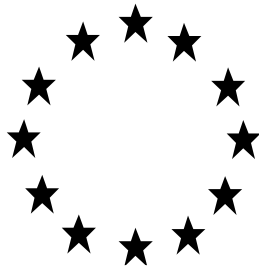
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



FR 6124 FROSCHTAL TO

Product types PT 8

ALKYL (C12-16) DIMETHYLBENZYL AMMONIUM CHLORIDE

BORIC ACID

IPBC

Case Number in R4BP: BC-JR014816-22

Evaluating Competent Authority: Spain

March 2021

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1 CONCLUSION

The assessment presented in this report has shown that FR 6124 FROSCHTAL TO, with the active substances IPBC, Boric Acid and Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides, at levels of 2.5%, 4% and 25% w/w, respectively, may be authorised for use as wood preservative (product-type 8) for the control against *sapstain fungi and mould fungi* for trained professional (Industrial users).

The biocidal product contains three active substances, of which boric acid is considered to meet the criteria for substitution listed in article 10(1) of Regulation 528/2012, also boric acid is considered to be toxic (T) and very persistent (vP), it can be considered to meet the criteria listed in Article 10(1)d. It meets two of the criteria for being PBT in accordance with Annex XIII to the regulation (EC) No 1907/2006. Therefore in accordance with Article 23 of Regulation 528/2012 a comparative assessment will be carried out for the biocidal product.

Regarding Physical-chemical properties

FROSCHTAL TO is yellowish liquid with a characteristic odour. The density is 1.038 g/cm^3 and the pH is 5.5.

The formulation was shown not to be stable under accelerated conditions (54°C during 2 weeks and 40ºC after 8 weeks). The long term stability test has shown that the product is stable up to 6 months.

FROSCHTAL TO is not considered potentially explosive and nor oxidising properties. This product has a flash point of 66ºC, so according to CLP Regulation, it's not categorized as flammable liquid.

The auto-ignition temperature of the product has been determined to be 399 °C, using EU Method A15 Auto-Ignition Temperature (Liquids and Gases).
The rest of physical properties are within specifications.

Regarding analytical methods, the reported methods for the estimation of the active substances proved to be specific, linear, precise and accurate.

Regarding efficacy, the product is determined to be effective at protecting wood samples at 3% (v/v) without batten and 2% (v/v) with batten against blueing and moulds on freshly sawn green wood.

Regarding Human health for industrial (trained-professional) uses, the risk is acceptable when the following RMM are implemented and PPE used:

- RMM
  - Good standard of general ventilation;
  - Minimisation of manual phases;
  - Regular cleaning of equipment and work area;
  - Avoidance of contact with contaminated tools and objects;

- PPE
  - Substance/task appropriate gloves;

- Skin coverage with appropriate barrier material based on potential for contact with the chemicals;
- Substance/task appropriate respirator;
- Face shield;
- Eye protection;

For professionals and general public, no unacceptable risk has been identified during the contact with treated wood with FR 6124 FROSCHTAL TO as preventive treatment with a superficial application by dipping treatment.

Regarding environment

FR 6124 FROSCHTAL TO uses claimed by the applicant are industrial dipping for wood which is going to use in classes 1 and 2 only.

According to the BPC conclusions in October 2016, ES CA agrees that mitigation measures, as indicated below, can be used to reduce emissions from the application and storage phases of the industrial treatment by dipping to acceptable levels.

Therefore, if these mitigation measures are applied during the application and the storage phases, the risks are acceptable for the environmental compartments.

Risk mitigation measures linked to risk assessment for the environment:

When FR 6124 FROSCHTAL TO is used by dipping in industrial process:
- Industrial application shall be conducted within a contained area on impermeable hard standing with bunding,
- 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 from the application of the product or the storage of treated wood shall be collected for reuse or disposal according to local regulations.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
FR 6124 FROSCHTAL TO	SPAIN

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	FROSCH CHEMIE SL
	Address	C/ Pintor Vila Cinca, 18 A, Pol. Ind. Can Humet de Dalt 08213 Polinya - Barcelona SPAIN
Authorisation number	ES/APP(NA)-2021-08-00741	
Date of the authorisation	09/03/2021	
Expiry date of the authorisation	31/01/2025	

2.1.1.3 Manufacturer of the product

Name of manufacturer	FROSCH CHEMIE, S.L
Address of manufacturer	C/ Pintor Vila Cinca, 18 A, Pol. Ind. Can Humet de Dalt 08213 Polinya - Barcelona SPAIN
Location of manufacturing sites	C/ Pintor Vila Cinca, 18 A, Pol. Ind. Can Humet de Dalt 08213 Polinya - Barcelona SPAIN

2.1.1.4 Manufacturer of the active substance

Active substance	**Alkyl (C12-16) dimethylbenzyl ammonium Chloride**
Name of manufacturer 1	**LONZA COLOGNE GmbH**
Address of manufacturer	Nattermannallee 1 50829 Cologne Germany
Location of manufacturing sites	Lonza Inc. 8316 West Route 24 Mapleton, IL 61547 USA
Name of manufacturer 2	**THOR ESPECIALIDADES, S.A**
Address of manufacturer	Pol.Ind.El Pla - Avda. de la Indústria Nº1

	08297 Castellgalí – Barcelona Spain
Location of manufacturing sites	Pol.Ind.El Pla - Avda. de la Indústria Nº1 08297 Castellgalí – Barcelona Spain

Active substance	**IPBC**
Name of manufacturer	**TROY CHEMICAL COMPANY BV**
Address of manufacturer	Uiverlaan 12e. PO Box 132. - 3145 XN-Maassluis-Netherlands
Location of manufacturing site 1	One Avenue L, 07105 Newark, New Jersey, United States
Location of manufacturing site 2	Troy Rheinland GmbH – (E.T.: TAP-D-1377728-13-00/F) Industriepark 23, 56593 Horhausen Germany

Active substance	**BORIC ACID**
Name of manufacturer 1	**Etimine S.A.**
Address of manufacturer	204, Z.I. Scheleck II L 3225 Bettembourg Luxemburg
Location of manufacturing sites	EMET, 43700 Kütahya Turkey
Name of manufacturer 2	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)

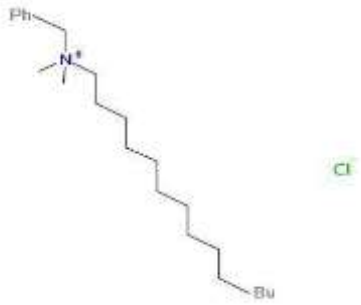
2.1.2 Product composition and formulation

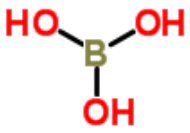
NB: the full composition of the product has been provided in the confidential annex.

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

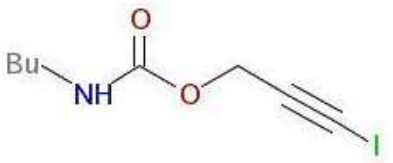
Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
IUPAC name	N-benzyl-N,N-dimethyltetradecan-1-aminium chloride
EC name	Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides
EC number	270-325-2
CAS number	68424-85-1
Index number in Annex VI of CLP	
Minimum purity / content	25
Structural formula	

Main constituent(s)	
IUPAC name	Ortho-boric acid
EC name	Boric acid
EC number	233-139-2
CAS number	10043-35-3
Index number in Annex VI of CLP	
Minimum purity / content	4
Structural formula	

Main constituent(s)	
IUPAC name	3-iodoprop-2-yn-1-yl butylcarbamate
EC name	3-iodo-2-propynyl butylcarbamate
EC number	259-627-5

CAS number	55406-53-6
Index number in Annex VI of CLP	
Minimum purity / content	2.5
Structural formula	

2.1.2.2 Candidate(s) for substitution

Boric acid is a substance of very high concern because of its CMR properties. Does meet the exclusion criteria according to Article 5(1) BPR because the following exclusion criteria are met:

- toxic for reproduction category 1B
- very persistent and toxic

And therefore, boric acid does meet the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	N-benzyl-N,N-dimethyltetradecan-1-aminium chloride	Active substance	68424-85-1	270-325-2	25
Boric acid	Ortho-boric acid	Active substance	10043-35-3	233-139-2	4
3-iodo-2-propynyl butylcarbamate (IPBC)	3-iodoprop-2-yn-1-yl butylcarbamate	Active substance	55406-53-6	259-627-5	2.5

2.1.2.4 Information on technical equivalence

The source of IPBC active substance of Manufacturing site 2 is a Technical equivalence **considered technically equivalent** compared to the reference source in respect of which the initial risk assessment was carried out. Asset number: EU-0020400-0000 – Decision number: TAP-D-1377728-13-00/F).

2.1.2.5 Information on the substance(s) of concern

Not relevant. No substances of concern have been identified.

2.1.2.6 Type of formulation

SL Soluble concentrate

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Acute Tox. 4
	Skin Corr. 1B
	Eye Damage 1
	Skin Sens. 1
	STOT RE 2
	Aquatic Acute 1
	Aquatic Chronic 1
Hazard statement	H302: Harmful if swallowed.
	H314: Causes severe skin burns and eye damage.
	H317: May cause an allergic skin reaction.
	H318: Causes serious eye damage.
	H373: May cause damage to organs <*larynx*> through prolonged or repeated exposure
	H400: Very toxic to aquatic life.
	H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Pictogram	GHS05;GHS 07; GHS08; GHS09
Signal words	Danger
Hazard statements	H302: Harmful if swallowed.
	H314: Causes severe skin burns and eye damage.
	H317: May cause an allergic skin reaction.
	H373: May cause damage to organs <*larynx*> through prolonged or repeated exposure
	H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P260: Do not breathe dust/fume/gas/mist/vapours/spray.
	P264: Wash … thoroughly after handling.
	P272: Contaminated work clothing should not be allowed out of the workplace.
	P273: Avoid release to the environment.
	P280: Wear protective gloves/protective clothing/eye protection/face protection.
	P391: Collect spillage.
	P501: Dispose of contents/container in accordance with local/regional/national/international regulation
Note	

2.1.4 Authorised use

2.1.4.1 Use description

Table 1. Intended use # 1 – Temporary preventive treatment of wood applied by manual or fully automated dipping by industrial (Trained-Professional) users

Product Type	PT8 wood preservatives.
Where relevant, an exact description of the authorised use	FR 6124 FROSCHTAL TO is used for the temporary protection of freshly felled green lumber against colonization by "saptain" and surface mould.
Target organisms (including development stage)	Sapstain fungi Mould fungui.
Field of use	Indoor use.
Application method	Open system: Dipping/immersion treatment. Apply by immersion for 5 minutes to ensure the contact of the product over the entire surface of the wood to be treated. 24 hours will be the minimum time taken for the product to set.
Application rate and frequency	Dilute the biocidal product between 2% -4 % (w/w) in water. Application rate: 25 l/m^3. -Solution retention: 2.68 (at 2%)-4.5 (at 3-4%) g/m^2 Use as a single application for preventive purposes.
Category of users	Industrial (Trained-professional) users.
Pack sizes and packaging material	Drums 30/60/200 kg IBC 600/1000 kg Plastic: HDPE

2.1.4.2 Use-specific instructions for use

See 2.1.5.1

2.1.4.3 Use-specific risk mitigation measures

See 2.1.5.2

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

See 2.1.5.3

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

See 2.1.5.4

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

See 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

- For application by manual or fully automated dipping.
- Dilute the product between 2-4% if the green timber is to be stored with battens and between 3-4% if it is to be stored without battens.
- To avoid risks to people and the environment, comply with the instructions for use.
- Read label carefully before using product.
- It must not be mixed with any other chemical.
- Keep the area where the product is to be applied well ventilated.
- The fixation time is at least 24 hours depending on storage and atmospheric conditions.
- Cleaning of the working component immediately after use with water.
- Suitable chemical resistant gloves (EN 374) also with prolonged, direct contac" and the following glove material: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374. E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm).
- A protective impermeable coverall (at least type 6, EN 13034) shall be worn.
- Always read the label.

2.1.5.2 Risk mitigation measures

- Industrial application shall be conducted within a contained area on impermeable hard standing with bunding.
- 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 from the application of the product or the storage of treated wood shall be collected for reuse or disposal according to local regulations.
- Automated dipping application phase have to be performed with a fully automated system.
- Gloves and impermeable coverall have to be worn during the handling of product and wet treated wood.
- The product may cause harm to bats. Do not use the product in areas where bats reside.

During **mixing and loading,** exposure (corrosive product) has to be limited by use of PPE and application of technical and organisational RMM such as:

- Minimisation of manual phases;
- Regular cleaning of equipment and work area;
- Avoidance of contact with contaminated tools and objects;
- Training and management of staff on good practice.

PPE for the mixing and loading phase are as following:

- Task appropriate gloves;
- Coated coverall with appropriate barrier material based on potential for contact with the chemicals;
- Eye protection.

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

Likely direct or indirect adverse effects:

- Irritation or caustic burn of eyes, skin, mucous membranes, respiratory and gastrointestinal tract.
- Metabolic acidosis, CNS depression, liver damage and pulmonary edema.

First aid measures:

- Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.
- Eye exposure; **ALWAYS** check for and remove contact lenses, wash eyes with plenty of water with eye lids open for at least 15 minutes.
- Skin contact; wash affected area with plenty of water and soap, **NO** scrubbing.
- Inhalation/aspiration; Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.
- Mouth contact/ingestion; do **NOT** induce vomiting unless indicated by medical or healthcare personnel.
- **NEVER** administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.
- If symptoms appear, persist or worsen seek medical attention **IMMEDIATELY** and bring the packaging or label whenever possible.

Advice for medical and healthcare personnel:

- In case of ingestion, evaluate realizing and endoscopic procedure.
- Contraindication of Ipecac Syrup.
- Provide symptomatic and supportive treatment.

EMERGENCY MEASURES TO PROTECT ENVIRONMENT IN CASE OF ACCIDENT:

- Do not empty into drains or the aquatic environment.
- Do not allow to enter into soil/subsoil.
- In case of gas being released or leakage into waters, ground or the drainage system, the appropriate authorities must be informed.

IF MEDICAL ADVICE IS NEEDED, KEEP THE LABEL OR CONTAINER HANDY AND CONSULT THE MEDICAL SERVICE FOR TOXICOLOGICAL INFORMATION

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.
- Code the waste according to Decision 2014/955 / EU.
- Do not release to soil, ground, surface water or any kind of sewer.

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

Keep only in original container. Keep container tightly closed and dry. Keep in a cool place. Dot not store at temperatures above 30 ºC. Self life: 6 months as from the manufacturing date.

2.1.6 Other information

Definitions: Trained professional: pest control operators, having received specific training in management of biocidal products according to the national legislation in force.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Drum	30/60/200 kg	Plastic: HDPE		Drum	
IBC (intermediate bulk container)	600/1000kg	Plastic: HDPE		IBC (intermediate bulk container)	

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the biocidal product described within this application.
The reference list (including updates) for the studies submitted in support of the BPD dossier has been included in Annex 3.1 whilst the reference list for the studies considered confidential has been included in the Confidential PAR.

2.1.8.2 Access to documentation

The applicant has submitted the letter of access (LoA) of each supplier and owners of active substances.

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant

Table 1. Intended use # 1 – name of the use.

Product Type(s)	Product type 8: Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Preventive fungicide treatment of wood in sawmills. User category: Industrial (A.20) Wood category: Softwood and hardwood (B.10; B.20) Wood product: Solid wood (C.10) Application aim: Temporary preventive treatment/green sawn timber (D.20) Field of use: Use Class 2 (E.20) Method of application: Superficial application / Dipping. Dilution: 2-4 % v/v. Application rate: 25 L/m3 (F.14) Target organisms: Sapstain and mould fungi (G.21.1; G.22)
Target organism (including development stage)	Sapstain fungi. Mould fungi.
Field of use	Indoor use.
Application method(s)	Open system: Dipping/immersion treatment. The product is applied by immersion for 5 minutes to ensure the contact of the product over the entire surface of the wood to be treated. 24 hours will be the minimum time taken for the product to set.
Application rate(s) and frequency	Dilute the biocidal product between 2% -4 % (v/v) in water. Application rate: 25 L/m^3. Use as a single application for preventive purposes.
Category(ies) of user(s)	Industrial
Pack sizes and packaging material	Drums 30/60/200 kg IBC 600/1000 kg Plastic: HDPE

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual determination	100	Liquid	Belussi C, 2018
Colour at 20 °C and 101.3 kPa	Visual determination	100	Yellowish	Belussi C, 2018
Odour at 20 °C and 101.3 kPa	Visual determination	100	other: Characteristic	Belussi C, 2018
Acidity / alkalinity	CIPAC MT 75.3.	100	5.5 at 20 ºC.	Belussi C, 2018
Relative density /	OECD 109	100	1.038 ± 0.05 at	Meluso A,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
bulk density			20 ºC.	2016
Storage stability test – **accelerated storage**	CIPAC MT 46.3	100	Not stable when stored at 54 ºC for 14 days due to the deacrease of Iodopropynyl butylcarbamate content (>10%).	Bugatti S, 2016
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 46.3	100	The product was determined not stable when stored at 40 ºC for 8 weeks due to the deacrease of Iodopropynyl butylcarbamate content (>10%).	Belussi C, 2016
Storage stability test – **low temperature stability test for liquids**	GIFAP monograph 17	100	The product resulted stable up to 6 months (active ingredient content decrease <10%). No reactivity towards container material was observed.	Belussi C, 2018
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	CIPAC MT 39.9.	100	The product was stable at low temperatures (0 ºC, 7 days).	Meluso A, 2016
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	*The biocidal products should be stored away from light and/or opaque material should be used for packaging.*			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity**	CIPAC MT 46.3	100	The product was determined not stable when stored at 40 ºC for 8 weeks due to the deacrease of Iodopropynyl butylcarbamate	Belussi C, 2016

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
towards container material			content (>10%). *Do not store at temperatures above 30 ºC.*	
Wettability	GIFAP monograph 17	100	No reactivity towards container material was observed up to 24 months.	Belussi C, 2018
Suspensibility, spontaneity and dispersion stability	*The study does not need to be conducted since the product is a liquid (soluble concentrate).*			
Wet sieve analysis and dry sieve test	*The study does not need to be conducted since the product is a liquid (soluble concentrate).*			
Emulsifiability, re-emulsifiability and emulsion stability	*The study does not need to be conducted since the product is a liquid (soluble concentrate).*			
Disintegration time	*The study does not need to be conducted since the product is a liquid (soluble concentrate).*			
Particle size distribution, content of dust/fines, attrition, friability	*The study does not need to be conducted since the product is a liquid (soluble concentrate).*			
Persistent foaming	*The study does not need to be conducted since the product is a liquid (soluble concentrate).*			
Flowability/Pourability/Dustability	CIPAC MT 47.2	3.5; 2	No foam was observed after 1 minute in both 3.5 and 2.0% of test item in water solution.	Meluso A, 2016
Burning rate — smoke generators	*The study does not need to be conducted since the product is a liquid (soluble*			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	concentrate).			
Burning completeness — smoke generators	*The study does not need to be conducted since the product is not applied as a smoke.*			
Composition of smoke — smoke generators	*The study does not need to be conducted since the product is not applied as a smoke.*			
Spraying pattern — aerosols	*The study does not need to be conducted since the product is not applied as a smoke.*			
Physical compatibility	*The study does not need to be conduced since the product is not an aerosol.*			
Chemical compatibility	*The physical and chemical compatibility with other products does not need to be investigated since the biocidal product is not intended to be used with other products.*			
Degree of dissolution and dilution stability				
Surface tension	*The study does not need to be conducted since the product is not used in water soluble bags or tablets.*			
Viscosity	*The study does not need to be conducted since the product is placed on the market in water solution, and thus it is considered stable when further diluted.*			

Conclusion on the physical, chemical and technical properties of the product
"FROSCHTAL TO" is yellowish liquid with a characteristic odour. The pH of the formulation at 20ºC is 5.5 (according to CIPAC Method MT 75.3). The density of product is 1.038 g/ml at 20 ºC, according to OECD 109. The viscosity of the product is 74.862 mPa*s at 20ºC and 31.379 mPa*s at 40ºC. The value obtained for surface tension of sample at 20ºC is 35 mN/m.

The results of the accelerated study show that the product is not stable after 2 weeks at 54ºC and after 8 weeks at 40ºC due to the deacrease of Iodopropynyl butylcarbamate content (>10%).
The results of long time stability study show that the The product resulted stable up to 6 months (active ingredient content decrease <10%).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	*The product is not considered to be potentially explosive since the active substances are not explosive and none of the co-formulants have explosive properties based on their chemical structure.*	*The product is not considered to be potentially explosive since the active substances are not explosive and none of the co-formulants have explosive properties based on their chemical structure.*	*The product is not considered to be potentially explosive since the active substances are not explosive and none of the co-formulants have explosive properties based on their chemical structure.*	*The product is not considered to be potentially explosive since the active substances are not explosive and none of the co-formulants have explosive properties based on their chemical structure.*
Flammable gases	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*
Flammable aerosols	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*
Oxidising gases	*The study does not need to be performed since the product is a liquid (soluble concentrate)*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*
Gases under pressure	*The study does not need to be performed since the product is a liquid (soluble*	*The study does not need to be performed since the product is a liquid (soluble*	*The study does not need to be performed since the product is a*	*The study does not need to be performed since the product is a*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	concentrate)	*concentrate).*	*liquid (soluble concentrate).*	*liquid (soluble concentrate).*
Flammable liquids	EU Method A.9 and ISO 3679:2015.	EU Method A.9 and ISO 3679:2015.	EU Method A.9 and ISO 3679:2015.	EU Method A.9 and ISO 3679:2015.
Flammable solids	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*
Self-reactive substances and mixtures	*Based on its structure, the product is not expected to be a self-reactive mixture.*	*Based on its structure, the product is not expected to be a self-reactive mixture.*	*Based on its structure, the product is not expected to be a self-reactive mixture.*	*Based on its structure, the product is not expected to be a self-reactive mixture.*
Pyrophoric liquids	*Pyrophoricity can be excluded since there are no functional groups that could cause pyrophoricity.*	*Pyrophoricity can be excluded since there are no functional groups that could cause pyrophoricity.*	*Pyrophoricity can be excluded since there are no functional groups that could cause pyrophoricity.*	*Pyrophoricity can be excluded since there are no functional groups that could cause pyrophoricity.*
Pyrophoric solids	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*
Self-heating substances and mixtures	*Based on the chemical structure of the components, the product is not expected to be self-heating.*	*Based on the chemical structure of the components, the product is not expected to be self-heating.*	*Based on the chemical structure of the components, the product is not expected to be self-heating.*	*Based on the chemical structure of the components, the product is not expected to be self-heating.*
Substances and mixtures which in contact with water emit flammable gases	*Flammability in contact with water can be excluded since the product is presented in water dilution and there are no functional groups that could cause flammability in*	*Flammability in contact with water can be excluded since the product is presented in water dilution and there are no functional groups that could cause flammability in contact with water.*	*Flammability in contact with water can be excluded since the product is presented in water dilution and there are no functional groups that could cause*	*Flammability in contact with water can be excluded since the product is presented in water dilution and there are no functional groups that could cause*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	contact with water.		*flammability in contact with water.*	*flammability in contact with water.*
Oxidising liquids	*The product is not considered to have oxidising properties since it does not contain any oxidising or reducing agent.*	*The product is not considered to have oxidising properties since it does not contain any oxidising or reducing agent.*	*The product is not considered to have oxidising properties since it does not contain any oxidising or reducing agent.*	*The product is not considered to have oxidising properties since it does not contain any oxidising or reducing agent.*
Oxidising solids	*The study does not need to be performed since the product is a liquid (soluble concentrate)*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*	*The study does not need to be performed since the product is a liquid (soluble concentrate).*
Organic peroxides	*Based on the chemical structure of the components, the product is not organic peroxide.*	*Based on the chemical structure of the components, the product is not organic peroxide.*	*Based on the chemical structure of the components, the product is not organic peroxide.*	*Based on the chemical structure of the components, the product is not organic peroxide.*
Corrosive to metals	UN-MTC, Section 37.4	UN-MTC, Section 37.4	UN-MTC, Section 37.4	UN-MTC, Section 37.4
Auto-ignition temperatures of products (liquids and gases)	EU Method A.15	EU Method A.15	EU Method A.15	EU Method A.15
Relative self-ignition temperature for solids	*The study does not need to be performed since the product is a non-flammable liquid (soluble concentrate)*	*The study does not need to be performed since the product is a non-flammable liquid (soluble concentrate).*	*The study does not need to be performed since the product is a non-flammable liquid (soluble concentrate).*	*The study does not need to be performed since the product is a non-flammable liquid (soluble concentrate).*
Dust explosion hazard	*The study does not need to be perforomed since the product is a liquid (soluble concentrate)*	*The study does not need to be perforomed since the product is a liquid (soluble concentrate).*	*The study does not need to be perforomed since the product is a liquid (soluble concentrate).*	*The study does not need to be perforomed since the product is a liquid (soluble concentrate).*

Conclusion on the physical hazards and respective characteristics of the product

"FROSCHTAL TO" is not considered to be potentially explosive as no chemical structures that have explosive properties are present in the formulation.

No chemical structures that have oxidising properties are present in the formulation. So the product is considered non-oxidising.

This product has a flash point of 66ºC, so according to CLP Regulation, it's not categorized as flammable liquid.

The auto-ignition temperature of the product has been determined to be 399 °C, using EU Method A15 Auto-Ignition Temperature (Liquids and Gases).

2.2.4 Methods for detection and identification

Active substance determination in the product:
Benzalkonium chloride (BKC): SANCO3030/99 Rev. 4. GLP study. A sensitive and accurate HPLC chromatography technique was applied for the determination of the active ingredient. The calibration curve was found to be linear (r=0.9999) over the concentration range of 0.26 -0.77 mg/ml. The samples for accuracy were prepared at 0.26, 0.52 and 0.78 mg/ml of BKC reference standard having known purity, representing low, middle and high controls, respectively. Mean percentage (%) recovery ± relative standard deviation % (RSD%) ranged from 99.4 ± 0.2 to 99.5 ± 0.2. Within-day precision and instrumental repeatability were also in acceptable range: 0.32% and 0.25% respectively. The reported method, HPLC-UV, for the estimation of the active substance proved to be specific, linear, precise and accurate.

Boric acid (as boron): SANCO3030/99 Rev. 4. GLP study. A sensitive and accurate ICP-OES (Inductively Coupled Plasma Optical Emission Spectrometry) technique was applied for determination of the active ingredient. The calibration curve was found to be linear (r=1000) over the concentration range of 1.50 -4.50 mg/ml. The samples for accuracy were prepared at 1.50, 3.00 and 4.50 mg/ml of Boron reference standard having known purity, representing low, middle and high controls, respectively. Mean percentage (%) recovery ranged from 97.46 to 101.97. Within-day precision and instrumental repeatability were also in acceptable range: 0.57% and 0.48% respectively. Therefore the ICP-OES method was validated for the identification of the active substance in the tested product.

Iodopropynyl butylcarbamate (IPBC): SANCO3030/99 Rev. 4. GLP study. A sensitive and accurate HPLC chromatography technique was applied for the determination of the active ingredient. The calibration curve was found to be linear (r=0.9999) over the concentration range of 0.1 -0.3 mg/ml. The samples for accuracy were prepared at 0.1, 0.2 and 0.3 mg/ml of IPBC reference standard having known purity, representing low, middle and high controls, respectively. Mean percentage (%) recovery ± relative standard deviation % (RSD%) ranged from 100.7 ± 0.3 to 103.3 ± 0.6. Within-day precision and instrumental repeatability were also in acceptable range: 0.23% and 0.28% respectively. The reported method, HPLC-UV-DAD, for the estimation of the active substance proved to be specific, linear, precise and accurate.

Analytical methods for monitoring purposes:
The monitoring methods and justification of non-submission for air, soil, drinking water, surface water, animal and human body fluids and tissues and residues in food and feed) are provided in the active substance dossier/CAR.

Conclusion on the methods for detection and identificationof the product

The reported methods for the estimation of the active substances proved to be specific, linear, precise and accurate.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

FR 6124 FROSCHTAL TO is a wood preservative for preventive use which is effective against sapstain fungi and mould fungi on fresh sawn timber. The biocidal product is intended to be used indoors by industrial users. The application method is by dipping/immersion.

The following matrix of categories and codes for product are applicable to FR 6124 FROSHTAL TO:

Category	**Matrix wording**	**Code product**
User category	Industrial and trained profesional	A.20; A.30
Wood category	Softwood and hardwood	B.10; B.20
Wood product	Solid wood	C.10
Application aim	Temporary preventive treatment/green sawn timber	D.20
Field of use	Not applicable.	-
Method of application	Superficial application / Dipping Dilution: 2-4 % v/v Application rate: 25 L/m^3	F.14
Target organisms	Sapstain and mould fungi	G.21.1; G.22

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

FR 6123 FROSCHTAL TO is used for the protection of green timber against colonization by blue stain and other discolouring micro-organisms (saptain) and surface mould.
The following organisms/species were tested in the studies:
- Blue stain fungi
- Mould fungi

2.2.5.3 Effects on target organisms, including unacceptable suffering

The active substances work by preventing growth of organisms, not by killing organisms that are present, thus reducing the potential for resistant organisms to develop.
Unacceptable suffering for fungi cannot be assessed.

2.2.5.4 Mode of action, including time delay

According to the active substance dossiers/CARs:ADBAC/BKC: The active substance is a cationic surfactant type active substance. Since it is surface active, it has fair wetting properties and reacts strongly with cell-walls of micro-organisms. Its mode of action, therefore, is to destroy the cell walls by sticking on the exterior structure and by entering and disintegrating the inner phospholipid-bilayer-based membrane structures. Its interaction with phospholipid-bilayer structures severely alters the cell wall permeability, disturbs membrane-bound ion-translocation mechanisms and may facilitate the uptake of other biocides.

Boric acid: Accoridng to the assessment report of acid boric, borat ions form chelate compexies with polyols of biological significance (oxidised co-enzymes) leading to disruption of the organisms metabolic pathways. The primary mode of action is the interaction of the borate anion with polyols of biological significance e.g. oxidised co-enzymes (NAD+, NMN+ and NADP+). The same mechanism was likely in all organisms, not just decay fungi.
This effect in micro-organisms has been shown to be more biostatic tha biocidal, with organisms appearing to "starve".
There is no information of time delay.
Boric acid documentation does not provide information on resistance or strategies.
IPBC: The active substance has a carbamate structure. The target sites of carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee).

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Wood preservative - Fungicide	PT8	FR 6124 FROSCHTAL TO	Sapstain fungi. Mould fungui	Determination of the preservative effectiveness against sapstain fungi and mould fungi on freshly sawn timber – Field Test (prCEN/TS 15082).	Test system: Wood samples (*Pinus pinaster*) of standard size (1000 x 100 x 20 mm). Application: Dipping: 15-20 s Concentrations: 2%, 3% and 4% (v/v). Exposure time: Treated wood samples were stored, in an open space, over a concrete floor, in a place where the presence of sapstain spores is permanent for 3 months. Replicates: 55 per concentration with battens, 55 per concentration without battens. Solution retentions (mean): 2.68, 4.56 and 4.08 g/m^2	The test complies with the validation. The attack degree can be summarized as follows: 2% without batten: medium - strong attack (score 2.46) 2% with batten: minor attack (score 1.08) 3% without batten: minor attack (score 0.72) 3% with batten: minor attack (score 0.60) 4% without batten: minor attack (score 1.04) 4% with batten: minor attack (score 0.04) FR 6124 FROSCHTAL TO was effective at protecting wood samples.	[redacted] *Report nº 14682.*

Conclusion on the efficacy of the product
The efficacy test of the FR 6124 FROSCHTAL TO against sapstain fungi and mould fungi on freshly sawn timber, was performed according to prCEN/TS 15082. Wood samples (Pinus pinaster) were treated with 2%, 3% and 4% (v/v) product concentrations by dipping for 15 -20 seconds and were exposed to sapstain spores for 3 months in a sawmill. Sapstain fungi and mould fungi growth were observed in several wood samples treated at the three different concentrations. The incidence of these organisms is lower in the wood samples treated at higher concentrations. A reduction of the presence of these organisms was observed in the wood samples stored in a pile with batten since they dry faster than those stored in a pile without batten. Taking into account that according to the current guidelines, a minimum of 95% of planks with a rating strictly < 2 is required, the product is determined to be effective at protecting wood samples at 3% (v/v) without batten and 2% (v/v) with batten.

2.2.5.6 Occurrence of resistance and resistance management

According to the active substance dossiers/CARs, no resistence has been reported by notifiers.

2.2.5.7 Known limitations

There are no known limitations on efficacy

2.2.5.8 Evaluation of the label claims

The product claims the function of the product as a preventive fungicide treatment of wood in sawmills. In reference to the dose and application, the product should be diluted between 2-4% in water and that the wood to be treated should be immersed in the mixture for 5 minutes to ensure the contact of the product over the entire surface of the wood.

The efficacy of the product is correctly reflected in the claims since the dose and application methods are in accordance with the conditions for which effectiveness of the product FR 6124 FROSCHTAL TO was proven in the Test prCEN/TS 15082 "Determination of preventive efficacy against blueing and moulds on freshly sawn green wood Field test", being the effective doses 2, 3 and 4% after an application by immersion of 15-20 seconds

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

The product is not intended for use with another biocidal.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Testing on the product has been considered as not required since there is 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).

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	FR 6124 FROSCHTAL TO is corrosive for the skin.
Justification for the value/conclusion	The product contains: 25% (w/w) Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides (CAS 68424-85-1): Skin Corrosive Category 1B, H314 4% (w/w) Boric acid (CAS 10043-35-3): Not irritating. None of the co-formulants is classified for skin irritation. According to CLP Regulation: The product contains a concentration greater than 5% w/w of a substance classified as Skin corrosive Category 1B, H314 Therefore, the product is classified as Skin corrosive Category 1B, H314
Classification of the product according to CLP and DSD	Skin corrosive Category 1B, H314

Data waiving	
Information requirement	Study with the product is scientifically unjustified.
Justification	Testing on the product does not need to be conducted since 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).

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	FR 6124 FROSCHTAL TO produce serious eye damage
Justification for the value/conclusion	The product contains : 25% (w/w) Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides (CAS 68424-85-1): Skin Corrosive Category 1B, H314 2.5% (w/w) 3-iodo-2-propynyl butyl Carbamate (IPBC) (CAS 55406-53-6): Irreversible effects to the eye Category 1, H318. 4% (w/w) Boric acid (CAS 10043-35-3): Not irritating. None of the co-formulants is classified for eye irritation. According to CLP Regulation:

	The product contains a concentration greater than 3% w/w of a substance classified as Skin corrosive Category 1B, H314. Moreover, it contains 2.5% of a substance classified as Irreversible effects to the eye Category 1, H318. Therefore, the product is classified as Irreversible effects to the eye Category 1, H318.
Classification of the product according to CLP and DSD	Irreversible effects to the eye Category 1, H318. As the product has been classified as H314 already includes this hazard

Data waiving	
Information requirement	Study with the product is scientifically unjustified.
Justification	Testing on the product does not need to be conducted since 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).

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	FR 6124 FROSCHTAL TO is not irritating to the respiratory tract
Justification for the value/conclusion	The mixture is not classified regarding this category.
Classification of the product according to CLP and DSD	Not classified

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

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	FR 6124 FROSCHTAL TO is skin sensitizer
Justification for the value/conclusion	The product contains : 25% (w/w) Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides (CAS 68424-85-1): Not sensitizing. 2.5% (w/w) 3-iodo-2-propynyl butyl Carbamate (IPBC) (CAS 55406-53-6): Skin sensitizer Category 1, H317 4% (w/w) Boric acid (CAS 10043-35-3): Not sensitizing. None of the co-formulants is classified for skin sensitization. According to CLP Regulation: The product contains a concentration greater than 1% w/w of a substance classified as Skin sensitizer Category 1, H317.

	Therefore, the product is classified as Skin sensitizer Category 1, H317.
Classification of the product according to CLP and DSD	Skin sensitizer Category 1, H317.

Data waiving	
Information requirement	Study with the product is scientifically unjustified.
Justification	Testing on the product does not need to be conducted since 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).

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	FR 6124 FROSCHTAL TO is not a respiratory sensitizer
Justification for the value/conclusion	None of the substances listed in the formulation is classified as respiratory sensitizer. Thus the mixture is not classified regarding this category.
Classification of the product according to CLP and DSD	Not classified

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

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	ATE mixture (oral) = 1251.5 mg/kg
Justification for the selected value	Based on the available data on active substances and co-formulants, The acute toxicity estimate (ATE) of the mixture is determined by calculation from the ATE values, according to the additivity formula for acute toxicity: $\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$ 25% (w/w) Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides (CAS 68424-85-1): Rat LD50 oral = 350 mg/kg bw 2.5% (w/w) 3-iodo-2-propynyl butyl Carbamate (IPBC) (CAS 55406-

	53-6): Rat LD50 oral = 300-500 mg/kg bw 4% (w/w) Boric acid (CAS 10043-35-3): Rat LD50 oral > 2000 mg/kg bw None of the co-formulants is classified for oral acute toxicity. According to CLP Regulation: The following formula is to be applied: 100/ATE mix = ∑ Ci/ATEi Ci = concentration of each component ATEi= acute toxicity estimation Taking into account the worst case (IPBC LD50 oral = 300 mg/kg): 100/ATE mix = 25/350 + 2.5/300 ATE mix = 1251.56 mg/kg bw According to CLP Regulation: The product is classified for Acute (oral) Toxicity Category 4, H302 since ATE is between 300 and 2000 mg/kg bw.
Classification of the product according to CLP and DSD	Acute Tox. 4 H302: Harmful if swallowed

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

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	FR 6124 FROSCHTAL TO is not classified for acute inhalation toxicity
Justification for the selected value	The acute toxicity estimate (ATE) of the mixture is determined by calculation from the ATE values according to the additivity formula for inhalation toxicity. $\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$ 2.5% (w/w) 3-iodo-2-propynyl butyl Carbamate (IPBC) (CAS 55406-53-6): Rat LC50 inhalation = 0.67 mg IPBC/L (for respirable dust) None of the co-formulants is classified for inhalation acute toxicity. According to CLP Regulation: The following formula is to be applied: 100/ATE mix = ∑ Ci/ATEi Ci = concentration of each component

	ATEi= acute toxicity estimation 100/ATE mix = 2.5/0.67, ATE mix = 26.80 mg/kg bw
Classification of the product according to CLP and DSD	According to CLP Regulation: The product is not classified for Acute (inhalation) Toxicity since ATE > 5 mg/L.

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

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	FR 6124 FROSCHTAL TO is not classified for acute dermal toxicity
Justification for the selected value	None of the substances listed in the formulation is classified as acute dermal toxic. Thus the mixture is not classified regarding this hazard class.
Classification of the product according to CLP and DSD	Not classified

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

Specific target organ toxicity, repeated exposure (STOT RE)

Value used in the Risk Assessment – STOT RE	
Value	FR 6124 FROSCHTAL TO is classified for specific target organ toxicity after repeated exposure
Justification	For IPBC a concern for specific target organ toxicity was identified. 2.5% (w/w) 3-iodo-2-propynyl butyl Carbamate (IPBC) (CAS 55406-53-6) STOT RE (Larynx), category 1 (H372). In line with other biocides dossier evaluations, this classification and the generic concentration limit for mixture classification (if the concentration is ≥1% →STOT RE 2; H373),
Classification of the products according to CLP	According Regulation (EC) Nº 1272/2008 (CLP Regulation). IPBC is ≥1% is classified as STOT RE 2, H373: May cause damage to organs (larynx) through prolonged or repeated exposure.

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

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	ADBAC	Boric acid	IPBC
Value(s)*	25%	75%	75%
Justification for the selected value(s)	FR 6124 Froschtal TO contains three active substances already authorised. For all these substances a dermal absorption in vitro study with human skin was performed. The values in assessment report are shown in the following table:		

CAS number	**EC number**	**Name**	**% (w/w)**	**Dermal absorption**
68424-85-1	270-325-2	Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	25	8.3% (0.03% and 0.3% ai in solution)
10043-35-3	233-139-2	Bori acid	4	0.5% assumed for RA
55406-53-6	259-627-5	3-iodo-2-propynyl butylcarbamate	2.5	30% (0.6% ai in solution) 10% (2.3% ai in solution) 1.6% (17.1% ai in solution)

According to the EFSA (2012) guidance on dermal absorption, the read across between the products is not acceptable. Therefore it is recommended to use the default values established according to the concentration in active substances:

- 25% may be applied for products containing > 5%
- 75% should be used for products or in use dilutions containing ≤ 5% active substance.

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

Not applicable. The product does not contain any substances of concern.

Available toxicological data relating to a mixture

Not relevant.

Endocrine disruption

Assessment of the ED properties of the active substances:

The biocidal product contains Alkyl (C12-16) dimethylbenzyl ammonium chloride, IPBC and boric acid.

The CAR of **Alkyl (C12-16) dimethylbenzyl ammonium chloride** indicate: "*Based on available experimental results, there is no indication that Alkyl (C12-16) dimethylbenzyl ammonium chloride affects the endocrine system. Structural characteristics and SAR do not hint to possible effects of Alkyl (C12-16) dimethylbenzyl ammonium chloride as endocrine disruptor*"

The CAR of **IPBC**: "IPBC are not included in the EU list of potential endocrine disruptors (COM DGENV, 2000). IPBC have not been found on the Endocrine disruptor website of the European Commission: Annex 13 (List of 146 substances with endocrine disruption categorizations prepared in the Expert meeting) and 15 (List of 66 Category 1 substances with categorisation high, medium or low exposure concern). IPBC are not covered by the interim criteria described in Article 5.3 in BPR.
Conclusion is that IPBC hasn´t endocrine disruptor properties.

The CAR of Boric Acid: "boric acid is not considered to have endocrine disrupting effects"

According to *List compilation exclusion or substitution criteria (Version. January 2019)*, **Alkyl (C12-16) dimethylbenzyl ammonium chloride IPBC and boric acid**: there are no concern for endocrine disruption.

Assessment of the ED properties of non-active substances (co-formulants):

Regarding *CA-March18-Doc.7.3.b-final* document, the co-formulant have not been assessed or identified for endocrine disruption properties.

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge, there is no indication of concern regarding the ED properties of the substances used in the biocidal product FR 6124 FROSCHTAL TO .

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

2.2.6.2 Exposure assessment

The scenarios used in this assessment are described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a). This scenarios are in accordance with ECHA Guidance document "Biocides Human Health Exposure Methodology, first ed. (October 2015).

The biocidal product FR 6124 Froschtal TO, containing 3 active substances, is used as wood preservative by immersion of the timber in dissolved product. The product is delivered in form of concentrate containing 25% Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides (ADBAC), 4% boric acid and 2.5% Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides (IPBC). For use purposes it is diluted in water at 2-4%. Therefore final concentration of each active substance is as follows:

Active substance	In biocidal product (%)	Use solution (%) worst case (4%)
ADBAC	25	1
Boric acid	4	0.16
IPBC	2.5	0.1

The application is in open system: Dipping/immersion treatment. Apply by immersion for 5 minutes to ensure the contact of the product over the entire surface of the wood to be treated. However in accordance to current guidances, for risk assessment purposes the application time will be assumed as the default median of 30 minutes per batch. One batch is the default for dipping process and 3 operations per day for the mixing and loading.
Dermal absorption figures are available for all three active substances. However no dermal absoption test was performed with the biocidal product. According to ECHA's Guidance on the Biocidal Products Regulation Volume III: Human health Part A: Information Requirements,
"It is not always mandatory to submit experimental data. If such data are not available, as a first step default values (depending on physicochemical properties of the active substance) can be used (additional guidance provided in Part B of Hazard Identification within the Toxicokinetics chapter (BPR guidance under development)).
The OECD Guidance Document on Percutaneous absorption/penetration (OECD, 2004a) and the EFSA Guidance Document on Dermal Absorption (EFSA, 2012) should be followed where applicable for the estimation of dermal absorption both for the active substance and the biocidal product (Chapter III Section 8.6)."
Therefore, dermal absorption values from assessment of effects on human health of this product will be used for exposure assessment porposes:

<table>
<tr><th colspan="4">Value(s) used in the Risk Assessment – Dermal absorption</th></tr>
<tr><td>Substance</td><td>ADBAC</td><td>Boric acid</td><td>IPBC</td></tr>
<tr><td>Value(s)*</td><td>25%</td><td>75%</td><td>75%</td></tr>
<tr><td>Justification for the selected value(s)</td><td colspan="3">FR 6124 Froschtal TO contains three active substances already authorised. For all these substances a dermal absorption in vitro study with human skin was performed. The values in assessment report are shown in the following table:
<table>
<tr><th>CAS number</th><th>EC number</th><th>Name</th><th>% (w/w)</th><th>Dermal absorption</th></tr>
<tr><td>68424-85-1</td><td>270-325-2</td><td>Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides</td><td>25</td><td>8.3% (0.03% and 0.3% ai in solution)</td></tr>
<tr><td>10043-35-3</td><td>233-139-2</td><td>Bori acid</td><td>4</td><td>0.5% assumed for RA</td></tr>
<tr><td>55406-53-6</td><td>259-627-5</td><td>3-iodo-2-propynyl butylcarbamate</td><td>2.5</td><td>30% (0.6% ai in solution)
10% (2.3% ai in solution)
1.6% (17.1% ai in solution)</td></tr>
</table>
According to the EFSA (2012) guidance on dermal absorption, the read across between the products is not acceptable. Therefore it is</td></tr>
</table>

	recommended to use the default values established according to the concentration in active substances: • 25% may be applied for products containing > 5% • 75% should be used for products or in use dilutions containing ≤ 5% active substance.

For Boric acid and IPBC, a quantitative risk characterization for systemic effects was performed taking into account the following values from substances CAR:

Boric Acid	Value	Study	Safety factor
AOEL (Operator/Worker Exposure) acute/semi-chronic and chronic	Rounded 0,1* mg B/kg bw/day.	Developmental study rat	100

* A rounded (systemic) AOEL value of 0.1 mg B/kg bw/day was used for boric acid based on the NOAEL for embryotoxic/teratogenic effects of 9.6 mg B/kg bw/day and a standard assessment factor of 100 even though an AOEL value of 0.06 mg B/kg bw/day (based on a NOAEL of 17.5 mg B/kg bw/day in a 2-year study in the rat and an assessment factor of 300 due to serious effects) and an AOEL value of 0.07 mg B/kg bw/day (based on a NOAEL of 21.8 mg B/kg bw/day in a teratogenicity study in the rabbit and an assessment factor of 300 due to serious effects) could be derived from the critical effects.

IPBC	Value	Study	Safety factor
AOELlong term (Operator/Worker Exposure)AOEL	0.2 mg/kg bw/day	2-years rats study	100
AOELshort term (Operator/Worker Exposure)	0.35 mg/kg bw/ day	90-day gavage rat study	100
*AOEL (Operator/Worker Exposure) – acute	0.35 mg/kg bw/day	90-day gavage rat	100

* Based on the exposure situation and expected exposure time durations (amateur use estimated to be 1-2 days/year) and the toxicological profile of the active substance (where the critical effects are due to repeated exposure) an acute AOEL is not justified for IPBC used in PT8. The AOEL for short-term exposure (0 35 mg/kg bw/day) could also cover potential acute exposure as a conservative approach.

For C12-C16-ADBAC a semi-quantitative risk characterization for local effects for the dermal route was performed. Also a local exposure estimate after oral uptake was calculated.

ADBAC	Value	Study
Local Dermal NOEC	0.3% 0.045 mg/cm^2	2-week skin irritation study with rats (US ISC)
Local Oral NOAEC	0.03% 0.3mg/ml	1-year oral gavage toxicity study in dogs

Repeated C12-16-ADBAC intake in the diet in toxicological studies resulted in effects up to death in rodents at concentrations affecting the gastrointestinal mucosa and flora resulting in dehydration. Irritation and corrosion are the major outcomes of toxicity related to C12-16-ADBAC with reduction in body weight and body weight gain, consistent with decreased food consumption. It was concluded that all effects could be attributed to local gastrointestinal irritation/corrosion and consequent reduced food intake without observing any primary systemic effect. Therefore, the systemic effects observed in these studies are regarded as secondary to the local irritation/corrosion caused by the test substance and as a result no adverse systemic effects were identified and no systemic risk characterisation is required according to Italy (2015). At BPC-WGII 2015 the Human Health Working Group

agreed that the revised local risk assessment carried out for ATMAC/TMAC should be relevant for all QUATs having the same application (cf. local oral NOAEC in the table).
FR 6124 Froschtal TO is classified for local effects as skin corrosive 1B (H314), Eye damage 1 (H318) and skin sensitiser 1 (H317). Therefore local exposure should be considered for qualitative risk assessment.

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	yes	yes	na	na	na	no	na
Dermal	yes	yes	na	na	na	yes	na
Oral	na	na	na	na	na	yes	na

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	mixing and loading	primary exposure connecting lines automated/manual inhalation and dermal route.	industrial (trained-professional) users
2.	Dipping	primary exposure dipping and cleaning out dipping tank inhalation and dermal route.	industrial (trained-professional) users
3.	adult sandig	secondary exposure sanding treated wood from impregnated timber - inhalation and dermal route.	professionals
4.	adult sandig	secondary exposure sanding treated wood from impregnated timber - inhalation and dermal route.	non professionals
5.	Toddler mouthing	secondary exposure chewing wood off-cut – oral route	non professionals
6.	Toddler playing and mouthing	secondary exposure playing on playground structure outdoors – dermal and oral routes.	non professionals
7.	Toddler inhaling volatile residues	secondary exposure inhaling volatile residues at home- dermal route	Non professionals

Industrial (trained-professional) exposure

Scenario [1]: **Mixing and Loading**

Description of Scenario [1]
Different models has been used for Mixing and loading for PT8. Active substances risk assessment were developed by Mixing and loading Model 7 and Model 3. Model 7 has been challenged by HEEG. According to the HEEG opinion 1 - Mixing loading model 7 alternatives, the Model 7 should be used with care as it was no longer taken up in TNsG 2007, which might indicate little confidence in the model. Delivery takes place in drums and/or ICBs. Two tasks are described for the mixing and loading phase in the Guidance Biocides Human Health Exposure Methodology V1(October 2015), as connect tanker transfer lines and dilute concentrates in plant. The first one assumes possible exposure of hands. However the dilution process assumes no exposure is involved. It is assumed that most facilities have automated systems and therefore mixing and loading is not of concern (HEEG OPINION 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping): Where the wood preservative fluid is delivered by tanker and is transferred from the tanker into the dip tank using connecting hosing then, it could be assumed, providing the operator wears suitable PPE, exposure of the operator's skin is minimal and does not need to be quantified. However as worst case scenario and in order to include in this assessment the non fully automated facilities, HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale - Agreed at TM I08) will be used. In order to be as much concordant to active substances assessments and being an acceptable possibility acoording to HEEG Opinion nº 1 on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale, Mixing & loading model 7; TNSG part 2 p.142 (corrected) was used. Furthermore, this models also provides inhalatory exposure. Tier 1 assessment should be carried out considering no personal protective equipment or 100% penetration through protective clothes. For inhalation uptake 100% figure was used as well. Due to moderate physical activity the inhalation rate a value of 1.25 m3/hour was used for calculations. In Tier 2 assessment, values from model are used, Dermal penetration is assumed as 75% as a worst case default. Exposure of each active substance is related to its relative contribution to the product. The biocidal product is assumed as undiluted for this process.

	Parameters	Value
	Boric acid concentration	4%
	IPBC comcentration	2.5%
Tier 1	Dermal exposure, without gloves[1]	101 mg/min
	Inhalation[1]	0.94 mg/m^3
	Exposure duration[2]	10 min
	Body weight, adult[3]	60 kg

	Inhalation rate, adult	1.25m^3/h
Tier 2[2]	Clothes and gloves penetration[1]	1%
	Dermal exposure, under clothes and gloves[1]	1.01 mg/min

[1] HEEG Opinion 1 Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale [2] Biocides Human Health Exposure Methodology
[3] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

Calculations for Scenario [1]

[Please include any relevant calculations in Annex 3.2]

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake**	**Estimated total uptake mg/kg bw/d**
Scenario [1] Boric acid	Tier 1	1,31E-04	5,05E-01	-	5,05E-01
	Tier2	1,31E-04	5,05E-03	-	5,18E-03
Scenario [1]IPBC	Tier 1	8,16E-05	3,16E-01	-	3,16E-01
	Tier2	8,16E-05	3,16E-03	-	3,24E-03

[Add and delete lines as needed. Output tables from exposure assessment tools can be included in Annex 3.2 to complement the table].

***Scenario [2]:* Dipping**

Description of Scenario [2]

HEEG opinion 8 (2009) is applied for exposure assessment. Two different processes might occur depending on the whether it is a manual or automated facility. Manual dipping is defined as manual dipping of wooden articles in open tanks (p. 26 of the User Guidance, 2002). This models were agreed at the Human Health Working Group I on 28 January 2015.
In manual dipping operations, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts by his/her gloved hand the wooden article from the dipping tank and stacks the article to dry. The operator gets relatively highly contaminated by the wood preservative, as demonstrated by a video recording of this operation (UK HSE). Duration is assumed as 30 minutes. For exposure assessment Dipping Model 1 is used, including dermal and inhalatory exposure.

Automated dipping includes the following operations: an operator using a fork-lift truck or similar equipment lowers the wood into the dipping tank or transfers the wood to a bathing tray. The wood stays in the wood preservative for a few minutes or for a few hours before being lifted out of the tank by the fork-lift truck (or similar). The wood is then transferred by the fork-lift truck (or similar) to a storage area where it is placed to dry. For duration a default value of 60 minutes was used, by 4 cycles per day. Handling Model 1 for dermal exposure is used. Negligible inhalatory exposure to aerosols is assumed.
According to the HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8), inhalation exposure resulting from aerosol formation should be negligible.
According to the HEEG OPINION 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4.

Scenario [2a]: **Manual Dipping**

	Parameters		Value
	Boric acid concentration		0.16%
	IPBC comcentration		0.1%
Tier 1	*Dermal exposure*[1]	Hands	25.7 mg/min (inside gloves)
		Body	178 mg/min
	Inhalation exposure[1] Inhalation (non-volatile compounds)		<1 mg/m3
	Exposure duration[1]		30 min
	Body weight, adult[2]		60 kg
	Inhalation rate, adult[2]		1.25m^3/h
Tier 2	Coverall penetration[3]		5%

[1] HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8)
[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products
[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

***Scenario [2b]:* Automated Dipping**

	Parameters		Value
	Boric acid concentration		0.16%
	IPBC comcentration		0.1%
Tier 1	*Dermal exposure*[1]	Hands	1080 mg/cycle (inside gloves)
		Body	8570 mg/cycle
	Exposure duration[1]		4 cycles
	Body weight, adult[3]		60 kg
	Inhalation rate, adult[3]		1.25m^3/h
Tier 2	Coverall penetration[4]		5%
Tier3	Decrese factor dermal exposure fully automated dipping[2]		4

[1] HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8)
[2] HEEG OPINION 18 For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping
[3] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products
[4] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

Calculations for Scenario [2a]

Summary table: estimated exposure manual dipping					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake**	**Estimated total uptake mg/kg bw/d**
Scenario [2a] Boric acid	Tier 1	1,67E-05	1,22E-01	-	1,22E-01
	Tier2	1,67E-05	5,34E-03	-	5,36E-03
Scenario [2a]IPBC	Tier 1	1,04E-05	7,64E-02	-	7,64E-02
	Tier2	1,04E-05	3,34E-03	-	3,35E-03

Calculations for Scenario [2b]

Summary table: estimated exposure automated dipping					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake**	**Estimated total uptake mg/kg bw/d**
Scenario	Tier 1	-	**8,12E-01**	-	**8,12E-01**

[2b] Boric acid	Tier2	-	**7,44E-02**	-	**7,44E-02**
	Tier 3	-	**1,86E-02**		**1,86E-02**
Scenario [2b]IPBC	Tier 1	-	**5,08E-01**	-	**5,08E-01**
	Tier2	-	**4,65E-02**	-	**4,65E-02**
	Tier 3	-	**1,16E-02**		**1,16E-02**

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment mixing and loading and manual dipping/automated dipping was combined for each active substance.

Combined Scenarios M&L/manual dipping					
Active subsance	**Scenarios combined**	**Tier**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Boric acid	Scenario [1+2a]	Tier 1	1,48E-04	6,27E-01	5,05E-01
		Tier2	1,48E-04	1,04E-02	5,18E-03
IPBC	Scenario [1+2a]	Tier 1	8,16E-05	3,63E-01	3,16E-01
		Tier2	8,16E-05	1,48E-02	3,24E-03
Combined Scenarios M&L/Automated dipping					
Active subsance	**Scenarios combined**	**Tier**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Boric acid	Scenario [1+2b]	Tier 1	1,31E-04	1,32E+00	1,32E+00
		Tier 2	1,31E-04	7,95E-02	7,96E-02
		Tier 3	1,31E-04	2,37E-02	2,38E-02
IPBC	Scenario [1+2b]	Tier 1	8,16E-05	8,24E-01	8,24E-01
		Tier2	8,16E-05	4,97E-02	4,97E-02
		Tier3	8,16E-05	1,48E-02	1,48E-02

Professional exposure

Scenario [3] **Sanding treated wood from dipping impregnated timber**

Description of Scenario [n]		
The scenario is described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a).		
	Parameters[1]	Value
	Boric acid concentration	0.16%
	IPBC comcentration	0.1%
Tier 1	Volume of wood to be sanded in 1h	4,00E+03 cm^3
	Rate of product absorbed in wood (2l/4m^2)	5 mg/cm^2

	Product density	1 g/ml
	Wood density	0.4 g/ml
	Dust concentration in air (occupational exposure limit for wood dust)	5 mg/m^3
	Inhalation rate[2]	1.25 m^3/h
	Exposure duration	6 h
	Body weight[2]	60 kg
	Percentage dislodgeable[3]	2%
	Hand surface[2]	420 cm^2
	Transfer to hands (%)	20%

[1] TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a)
[2]HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products
[3] *Biocides Human Health Exposure Methodology* 2015, p. 171.

Calculations for Scenario [3]
[Please include any relevant calculations here. If not relevant, delete the title.]

Summary table: systemic exposure from professional uses sanding treated wood from dipping impregnated timber				
Exposure scenario	**Active substance**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Scenario [3]	Boric acid	1,26E-05	1,68E-04	1,81E-04
	IPBC	7,88E-06	1,05E-04	1,13E-04

Non-professional exposure

Scenario [4] **Sanding treated wood from dipping impregnated timber**

Description of Scenario [4]		
The scenario is described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a).		
	Parameters[1]	Value
	Boric acid concentration	0.16%
	IPBC comcentration	0.1%
Tier 1	Volume of wood to be sanded in 1h	4,00E+03 cm^3
	Rate of product absorbed in wood (2l/4m^2)	5 mg/cm^2
	Product density	1 g/ml
	Wood density	0.4 g/ml

	Dust concentration in air (occupational exposure limit for wood dust)	5 mg/m^3
	Inhalation rate[2]	1.25 m^3/h
	Exposure duration	1 h
	Body weight[2]	60 kg
	Percentage dislodgeable[3]	2%
	Hand surface[2]	420 cm^2
	Transfer to hands (%)	20%

[1] TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a)
[2]HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products
[3] *Biocides Human Health Exposure Methodology* 2015, p. 171.

Calculations for Scenario [4]

Summary table: systemic exposure from non professional uses sanding treated wood from dipping impregnated timber				
Exposure scenario	**Active substance**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Scenario [3]	Boric acid	2,10E-06	1,68E-04	1,70E-04
	IPBC	1,31 E-06	1,05E-04	1,06E-04

Scenario [5] **Toddler chewing treated wood chip (acute exposure)**

Description of Scenario [5]		
According to TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a).		
Tier 1	Parameters[1]	Value
	Boric acid concentration	0.16%
	IPBC comcentration	0.1%
	Application rate	5 mg/cm^2
	Extraction by chewing	10%
	Size of wood composites chip	48cm^2
	Oral absorption	100%
	Body weight	10 kg

[1] TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a [2] Only include the parameters changed with respect to the previous Tier.

Calculations for Scenario [5]

[Please include any relevant calculations here. If not relevant, delete the title.]

Summary table: systemic exposure from toddler chewing treated wood chip					
Exposure scenario	**Active substance**	**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]	Boric Acid	-	-	3,84E-03	3,84E-03
Scenario [5]	IPBC	-	-	2,40E-03	2,40E-03

Scenario [6] **Toddler playing on playground structure outdoors and mouthing (chronic exposure via dermal route and ingestion)**

Description of Scenario [6]		
According to TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a).		
Tier 1	Parameters[1]	Value
	Boric acid concentration	0.16%
	IPBC comcentration	0.1%
	Application rate	5 mg/cm^2
	Contact surface	2,30E+02 cm^2
	Contaminated area (%)	20%
	Dislogeable fraction (%)	2%
	Dermal absortion	75%
	Extraction by chewing	10%
	Oral absorption	100%
	Body weight	10 kg

[1] TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a [2] Only include the parameters changed with respect to the previous Tier.

Calculations for Scenario [6]

[Please include any relevant calculations here. If not relevant, delete the title.]

Summary table: systemic exposure from Toddler playing on playground structure outdoors and mouthing					
Exposure scenario	**Active substance**	**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]	Boric Acid	-	5,55E-04	4,00E-03	4,56E-03
Scenario [5]	IPBC	-	3,49E-04	2,50E-03	2,85E-03

Scenario [7] **Inhalation of volatilised residues indoors**

The product could be used on joinery elements that are used indoors and so inhalation of volatilised residues has been considered.
According to HEEG opinion 13 Assessment of Inhalation Exposure of Volatilised Biocide Active Substance, as a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed.

Let *mw* and *vp* denote the molecular weight (in g/mol) and the vapour pressure (in Pa). For toddler (based on an inhalation rate of 8 m^3/24 hr and bw of 10 kg) and using an *AEL* in mg a.s./kg bw/d, if

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

then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is negligible then the inhalation risk for the infant, child and for the adult can also be considered to be negligible.

In case an *AEC* (mg a.s./m^3) is given (e.g. in the case of local effects), the following screening test is used instead; if

$$0.410 \cdot \frac{mw \cdot vp}{AEC_{long-term}} \leq 1$$

then risk from inhalation exposure for the infant, toddler, child and adult is negligible, otherwise inhalation exposure should be included in the risk assessment.

ABBAC and Boric Acid have vapour pressure<1 10^{-5} Pa then, we are using this value for calculations and IPBC have a vapour pressure of 4.5 10^{-3} Pa,

Active substance	Vapour Pressure	Molecular weight	AEL/AEC	Constante	Cte.mw.vp/AEL(C)	Negligible
ADBAC	<1 10^{-5} Pa	396.1	3 10^5 mg/m^3	0.410	5,29E-09	Yes
Boric acid	<1 10^{-5} Pa	61.83	0.1mg/kg/d	0.328	2.03	No
IPBC	4.5 10^{-3} Pa	251.1	0.2mg/kg7d	0.328	2.07	No

In view of these results, an exposure assessment for volatile boric acid and IPBC residues fot toddler is calculated.

Description of Scenario [7]			
According to TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a).			
Tier 1	Parameters[1]		Value
	Vapour pressure	Boric acid	1 10^{-5}Pa
		IPBC	4.5 10^{-3}Pa
	Molecular weight	Boric acid	61.83g/mol

		IPBC	281g/mol
	Constant		8.31 J/molK
	Temperature		298K
	Inhalation rate		8 m^3/d
	Body weight		10 kg
	SVC available for inhalation		1%

[1] TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a [2] Only include the parameters changed with respect to the previous Tier.

Calculations for Scenario [7]

[Please include any relevant calculations here. If not relevant, delete the title.]

Summary table: Inhalation of volatilised residues indoors					
Exposure scenario	**Active substance**	**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]	Boric Acid	1,69E-06			1,69E-06
Scenario [5]	IPBC	4,08E-03			4,08E-03

Monitoring data

[Please add any information on surveys or studies with the actual product or with a surrogate.]

Dietary exposure

No exposure to food, drinking water or livestock exposure is foreseen.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

ADBAC	Value	Study	
Local Dermal NOEC	0.3% 0.045 mg/cm^2	2-week skin irritation study with rats (US ISC)	
Local Oral NOAEC	0.03% 0.3mg/ml	1-year oral gavage toxicity study in dogs	
Boric Acid	Value	Study	Safety factor
AOEL (Operator/Worker Exposure) acute/semi-chronic and chronic	Rounded 0,1* mg B/kg bw/day.	Developmental study rat	100
IPBC	Value	Study	Safety factor
AOELlong term (Operator/Worker Exposure)AOEL	0.2 mg/kg bw/day	2-years rats study	100
AOELshort term (Operator/Worker	0.35 mg/kg bw/ day	90-day gavage rat	100

Exposure)		study	
**AOEL (Operator/Worker Exposure) – acute	0.35 mg/kg bw/day	90-day gavage rat	100

* A rounded (systemic) AOEL value of 0.1 mg B/kg bw/day was used for boric acid based on the NOAEL for embryotoxic/teratogenic effects of 9.6 mg B/kg bw/day and a standard assessment factor of 100 even though an AOEL value of 0.06 mg B/kg bw/day (based on a NOAEL of 17.5 mg B/kg bw/day in a 2-year study in the rat and an assessment factor of 300 due to serious effects) and an AOEL value of 0.07 mg B/kg bw/day (based on a NOAEL of 21.8 mg B/kg bw/day in a teratogenicity study in the rabbit and an assessment factor of 300 due to serious effects) could be derived from the critical effects.
** Based on the exposure situation and expected exposure time durations (amateur use estimated to be 1-2 days/year) and the toxicological profile of the active substance (where the critical effects are due to repeated exposure) an acute AOEL is not justified for IPBC used in PT8. The AOEL for short-term exposure (0 35 mg/kg bw/day) could also cover potential acute exposure as a conservative approach.

For C12-C16-ADBAC a semi-quantitative risk characterization for local effects for the dermal route was performed. Also a local exposure estimate after oral uptake was calculated.

Risk for industrial users

Scenario 1 and Scenario 2

Systemic effects

Task/ Scenario	Active substance	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Mixing and Loading	Boric Acid	Tier1	1,00E-01	5,05E-01	5,05E+02	NO
		Tier2	1,00E-01	5,18E-03	5,18E+00	
	IPBC	Tier1	2,00E-01	3,16E-01	1,58E+02	NO
		Tier2	2,00E-01	3,24E-03	1,62E+00	
Manual Dipping	Boric Acid	Tier1	1,00E-01	1,22E-01	1,22E+02	NO
		Tier2	1,00E-01	5,36E-03	5,36E+00	
	IPBC	Tier1	2,00E-01	7,64E-02	3,82E+01	
		Tier2	2,00E-01	3,35E-03	1,68E+00	
Automated Dipping	Boric Acid	Tier1	1,00E-01	**8,12E-01**	8,12E+02	NO
		Tier2	1,00E-01	**7,44E-02**	7,44E+01	
		Tier3	1,00E-01	**1,86E-02**	1,86E+01	
	IPBC	Tier1	2,00E-01	**5,08E-01**	2,54E+02	NO
		Tier2	2,00E-01	**4,65E-02**	2,33E+01	
		Tier3	2,00E-01	**1,16E-02**	5,80E+00	

[Please include a row for each task/scenario where primary or secondary industrial exposure is foreseen. If no exposure is foreseen and/or no systemic effect is observed, then only indicate this and delete the table.]

Combined scenarios

Task/ Scenario	Active substance	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Mixing and Loading + Manual Dipping	Boric Acid	Tier1	1,00E-01	6,27E-01	6,27E+02	NO
		Tier2	1,00E-01	1,05E-02	1,05E+01	
	IPBC	Tier1	2,00E-01	3,63E-01	1,81E+02	NO

		Tier2	2,00E-01	1,49E-02	7,43E+00	
Mixing and Loading + Automated Dipping	Boric Acid	Tier1	1,00E-01	1,32E+00	1,32E+03	NO
		Tier2	1,00E-01	7,96E-02	7,96E+01	
		Tier3	1,00E-01	2,38E-02	2,38E+01	
	IPBC	Tier1	2,00E-01	8,24E-01	4,12E+02	NO
		Tier2	2,00E-01	4,97E-02	2,49E+01	
		Tier3	2,00E-01	1,48E-02	7,42E+00	

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to both active substances in product has been carried out.

The effects used to establish the AELs for each of the substances in the mixture/biocidal product are considered concentration or dose-additive. This approach is known to be conservative but corresponds to a pragmatically approach avoiding wasted time in a regulated context with many dossiers to assess.
Hazard Quotient is defined by the ratio of internal exposure and AEL:
HQ= Internal Exposure / AEL
HQ for each substance will be used to calculate a HI for the mixture/biocidal product according to the following method:
HI = Σ HQa.s.
The HI being the sum of the HQs for each substance.
The Hazard Quotient is defined as: estimation of internal exposure/AEL.
If HI ≤1 the risk related to use of the mixture will be considered acceptable;
If HI >1 the risk related to use of the mixture will be considered unacceptable and refinement is needed.

Task/ Scenario	**Tier**	**Active substance**	**Estimated total uptake mg/kg bw/d**	**AEL mg/kg bw/d**	**HQas**	**HI = Σ HQ**a.s	**Acceptable (yes/no)**
Mixing and Loading + Manual Dipping	Tier1	Boric Acid	6,27E-01	1,00E-01	6,27E+00	8,09E+00	NO
		IPBC	3,63E-01	2,00E-01	1,82E+00		
	Tier2	Boric Acid	1,05E-02	1,00E-01	1,05E-01	1,80E-01	YES
		IPBC	1,49E-02	2,00E-01	7,45E-02		

Risk is accesptable for combinated scenarios of mixing and loading and manual dipping in Tier 2, using gloves and coating coverall.

Task/ Scenario	**Tier**	**Active substance**	**Estimated total uptake mg/kg bw/d**	**AEL mg/kg bw/d**	**HQas**	**HI = Σ HQ**a.s	**Acceptable (yes/no)**
Mixing and Loading + Automated Dipping	Tier1	Boric Acid	1,32E+00	1,00E-01	1,32E+01	1,73E+01	NO
		IPBC	8,24E-01	2,00E-01	4,12E+00		
	Tier2	Boric Acid	7,96E-02	1,00E-01	7,96E-01	1,044518	NO
		IPBC	4,97E-02	2,00E-01	2,49E-01		
	Tier3	Boric Acid	2,38E-02	1,00E-01	2,38E-01	0,312018	YES
		IPBC	1,48E-02	2,00E-01	7,42E-02		

Risk is accesptable for combinated scenarios of mixing and loading and automated dipping in Tier 3, when dipping is a **fully automated process** and using gloves and impermeable coverall.

Local effects

According to ADBAC CAR (Italy 2015), exposure and risk form use of products containing ADBAC as active substance, should be made in relation to local effects.
For local dermal effects, the NOAEC expressed in terms of % should be compared with the inuse concentration of the active substance in the product.
In this regards, the formulation FR FROSCHTAL TO contain 25% C_{12-16}-ADBAC. On the other hand, the in-use concentration of C_{12-16}-ADBAC in the diluted product is 1%.Therefore, being the concentrations of the C_{12-16}-ADBAC solutions applied higher than the (marginal) NOAEC of 0.3% C_{12-16}-ADBAC for all intended uses, an unacceptable risk can occurs and personal protective equipments (PPEs) should be prescribed to protect operators against the local effects of C_{12-16}-ADBAC.

FR 6124 Froschtal TO is delivered in drums and/or ICBs containing 25% ADBAC, 4% boric acid and 2.5% IPBC. Classification according to Regulation (EC) No 1272/2008 on classification, labeling and packaging of the biocidal producy is as follows:

Acute toxicity, Category 4, H302
Skin corrosive, Category 1B, H314
Serious eye damage, Category 1, H318
Skin sensitisation, Category 1, H317
Specific target organ toxicity — repeated exposure, Category 2, H373
Hazardous to the aquatic environment, Acute Hazard Category 1, H400
Hazardous to the aquatic environment, Chronic Hazard Category 1, H410

According to section 4.3.2 Local effects (Irritation/corrosion, Sensitisation) – Qualitative and Semi-Quantitative risk characterisation in the guidance document Guidance for Human Health Risk Assessment Volume III, Part B, FR 6124 Froschtal TO should be classified within High hazard category for local effects assessment purposes due to Skin sensitisation, Category 1, H317, Skin corrosive, Category 1B, H314 and Serious eye damage, Category 1, H318.

Hazard			Exposure							Risk
Hazard Category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk
High	Skin Corr. 1B	-	8	Industrias (Trained-Professional)	Pouring and mixing pure product in receiving container	Dermal and inhalation	Few minutes per day or less	Low	**RMM Technics:** - Containment as appropriate; - Segregation of the emitting process; - Effective contaminant extraction; - Good standard of general ventilation; - Minimisation of manual phases; - Regular cleaning of equipment and work area; - Avoidance of contact with contaminated tools and objects; **RMM Organisation:** - Minimise number of staff exposed; -Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene **PPE** -Task appropriate gloves	**Exposure must be limited (Practically no exposure, no splashes, no hand to eye transfer, no aerosol formation) with technical RMM and PPE (gloves, goggles/mask, impermeable chothes).** **Considering that these recommendations can be followed during this task, ,the risk is acceptable according to RMM and PPE.**

									- Skin coverage with appropriate barrier material based on potential for contact with the chemicals - Eye protection	
	Eye dam. 1, H318			Professional	Pouring and mixing pure product in receiving container	Dermal	Few minutes per day or less	Low	High level of containment, practically no exposure; no splashes, no hand to eye transfer, no (liquid or solid) aerosol formation e.g. exposure below or similar to brief contact with technical RMM and PPE as touching of contaminated surfaces - Chemical goggles	
	Skin Sens. 1 (H317)								- Substance/task appropriate gloves; - Skin coverage with appropriate barrier material based on potential for contact with the chemicals; - Substance/task appropriate respirator; - Optional face shield; - Eye protection;	

Conclusion

The risk is acceptable for the combination of scenarios 1 and 2 (a and b) when the following RMM are implemented and PPE used:

- RMM
  - Good standard of general ventilation;
  - Minimisation of manual phases;
  - Regular cleaning of equipment and work area;
  - Avoidance of contact with contaminated tools and objects;

- PPE
  - Substance/task appropriate gloves;
  - Skin coverage with appropriate barrier material based on potential for contact with the chemicals;
  - Substance/task appropriate respirator;
  - Face shield;
  - Eye protection;

As described at active substance authorisation stage, following personal protective equipment and risk management measures should be in place:

Hygiene measures
Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Respiratory protection
In the case of vapour formation, use a respirator with an approved filter. Respirator with a vapour filter of the following type should be used: EN 141.

Hand protection for long-term exposure
Suitable material for gloves: Nitrile rubber
Break through time / glove: > 480 min
Minimal thickness / glove: 0.7 mm
Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).

Hand protection for short-term exposure (e.g. accidental aerosols from splashing etc.)
Suitable material for gloves: Nitrile rubber
Break through time / glove: > 30 min
Minimal thickness / glove: 0.4 mm
Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).

Eye protection
Tightly fitting safety goggles; Face-shield.

Skin and body protection

Choose body protection according to the amount and concentration of the dangerous substance at the work place, Rubber or plastic apron, Rubber or plastic boots.

Risk for professional users

Scenario 3: Professional sanding treated wood

Systemic effects

Task/ Scenario	Active substance	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Sanding treated wood	Boric Acid	Tier1	1,00E-01	1,81E-04	1,81E-01	YES
	IPBC	Tier1	2,00E-01	1,13E-04	5,64E-02	YES

Local effects

According to ADBAC CAR (Italy 2015), exposure and risk form use of products containing ADBAC as active substance, should be made in relation to local effects.
For local dermal effects, the NOAEC expressed in terms of % should be compared with the inuse concentration of the active substance in the product.
For local dermal effects, the NOAEC expressed in terms of **mg/cm²** should be compared with the concentration of the active substance incontact with skin in terms of **mg/cm²** also.

NOAEC dérmico: 0.3%; 0.045 mg/cm²

Scenario	NOAEC	Exposure	Exposure/NOAEC	Risk
Sanding treated wood	0.045 mg/cm²	2.0 x 10^{-4} mg/cm²	0.44	Acceptable

Conclusion

The risk is acceptable for the scenario professional sanding treated wood.

Risk for non-professional users
Scenario 4: Non-Professionals sanding treated wood

Systemic effects

Task/ Scenario	Active substance	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Non professionals sanding treated wood	Boric Acid	Tier1	1,00E-01	1,70E-04	1,70E-01	YES
	IPBC	Tier1	3,50E-01	1,06E-04	3,04E-02	YES

Local effects

According to ADBAC CAR (Italy 2015), exposure and risk form use of products containing ADBAC as active substance, should be made in relation to local effects.
For local dermal effects, the NOAEC expressed in terms of % should be compared with the inuse concentration of the active substance in the product.
For local dermal effects, the NOAEC expressed in terms of **mg/cm²** should be compared with the concentration of the active substance incontact with skin in terms of **mg/cm²** also.

Dermal NOAEC: 0.3%; 0.045 mg/cm²

Scenario	NOAEC	Exposure	Exposure/NOAEC	Risk
Non professionals sanding treated wood	0.045 mg/cm²	2.0 x 10^{-4} mg/cm²	0.44	Acceptable

Conclusion

The risk is acceptable for the scenario non-professional sanding treated wood.

Risk for the general public

Scenario 5: **Toddler chewing wood composites chips (acute)**

Systemic effects

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Toddler chewing wood composites	Tier 1	Boric acid	1,00E-01	3,84E-03	3,84E+00	YES
		IPBC	3,50E-01	2,40E-03	6,86E-01	YES

Local effects

According to ADBAC CAR (Italy 2015), exposure and risk form use of products containing ADBAC as active substance, should be made in relation to local effects.
For local oral effects, the NOAEC expressed in % should be compared with the concentration of the active substance in saliva due to exposure in % also or both in mg/ml.

Oral NOAEC: 0.3mg/ml; 0.03%**.**

For the scenario « Infant chewing wood composites chips », the concentration of ADBAC in wood has been calculated in order to compare this value to the reference dose expressed in%. The following parameters have been used:

- concentration of a.s in the diluted product: 1%;
- application rate: 5 mg/cm²;
- released a.s by chewing: 10%;
- size of wood composites chips: 48 cm²; (piece of wood 4x4x1cm)
- amount of saliva produced: 1.5 mL/min (from CAR of a.s);
- event (chewing) duration: 1 min (from CAR of a.s).

Considering these parameters, an exposure value can be calculated as follows:
Oral exposure = 5 mg pb/cm^2 x 1% x 10% x 48 cm^2 x / (1.5 mL/min x 1 min) = 0.160mg/mL

Scenario	NOAEC	Exposure	Exposure/NOAEC	Risk
Toddler chewing wood composites chips	0.3 mg/ml	0.160 mg/ml	0.53	Acceptable

Scenario 6: Toddler playing on playground structure and mouthing

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Toddler playing and mouthing	Tier1	Boric acid	1,00E-01	4,56E-03	4,55536	YES
		IPBC	2,00E-01	2,85E-03	1,4243	YES

Local effects

According to ADBAC CAR (Italy 2015), exposure and risk form use of products containing ADBAC as active substance, should be made in relation to local effects.

For local dermal effects, the dermal NOAEC expressed in terms of mg/cm^2 should be compared with the concentration of the active substance in contact with skin in terms of mg/cm^2 also.

Dermal NOAEC: 0.3%;

Scenario	NOAEC	Exposure	Exposure/NOAEC	Risk
Toddler playing	0.045 mg/cm^2	0.001 mg/cm^2	0.02	Acceptable

For local oral effects, the oral NOAEC expressed in % should be compared with the concentration of the active substance in saliva due to exposure in % also or both in mg/ml

Oral NOAEC: 0.3mg/ml; 0.03%.

For the scenario « Toddler playing and mouthing », the concentration of ADBAC in wood has been calculated in order to compare this value to the reference dose expressed in%. The following parameters have been used:

- concentration of a.s in the diluted product: 1%;
- application rate: 5 mg/cm^2;
- released a.s by chewing: 10%;
- hand surface area mouthing: 50 cm^2
- amount of saliva produced: 1.5 mL/min (from CAR of a.s);
- event (chewing) duration: 1 min (from CAR of a.s).

Considering these parameters, an exposure value can be calculated as follows:
Oral exposure = 5 mg pb/cm^2 x 1% x 10% x 50 cm^2 x / (1.5 mL/min x 1 min) = 0.167mg/mL

Scenario	NOAEC	Exposure	Exposure/NOAEC	Risk
Toddler mouthing	0.3 mg/ml	0.167 mg/ml	0.56	Acceptable

Scenario 7: Volatilised residues

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Toddler breathing indoors	Tier1	Boric acid	1,00E-01	1,69E-06	1,69E-03	YES
		IPBC	2,00E-01	4,08E-03	3,40E-01	YES

Conclusion
The risk for the general public is acceptable.

2.2.7 Risk assessment for animal health

Not relevant

2.2.8 Risk assessment for the environment

The biocidal product FR 6124 FROSCHTAL TO contains 25% of ADBAC-BKC and IPBC as the ingredients to contribute to the classification regarding environmental properties. ADBAC-BKC is classified as aquatic acute (H400) with M factor of 10 and aquatic chronic (H410) with an M factor of 1 and IPBC is classified as aquatic acute (H400) with M factor of 10 and aquatic chronic (H410) with an M factor of 1. The concentration of the active substance in the product leads to classification according to M factor multiplication as set out in the Regulation EC 1272/2008. The biocidal product FR 6124 FROSHCTAL TO is classified as Aquatic Acute (H400), Aquatic Chronic Category 1 (H410). H410 for labelling purposes.

2.2.8.1 Effects assessment on the environment

Data waiving	
Justification	It is proposed that data submitted for the active substance provides sufficient information for assessment of the effects on organisms and that there are no further indications of risk due to the specific properties of the biocidal product. Therefore, it is proposed that no further studies are required. The product is a wood preservative to be applied onto the wood surface only by industrial users.

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

Data waiving	
Justification	It is proposed that data submitted for the active substance provides sufficient information for assessment of the effects on non-target organisms and that there are no further indications of risk due to the specific properties of the biocidal product. Therefore, it is proposed that no further studies are required. The product is a wood preservative to be applied onto the wood surface only by industrial users.

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

No data is available.

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

No data is available.

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

Not applicable since the biocidal product is not used to treat large proportion of habitats. The product is a wood preservative to be applied indoor onto the wood surface only by industrial users.

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

In accordance with Annex III of the BPR and the ECHA Guidance on the Biocidal Product Regulation, Volume IV: Environment, Part A: Information Requirements, this endpoint is only applicable to relevant components of the biocidal product. The biocidal product is a wood preservative for preventive use against sapstain fungi and mould fungi on freshly sawn timber. The application method is by dipping/immersion. The biocidal product is intended to be used indoors by industrial users. It is not intended for direct release into the aquatic environment nor to the soil.

According to the Emission Scenario Document for Product Type 8: Revised Emission Scenario Document for Wood Preservatives (OECD series N°2), 2013" in section 3.1, a general overview on emission pathways and environmental compartments of concer is given.
The product is applied industrially through dipping after dilution in water to be used for wood protection against fungi and the treated wood in going to be used for classes 1 and 2.

According to the Emission Scenario Document for Product Type 8: Revised Emission Scenario Document for Wood Preservatives (OECD series N°2), 2013" in section 3.1, a

general overview on emission pathways and environmental compartments of concer is given.
The product is applied industrially through dipping after dilution in water to be used for wood protection against fungi and the treated wood in going to be used for classes 1 and 2.
During the product application and the service life the following environmental compartments are considered:

Scenario	Environmental compartment considered
Lyfe cycle stage: Product applcation	
Industrial preventive processes Storage place	Air STP Freshwater / sediment Soil (via sewage sludge application) Soil Groundwater (leaching from soil) Freshwater / sediment
Lyfe cycle stage: Service life	
For wood UC1 and UC2 the potential emissions from treated wood to the outer environment are considered negligible. However, these emissions are relevant for human exposure assessment.	

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

Data waiving	
Justification	Further studies may be required for the product if the composition or application of the product is suspected to influence the degradation, transformation, mobility or adsorption properties of the active substance in a way which may be considered to alter the conclusions made on the risk characterisation of the product. The composition of the biocidal product is not expected to influence any of the processes described above or alter the risk characterisation of the product. Furthermore, the method of application is also not expected to exert influence on degradation, transformation, mobility, adsorption properties or the risk characterisation of the product. Please refer to the active substance dossiers/CARs for further information.

Leaching behaviour (ADS)

No further tests are deemed necessary since there is sufficient information on the components of the products to enable an environmental fate and behaviour assessment.
Leaching value for ADBAC used for risk assessment on active substance authorisation phase was 0.19% per day (ie 2.6% in 14 days). For boric acid, majority of leaching from treated wood can occur within days/months, according to risk assessment submitted by active substance notifier.

The biocidal product is intended to be used indoors by industrial users. The application method is by dipping/immersion. It is recommended to store the treated wood indoors in a well-ventilated place until the product has been set to the wood.

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

Data waiving	
Justification	Testing of the products concerning the distribution and dissipation in soil, water and air is not require d because the composition and application technique of the products are not suspected to influence the degradation and transformation or mobility and adsorption properties of the active substances in a way that may considerably alter the conclusions of the risk assessments.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Justification	Testing of the products concerning the distribution and dissipation in soil, water and air is not require d because the composition and application technique of the products are not suspected to influence the degradation and transformation or mobility and adsorption properties of the active substances in a way that may considerably alter the conclusions of the risk assessments.

Acute aquatic toxicity

Data waiving	
Justification	Testing on the product does not need to be conducted since 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).

Chronic aquatic toxicity

Data waiving	
Justification	Testing on the product does not need to be conducted since 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).

Estimated aquatic bioconcentration

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	Not bioconcentration potential
Justification for the value/conclusion	Any active substance or other components of the mixture have bioconcentration potential

2.2.8.2 Exposure assessment

FR 6124 Froschtal TO is intended for use at industrial sites as a wood preservative. It is applied by dipping. Subsequent exposure theoretically may arise from storage stage and during service live.

General information

Assessed PT	PT 8
Assessed scenarios	Scenario 1: Industrial Preventive processes and storage of treated Wood: Dipping and storage Scenario 2: Treated wood in service: pallets
ESD(s) used	Emission Scenario Document for Product Type 8: Revised Emission Scenario Document for Wood Preservatives, September 2013
Life cycle steps assessed	Production: No Formulation No Use: No Service life: No

FR 6124 FROSCHTAL TO is intended for wood treatment to manufacture pallets, used at industrial sites. No specific scenario has been developed so far for pallets treated wood. According to the last available guidance (Revised Emission Scenario Document for Wood Preservatives , 2013) this scenario should be developed in future revisions.

FR 6124 Froschtal TO should be used for classes 1 and 2:

- Use Class 1: Situation in which the wood or wood-based product is under cover, fully protected from the weather and not exposed to wetting
- Use Class 2: Situation in which the wood or wood-based product is under cover and fully protected from the weather but where occasional but not persistent wetting may occur.

No other use classes are intended since boric acid is not permited for wood classes 3 and 4a.

According to the Revised Emission Scenario Document for Wood Preservatives (2013), for wood UC1 and UC2 the potential emissions from treated wood to the outer environment are considered negligible. The available emission scenarios for dipping (including post-treatment storage) assume that the storage area is uncovered, unprotected and exposed to rain. Therefore, these calculations are not applicable to FR 6124 FROSCHTAL TO.

For use classes 1 and 2, the storage places are sealed to prevent any direct release to soil and/or surface water. 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.

According to the BPC conclusions in October 2016 that mitigation measures can be used to reduce emissions from the application and storage phases of the industrial treatment by dipping to acceptable levels. Such industrial use shall be performed only:

- when application is conducted within a contained area on impermeable hard standing with bunding,

- when freshly treated timber are stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer, or water;
- if any losses from the application of the product or the storage of treated wood can be collected for reuse or disposal according to local regulations.

2.2.8.3 Risk characterisation

No assessment is needed for wood treatment for use classes 1 and 2. However, some working conditions and risk managent measures should be followed.
In accordance with Best Available Techniques in wood preservation with chemicals (BAT, 2014) the plants, process and equipment are designed and constructed in a way to prevent any leakages of chemicals into the environment.

For soil protection:
1)Process and equipment
Roof, walls and floor of the plant are made of water-tight material.
The floor in the plant slopes towards a well or a spill storage tank.
An embankment has the capacity to retain all preservation fluid in the process in case of leakage or accident.
There shall be automatic protection (equipped with an alarm) against over-filling of storage tanks, mixing tanks and cylinders.
The filling pipe shall end at least 0.5 m above the fluid surface level in the storage tanks, dipping and mixing tanks, in order to prevent a siphon effect that allows the preservation fluid backwards.
Old underground storage tanks shall be lined with impermeable foil and equipped with a leachate warning. The new construction of underground storage tanks for preservation fluid is forbidden.
Chemicals and hazardous wastes shall be kept dry and insulated so that leaching cannot influence the surroundings.
Spill kits, fire extinguishers and other emergency provisions and procedures shall be adequate and regularly inspected and maintained.

2) Dripping and storage of impregnated wood:
Impregnated wood shall be stored in paved and roofed areas.
Preserved wood shall reach fixation stage before being removed from the preservation site. A dripping plate shall be made of water-tight material and have the capacity to store one day's production. It shall slope against the rail from the pressure cylinder, be protected from rain by a roof and walls, be protected from surface run-off, the work area shall be covered with gratings and, if used at temperatures below 0 C°, the floor shall be heated.

3) Environmental monitoring:
When operations are ceased and, in some cases, also when the environmental permit renewed or when the facilities are expanded, soil and groundwater is sampled and analysed for the chemicals used in order to show any contamination of the chemicals. The local authority decides if any remedial action is needed.

For control of water emissions:
Collect, treat and recycle, when possible, all wastewater streams as well as storm water from areas that have potential for being contaminated by impregnating agents. Only clean storm water can be discharged into surrounding ditches as untreated.
Regularly inspect, empty, and clean oil separators, canals and sumps.
Monitor wastewater and the quality of storm water and groundwater.

Adequate and regularly inspected and maintained spill kits, fire extinguishers and other emergency provisions and procedures minimize damages in case of an emergency situation.
In dripping and storage areas, impregnated wood is stored in paved and roofed areas minimizing leaching along with storm water.
Impregnation chemical residues shall not be discharged as wastewater, but shall be treated as hazardous waste

Conclusion: Risks are considered to be acceptable according to the above presented conditions.

According to the BPC conclusions in October 2016 that mitigation measures can be used to reduce emissions from the application and storage phases of the industrial treatment by dipping to acceptable levels. Such industrial use shall be performed only:

- when application is conducted within a contained area on impermeable hard standing with bunding,
- when freshly treated timber are stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer, or water;
- if any losses from the application of the product or the storage of treated wood can be collected for reuse or disposal according to local regulations.

Groundwater

Emisions to groundwater during industrial treatment is not expected to be relevant for FR 6124 Froschtal TO. Furthermore directions for use include risk reduction during storage using hard impermeable standing and collection of rainwater.

According to Revised ESD (2013), the applicability of these models for treated wood-in-service and storage prior to shipment was discussed on EU level in several Technical Meetings. As result of these discussions, a separate scenario was prepared on EU level for transferring the emissions from treated wood (house walls) to a surface area. However this scenario is not relevant for the storage of treated wood and/or treated wood-in-service as pallets (class 1 & 2).

According to the BPC conclusions in October 2016 that mitigation measures can be used to reduce emissions from the application and storage phases of the industrial treatment by dipping to acceptable levels. Such industrial use shall be performed only:

- when application is conducted within a contained area on impermeable hard standing with bunding,
- when freshly treated timber are stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer, or water;
- if any losses from the application of the product or the storage of treated wood can be collected for reuse or disposal according to local regulations.

Mixture toxicity

According to Transitional Guidance on mixture toxicity assessment for biocidal products for the environment, May 2014, a tiered approach was followed for risk assessment of FR 6124 FROSCHTAL TO.

Screening step

Screening Step 1: Identification of the concerned environmental compartments
Primary receiveing compartments are soil and surface water. However, as referred in the previous sections, it is assumed that for wood use classes 1 and 2, environmental releases are not relevant. Consequently, no environmental risk assessment and mixture toxicity assessment were performed.

Aggregated exposure (combined for relevant emmission sources)

No information is available about other uses of active substances and/or the tonnage band of thses potential uses. The biocidal product FR 6124 FROSCHTAL TO is to be used for PT8 in a non wide dispersive patern of use. No other product tipes are intended. No overlap in time and space is expected. Therefore no aggregate exposure estimation is required for FR 6124 FROSCHTAL TO.

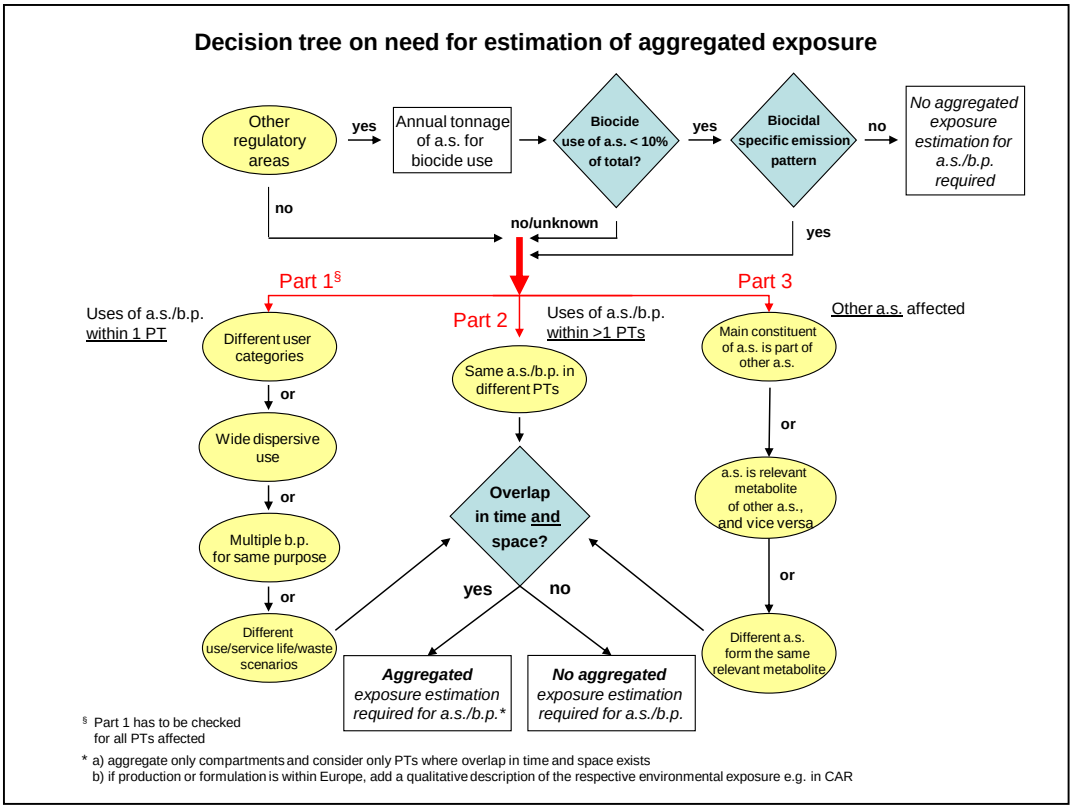


Figure 1: Decision tree on the need for estimation of aggregated exposure

2.2.9 Measures to protect man, animals and the environment

See Summary of Product Characteristics (SPC)

A. Recommended methods and precautions

Keep only in original container. Keep container tightly closed and dry. Keep in a cool place.
Do not store at temperatures above 30 ºC.
Expiry date: 6 months as from the manufacturing date.
Wear personal protection equipment.

Avoid contact with skin and eyes.
Do not breathe gas/fumes/vapour/spray.
Provide adequate ventilation.
Keep away from sources of ignition - No smoking.

B. Identity of relevant combustion products in cases of fire

Special hazards arising from the substance or mixture: Can be released in case of fire: Gas/vapours, toxic.

C. Specific treatment in case of an accident

Remove casualty to fresh air and keep warm and at rest. In case of breathing difficulties administer oxygen.
After contact with skin, wash immediately with plenty of water and soap.
Take off contaminated clothing and wash before reuse
In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses.
If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Do NOT induce vomiting. If the person is unconscious, lay him side down with the head lower than the rest of the body and the knees bended.
NEVER LEAVE THE AFFECTED PERSON ALONE.
Indication of any immediate medical attention and special treatment needed:
In case of ingestion, evaluate the performance of endoscopy.
Contraindication: Syrup of Ipecac.
Treat symptomatically.

Do not empty into drains or the aquatic environment.
Do not allow to enter into soil/subsoil.
In case of gas being released or leakage into waters, ground or the drainage system, the appropriate authorities must be informed.

D. Possibility of destruction or decontamination following release

No data available.

E. Procedures for waste management of the biocidal product and its packaging

Waste wood, waste wood dust, protection foil, cleaning solvents, used cans and unused product should be disposed of according to national waste disposal regulations.

F. Procedures for cleaning application equipment where relevant

No data available.

G. Specify any repellents or poison control measures included in the product

No data available.

2.2.10 Assessment of a combination of biocidal products

FR 6124 FROSCHTAL TO is not intended to be authorised for the use with other biocidal products. Exposure to several productsis not forensee.

2.2.11 Comparative assessment

Background

The biocidal product contains three active substances, of which boric acid is considered to meet the criteria for substitution listed in article 10(1) of Regulation 528/2012, also boric acid is considered to be toxic (T) and very persistent (vP), it can be considered to meet the criteria listed in Article 10(1)d. It meets two of the criteria for being PBT in accordance with Annex XIII to the regulation (EC) No 1907/2006. Therefore in accordance with Article 23 of Regulation 528/2012 a comparative assessment will be carried out for the biocidal product. This comparative assessment has been carried out by the ES CA using the agreed guidance, including the Technical Guidance Note on comparative assessment of biocidal products (TNsG-CA i.e. CA-May15-Doc4.3a-final).

1.Application administrative details:

Procedure: NA-APP

Purpose: Authorisation

Case Number in R4BP:

Evaluating Competent Authority: ES CA

Applicant: FROSCH CHEMIE S.L.

(Prospective) Authorisation holder: FROSCH CHEMIE S.L.

2.Administrative information of the BP/BPF

Trade name(s): FR 6124 FROSCHTAL TO

Product type(s): 08 (wood preservative)

Active substance(s): Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides (CAS: 68424-85-1)
Boric acid (CAS: 10043-35-3)
IPBC (CAS: CAS: 55406-53-6)

3. Screening phase

The ES CA began the comparative assessment with the screening phase described in section 6.1 of the TNsG-CA to identify whether the diversity of the active substances - mode of action combination in authorised biocidal products is adequate.

3.1. Intended use and properties of the biocidal product

Category	Matrix wording	Code product
User category	Industrial and trained profesional	A.20; A.30
Wood category	Softwood and hardwood	B.10; B.20
Wood product	Solid wood	C.10

Application aim	Temporary preventive treatment/green sawn timber	D.20
Field of use	Not applicable.	-
Method of application	Superficial application / Dipping Dilution: 2-4 % v/v Application rate: 25 L/m^3	F.14
Target organisms	Sapstain and mould fungi	G.21.1; G.22

3.2. Chemical diversity of the active substances - mode of action combination in authorised biocidal products

According to the information available to the ES CA, there are over 73 biocidal products authorised in Spain under Product Type 8 (Wood Preservatives) of the Biocidal Products Directive and Biocidal Products Regulations (including Mutual Recognitions and same product authorisations). There are 9 active substances which have been included in authorised PT8 products.
These active substances are listed in Table 3.2.2, along with information on the potential for resistance from the Fungicide Resistance Action Committee (FRAC), an international scientific committee with an overview of the global position. This information has been derived from experience with plant protection products rather than wood preservative products.

3.2.2 Mode of action and risk of resistance formation for PT8 fungicidal substances in authorised biocidal products

Active substance	Target organism (from Annex I AR)	Mode of action	FRAC code	Risk of resistance formation
Boric acid	Wood-destroying fungi, wood boring insects and termites	Inhibition of metabolism		No cases reported
Fenpropimorph	Discolouring and wood –destroying fungi	G: sterol biosynthesis in membranes G2: Δ14-reductase and Δ8-Δ7-isomerase in sterol biosynthesis (erg24, erg2)	**3**	Low to medium (resistance management required)
Tebuconazole	Wood-destroying fungi	G: sterol biosynthesis in membranes G1: C14- demethylase in sterol biosynthesis	3	Medium (resistance management required)
Propiconazole	**Wood-disfiguring fungi** and wood destroying fungi	G: sterol biosynthesis in membranes G1: C14- demethylase in sterol biosynthesis	3	Medium (resistance management required)
IPBC	**Wood-disfiguring fungi** and wood destroying fungi	F: lipid synthesis and membrane integrity F4: cell membrane permeability, fatty	28	Low to medium (resistance management required)
Thiacloprid	Wood-destroying	Nicotinic acetylcholine	Not	Low

	insects	receptors (IIRAC code 4)	reported	
Sulfuryl fluoride	Wood destroying pests including termites, wood boring beetles and pinewood nematode	Glycolysis and fatty acid cycle	Not reported	Not reported
Copper carbonate	wood destroying fungi	Multi-site action	Not reported	Low
Creosote	Wood rotting basidiomycetes Soft rot micro-fungi	Multi-site action	Not reported	Not reported

Of the active substances in Table 3.2.2, other than the candidates for substitution; boric acid, propiconazole and creosote. IPBC and Propiconazole are identified in the Assessment Reports as being effective against wood-disfiguring fungi, the proposed target organisms for FR 6124 FROSCHTAL TO (with other PT8 active substances being effective against wood destroying insects and/or wood destroying fungi). Therefore based on the information provided at active substance approval there are potentially two available mode of action-active substance (propiconazole and IPBC) combinations for the intended uses of the biocidal product .

3.3 Conclusions on screening phase

As paragraph 57 of the TNsG for comparative assessment states that at least three different and independent active substance/mode of action combinations should remain available through authorised biocidal products for a given use, the ES CA considers that there is not currently an adequate chemical diversity of active substance-mode of action combinations to minimise the occurrence of resistance in the target organisms.

However as boric acid meets the exclusion criteria in article 5, it is proposed that the comparative assessment for boric acid must be taken forward to Tier IB (quantitative analysis) in line with section 6.2 of the TNsG-CA.

3.4 Tier IB – Comparison to other authorised biocidal products

According to the information available to the ES CA, there are 73 biocidal products authorised in Spain under Product Type 8 (Wood Preservatives) of the Biocidal Products Directive and Biocidal Products Regulations (including Mutual Recognitions and same product authorisations). Of them, only 2 PT8 biocidal products have been authorised in the ES CA for the same intended uses as FR 6124 FROSCHTAL TO. These products are based on three active substances; Propiconazole, Tebuconazole and IPBC

As per documents CA-March14-Doc.4.1-Final and CA-Nov14-Doc.4.4-Final, only data available in the PAR associated to the following exclusion/substitution criteria will have to be compared.

3.4.1 Concerning Human Health

- CMR PROPERTIES (exclusion criterion)

Boric acid meet the Criteria for Exclusion due to their classification as toxic for reproduction category 1B, therefore this criteria is to be compared.

The active substance in the alternative biocidal product (propiconazole) has harmonised classification revised to toxic for reproduction category 1B. the other active substances in alternative biocidal products (IPBC and Tebuconazole) do not have exclusion criteria

It can therefore be considered that the alternative biocidal product on the market does not have a lower risk to human health compared to FR 6124 FROSCHTAL TO

- RISK CHARACTERISATION RATIOS

The ES CA has made a comparison of the toxicological end points and risk to human health of the systemic effects due to the active substances in **FR 6124 FROSCHTAL TO** and the potential alternative products **1 (Propiconazole and IPBC)** and **2 (Propiconazole, IPBC and Tebuconazole) (See confidential annex)**

1. Primary exposure

The three products are used with similar application method, dipping procceses. In the case of product 1, the dipping is only automated while for Y and FR 6124 Froschtal TO, dipping can be manual and automated. Thus, comparison is made for the automated dipping application method.

Product 1

Scenario		*AEL [mg/kg bw/day]*	*Systemic dose [mg/kg bw/day]*	*% AEL*	*NOAEL [mg/kg bw/day]*	*MoE*
Propiconazole						
Dipping, incl. handling	*2 cycles*	*0.08*	*2.82×10^{-3}*	*3.53*	*8*	*2837*
	4 cycles	*0.08*	*5.40×10^{-3}*	*6.75*	*8*	*1481*
Cleaning tank		*0.3*	*1.53×10^{-3}*	*0.51*	*30*	*19623*
IPBC						
Dipping, incl. handling	*2 cycles*	*0.2*	*0.19*	*97.03*	*20*	*103*
	4 cycles	***0.2***	***0.39***	***193.88***	***20***	***52***
Cleaning tank		*0.35*	*9.72×10^{-2}*	*27.77*	*35*	*360*

Product 2

Calculated for 4 process cycles

Task/ Scenario	*Active substance*	*Tier*	*AEL mg/kg bw/d*	*Estimated uptake mg/kg bw/d*	*Estimated uptake/ AEL (%)*	*Acceptable (yes/no)*
Automated Dipping	*Tebuconazol*	*Tier2*	*0.03*	*0.0291*	*97*	*YES*
	Propiconazol	*Tier2*	*0.08*	*0.0015*	*2*	*YES*
	IPBC	*Tier2*	*0.2*	*0.115*	*57*	*YES*

FR 6121 Froschtal TO

Calculated for 4 process cycles

Task/ Scenario	*Active substance*	*Tier*	*AEL mg/kg bw/d*	*Estimated uptake mg/kg bw/d*	*Estimated uptake/ AEL (%)*	*Acceptable (yes/no)*
Automated Dipping	*Boric Acid*	*Tier1*	*0.1*	*0.81*	*812*	*NO*
		Tier2	*0.1*	*0.074*	*74.4*	*YES*

		Tier3	*0.1*	*0.019*	*18.6*	*YES*
	IPBC	*Tier1*	*0.2*	*0.51*	*254*	*NO*
		Tier2	*0.2*	*0.046*	*23.3*	*YES*
		Tier3	*0.2*	*0.012*	*5.8*	*YES*

The first difference we can see is that for product 1 to obtain an acceptable risk characterisation, the number of process cycles stated in model has to be reduced from 4 to 2, while for product 2 and FR 6124 Froschtal TO, this value does not has to be reduced.
Unfortunately, due to the time elapsed between the three authorizations, the same default values have not been used in the calculations. Thus, although the comparison will have to be approximate, we can assume that exposure calculations for product 1 with 4 process cycles are similar to those calculated for Product 2 and FR 6121 Froschtal TO in Tier 2.

Product/active	***Exposure scenario and exposure/AEL value (%)*** *Dipping automated application 4 process cycles*	***Acceptable (yes/no)***
FR 6121 Froschtal TO		
Boric acid	*74,4*	*YES*
IPBC	*23,3*	*YES*
Product 1		
Propiconazole	*6,75*	*YES*
IPBC	*194*	*NO*
Product 2		
Tebuconazol	*97*	*YES*
Propiconazol	*2*	*YES*
IPBC	*57*	*YES*

In these conditions, as it is shown in table above, the risk for product 1 is not consider acceptable due to the exposure to IPBC, while for product 2 and FR 6124 Froschtal TO the risk is acceptable when it is assessed substance by substance.
However, when the risk is assessed by combination of exposures to the active substances of the mixture, product 2 leads to a concern situation:

Product/active	***Exposure scenario and exposure/AEL value (%)*** *Dipping automated application 4 process cycles*	***HQas***	***HI = Σ HQa.s***	***Acceptable (yes/no)***
FR 6121 Froschtal TO				
Boric acid	*74,4*	*0.744*	*0.977*	*YES*
IPBC	*23,3*	*0.233*		
Product 1				
Propiconazole	*6,75*	*0.0675*	-	*NO*
IPBC	*194*	*1.97*		
Product 2				
Tebuconazol	*97*	*0.997*	*1.587*	*NO*
Propiconazol	*2*	*0.02*		
IPBC	*57*	*0.57*		

It can therefore be considered that FR 6124 FROSCHTAL TO has a lower risk to human health compared with alternative biocidal products on the market (1 and 2) when the risk is assessed by combination of exposures to the active substances of the mixture.

2. Secondary Exposure

A comparison of the secondary exposure assessment of the three products from the respective PARs has been done.
The table with the Exposure / AEL (%) values for the three products is shown below.

Product/active	*Exposure scenario and exposure/AEL value (%)*				
	Adult sanding treated wood – acute phase	*Adult sanding treated wood – chronic phase*	*Toddler chewing wood off-cut*	*Toddler inhaling vapour from treated surfaces*	*Toddler playing on playground structure and mouthing*
FR 6121 Froschtal TO					
Boric acid (0.16%)	*0.170*	*0.181*	*3.84*	*0.00169*	*4.55536*
IPBC (0.1%)	*0.0304*	*0.0564*	*0.686*	*0.340*	*1.4243*
Product 1					
Propiconazole(0.2%)	*0.0070*	*0.08*	*1.05*	*0.04*	*2.02*
IPBC (0.3%)	*0.29*	*0.54*	*1.65*	*0.59*	*2.88*
Product 2					
Tebuconazol (2%)	*2*	*0.4*	*2.7*	*-*	*2*
Propiconazol (4%)	*0.002*	*0.1*	*0.5*	*-*	*6*
IPBC (7.9%)	*43*	*0.77*	*0.9*	*0.85*	*5*

No significant lower risk for human health in secondary exposure assessment with the use of the alternatives products can be identified.

3.4.2 Concerning environment

The table below indicate the environment classification and the relevant RMMS with regards to the environment:

Product	**Active substances**	**Environmental classification of the product**	**Application method**	**Relevant RMMs with regards to environment**
FR 6124 FROSCHTAL TO	ADBAC-BKC Boric acid IPBC	A1 C1	Dipping	Industrial application shall be conducted within a contained area on impermeable hard standing with bunding. 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 from the application of the product or the storage of treated wood shall be collected for reuse or disposal according to local regulations.
PRODUCT 1	IPBC	A1	Dipping	Industrial application shall

(see confidential Annex)	Pripiconazole	C1		be conducted within a contained area on impermeable hard standing with bunding. 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 from the application of the product or the storage of treated wood shall be collected for reuse or disposal according to local regulations.
PRODUCT 2 (see confidential Annex)	IPBC Propiconazole Tebuconazole	A1 C1	Spen system: dip treatment Dip Enclose deluge	Appication 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). Storage of freshly treated wood must be either undercover with a recovery system in place (e.g. sump) or on impermeable hard standing or bunded to prevent run-off with a recovery system in place.

The alternatives products has the same environmental classification of the product FR 6124 FROSCHTAL TO.
Consecuently ES CA do not identify significant lower risk for environment with the use of the alternatives products.

Further, an assessment of the economic and practical disadvantages have to be taken into consideration according to section 6.2.1.2 of the 'Technical Guidance Note on Comparative Assessment of Biocidal Products'.
Boric acid has a unique characteristic as it can be used for remedial treatment and treatment where damage to the wood is likely or imminent, when the wood has a high moisture content; for example, to stop beginning degradation in a window frame outdoor or a beam in a cellar indoors. In both cases, it can be impossible to dry the wood enough before treatment and boron-containing products may be the only option.
Borates are unique preservatives, as they are the only system that so actively diffuses, making them useful materials in remedial applications and where traditional vacuum pressure applications are not effective enough (e.g. in the treatment of heartwood or refractory species).

As other authorised active substances do not show the same ability to diffuse and as this is a significant advantage for wood preservation.

3.4.3 Conclusions of Tier IB assessment

It has not been demonstrated that alternative authorised biocidal products provide a significant lower risk to human health. And it can be argued that the alternative biocidal product show more economical and practical disadvantages than the biocidal product relevant.So that the comparative assessment must move to Tier II.

3.5 Tier II- comparision to eligible non-chemical alternatives

Kiln drying is a possible alternative to temporary wood preservative treatment of wood disfiguring fungi. If wood can be quickly kiln dried after sawing then wood preservative treatment may not be necessary. However, the length of time timber needs to stay in a kiln may mean it is not practical for timber to move straight from the saw to the kiln even when kilning facilities are available - so that timber may still need temporary treatment. Kilning is time and power-consuming, so very expensive for the equipment

So, a non-chemical alternative has been identified but concerns have been raised of whether it provides a practicable and economically viable alternative to PT8 wood preservatives.

3.6 Overal conclusion. Comparative assessement report

ES CA considers that there is not currently an adequate chemical diversity of active substance-mode of action combinations to minimise the occurrence of resistance in the target organisms. However as boric acid meets the exclusion criteria in article 5, it is proposed that the comparative assessment for boric acid must be taken forward to Tier IB.

The ES CA has made a comparison of the toxicological end points and risk to human health of the active substances in **FR 6124 FROSCHTAL TO** and the potential alternative products **1 (Propiconazole and IPBC)** and **2 (Propiconazole, IPBC and Tebuconazole).** Concluding that It can be considered that the alternative biocidal product on the market does not have a lower risk to human health compared to FR 6124 FROSCHTAL TO. Even, for primary exposure, FR 6124 FROSCHTAL TO has a lower risk to human health compared with alternative biocidal products on the market (1 and 2) when the risk is assessed by combination of exposures to the active substances of the mixture.

A possible non-chemical alternative to wood preservatives has been identified. It has not been demonstrated that the non-chemical alternative is sufficiently effective and does not pose any significant economic or practical disadvantages.

The conclusions of the comparative assessment are not sufficiently conclusive to support the prohibition or restriction of biocidal product under Article 23(3) of Regulation 528/2012, and the ES CA proposes that the biocidal product should be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation 528/2012.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
2.2.5.5. Efficacy data.	[redacted]	[redacted]	Title: Protector de madera. Ensayo biológico. Laboratory: CIDEMCO Sponsor: FROSH CHEMIE S.L. Test report: 14682	Yes	FROSH CHEMIE, S.L.
2.2.6 Human health	ECHA	2015	Guidance on the Biocidal Products Regulation Volume III Human Health - Part B Risk Assessment Version 2.0 October 2015.	No	
	ECHA	2008	Competent Authority Report and Assessment Report of 3-iodo-2-propynyl butylcarbamate (IPBC)	No	
	ECHA	2009	Competent Authority Report and Assessment Report of boric acid	No	
	ECHA	2015	Competent Authority Report and Assessment Report of Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	No	

3.1 Output tables from exposure assessment tools

Exposure FR 6124 Froschal.xlsx

3.2 New information on the active substance

Not applicable

3.3 Residue behaviour

Not applicable

3.4 Summaries of the efficacy studies

Summaries of efficacy studies are provided in section 2.2.5.5.

3.5 Confidential annex

See the document PAR confidential Annex.