	**Estimated residue concentration in food** (mg/kg)	**Estimated uptake** (mg/kg bw/d) (% tox ref value) **Estimated uptake/ tox ref value** (%)	**Acceptable** (yes/no)
Livestock chewing wood					
TMAC (active subst)	Tier 1 (calculation)	no reference value derived as no relevant systemic effect [a]	0.0197	n.a.	yes
TMAC (active subst)	Tier 2 (refined calculation)	no reference value derived as no relevant systemic effect [a]	0.0020	n.a.	yes
disodium tetraborate pentahydrate (active subst)	Tier 1 (calculation)	Oral AOEL[b]: 0.1 mg/kg bw/d boron	calculated as boron 0.0005	not calculated as residues in food < trigger value	yes
sodium-2-ethylhexanoate (SoC)	Tier 1 (calculation)	oral DNEL[c]: 1 mg /kg bw/d	0.0199	0.00012 mg/kg bw/d 0.01 % tox ref value	yes
Wooden pallet					
TMAC (active subst)	Tier 1	no reference value derived as no relevant systemic effect [a]	5.040	adult 0.08400 mg/kg bw/d toddler 0.50400 mg/kg bw/d	yes
+TMAC (active subst)	Tier 2 (residue study)	no reference value derived as no relevant systemic effect [a]	< 0.1* (* LOQ)	not calculated	yes

disodium tetraborate pentahydrate (active subst)	Tier 1	Oral AOEL[b]: 0.1 mg/kg bw/d boron	calculated as boron 0.213	**calculated as boron** adult 0.00355 mg/kg bw/d 3.6 % tox ref value toddler 0.0213 mg/kg bw/d 21 % tox ref value	yes
disodium tetraborate pentahydrate (active subst)	Tier 2 (residue study)	Oral AOEL[b]: 0.1 mg/kg bw/d boron	no indication that boron levels in food are elevated compared to background levels	n.a.	yes
sodium-2-ethylhexanoat (SoC)	Tier 1	Oral DNEL[c]: 1 mg /kg bw/d	0.156	adult 0.156 mg/kg bw/d 16 % tox ref value toddler 0.936 mg/kg bw/d 94 % tox ref value	yes

[a] AR, ATMAC/TMAC PT8, eCA: IT, 2016
[b] AR, Disodium tetraborate pentahydrate, PT8, eCA: NL, 2009
[c] ECHA Brief profile, sodium 2-ethylhexanoate, https://echa.europa.eu/brief-profile/-/briefprofile/100.039.334

Conclusion on dietary risk assessment

Dietary risk assessment has been performed for the scenarios “Livestock chewing wood” and “Food stored/transported on wooden pallets”.

For both scenarios relevant residues of **ATMAC/TMAC** from the intended uses of Sinesto B are not expected. For the scenario “Livestock chewing wood” this is concluded from model calculations while for the scenario “Food stored/transported on wooden pallets” residues below the LOQ of 0.1 mg/kg were observed in a migration study. No risk for consumers via ATMAC/TMAC residues in food has been identified as the substance does not exhibit relevant systemic effects (according to AR, PT8, 2016, eCA: IT).

For **disodium tetraborate pentahydrate** there is no indication that the intended uses of Sinesto B will lead to elevated boron levels in food compared to background levels in food. For the scenario “Livestock chewing wood” this is concluded from model calculations while for the scenario “Food stored/transported on wooden pallets” this was observed in a migration study. No risk for consumers via residues in food has been identified.

For the **SoC sodium 2-ethylhexanoate** the model calculations did not identify a consumer risk via residues in food for the scenarios “Livestock chewing wood” and “Food stored/transported on wooden pallets”. It should be noted that under REACH sodium 2-ethylhexanoate is notified as Repro 2, which may have an impact on the risk assessment in the future.

Need for MRL evaluation

ATMAC/TMAC

For the scenario “Livestock chewing on wood used for paddocks” estimated refined external livestock exposure was below the trigger value of 0.004 mg/kg bw for the active substance ATMAC/TMAC. Consequently, significant residues in food of animal origin are not expected. No further MRL assessment is considered necessary with regard to the application of the biocidal product Sinestro B on wooden materials used in animal husbandry.

In a migration study analysing transfer of Sinesto B constituents from treated wood onto food ATMAC/TMAC residues were observed below the LOQ of 0.1 mg/kg. It must be noted that the LOQ of the analytical method is not sufficient to conclude on the compliance with the default MRL of 0.01 mg/kg that applies for alkyltrimethyl ammonium chloride according to of Reg (EC) No. 396/2005. However, for the “wooden pallet” scenario generally processed foods are relevant which are often complex matrices with LOQs above 0.01 mg/kg. Moreover, ATMAC/TMAC is determined as sum of six individual substances with varying alkyl-chain lengths which may lead to an overall LOQ above 0.01 mg/kg. Based on these considerations it is concluded that there is no need for an MRL evaluation for ATMAC/TMAC.

Disodium tetraborate pentahydrate

For borates two deviating MRLs exist: (1) a default default MRL of 0.01 mg/kg that applies to sodium pentaborate in the framework of Reg (EC) No. 396 / 2005 and (2) a “No MRL required” entry for boric acid and borates in Reg. (EU) No.37/2010.

For the scenario “Livestock chewing on wood used for paddocks” estimated external livestock exposure was below the trigger value of 0.004 mg/kg bw for the active substance disodium tetraborate pentahydrate. Consequently, significant residues in food of animal origin are not expected. No further MRL assessment is considered necessary with regard to the application of the biocidal product Sinesto B on wooden materials used in animal husbandry.

In a migration study transfer of Sinesto B constituents from treated wood onto food boron levels were analysed in several food commodities stored on treated and untreated wooden boards. Boron levels in samples stored on untreated wood ranged from 0.049 to 23.9 mg/kg food, while samples stored on Sinesto B-treated wood contained 0.048 to 25.2 mg boron / kg food. These values are well above the default MRL of 0.01 mg/kg that applies to sodium pentaborate in the framework of Reg (EC) No. 396 / 2005 (which would correspond to 0.001 mg boron /kg). Thus, the default MRL is already exceeded from natural boron levels in food. As there is no indication that the intended uses of Sinesto B will lead to significantly elevated levels of boron in food an MRL evaluation for sodium pentaborate is not considered necessary.

Even though an MRL evaluation for sodium pentaborate is not considered necessary in the context of Sinesto B assessment, an alignment of the two deviating MRLs in the frameworks of Reg (EC) No. 396/2005 and Reg. (EU) No.37/2010 is recommended.

As a result of the dietary risk assessment, the following risk mitigation measure (RMM) is proposed:

- Do not use on wood which may come in direct contact with food, feed and livestock. (Frequently used sentences N-15)

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is required, as the product contains the active substance disodium tetraborate pentahydrate and the substance of concern sodium 2-ethylhexanoate. For this purpose, the approach described in chapter 4.4.1 of the Guidance for Human Health Risk Assessment for Biocidal Active Substances and Biocidal Products (ECHA-13-G-18-EN) is applied.
Synergsitic effects between the components are not expected.

Professional user

Table 90: Systemic effects Cumulative assessment for the professional user

Scenario		HQ Boron	HQ EHA	HI[1]	acceptable (yes/no)
1 Fully automated dipping - daily	Tier 1	1.52	6.71	8.23	no
	Tier 2	0.08	0.34	0.41	yes
1 Fully automated dipping - weekly	Tier 1	0.38	1.67	2.05	no
	Tier 2	0.08	0.34	0.41	yes
2 Automated dipping - daily	Tier 1	1.52	6.71	8.23	no
	Tier 2	0.22	0.97	1.19	**no**
2 Automated dipping - weekly	Tier 1	0.38	1.67	2.05	no
	Tier 2	0.05	0.24	0.30	yes
3 Deluge treatment	Tier 1	1.21	5.32	6.52	no
	Tier 2	0.13	0.57	0.70	yes
4 Mechanical processing of treated wood	Tier 1	0.10	0.43	0.52	yes
	Tier 2	0.10	0.43	0.52	yes

[1]HI: Hazard Index; sum of the Hazard Quotients (HQs) for each substance. HQ: estimation of internal exposure/AEL. Acceptable, if HI ≤ 1

Calculation of the Hazard Index (HI) indicated a risk for the scenario “Automatic dipping – daily”.
Since the AEL of the active substance disodium tetraborate pentahydrate and the DNEL of the SoC Sodium-2-ethylhexanoate were both derived based on reproductive toxic effects, further refinement of the assessment (Tier 3) is not possible for the professional user.
General public

Table 91: Systemic effects Cumulative assessment

Task / Scena-rio	Tier	AEL boron [mg/kg bw(/d)]	DNEL EHA [mg/kg bw(/d)]	Exposure boron [mg/kg bw(/d)]	Exposure EHA [mg/kg bw(/d)]	HI	Acceptable (yes/no)
5	1	0.1	1	0.00486	0.40	0.449	yes
6	1	0.1	1	0.001133	0.04992	0.061	yes
7	1	0.1	1	0.000142	0.00005	0.001	yes
8	1	0.1	1	0.000979	0.06470	0.074	yes
7 +8	1	0.1	1	0.001120	0.06475	0.076	yes

For simplification, inhalation exposure was not assessed separately. Instead the DNEL for oral and/or dermal exposure was applied.

Calculation of the Hazard Index (HI) indicated no risk for any of the exposure scenarios. Hence, no further refinement of the assessment (Tier 3) is required for the general public.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

The risk characterisation for industrial users is described in chapter 3.7.4.5.

3.6.4.10.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product Sinesto B is unlikely for the intended uses ‘Fully automated dipping’, ‘Automated dipping - weekly’, ‘Deluge treatment’, as well as from secondary exposure (‘Mechanical processing of treated wood’).
Risk mitigation measures described in chapter 2.5.2 have to be taken into account in order to ensure safe use of the biocidal product Sinesto B.

However, based on the cumulative risk assessment of the active substance disodium tetraborate pentahydrate and the substance of concern sodium 2-ethylhexanoate via the dermal route, a risk for professional users resulting from the ‘Automated dipping – daily’ with the biocidal product Sinesto B cannot be excluded.

For details see Table 77, Table 78, Table 81 to Table 84,Table 88 and **Fehler! Verweisquelle konnte nicht gefunden werden.**..

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.10.3 Summary of risk characterisation for non-professional user

Not relevant

3.6.4.10.4 Summary of risk characterisation for indirect exposure

Table 92 Disodium tetraborate pentahydrate as boron

Scenario, Tier	Relevant reference value [mg/kg bw(/d)]	Estimated uptake [mg/kg bw(/d)]	Estimated uptake/reference value (%)	Acceptable (yes/no)
5	0.1	0.00486	4.9	yes
6	0.1	0.001133	1.1	yes
7	0.1	0.000957	1.0	yes
8	0.1	0.000142	0.1	yes
7 + 8	0.1	0.001120	1.1	yes

Table 93 Sodium ethyl hexanoate

Scenario, Tier	Relevant reference value [mg/kg bw(/d)]	Estimated uptake [mg/kg bw(/d)]	Estimated uptake/reference value (%)	Acceptable (yes/no)
5	1	0.40	40	yes
6	1	0.04992	5.0	yes
7	1	0.00005	0.01	yes
8	1	0.06470	6.5	yes
7 + 8	1	0.06475	6.5	yes

3.7 Risk assessment for animal health[12]

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 intened 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. However, a clear note in the instructions for use is required that the biocidal product is not intended for wood used in animal housing or fencing.

[12] Pets and domestic animals. Regarding wild animals, please refer to chapter 3.8.

3.8 Risk assessment for the environment

3.8.1 General information

Sinesto B is a concentrated wood preservative containing the active substances ATMAC/TMAC (14%; CAS: 61789-18-2) and Disodium tetraborate pentahydrate (3.97%; CAS: 12179-04-3), which is to be diluted with water to reach the final in-use concentration. The product is intended to temporarily prevent wood discolouring 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 B is based on the active substances, only.
Regarding the leaching behaviour of Sinesto B, a semi-field study was submitted by the applicant, from which leaching data for the environmental exposure assessment was derived.

Regarding the active substance Disodium tetraborate pentahydrate, it has to be considered that the following assessment is based on the element Boron. According to the AR on Disodium tetraborate pentahydrate (NL, April 2009), the active substance will dissolute in water at environmentally relevant conditions, forming Boric acid/ Borate:

$$Na_2B_4O_7.5H_2O + 2\ H_2O = 2\ NaB(OH)_4 + 2\ B(OH)_3$$

According to the Assessment report, for practical reasons Tetraborates, Boric acid and other Borates are usually expressed on the basis of Boron (B).
Boron is a naturally occurring element that is essential to a variety of organisms. Consequently, the background concentrations should be considered when deriving "Predicted Environmental Concentrations" (PECs) and the "Predicted No Effect Concentration" (PNECs).
In the CAR for Disodium tetraborate pentahydrate, an added risk approach was applied. In this added risk approach both the PEC and the PNEC are expressed as B added by man to the natural background concentration, resulting in an “added Predicted Environmental Concentration” (PEC_{add}) and “added Predicted No Effect Concentration” ($PNEC_{add}$), respectively. The use of the added risk approach implies that only the anthropogenic amount of a substance is considered to be relevant for the effect assessment of that substance. For the assessment of the product Sinesto B this approach is followed as well.

3.8.2 Effects assessment

Two ecotoxicological effect studies (acute toxicity to fish and acute toxicity to daphnia) with the b.p. Sinesto B were provided by the applicant. From our point of view these studies are not usable for the risk assessment of the b.p. as no detailed composition of the test material is stated and no analytical monitoring of the test material was conducted. Furthermore, the tests were conducted according to a national Finnish standard protocol and the description of the test performance is not given in enough detail to validate the studies adequately. No ecotoxicological test for Sinesto B for acute toxicity against algae is available.

Therefore, the environmental effects assessment for the product is based on the information provided in in the respective CA reports of the active substances (ATMAC/TMAC: eCA IT, PT 8 final AR, 2016; Disodium tetraborate pentahydrate: eCA NL, PT 8 final AR 2009).

3.8.2.1 Mixture toxicity

Screening step

- **Screening Step 1:**

The biocidal product affects both, aquatic and terrestrial environment. For further information on the release pathway and the relevant compartments for the assessment of the product, see chapter 3.9.4.2.

- **Screening Step 2:**

The product contains more than one biocidal active substances. Besides the active substances no other substances, which trigger the classification with respect to environmental hazards of the product are included in the product composition. Thus, the relevant substances for environmental risk assessment are the active substance ATMAC/TMAC and Disodium tetraborate pentahydrate.

- **Screening Step 3: Screen on synergistic interactions**

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

Table 94

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

Conclusion of mixture toxicity

Mixture toxicity assessment is required, as more than one ecotoxicologically relevant components/ active substances were identified. The mixture toxicity assessment was performed by PEC/PNEC summation and will be provided in the Risk assessment chapter for the environment (3.9.5).

3.8.2.2 Aquatic compartment (including sediment and STP)

- **Aquatic toxicity**

ATMAC/TMAC

As agreed at WGII2015, the hazard assessment of Coco alkyltrimethylammonium chloride to aquatic organisms relies on read across data, mostly to DDAC. While on acute toxicity basis, fish appear to be less sensitive than Daphnia magna and algae, the sensitivity of the three taxa is very similar when chronic endpoints are compared.

Considering the chronic endpoints selected as most reliable among all those available in the ATMAC and TMAC dossier, a PNECwater for Coco alkyltrimethylammonium chloride can be derived from the lowest of the chronic endpoints available for the three trophic levels, which is the algae 96h NOEC = 0.011 mg/L (mean measured) corrected for difference in molecular weight (MW) (96h NOErC = 0.008 mg/L, mean measured), hence:

PNECwater = 0.008 mg a.s./L / AF 10 = 0.8 µg a.s./L

PNECsediment = 397.5 mg/kg dw /100= 3.98 mg/kg dw, equivalent to 2.67 mg/kg ww (based on read across to DDAC and correction for MW).

Please note:

In the up-to-date final Assessment Report for the active substance DDAC (PT 1-4), published in 2021, the conclusion from WG II/2015 was included and the risk assessment for the sediment compartment was done with the lowest PNEC_sediment:

PNEC sediment (EPM) = 1.35 mg/kg ww (6.19 mg/kg dw, based on the conversion factor of 4.6) (Additional factor of 10 included).

As the product application was submitted in April 2018 and the ERA was conducted in 2020, RefMS DE decided not to change the calculations presented in **Fehler! Verweisquelle konnte nicht gefunden werden.**. When using the PNEC_sediment (EPM) for the risk assessment, the corresponding PEC/PNEC ratios (for the a.s. and for mixture toxicity) will change, but will still be below 1 and therefore, the conclusion for the sediment compartment, i.e. that the use of the product will not lead to unacceptable risks, is still valid.

Disodium tetraborate pentahydrate

In the final assessment report of Boric acid it was agreed to perform the risk assessment on “added Boron concentrations”. Therefore, all PEC and PNEC values are given in Boron units. Boron is known to be an essential micronutrient for terrestrial plants. The following PNEC values for Boron from the final assessment report were used.

PNECwater = 0.18 µg B/L
PNECsediment = 0.24 mg B/kg ww

- **Inhibition of microbial activity (STP)**

For ATMAC/TMAC the PNEC in sewage treatment plant is 0.122 mg a.i./L.
For Boron the PNEC in sewage treatment plant is 1.8 mg B/L.

Please note:

The derivation of $PNEC_{microorganisms}$ for ATMAC/TMAC was discussed at WG ENV II 2015. The conclusion is presented in the document “WGII2015_ENV_7-2_ATMAC-TMAC_PT 8_Final minutes_AHF.docx”. According to this WG decision, two options for derivation of $PNEC_{microorganism}$ can be applied at product authorisation stage. In addition to the $PNEC_{microorganism}$ based on the EC50 with an AF of 100, which was applied in this assessment, it would also be possible to use the EC10 (AF 10) for PNEC derivation but in this case the endpoint needs to be calculated from the study.

However, for Sinesto B the highest calculated PEC/PNEC for STP microorganisms is 2.39E-05. It is mentioned in the minutes of WGII2015 AHF follow-up that the difference between the PNEC values resulting from the two approaches is very small. Consequently, there will be no effect on the overall outcome of the ERA.

3.8.2.3 Terrestrial compartment (including groundwater)

ATMAC/TMAC

Based on the lowest of the two chronic endpoints available for earthworms and micro-organisms, i.e. 28 d EC10 of 70 mg/kg ww (79.1 mg/kg dw) for microorganisms for the DDAC data (recalculated as 28 d EC10 = 52.5 mg/kg ww and 59.3 mg/kg dw, upon correction for MW), the PNEC soil for Coco alkyltrimethylammonium chloride is derived as follows:
PNEC soil = 52.5 mg/kg ww/ 50 = 1.05 mg/kg ww equivalent to 1.19 mg/kg dw (based on read across to DDAC).

Disodium tetraborate pentahydrate
It was concluded that the PNEC for terrestrial species would be 0.4 mg B/kg dwt soil corresponding to 0.35 mg B/kg wwt soil. This was based on a single species NOEC endpoint from a greenhouse study of *Hordeum vulgare*, and an application factor of 5.
PNEC soil = 0.35 mg B/kg ww

3.8.2.4 Atmosphere

The vapour pressure of both active substances is very low. Therefore, exposure of the atmosphere is not considered relevant for Sinesto B.

ATMAC/TMAC
Due to the low vapour pressure, ATMAC/TMAC is not expected to partition into the atmosphere. Furthermore, the substance is not expected to contribute to global warming, ozone depletion in the stratosphere, or acidification on the basis of its physical and chemical properties (CAR 2014).

Disodium tetraborate pentahydrate
According to the AR (2009), vapour pressure and Henry's law constant are not applicable, because the melting point lies above 300 °C and at ambient temperature vapour pressure is expected to be less than 10^{-5} Pa. Because of the low vapour pressure, release of Disodium tetraborate pentahydrate to air is negligible.

3.8.2.5 Non-compartment specific effects

3.8.2.5.1 Further ecotoxicological studies

No further ecotoxicological studies are available and are not required for this product.

3.8.2.6 Summary of effects assessment

Table 95

Summary table on calculated PNEC values		
Compartment	**ATMAC/TMAC**	**Disodium tetraborate pentahydrate**
Surface water	0.0008 mg/L	0.18 mg B/L
Sediment	2.67 mg/kg wwt	0.24 mg B/kg ww
Soil	1.05 mg/kg wwt	0.35 mg B/kg ww
STP	0.122 mg/L	1.8 mg B/L
Birds	Not relevant	Not relevant

Summary table on calculated PNEC values		
Compartment	**ATMAC/TMAC**	**Disodium tetraborate pentahydrate**
Mammals	Not relevant	Not relevant

3.8.3 Fate and behaviour

For a detailed assessment of the environmental fate and behaviour of the active substances, please refer to the respective assessment reports:

- ATMAC/TMAC (CAS: 61789-18-2): Assessment report PT 8, April 2016, Italy
- Disodium tetraborate pentahydrate (CAS: 12179-04-3): Assessment report PT 8, February 2009, The Netherlands

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 °C 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.

Disodium tetraborate pentahydrate

Disodium tetraborate pentahydrate is an inorganic substance. Hence, biodegradation is not relevant.

Abiotic degradation in water is not relevant for this substance.

At environmentally relevant conditions Disodium tetraborate pentahydrate will dissolute in water, forming Boric acid/Borate:

$$Na_2B_4O_7.5H_2O + 2\ H_2O = 2\ NaB(OH)_4 + 2\ B(OH)_3$$

According to the assessment report, for practical reasons Tetraborates, Boric acid and other Borates are usually expressed on the basis of Boron.

Therefore, water solubility, dissociation constant, partition coefficient as well as the fate and behaviour in the aquatic system are the ones of an equivalent amount of Boric acid in the presence of sodium ions.

The equilibrium formed in water and the occurring main Boron species are dependent on Boron concentration, temperature and pH. In the presence of metal ions, ion pair complexes are to be expected.

Regarding sorption in soil, the average K_F value given in the CA report for boric acid amounts to 2.6 L/kg (range 0.4 - 8.41 L/kg, n=9). The vapour pressure reported in the CA report for Boric acid is 9.9×10^{-6} Pa at 25 °C. Therefore, no volatilisation is expected.

3.8.3.1 Leaching behaviour (ADS)

A 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.

Semi-field leaching tests
The leaching of ATMAC/TMAC and Disodium tetraborate pentahydrate from treated timber was investigated in a semi-field study for a period of one year 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 was 0.8155 m^2 according to DIN CEN/TR 16663:2014. Wood of *Pinus sylvestris* was treated with a solution containing 4.17% of TH3810A (development code of Sinesto B) by short-term dipping. The mean retention rate of the product was 7.63 g/m^2, equivalent to a retention rate of 1.07 g TMAC per m^2 and 0.045 g boron per m^2 (or 0.303 g Disodium tetraborate pentahydrate 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 Boron after each major rain event. Leachates were collected from 22 September 2016 to 22 September 2017.

The calculated flux rates based on the leaching test are summarised below. The detailed calculations are presented in chapter 4.3.2. A correction factor of 1.57 was applied to calculate leaching rates, since the product retention of 7.63 g product per m^2 in the study is lower than the maximum intended retention rate of the product of 12 g/m^2.

Table 96

Leaching of Sinesto B [mg/m^2/d]		
Active substance	**TIME 1 (30 days)**	**TIME 2 (5 years)**
Cumulative leaching $Q^*_{leach,time}$ (mg/m^2)		
ATMAC/TMAC	2.69	64.21
Boron	2.88	21.24
Leaching rate FLUX (mg/(m^2*d))		
ATMAC/TMAC	0.090	0.035
Boron	0.096	0.012

3.8.3.2 Bioconcentration

The bioaccumulation potential of the active substances of Sinesto B is low:

ATMAC/TMAC
A bioconcentration test with fish exposed to the read-across substance DDAC provided a $BCF_{whole\ fish}$ of 81 L/kg. In addition, experimental $BCF_{whole\ fish}$ of 79 L/kg measured for the other quaternary ammonium compound Alkyl (C12-16) dimethylbenzyl ammonium chloride (C12-16-BKC/ADBAC) shows the same low bioaccumulation potential.

Disodium tetraborate pentahydrate
At environmentally relevant conditions Disodium tetraborate pentahydrate will dissolute to Boric acid. Boric acid has a low bioaccumulation potential, with a BAF < 10 L/kg for fish and < 30 L/kg for plankton and invertebrates.

3.8.4 Exposure assessment

3.8.4.1 General information

The wood-preservative Sinesto B 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 Disodium tetraborate pentahydrate (3.97%; CAS: 12179-04-3) is to be diluted with water to reach the final in-use concentration. The dilution rate is dependent on the intended use of the wood, climate conditions and type of wood. The intended product retention in wood is 5-12 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"[13] (adopted at WG ENV II 2018). Following life cycle steps of the product were assessed:

Table 97

Assessed PT	PT 8
Assessed scenarios	Wood in service (UC3), house Wood in service (UC3), noise barrier Wood in service (UC3), bridge over pond
ESD(s) used	OECD Emission Scenario Documents, Number 2, Revised Emission Scenario Document for Wood Preservatives, September 2013
Approach	Average consumption (all scenarios)
Distribution in the environment	Calculated based on Guidance on the BPR, Vol. IV Env., Parts B+C, October 2017
Groundwater simulation	no
Confidential Annexes	no
Life cycle steps assessed	Production: No Formulation No Use (application): Yes (qualitative) Storage: Yes (qualitative) Service life: Yes (quantitative)
Remarks	-

Emission of Sinesto B or single product components to the environment could generally occur during application of the product and storage and service life of treated wood.

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

3.8.4.2 Fate and distribution in exposed environmental compartments

In Table 98 the environmental compartments are summarized, which might potentially be exposed to the active substances ATMAC/TMAC and Disodium tetraborate pentahydrate due to the use of wood treated with the biocidal product Sinesto B in use class 3 (UC3).

Table 98

Identification of relevant receiving compartments based on the exposure pathway						
Scenario	**Freshwater**	**Freshwater sediment**	**STP**	**Soil**	**Groundwater**	**Air**
House	-	-	-	++	+	-
Noise barrier	+	+	++	++	+	-
Bridge over pond	++	++	-	-	-	-

++ direct release to receiving compartment
+ indirect release to receiving compartment
- no release to receiving compartment

Direct and indirect emissions from service-life of wood treated with Sinesto B to the affected receiving compartments are assessed in 3.8.4.4.

The assessment is based on the active substances of Sinesto B. There are no substances of concern and no relevant metabolites. A summary of the relevant parameters used in the risk assessment is given in the following table:

Table 99

Input parameters used for calculating the fate and distribution in the environment			
Parameter	**Unit**	**ATMAC/TMAC**	**Disodium tetraborate pentahydrate**
Molecular weight	g/mol	275.35 (mean)	291.296
Vapour pressure	Pa	$1.8*10^{-6}$ (at 20 °C)	$9.9*10^{-6}$ (at 25 °C)
Henry's law constant	$Pa \cdot m^3 \cdot mol^{-1}$	$1.38*10^{-9}$ (at 20 °C)	$3.218*10^{-5}$ (calculated)
Water solubility	g/L	346 (at 20 °C, pH 7)	40.06 (at 20 °C, pH 9.66)
Sorption coefficient	L/kg	562314 (K_{OC})	2.6 (K_F)
Log Pow		deemed unreliable for surface-active substance	-0.757 (at 25 °C)
Hydrolysis		stable	stable
Aqueous photolysis		stable	stable
Readily biodegradable		Yes, fulfilling 10-day window	not applicable
DT50 soil (12 °C)	d	30,000	not applicable
DT_{50} surface water (12 °C)	d	15	not applicable
DT_{50} air	hr	13.505	not applicable

The distribution of the ATMAC/TMAC in the STP was remodelled with Simple Treat 4.0. For Disodium tetraborate pentahydrate the distribution of boric acid in the STP according to the CAR on Disodium tetraborate pentahydrate is applied.
The following distributions in the sewage treatment plant (STP) are used for the risk assessment

Table 100

Distribution in the STP [%]		
	ATMAC/TMAC	**Boron**
water	6.212	99.9
sludge	85.09	-
degraded	8.695	-
air	0	-

3.8.4.3 Formulation, industrial application and storage

Sinesto B 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 intended use of the wood, climate conditions and type of wood. Application takes place automatically in an industrial treatment plant by spraying or dipping. The product containing the active substances ATMAC/TMAC and Disodium tetraborate pentahydrate is supposed to temporarily prevent wood discolouring fungi on freshly sawn timber and pallets.

The following qualitative assessment evaluates potential emission of Sinesto B or single product components to the environment during the life cycle steps formulation, production and application of the product and storage of 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 B 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[14]).

Safety measures regarding the application process are also demanded in the Implementation Directive (IR) of the active substance ATMAC/TMAC (2016) and apply to the application of Sinesto B 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 B 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 treated wood

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

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 respective Inclusion Directives on ATMAC/TMAC and Disodium tetraborate pentahydrate, 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 negligible emissions to the environment are expected. Therefore, according to the Inclusion Directives, the following RMM is part of the authorisation of Sinesto B:

- *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 is performed for the assessment of storage of wood after industrial application.

3.8.4.4 Service life of treated wood

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

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

During the Arona Leaching Workshop in June 2005 (EC, 2005[15]), 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 fungi, following amendments according to the agreements of WG ENV II 2018 regarding the assessment of temporary anti-sapstain wood-preservatives[16] 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 applied

According to the applicant, freshly sawn timber is treated with Sinesto B 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 PECs in the environmental compartments derived in the following sections 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 PEC values presented in the following tables are rounded values, whereas the calculations for the different PECs are always carried out with unrounded values.
Stated PEC values for Boron represent “added Predicted Environmental Concentration” (PEC_{add}), Boron which is added by man to the natural background concentration.

3.8.4.4.1 Aquatic compartment (including sediment and STP)

According to ESD PT8, the aquatic compartment is considered a relevant receiving compartment during service life of wood treated with Sinesto B for the following scenarios:

- Scenario 2: noise barrier
- Scenario 3: bridge over pond

The emission estimation was conducted according to ESD PT8 (2013), chapter 4.3.3.3 and 4.3.3.4, considering the specifications above (chapter 3.8.4.4).

- **Emission to STP**

Emissions to the STP are calculated for wood treated with Sinesto B, which is used for the construction of noise barriers.

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[15] 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.
[16] https://webgate.ec.europa.eu/s-circabc/faces/jsp/extension/wai/navigation/container.jsp

The STP effluent concentrations do represent the PECs of the active substances of Sinesto B for this compartment. The distribution of the compounds to air, water and sludge is listed in

Table 100.
The following table contains the PEC values for STPs.

Table 101

PECs for the active substances of Sinesto B in the STP			
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Boron
		PEC_{STP} in µg/L	
Noise barrier	30 days	0.003	0.050
	5 years	0.001	0.006

- **Emission to surface water**

Emissions to surface water are assessed either for indirect emissions via the STP with the noise barrier scenario or direct emissions with the bridge over pond scenario. The calculated PEC values for surface water are presented in the table below. For the bridge over pond scenario, the values for ATMAC/TMAC include degradation (acc. eq. 3.16 and 3.17 of ESD PT 8 (2013)).

Table 102

PECs for the active substances of Sinesto B in surface water			
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Boron
		$PEC_{surfacewater}$ in µg/L	
Noise barrier	30 days	1.58E-04	0.005
	5 years	6.23E-05	5.99E-04
Bridge over pond	30 days	0.004*	0.014
	5 years	0.004*	0.106

*with degradation

- **Emission to sediment**

Emissions to sediment are assessed either for indirect emissions to surface water via the STP with the noise barrier scenario or direct emissions to surface water with the bridge over pond scenario. The predicted concentration in sediment is deduced from the $PEC_{surfacewater}$ by a partition of the active substance between suspended matter and the water phase. For the bridge over pond scenario, $PEC_{surfacewater}$ including degradation was considered for ATMAC/TMAC.
Regarding Boron, the $PNEC_{sediment}$ is based on equilibrium partitioning. Hence, the calculation of $PEC_{sediment}$ also using equilibrium partitioning would give no additional information since the resulting PEC/PNEC ratios would be the same as for the aquatic compartment. Consequently, Boron concentrations in sediment were not quantified.

Table 103

PECs for the active substances of Sinesto B in sediment		
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC
		$PEC_{sediment}$ in $\mu g/kg_{wwt}$
Noise barrier	30 days	1.93

	5 years	0.762
Bridge over pond	30 days	54.44*
	5 years	45.99*

* with degradation in surface water

3.8.4.4.2 Terrestrial compartment (including groundwater)

According to ESD PT8, the terrestrial compartment is considered a relevant receiving compartment during service life of wood treated with Sinesto B for the following scenarios:

- house
- noise barrier

No PECs were calculated for release to soil and groundwater via sewage sludge for the noise barrier scenario, since direct emission to soil is considered the worst case.

- **Emission to soil**

The emission estimation was conducted according to ESD PT8 (2013), chapter 4.3.3.1 and 4.3.3.3, considering the specifications above (chapter 3.8.4.4). The values stated for ATMAC/TMAC consider degradation (acc. eq. 3.11 and 3.12 of ESD PT 8 (2013)).

Table 104

PECs for the active substances of Sinesto B in soil			
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Boron
		PEC_{soil} in mg/kg_{wwt}	
Noise barrier	30 days	0.003	0.003
	5 years	0.067	0.022
House	30 days	0.008	0.008
	5 years	0.178	0.060

- **Emission to groundwater**

According to Guidance on BPR, Vol. IV ENV, Part B+C the predicted porewater concentration is an indicator for concentrations in groundwater. In Table 105 the predicted porewater concentrations for the active substances of Sinesto B are shown.

Table 105

PECs for the active substances of Sinesto B in porewater			
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Boron
		$PEC_{porewater}$ in µg/L	
Noise barrier	30 days	2.87E-04	1.25
	5 years	0.007	8.99
House	30 days	7.66E-04	3.33
	5 years	0.018	24.5

3.8.4.4.3 Atmosphere

The vapour pressure of the active substances is very low. Therefore, exposure of the atmosphere is not considered relevant for Sinesto B. 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.

3.8.4.5 Non-compartment specific effects

- **Primary poisoning**

Not relevant for PT 8.

- **Secondary poisoning**

According to the BPR guidance Vol IV part B+C (2017) for substances with a log $K_{ow} \geq 3$, the uptake through the food chains eventually leading to secondary poisoning should be considered. The log K_{ow} of both active substances is below 3, though the log Kow might not be an appropriate indicator to evaluate bioaccumulation of the inorganic substance Disodium tetraborate pentahydrate. However, the average BAF <10 L/kg for fish and < 30 L/kg for plankton and invertebrates verify a low bioaccumulation potential.
No further assessment of secondary poisoning via the food chain is considered necessary and no PECs were derived.

3.8.4.6 Aggregated exposure (combined for relevant emission sources)

Biocidal active substances are used in various applications and are often contained in many different products. The environmental exposure assessment of single uses may therefore underestimate the actual concentrations of active substances to be found in the environment.
However, currently a guideline on how an aggregated exposure assessment shall be performed is in development. Therefore, in this PAR the aggregated exposure has not yet been assessed.

3.8.5 Risk characterisation

The environmental risk characterisation for biocidal active substances in the context of Annex VI of the Biocidal Products Regulation (Regulation (EU) No 528/2012) involves the comparison of PEC and PNEC values for each relevant environmental compartment as well as for non-target organisms. For this purpose, Risk Characterisation Ratios (PEC/PNEC) were derived for the use of the wood preservative Sinesto B. If the PEC/PNEC ratio is equal or below 1, this is interpreted as an acceptable risk to the environment. Exceptions are the assessments of industrial application of the biocidal product and the storage of treated wood, which were done qualitatively.

PEC/PNEC values were calculated for TIME1 and TIME2. The PEC/PNEC ratios for Boron refer to Boron, which is added by man to the natural background concentrations. The use of the added risk approach implies that only the anthropogenic amount of Boron is considered to be relevant for the effect assessment of that substance.

3.8.5.1 Industrial application and storage

Application (industrial)
Industrial treatment usually takes place in closed manufacturing systems with several kinds of control measures (e.g. to avoid leakage) and safety measures being on the state of the art of the chemical industry. Therefore, emissions to the environment are considered as negligible.

No unacceptable risk for the environment is expected during industrial application of Sinesto B.
The following risk mitigation measure is part of the authorisation:

- *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).*

The following instruction for use 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 treated wood
No risk quotients for the environment were derived. As it can be concluded from the respective Inclusion Directives of the two active substances, storage of treated timber may pose a risk to the environment unless risk mitigation measures are undertaken.

Therefore, the following risk mitigation measure is part of the authorisation and reduces potential risks to the environment to an acceptable level, as emission to the environment is prevented:

- *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.*

3.8.5.2 Service life of treated wood

3.8.5.2.1 Aquatic compartment (including sediment and STP)

- **STP**

Losses to STPs are calculated for the in-service leaching from the surface of noise barriers.
The following table contains the PEC/PNEC ratios for the single active substances as well as a mixture toxicity assessment, comprising the addition of the PEC/PNEC values for ATMAC/TMAC and Boron.

Table 106

PEC/PNEC values of the active substances of Sinesto B in the STP				
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Boron	Mixture Toxicity
		$PEC/PNEC_{STP}$		
Noise barrier	30 days	2.39E-05	2.78E-05	5.17E-05
	5 years	9.42E-06	3.33E-06	1.27E-05

Conclusion: 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 and the mixture of the active substances for Sinesto B.

- **Surface water**

The following table contains the PEC/PNEC ratios for the active substances as well as a mixture toxicity assessment for the “bridge over pond” and “noise barrier” scenarios, which represent exposure of surface water to Sinesto B.

Table 107

PEC/PNEC values of the active substances of Sinesto B in surface water				
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Boron	Mixture Toxicity
		$PEC/PNEC_{surfacewater}$		
Noise barrier	30 days	1.98E-04	2.80E-05	2.26E-04
	5 years	7.79E-05	3.33E-06	8.12E-05
Bridge over pond	30 days	0.006	7.78E-05	0.006
	5 years	0.005	5.89E-04	0.005

Conclusion: Both scenarios yield PEC/PNEC ratios below one for surface water for the single substances as well as the mixture of active substances, indicating an acceptable risk for surface water organisms.

- **Sediment**

The PEC/PNEC values for the active substances as well as the mixture toxicity assessment are summarized below for the representative scenarios “bridge over pond” and “noise barrier”.
No $PEC_{sediment}$ values were derived for Boron, since $PNEC_{sediment}$ is based on equilibrium partitioning. However, as resulting PEC/PNEC ratios for Boron in sediment would be the same as for the aquatic compartment, the PEC/PNEC ratios calculated for Boron in surface water are used for the mixture toxicity assessment.

Table 108

PEC/PNEC values of the active substances of Sinesto B in sediment				
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Boron	Mixture Toxicity
		$PEC/PNEC_{sediment}$		
Noise barrier	30 days	7.23E-04	2.80E-05	7,51E-04
	5 years	2.85E-04	3.33E-06	2,89E-04
Bridge over pond	30 days	0.020	7.78E-05	0.021
	5 years	0.017	5.89E-04	0.018

Conclusion: Acceptable risks for the sediment compartment were found for the “noise barrier” scenario as well as for the “bridge over pond” scenario for the active substances and the mixture toxicity assessment.

3.8.5.2.2 Terrestrial compartment (including groundwater)

- **Soil**

The calculated PEC/PNEC ratios for the soil compartment for the active substances of Sinesto B and the mixture toxicity assessment are shown in the table below.

Table 109

PEC/PNEC values of the active substances of Sinesto B in soil				
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Boron	Mixture Toxicity
		$PEC/PNEC_{soil}$		
Noise barrier	30 days	0.003	0.009	0.011
	5 years	0.064	0.063	0.127
House	30 days	0.007	0.023	0.031
	5 years	0.170	0.171	0.341

Conclusion: Acceptable risks for the soil compartment were identified for the active substances of Sinesto B. The mixture toxicity assessment resulted in acceptable risks for soil organisms, too.

- **Groundwater**

The predicted concentration in groundwater is represented by the porewater concentration as a first tier approach. The maximum permissible concentration for the organic biocide ATMAC/TMAC in groundwater is 0.1 µg/L according to Directive 2006/118/EC for groundwater.
For Boron a limit value of 1 mg/L in drinking water is defined in Directive 98/83/EC, which was also applied for the groundwater assessment in the CAR on Disodium tetraborate pentahydrate (NL, 2008) and was confirmed at AHEE 4 (2020, AP5-3).

Table 110

PEC values of the active substances of Sinesto B in porewater			
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Boron
		$PEC_{porewater}$ in µg/L	
Noise barrier	30 days	2.87E-04	1.25
	5 years	0.007	8.99
House	30 days	7.66E-04	3.33
	5 years	0.018	24.5

Conclusion: The calculated concentrations in porewater are below the respective quality standard of 0.1 µg/L for ATMAC/TMAC and 1 mg/L for Boron. Therefore, an acceptable level of emissions to groundwater is expected for service life of wood treated with Sinesto B.

3.8.5.3 Atmosphere

Due to the physicochemical properties of the active substances air is not regarded as a compartment of concern. The risk to the air compartment is considered acceptable.

3.8.5.4 Non-compartment specific

- **Primary poisoning**

Not relevant for PT 8.

- **Secondary poisoning**

The risk of secondary poisoning via the food chain is considered low (see chapter 3.8.4.5).

3.8.5.5 PBT assessment

ATMAC/TMAC
ATMAC/TMAC is not considered to be persistent. The B criterion is not fulfilled with a BCF_{fish} of 81. The T criterion is fulfilled with a NOEC for algae of 0.008 mg/L.
Hence, ATMAC/TMAC is not considered to be a PBT or vPvB substance.

Disodium tetraborate pentahydrate
Being an inorganic compound, Disodium tetraborate pentahydrate does not biodegrade in water and sediments, and should therefore be considered as very persistent (vP).
Boron is not bioconcentrated, based on the available data the BCF is < 2000 L/kg wwt.
The chronic NOEC of Boron for marine or freshwater organisms is > 0.01 mg B/L and Boron is not considered to have endocrine disrupting effects. However, based on toxicological data, the a.s. is classified as Toxic for Reproduction category 1B and assigned with the risk phrase H360FD. Therefore, the T criterion is fulfilled. The criteria for Persistence and Toxicity are fulfilled, but not for Bioaccumulation. The active substance should not be considered as PBT substance. But it meets two of the criteria for being PBT and has therefore to be considered as candidate for substitution.

3.8.5.6 Endocrine disrupting properties

According to the CARs for ATMAC/TMAC (eCA: Italy, April 2016) and disodium tetraborate (eCA: NL, February 2009), the active substances are not considered having endocrine disrupting properties. Disodium tetraborate is classified as Toxic for Reproduction, Cat.1B and is contained in the Candidate list of Substances of Very High Concern for Authorisation according to Regulation 1907/2006. 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.

The full composition of the product is listed in the confidental Annex. There are no indications that a non-active substance of the product may have endocrine disrupting properties based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation, the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-

hazards. For none of the co-formulants indications on potential ED effects on environmental non-target organisms were found in scientific literature.

3.8.5.7 Summary of risk characterisation

The biocidal product Sinesto B with the active substances ATMAC/TMAC and Disodium tetraborate pentahydrate contains no substance of concern for the environment. Therefore, the environmental risk assessment for the product is based on the active substances.

The wood-preservative is applied industrially to freshly sawn timber and pallets via spraying or dipping. The concentrated product is to be diluted with water to reach the final in-use concentration. The dilution rate is dependent on the intended use of the wood, climate conditions and type of wood. The intended product retention in wood is 5-12 g/m². The product is supposed to temporarily prevent wood discolouring fungi on freshly sawn timber and pallets.

During industrial application of Sinesto B no significant emissions to the environment (air, soil and water) will occur, since the treatment processes takes place in an industrial system with safety measures being on the state of the art of the chemical industry. Additionally, the following RMM shall ensure safe application of the product: "*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).*"
For the storage of treated wood or pallets no exposure/risk assessment was conducted. Potential emissions to the environment during storage of treated wood can be controlled by implementation of the risk mitigation measure "*Freshly treated derived timber products 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.*"
The assessment of service life of treated wood used in UC3 results in acceptable risks for all environmental compartments.
Therefore, it can be concluded that for the biocidal product Sinesto B acceptable risks for the environment are assessed if the imposed risk mitigation measures according to chapter 2.5.2 are considered and the instruction for use according to chapter 2.5.1 is followed.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

The biocidal product Sinesto B is a wood preservative containing the two active substances ATMAC/TMAC and disodium tetraborate pentahydrate. ATMAC/TMAC does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 (BPR) and is not a candidate for substitution. Disodium tetraborate pentahydrate is considered to be very persistent (vP) and toxic (T), meeting the conditions laid down in Article 10(1)(d) of BPR. Additionally, disodium tetraborate pentahydrate meets the criteria for exclusion under Article 5(1) of BPR as it is classified as toxic for reproduction category 1B[17].

However, the status of disodium tetraborate pentahydrates has not been identified as meeting the substitution criteria in Directive 2009/91/EC. According to the document “CA-June22-Doc.4.2 - New info available-consequences for BP authorisationsrev1”, a comparative assessment in accordance with Article 23 should be carried out only when the active substance is identified as meeting the substitution criteria in the renewal of approval Regulation in accordance with Article 10 (5) of the BPR and the authorisation for the biocidal product can be granted for up to ten years.
The renewal of approval of disodium tetraborate pentahydrate is currently ongoing. Therefore, no comparative assessment for Sinesto B is conducted at this point.

[17] See also the list of active substances meeting the exclusion/substitution criteria regularly updated by ECHA: https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d

4 Annexes

4.1 List of studies for the biocidal product

Table 111

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1.	3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour)	Odour, physical state and pH value of Sinesto B Report No.: 16-WD-022-R0	Anonymous	2016	BASF Wolman GmbH
2.	3.2 Acidity, alkalinity (pH)				
3.	3.2 Acidity, alkalinity (acidity / alkalinity)	Alkalinity of Sinesto B Report No.: 19-WD-001	Anonymous	2019	BASF Wolman GmbH
4.	3.3 Relative density (liquids) and bulk, tap density (solids) (relative density)	Density of Sinesto B Report No.: 16-WD-027	Anonymous	2016	BASF Wolman GmbH
5.	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Accelerated storage test by heating of Sinesto B Report No.: WD-16-067-R1	Anonymous	2016	BASF Wolman GmbH
6.	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Stability of Sinesto B Report No.: 17-WD-025	Anonymous	2017	BASF Wolman GmbH
7.	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Low temperature stability of Sinesto B Report No.: 16-WD-062-R0 ; Study No.: Ref. 3.4.1.3	Anonymous	2016	BASF Wolman GmbH
8.	3.5 Technical characteristics of the biocidal product (technical characteristics of the biocidal product)	Determination of the persistende of foaming of Sinesto B Report No.: 16-WD-052-R0	Anonymous	2016	BASF Wolman GmbH
9.	3.5 Technical characteristics of the biocidal product (technical characteristics of the biocidal	Dilution stability of Sinesto B Report No.: 16-WD-042-R0	Anonymous	2016	BASF Wolman GmbH

	product)				
10.	3.8 Surface tension (surface tension)	Determination of the surface tension of Sinesto B Report No.: R_PB_W24_16.09_596527.02	Anonymous	2016	BASF Wolman GmbH
11.	3.9 Viscosity (viscosity)	Viscosity of Sinesto B Report No.: 16-WD-032	Anonymous	2016	BASF Wolman GmbH
12.	4.1 Explosiveness (explosiveness, other)	Determination of physico-chemical properties according to UN Transport Regulation and Regulation (EC) No. 440/2008 - Sinesto B Report No.: CSL-16-1839.01	Anonymous	2017	BASF Wolman GmbH
13.	4.2 Flammability (flammable gases)				
14.	4.2 Flammability (flammable liquids: obsolete as covered by section 'Flash point')				
15.	4.2 Flammability (flammable solids)				
16.	4.4 Oxidising properties (oxidising liquids)				
17.	4.4 Oxidising properties (oxidising solids)				
18.	4.17 Additional physical indicators for hazards				
19.	4.17.1 Auto-ignition temperature (liquids and gases) (auto-ignition temperature (liquids))				
20.	4.16 Corrosive to metals (corrosive to metals)	Corrosive to metal of Sinesto B Report No.: 16-WD-037-R0	Anonymous	2016	BASF Wolman GmbH
21.	4.16 Corrosive to metals (corrosive to metals)	Determination of physico-chemical properties Corrosive properties of liquids (UN Test C.1) Report No.: CSL-19-1538.01 ; Study No.: Ref. 4.16-02	Anonymous	2020	BASF Wolman GmbH
22.	5 Methods of detection and identification (analytical methods)	Validation of a Potentiometric Titration Method for the Determination of TMAC in Sinesto B Report No.: 17-WD-034	Anonymous	2018	BASF Wolman GmbH
23.	5 Methods of detection and identification (analytical methods)	Validation of an Atom Absorption Spectrometer Method for the Determination of Boron in Sinesto B Report No.: 17-WD-033	Anonymous	2018	BASF Wolman GmbH

24.	5 Methods of detection and identification (analytical methods)	Qualitative Analysis of TMAC in sinesto B by Gas Chromatography (GC-FID) Report No.: 20-WD-012 ; Study No.: Ref. 5.1-04	Anonymous	2020	BASF Wolman GmbH
25.	6.7 Efficacy data to support these claims (efficacy data)	BAM test report 8.1/6536 Report No.: 8.1/6536	BAM	1995	BASF Wolman GmbH
26.	6.7 Efficacy data to support these claims (efficacy data)	Evaluation of the efficacy of Sinesto B in the control of sapstain on pine in a field test in Portugal	Anonymous	1990	BASF Wolman GmbH
27.	6.7 Efficacy data to support these claims (efficacy data)	CEN/TS 15082:2005 Wood preservatives - Determination of preventive effectiveness against sapstain fungi and mould fungi on fresh sawn timber - Field test; Sinesto B Report No.: 274/234 Bio	Latvian State Institute	2016	BASF Wolman GmbH
28.	6.7 Efficacy data to support these claims (efficacy data)	Determination of the preventive effectiveness of wood preservatives against sapstain fungi and mould fungi on freshly sawn timber - Field test prCEN/TS 15082 Report No.: B 2742 A	BASF Wolman GmbH	2016	BASF Wolman GmbH
29.	8.1.1 Skin irritation / corrosion (skin irritation / corrosion, other)	Irritant effects on rabbit skin of Sinesto B Report No.: 83614D/KKM 6/SE (G)	Anonymous	1983	BASF Wolman GmbH
30.	8.3.1 Skin sensitisation (skin sensitisation: in vivo (non-LLNA))	Delayed contact hypersensitivity in the Guinea-pig with Sinesto B Report No.: 871692D/KKM 9/SS,	Anonymous	1988	BASF Wolman GmbH
31.	8.5.1 Acute toxicity: oral (acute toxicity: oral)	Acute oral toxicity to rats of Sinesto B Report No.: 83635D/KKM 5/AC	Anonymous	1983	BASF Wolman GmbH
32.	8.5.3 Acute toxicity: dermal (acute toxicity: dermal)	Acute dermal toxicity to rats of Sinesto B Report No.: 87734D/KKM 8/AC	Anonymous	1987	BASF Wolman GmbH
33.	8.9 Effects of industrial processing and / or domestic preparation on the nature and magnitude of residues of the biocidal produc	Checking migration of wood preservative constituents from treated wood into fruits and vegetables (fruit box scenario) and into packaged foods (pallet scenario) Reprt No.: 31/21/4373/01	Anonymous	2022	BASF Wolman GmbH

34.	9.2.1.1 Short-term toxicity testing on fish (short-term toxicity to fish)	Acute toxicity to fish - Sinesto B	Oy Keskus Laboratorio	1986	BASF Wolman
35.	9.2.1.2 Short-term toxicity testing on aquatic invertebrates (short-term toxicity to aquatic invertebrates)	Acute toxicity to daphnia - Sinesto B Report No.: Z587-12	Oy Keskuslaboratorio – Centrallaboratorium AB	1988	BASF Wolman GmbH
36.	10.3 Leaching behaviour (emissions from preservative-treated wood)	NT Build 509 " Leaching of active ingredients from preservative-treated timber - Semi-field testing" Report No.: No 31/16/2855/01	Anonymous	2018	BASF Wolman GmbH

4.2 List of studies for the active substance(s)

4.2.1 ATMAC/TMAC

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval of the active substance ATMAC/TMAC for use in wood preservatives (product-type 08). Please, refer to the corresponding Assessment Report for a reference list.

4.2.1.2 New information on the active substance

Not relevant.

4.2.1.3 List of studies 3rd party dossier

Not relevant.

4.2.2 Disodiumtetraborate Pentahydrate

- The applicant has access to the data from the active substance approval (see chapter 4.2.2.1 for details).

4.2.2.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the inclusion into Annex I of Directive 98/8/EC[18] of the active substance Disodiumtetraborate Pentahydrate for use in wood preservatives (product-type 08). Please, refer to the corresponding Assessment Report for a reference list.

4.2.2.2 New information on the active substance

Not relevant.

4.2.2.3 List of studies 3rd party dossier

Not relevant.

18 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.

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Safety for professional users

Output_table-professional-Sinesto B.xls

4.3.2 Output tables from environmental exposure assessment tools

Derivation of the leaching rates used for the environmental risk assessment

The detailed results of the semi-field leaching study described in chapter 3.8.3.1 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}). Leached Boron from the active substance Disodium tetraborate pentahydrate was measured.

Table 112

Leaching values (mean values of three test set-ups) for ATMAC/TMAC and boron					
Exposure period (days)	Cumulated precipitation (mm)	Concentration in leachate			
		ATMAC/TMAC		Boron	
		mg/m² wood	% of applied	mg/m² wood	% of applied
22/09/2016 - 25/10/2016 (33 days)	52	1.12	0.105	0.893	1.971
25/10/2016 – 03/12/2016 (39 days)	104	4.6	0.431	2.71	5.98
03/12/2016 – 15/01/2017 (43 days)	187	8.007	0.75	2.57	5.671
15/01/2017 – 23/06/2017 (159 days)	434	9.36	0.876	1.808	3.99
23/06/2017 – 25/07/2017 (32 days)	636	1.619	0.152	0.531	1.172
25/07/2017 – 22/09/2017 (59 days)	764	0.011	0.001	0.031	0.068

Limits of quantification of active substances:

- TMAC: 5 µg/L per compound (TMAC-C_8/C_{10}/C_{12}/C_{14}/C_{16})
- Boron: 0.04 mg/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 113.

Table 113

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 Boron (mg/m²/d)
33	52	27	0.041	0.033
72	104	54	0.170	0.100
115	187	98	0.185	0.059
274	434	226	0.073	0.014
306	636	332	0.015	0.005
365	764	398	0.000	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

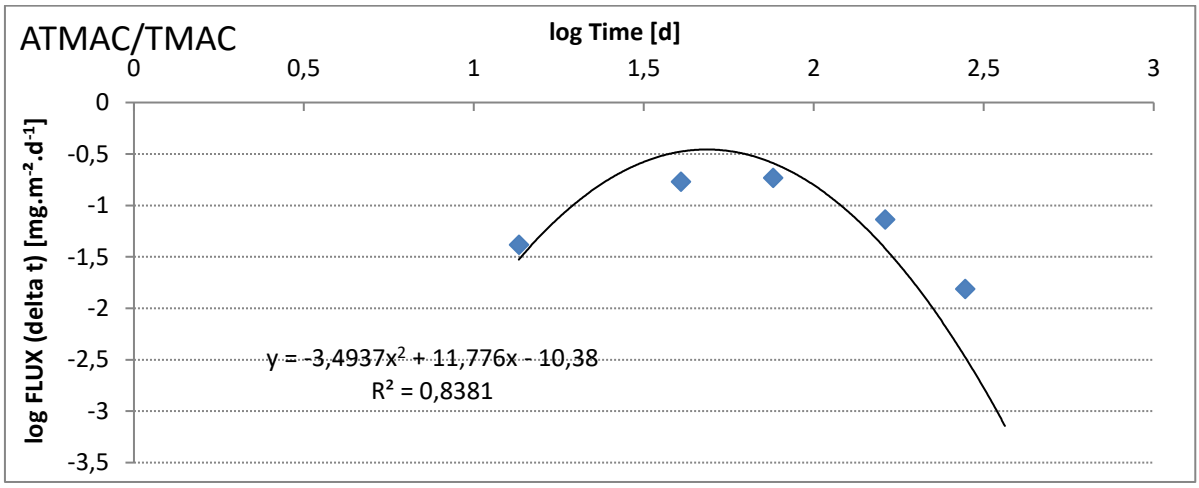
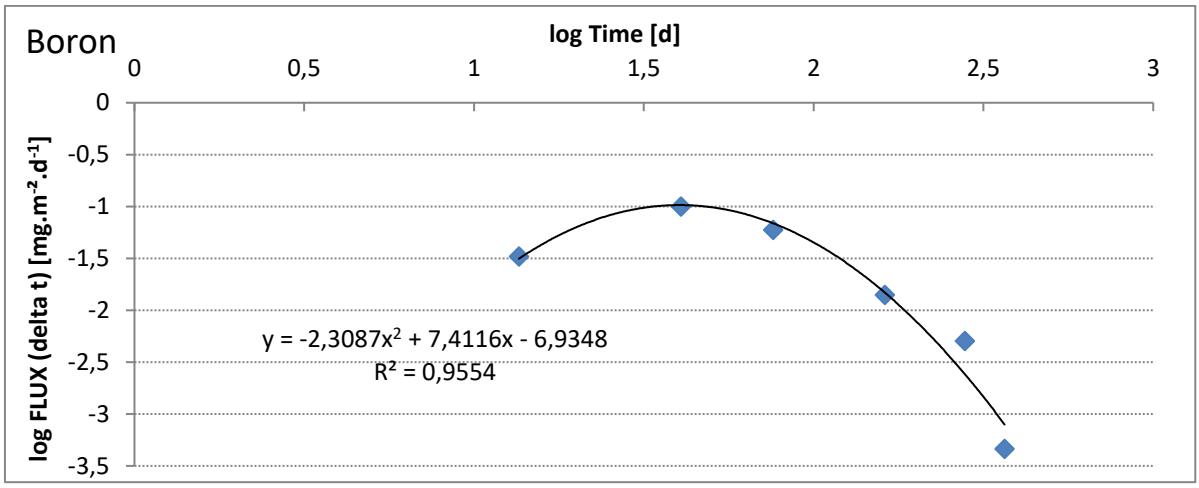


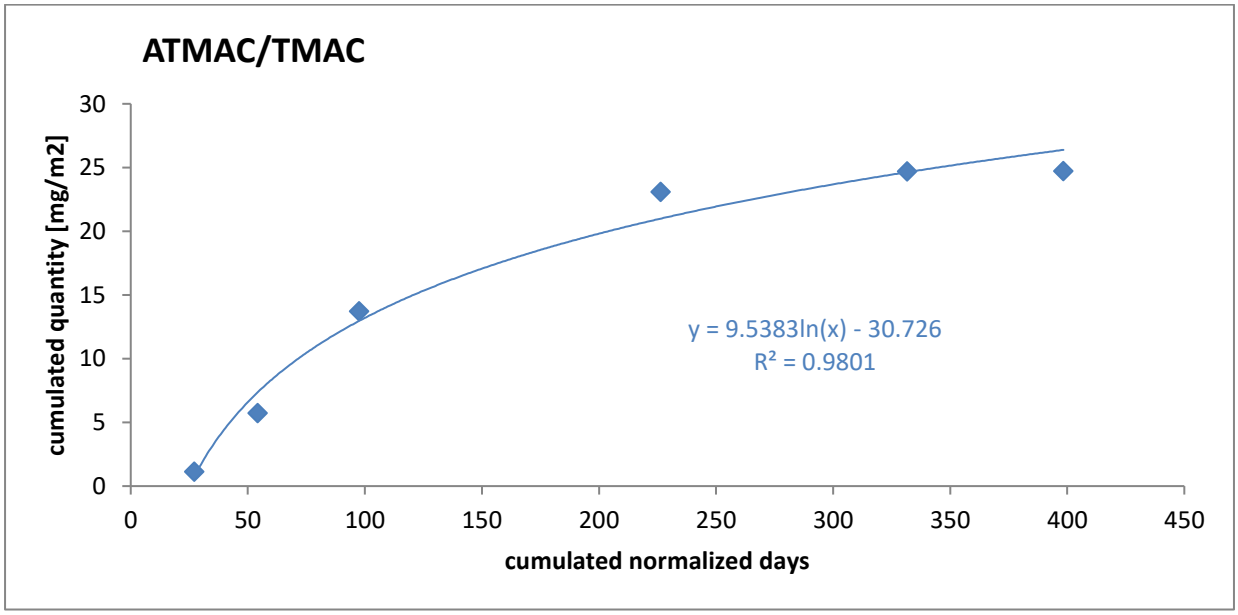
Figure 2



For the active substance ATMAC/TMAC, it can be assessed visually that long-term leaching is probably underestimated.
For Boron, the fitting suits the measured data points well, also underlined by a R^2 of 0.955. However, the flux at the first data point is much lower than at the second data point. Hence, the derived flux curve above differs from the curve progression as shown in ESD PT8, figure A1_3.

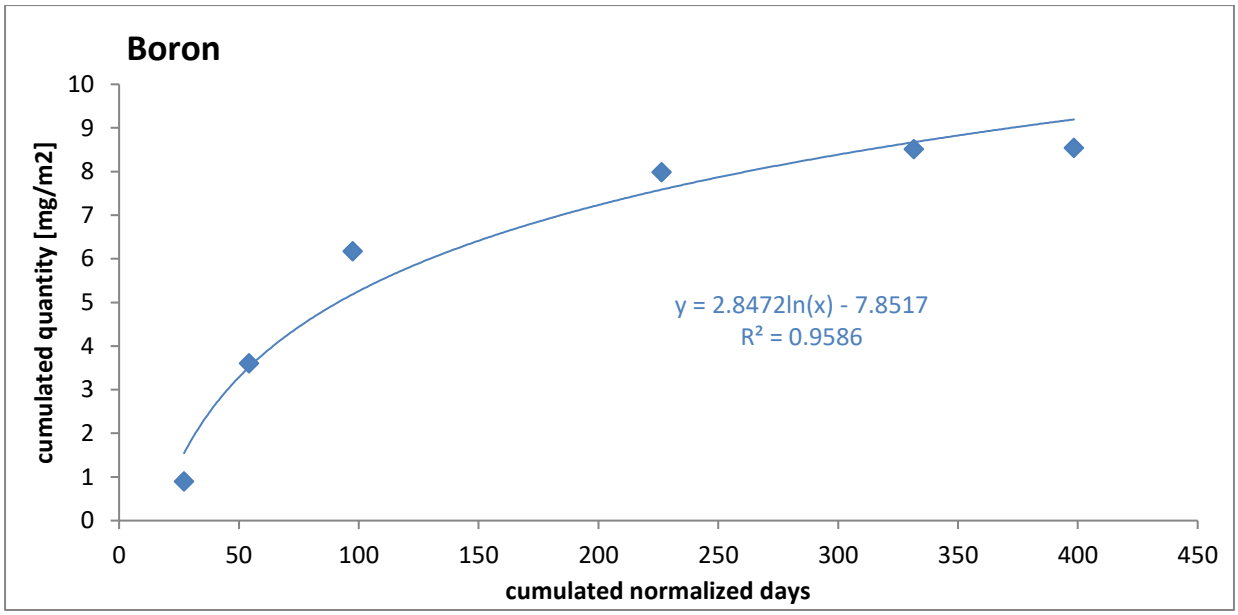
Therefore, the approach in Appendix 2 point 519 of the ESD for PT 8 (OECD, 2013) was chosen for both active substances, instead. The cumulative quantities leached [Qc(t)], normalized to 700 mm precipitation, were plotted in a diagram. All points are fitted with one logarithmic curve. This curve is used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

Figure 3



For ATMAC/TMAC the following rates are derived:
30 days: (9.5383 x Ln(30) – 30.726) / (30) days = 0.057 mg/m^2/d
5 years: (9.5383 x Ln(1825) – 30.726) / (1825) days = 0.022 mg/m^2/d

Figure 4



For Boron the following rates are derived:
30 days: (2.8472 x Ln(30) – 7.8517) / (30) days = 0.061 mg/m²/d
5 years: (2.8472 x Ln(1825) – 7.8517) / (1825) days = 0.007 mg/m²/d

A correction factor of 1.57 needs to be applied to calculate the cumulative leaching and leaching rates used for the environmental risk assessment, since the product retention of 7.63 g product per m² in the study is lower than the maximum intended retention rate of the product of 12 g/m². The corrected values are shown in chapter 3.8.3.1.