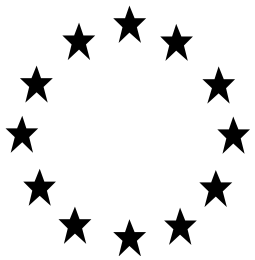
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE RENEWAL OF THE NATIONAL AUTHORISATION APPLICATIONS



TETOL FB Solution

Product type8

Boric acid and Disodium tetraborate decahydrate

Case Number in R4BP:
BC-TD046456-36

Evaluating Competent Authority: HU

Date: 29/08/2020

Authorisation number:
HU-2020-PA-08-00282-0000

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CONCLUSION
Tetol FB Solution belongs to Main group 2: preservatives, Product type 8: wood preservative.
The intended uses of the product are wood preservative against wood boring beetles and mould with a flame retardant effect in UC1 and UC2:

- 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, fully protected from the weather but where occasional but not persistent wetting may occur.

The product cannot be used in open space that is exposed to rain resulting in emission into groundwater.

The used amounts of the product are 0.16 L/m^2 (0.184 kg/m^2) against wood boring beetles and mould and 1.2 L/m^2 (1.38 kg/m^2) for the flame retardant effect.

The Tetol FB solution is an aqueous solution containing boric acid (40 g/kg) and disodium tetraborate decahydrate (20 g/kg) as active ingredients.
The product can be applied as preventive treatment by brushing, spraying and dipping.

The active ingredients of the biocidal product act on wood boring insects as stomach poisons. Most of the borate salts have also effects on chitin exoskeleton. The compounds containing boron inhibit the development of mould spores.

The non-active components of the product are not substances of concern.

Acute clinical studies were carried out and based on the experimental results of the acute oral toxicity and acute dermal toxicity tests Tetol FB solution is classified to GHS Category 5.
According to the results of the skin corrosion and irritation test, the eye irritation and skin sensitization tests Tetol FB solution is not classified into any GHS category.

Boric acid and disodium tetraborate decahydrate can be expressed on the basis of boric acid equivalents (BAE). The conversion factors of boric acid and disodium tetraborate decahydrate are 1 and 0.649.

Unacceptable environmental risks are not expected during in-situ application and during the service life of treated wood. However, a risk is identified to soil during storage after dipping application. Therefore, risk mitigation measures are required to prevent losses to soil.

History of the dossier

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	**HU**			**INITIAL ASSESMENT, first authorisation**

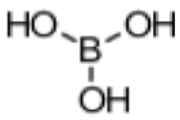
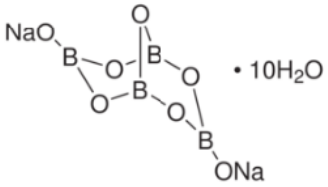
Phys-Chem: Full ambient storage stability test is missing.
Physical state, odour, colour, pH-value, alkalinity and state of packaging were checked after 6, 12, 24 months storage. Applicant's request of non submission data on concentration of active substances is not acceptable.
Condition of the renewal is to submit storage stability data in three years which contains concentration of active substances at least at start and after 24 months storage.
Label must indicate the followings: Do not store under 0°C, keep away from frost – as no low temperature storage study is submitted.

ASSESSMENT REPORT

1.1 SUMMARY

1.1.1 Presentation of the biocidal product

A. IDENTITY OF THE ACTIVE SUBSTANCE

Main constituent(s)	
ISO name	not available
IUPAC or EC name	Boric acid
EC number	233-139-2
CAS number	10043-35-3
Index number in Annex VI of CLP	005-007-00-2
Minimum purity / content	99% / 4 m/m%
Structural formula	
Main constituent(s)	
ISO name	Borax decahydrate
IUPAC or EC name	Disodium tetraborate decahydrate
EC number	215-540-4
CAS number	1330-43-4
Index number in Annex VI of CLP	005-011-01-1
Minimum purity / content	99% /2 m/m%
Structural formula	

B. PRODUCT COMPOSITION AND FORMULATION

Qualitative and quantitative information on the composition of the biocidal product

See the Confidential Annex.

Information on the substance(s) of concern

Common name	IUPAC name	Note	H-statements	Content (%)
Boric acid	Boric acid	Repr. 1B	H-360 FD	4
Disodium tetraborate decahydrate	Sodium tetraborate decahydrate	Repr. 1B	H-360 FD	2

C. INTENDED USE(S)

Table 1: Use # 1 – Wood preservative and flame retardant

Product Type(s)	Main group 2: preservatives Product type 8: wood preservative
Where relevant, an exact description of the authorized use	Tetol FB Solution is intended to be used as wood preservative against wood boring beetles and mould with flame retardant effect in Use Classes 1, and 2, according to CEN 335-1 standard. The use of TETOL FB Solution is not recommended: 1. in open space that is exposed to rain resulting in emission into groundwater 2. in rooms above the 75% relative humidity 3. use as preservatives of children's toys 4. as wood preservative of bee-hives 5. as preservative of wood equipment or containers that can be in contact with food and feed (e.g. fruit containers) 6. for preventive maintenance of wooden frames of greenhouses
Target organism (including development stage)	Wood boring insects: Pyrrhidiumsanguineum, Callidiumviolaceum, Hylecoetusdermestoides, Sirexgigas, Plagionotusarcuatus, Platypus cylindrus etc. Wood-destroying or wood-disfiguring organisms, fungi: Coniphoraputeana, Coriolusversicolor, Gloeaphyllumtrobeum etc.
Field of use	Use class: 1, Service condition: Interior, dry Typical using: Framing, roof timbers Biological agents: Insects : "A" wood boring beetles Use class: 2, Service condition: Interior, damp Typical using: Framing, roof timbers Biological agents: As#1 : "A" + decay + mould [allergic potential]
Application method(s)	Application phases: - Applying wood preservative using a brush - Coarse spraying of wood preservatives on wood - Dipping wood (manual, only professional use)
Application rate(s) and frequency	The TETOL FB Solution should be used undiluted. The recommended application rate: against wood boring beetles or mould: 0.16 L/m^2 as a flame retardant: 1.2 L/m^2 Applying the wood preservative against the wood boring beetles and mould (0.16 L/m^2) the necessary amount can be spread by brushing in 1-2 layers. Applying the product as flame retardant (1.2 L/m^2) the necessary amount can be spread by brushing in ca. 10 layers. In case of dipping application the amount applied can be controlled by weight measurement. The reapplication is necessary based on in-service experience in every 5-10 years.
Category(ies) of user(s)	Professional and non-professional
Pack sizes and packaging material	The Tetol FB Solution is placed on the market in 1, 5, 10 and 50 L packages. The packaging material is high density polyethylene (HDPE) that does not react with the product even in extreme circumstances.

D. HAZARD AND PRECAUTIONARY STATEMENTS[1]

Classification and Labelling according to Regulation (EC) No 1272/2008:

Classification	
Hazard category	-
Hazard statement	-
Labelling	
Signal words	
Hazard statements	
Precautionary statements	P102: Keep out of reach of children. P103: Read label before use. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+312: IF SWALLOWED: Call a doctor if you feel unwell. P501: Dispose of contents/container in accordance with current waste management regulations. The residues of the wood preservative and its packaging are considered hazardous waste. They have to be transported to a hazardous waste incinerator or the local hazardous waste dump site.
Note	

E. 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)**
Package	1 l	high density polyethylene (HDPE)	Polypropylene	professional, non-professional	Yes
Package	5 l	high density polyethylene (HDPE)	Polypropylene	professional, non-professional	Yes
Package	10 l	high density polyethylene (HDPE)	Polypropylene	professional, non-professional	Yes
Package	50 l	high density polyethylene (HDPE)	Polypropylene	professional, non-professional	Yes

1.1.2 Summary of the physical, chemical and technical properties

Measurements and information submitted allow reliable assessment of the physico-chemical properties of Tetol FB solution.

No physico-chemical hazard occurs, the product is not considered to be fire hazard. Consideration of the physico-chemical properties of the product based on its

[1] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

components does not suggest any explosive, oxidising, flammable and auto-flammable potential.

As no significant change of the active ingredient content occurred in the accelerated test, it is presumed that the product most likely has a satisfactory shelf life of at least two years.

Further stability studies at ambient temperature are required to confirm 2 years shelf life.

1.1.3 Summary of the Human Health Risk Assessment

Endpoint	Brief description
Skin corrosion and irritation	The acute skin irritation study of the test item Tetol FB solution was performed in New Zealand White rabbits. The irritation effects of the test item were evaluated according to the Draize method (OECD No.: 404, 2002). No irritation symptoms (erythema and oedema) or other signs occurred 1 hour after the patch removal and during the 72-hour observation period.
Eye irritation	The acute eye irritation study of the test item Tetol FB solution was performed in New Zealand White rabbits. The irritation effect of the test item was evaluated according to the Draize method (OECD No.: 405, 2002). 1 hour after the single application of test item Tetol FB solution into the eye of the rabbits, slight redness occurred. 24 hours after treatment animals were symptom-free. 72 hours after treatment the study was terminated, as all animals were free of symptoms of irritation.
Skin sensitization	A skin sensitization study was performed according to the Magnusson-Kligman method using Freund's complete adjuvant technique to evaluate the sensitization potential of test item Tetol FB solution. No signs of contact sensitization were detected in guinea pigs exposed previously to the test item during experiments.
Respiratory sensitization (ADS)	Respiratory sensitization effects are not expected, therefore ADS study was not required.
Acute toxicity by oral route	The method used is not intended to allow the calculation of a precise LD_{50} value. The acute oral LD_{50} of the test item is >2000 mg/kg bw. No pathological changes were found related to the effect of the test item during the macroscopic examination of animals.
Acute toxicity by inhalation	No acute inhalation toxicity was performed. Dermal route was selected as second route of administration of TETOL FB Solution for acute toxicity study, as the probability of human exposure by dermal route is much higher than by inhalation. The product is not volatile, and the components have low acute toxicity.
Acute toxicity by dermal route	The acute dermal LD50 of the test item is >2000 mg/kg bw. No pathological changes were found related to the effect of the test item during the macroscopic examination of animals.
Other effects	No other effect was indicated.
Available toxicological data relating to non-active substance(s)	None of the other ingredients in the product are expected to be of toxicological concern and therefore this data is not required.
Available toxicological data relating to a mixture	The product is not recommended for use in mixture with other biocidal products.
Other relevant information	No other relevant information is available.

Reference values

	Study	NOAEL/ LOAEL	Overall assessment factor	Value
$AEL_{short\text{-}term}$	Teratogenicity	9.6	100	0.1
$AEL_{medium\text{-}term}$	Teratogenicity	9.6	100	0.1
$AEL_{long\text{-}term}$	Teratogenicity	9.6	100	0.1

[Please insert rows for additional reference values if necessary, e.g. for local effects.]

Risk characterisation

Risk for professional users:

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1		9.6	0.1	0.0092	9.2	yes
Scenario 2		9.6	0.1	$1.9*10^{-7}$	$1.9*10^{-4}$	yes
Scenario 3		9.6	0.1	0.00108	1.08	yes
Scenario 4		9.6	0.1	0.00287	2.87	yes
Scenario 5		9.6	0.1	0.000096	0.096	yes
Scenario 7		9.6	0.1	0.007	7	yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 2+3		9.6	0.1	0.00108	1.08	yes
Scenarios 4+5		9.6	0.1	0.002966	2.966	yes

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 4		9.6	0.1	0,00287	2.87	yes
Scenario 5		9.6	0.1	0.000096	0.096	yes
Scenario 6		9.6	0.1	0.0164	16.7	yes
Scenario 7		9.6	0.1	0.007	7	yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 4+5		9.6	0.1	0.002966	2.966	yes

Risk for indirect exposure

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 8		9.6	0.1	0.07	70	yes

Conclusion: Risk is acceptable for every proposed use form of the product and for secondary exposure as well.

1.1.4 Summary of the Environmental Risk Assessment

Fate and behaviour in the environment

Summary table on compartments exposed and assessed		
Compartment	**Exposed (Y/N)**	**Assessed (Y/N)**
Freshwater	Y	Y
Freshwater sediment	Y	Y
STP	Y	Y
Air	Y	N
Soil	Y	Y
Groundwater	Y	N

Effects assessment

Summary table on calculated PNEC values	
Compartment	**PNEC**
Aquatic	0.18 mg B/L
STP	1.8 mg B/L
Sediment	0.24 mg B/kg_{wwt}
Terrestrial	0.35 mg B/kg_{wwt}

Exposure assessment

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}[1]**	**PEC_{air}**
	[mg B/m^3]	[mg B/l]	[mg B/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg B/kg_{wwt}]	[mg B/L]	[mg/m^3]
Scenario 1a	0.1 0.8	0.01 0.08	0.014 0.11					
Scenario 1b		0.014	0.018			17.88	7.3	

Risk characterization

Summary table on calculated PEC/PNEC values						
	PEC/PNEC$_{STP}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**	**PEC/PNEC$_{soil}$**
Scenario 1a	0.06 0.44	0.06 0.44	0.06 0.46			
Scenario 1b		0.08	0.075			51

Conclusion: Unacceptable risks are not expected during in-situ application and service life of the treated wood. However, a risk is identified to soil during storage after dipping application. Therefore, risk mitigation measures are required to prevent losses to soil.

1.2 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION

1.2.1 Administrative information

A. TRADE NAME OF THE PRODUCT

Trade name[2]	**Country (if relevant)**
TETOL FB oldat	Hungary

B. AUTHORISATION HOLDER

Name and address of the authorisation holder	Name	Tetol Kft.
	Address	1097 Budapest, Tagló u. 11-13. Hungary
Telephone:	+36 1 215 7370	
Fax:	+36 1 215 7980	
E-mail address:	info@kelikalart.hu	
Case number in R4BP3:	BC-AM010716-47 (2011/16829/14286/HU/AA/24885)	

C. PERSON AUTHORISED FOR COMMUNICATION ON BEHALF OF THE APPLICANT

Name:	Elderics Sándor
Function:	
Address:	Tagló u. 11-13.
City:	Budapest
Postal Code:	1097
Country:	Hungary
Telephone:	+36 1 215 7370
Fax:	+36 1 215 7980
E-mail address:	erdelics.sandor@kemikalrt.hu

[2] In case the product would have more than one name, all names can be provided in this field, if the other elements of the SPC are identical. Otherwise additional SPCs would have to be provided (one SPC per name).

D. MANUFACTURER(S) OF THE PRODUCT/OF THE PRODUCTS OF THE FAMILY[3]

Name of manufacturer	Tetol Kft.
Address of manufacturer	1097 Budapest, Tagló u. 11-13. Hungary
Location of manufacturing sites	1097 Budapest, Tagló u. 11-13. Hungary

E. CANDIDATE(S) FOR SUBSTITUTION

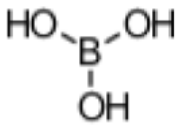
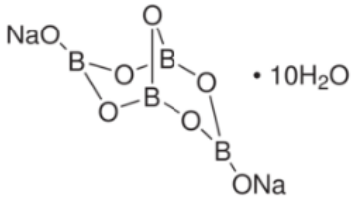
Active substances boric acid and disodium tetraborate decahydrate are classified under CLP as Toxic for reproduction (Repr 1B) and they are included in the list of substances of very high concern (SVHC), therefore both are candidates for substitution. See the comparative assessment in the separate document.

1.2.2 Product composition and formulation

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 X

A. IDENTITY OF THE ACTIVE SUBSTANCE

Main constituent(s)	
ISO name	not available
IUPAC or EC name	Boric acid
EC number	233-139-2
CAS number	10043-35-3
Index number in Annex VI of CLP	005-007-00-2
Minimum purity / content	99%/4 m/m%
Structural formula	
Main constituent(s)	
ISO name	Borax decahydrate
IUPAC or EC name	Disodium tetraborate decahydrate
EC number	215-540-4
CAS number	1330-43-4
Index number in Annex VI of CLP	005-011-00-4
Minimum purity / content	99%/2 m/m%
Structural formula	

3 Please delete as appropriate.

B. QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE BIOCIDAL PRODUCT (FAMILY)

Not relevant.

C. INFORMATION ON TECHNICAL EQUIVALENCE

Not relevant.

D. INFORMATION ON THE SUBSTANCE(S) OF CONCERN

Active substances are hazardous materials.
Other substances of concern:

- ammonium-sulphate: Skin Irrit. 2, Eye, Irrit. 2 and STOT RE 3

E. TYPE OF FORMULATION

Ready-to use aqueous suspension

1.2.3 Intended use(s)

Table 1: Use # 1 – Wood preservative and flame retardant

Product Type(s)	Main group 2: preservatives Product type 8: wood preservative
Where relevant, an exact description of the authorised use	Tetol FB Solution is intended to be used as wood preservative against wood boring beetles and mould with flame retardant effect in Use Classes 1, and 2, according to CEN 335-1 standard. The use of TETOL FB Solution is not recommended: 1. in open space that is exposed to rain resulting in emission into groundwater 2. in rooms above the 75% relative humidity 3. use as preservatives of children's toys 4. as wood preservative of bee-hives 5. as preservative of wood equipment and containers that can be in contact with food and feed (e.g. fruit containers) 6. for preventive maintenance of wooden frames of greenhouses
Target organism (including development stage)	Wood boring insects: Pyrrhidiumsanguineum, Callidiumviolaceum, Hylecoetusdermestoides, Sirexgigas, Plagionotusarcuatus, Platypus cylindrus etc. Wood-destroying or wood-disfiguring organisms, fungi: Coniphoraputeana, Coriolusversicolor, Gloeaphyllumtrobeum etc.
Field of use	Use class: 1, Service condition: Interior, dry Typical using: Framing, roof timbers Biological agents: Insects : "A" wood boring beetles Use class: 2, Service condition: Interior, damp Typical using: Framing, roof timbers Biological agents: As#1 : "A" + decay + mould [allergic potential]
Application method(s)	Application phases: - Applying wood preservative using a brush - Coarse spraying of wood preservatives on wood - Dipping wood (manual, only professional use)
Application rate(s) and frequency	The TETOL FB Solution should be used undiluted. The recommended application rate: against wood boring beetles or mould: 0.16 L/m^2 as a flame retardant: 1.2 L/m^2

	Applying the wood preservative against the wood boring beetles and mould (0.16 L/m^2) the necessary amount can be spread by brushing in 1-2 layers. Applying the product as flame retardant (1.2 L/m^2) the necessary amount can be spread by brushing in ca. 10 layers. In case of dipping application the amount applied can be controlled by weight measurement. The reapplication is necessary based on in-service experience in every 5-10 years.
Category(ies) of user(s)	Professional and non-professional
Pack sizes and packaging material	The Tetol FB Solution is placed on the market in 1, 5, 10 and 50 L packages. The packaging material is high density polyethylene (HDPE) that does not react with the product even in extreme circumstances.

1.2.4 Hazard and precautionary statements

A. PROPOSED CLASSIFICATION AND LABELLING OF THE BIOCIDAL PRODUCT

Classification and Labellingaccording to Regulation (EC) No 1272/2008:

Classification	
Hazard category	-
Hazard statement	-
Labelling	
Signal words	
Hazard statements	
Precautionary statements	P102: Keep out of reach of children. P103: Read label before use. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+312: IF SWALLOWED: Call a doctor if you feel unwell. P501: Dispose of contents/container in accordance with current waste management regulations. The residues of the wood preservative and its packaging are considered hazardous waste. They have to be transported to a hazardous waste incinerator or the local hazardous waste dump site.
Note	**-**

B. 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)**
Package	1 l	high density polyethylene (HDPE)	Polypropylene	professional, non-professional	Yes

Package	5 l	high density polyethylene (HDPE)	Polypropylene	professional, non-professional	Yes
Package	10 l	high density polyethylene (HDPE)	Polypropylene	professional, non-professional	Yes
Package	50 l	high density polyethylene (HDPE)	Polypropylene	professional, non-professional	Yes

1.2.5 Directions for use

A. INSTRUCTIONS FOR USE

TETOL FB Solution should be used undiluted.
The recommended application rate:

- against wood boring beetles or mould: 0.16 L/m2
- as a flame retardant: 1.2 L/m2

The reapplication is necessary based on in-service experience in every 5-10 years.

Use # 1 - Dipping application (manual)

In case of dipping application the amount applied can be controlled by weight and surface measurement.

Use # 2 - Coarse spraying of wood preservatives on wood

Applying the wood preservative against the wood boring beetles and mould (0.16 L/m^2) the necessary amount can be spread by coarse spraying. Applying the product as flame retardant (1.2 L/m^2) the necessary amount can be spread by sparying in ca. 10 layers. 4 hours of drying time should be granted.

Use # 3 - Applying wood preservative using a brush, indoor

Applying the wood preservative against the wood boring beetles and mould (0.16 L/m^2) the necessary amount can be spread by brushing in 1-2 layers. Applying the product as flame retardant (1.2 L/m^2) the necessary amount can be spread by brushing in ca. 10 layers. 4 hours of drying time should be granted.

Use Restrictions:	The use of TETOL FB Solution is not recommended: 1. in open space that is exposed to rain resulting in emission into groundwater 2. in rooms above the 75% relative humidity 3. use as preservatives of children's toys 4. as wood preservative of bee-hives 5. as preservative of wood equipment and containers that can be in contact with food and feed (e.g. fruit containers) for preventive maintenance of wooden frames of greenhouses

B. PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

No special first aid measures are necessary in case of accident or poisoning.

Ingestion: Drink at least two glasses of water if swallowed. Seek medical advice immediately and show the container or label.

Inhalation: The product does not contain volatile components. In case of aerosol inhalation, the mucous membranes or the respiratory tract might be irritated. Leave the contaminated area and stay in the fresh air as long as irritation disappears.

Eye contamination: Immediately rinse eyes with water, when needed open eyelids by hand. If the affected person wears contact lens, remove them before rinsing. If eye irritation does not disappear even after 15 minutes, seek medical help.

Skin contamination: Remove contaminated clothing or protective equipment. Wash the skin thoroughly with water or soap and water.

If a small amount of the product reaches the surface water or the groundwater, removal is unnecessary. In case of a large contamination, the contaminated water body should be treated with lime. The components of the product can be removed from the contaminated soil by acid washing or by water.

C. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

The unused or spilled preservative solution, the contaminated materials (sawdust or sand used for soaking up or the collected contaminated soil), empty containers and waste timber should be disposed of according to national waste disposal regulations.

D. CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

Storage: In closed original container on covered spaced protected from radiating heat.
It should be kept away from food, water, feed, and keep out of the reach of children.
The predicted shelf-life of the product is 2 years, real-time evaluation in room temperature is in progress.

1.2.6 Documentation

A. DATA SUBMITTED IN RELATION TO PRODUCT APPLICATION

A full list of studies and other information submitted in support of the authorization of the product is provided.

B. ACCESS TO DOCUMENTATION

The applicant has submitted a letter of access, issued by European Borates Association A.I.S.B.L. (in short EBA) acting as a consortium. In the work program for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC EBA has registered boric acid and disodium tertaborate anhydrous, pentahydrate and decahydrate as active biocidal substances for use in wood preservatives.
EBA has submitted a letter of proof stating the fact that Etimine S.A. listed as a substance supplier pursuant to Article 95(1) of Regulation (EU) No 528/2012, is a part of the consortium.

1.2.7 Other information

Application codes: Case Number in R4BP: BC-AM010716-47 (2011/16829/14286/HU/AA/24885)

1.3 ASSESSMENT OF THE BIOCIDAL PRODUCT

1.3.1 Physical, chemical and technical properties of Tetol FB solution

Property	Guideline and Method	Results	Reference
Physical state at 20 °C and 101.3 kPa	OPPTS 830.6303	Ocher yellow dilute suspension containing rust brown solid material. suspended material: yellow iron oxide dye, which on standing forms sediment	13/164-314ANH CiToxLAB Hungary Ltd., Hungary (GLP)
Colour at 20 °C and 101.3 kPa	OPPTS 830.6302	Dilute suspension: yellow ocher	
Odour at 20 °C and 101.3 kPa	OPPTS 830.6304	pungent odour	
pH-value	CIPAC MT 75.3	7.508 at 20 ±1°C	13/164-314ANH CiToxLAB Hungary Ltd., Hungary (GLP)
Acidity / alkalinity	CIPAC MT 191	2.016 ± 0.015%	
Relative density / bulk density	*Oscillating U-tube method*	D^{20}_4 = 1.1508	13/164-325AN, CiToxLAB Hungary Ltd., Hungary (GLP)
Storage stability test – **long term storage at ambient temperature**	The accelerated storage stability test was performed: at 54±2°C for14 days.No decrease of active substance content measured by validated analytical method:	The product most likely has a satisfactory shelf life of at least 2 years. mean of borax decahydrat: Start: 1,78% End: 1,79% Mean of boric acid: Start: 4,06/ End: 4,00% Full ambient storage stability test is still missing. Physical state, odour, colour, pH-value, alkalinity and state of packaging were checked after 6, 12, 24 months storage. Applicant's request of non submission data on concentration of active	13/164-314ANH CiToxLAB Hungary Ltd., Hungary (GLP)

Property	Guideline and Method	Results	Reference
		substances is not acceptable. Condition of renewal is to submit storage stability data in three years which contains concentration of active substances at least at start and after 24 months.	
Storage stability test – **low temperature stability test for liquids**	not available	No study is required as the following is on the label: Do not store under 0°C, keep away from frost.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	not available		
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	no data		
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	it is an aqueous solution		
Wettability	no data available		
Suspensibility, spontaneity and dispersion stability	not relevant		
Wet sieve analysis and dry sieve test	not relevant		
Emulsifiability, re-emulsifiability and emulsion stability	not relevant		
Disintegration time	not relevant		
Particle size distribution, content of dust/fines, attrition, friability	not relevant		
Persistent foaming	not relevant		
Flowability/Pourability/Du stability	not relevant		
Burning rate — smoke generators	not relevant		
Burning completeness — smoke generators	not relevant		
Composition of smoke — smoke generators	not relevant		
Spraying pattern — aerosols	not relevant		

Property	Guideline and Method	Results	Reference
Physical compatibility			
Chemical compatibility			
Degree of dissolution and dilution stability	not relevant		
Surface tension	no data		
Viscosity	no data		

1.3.2 Physical hazards and respective characteristics

Property	Guideline and Method	Results	Reference
Explosives	not relevant		
Flammable gases	not relevant		
Flammable aerosols	not relevant		
Oxidising gases	not relevant		
Gases under pressure	not relevant		
Flammable liquids			
Flammable solids	not relevant		
Self-reactive substances and mixtures	not relevant		
Pyrophoric liquids	not relevant		
Pyrophoric solids	not relevant		
Self-heating substances and mixtures	not relevant		
Substances and mixtures which in contact with water emit flammable gases	not relevant		
Oxidising liquids			
Oxidising solids	not relevant		
Organic peroxides	not relevant		
Corrosive to metals			
Auto-ignition temperatures of products (liquids and gases)			
Relative self-ignition temperature for solids			
Dust explosion hazard	not relevant		

1.3.3 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measure-ments**	**Linea-rity**	**Specifi-city**	**Recovery rate (%)**			**Limit of quantify-cation (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Boric acid	titri-metric	3 -3		confir-med	at boric acid content 0-4%	88-105 %	0-1%		BS 5688-3:1979, ISO 1916:1972 standard

					at boric acid content of 5%	78-86%			Validation of the analytical method for the measurement of borax and boric acid content (GLP) Study code: 13/163-316AN CiTox LAB Hungary Ltd
borax deca-hydrate	titri-metric	3 -3			at borax decahydrate content 1-4% at borax deca-hydrate content of 5%	91-99% 85-94%			

Titrimetric method with two step titration:

1. Determination of sodium-oxid (calculated as borax decahydrate) content by converting borax decahydrate to boric acid with excess of hydrochloric acid solution and back titration the excess with sodium hydroxide solution – using methyl red indicator.

$Na_2B_4O_5 + 2\ HCl + 3\ H_2O = 4\ H_3BO_3 + 2NaCl$

2. Subsequent titration of titrated solution using sodium hydroxide solution in the presence of mannitol which fortifies weak boric acid using phenolphthalein indicator to determine total boron-oxid (calculated as boric acid) content.

Analytical methods for soil

Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measure-ments**	**Linea-rity**	**Specifi-city**	**Recovery rate (%)**			**Limit of quantify-cation (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
boric acid	Total boron can be extracted from soil by hot acid extraction with HNO_3 and HCl under reflux or by microwave digestion with HNO_3 and HF, with addition of HCl and H2O2 when needed.								
borax								depends on the extraction method.	CAR of active substan-ces

Analytical methods for air

no method is required due to low vapour pressure of active substances

Analytical methods for animal and human body fluids and tissues

not required

Analytical methods for monitoring of active substances and residues in food and feeding stuff
not required

1.3.4 Efficacy against target organisms

A. FUNCTION AND FIELD OF USE

Tetol FB Solution belongs to Main group 2: preservatives, Product type 8: wood preservative.
Tetol FB Solution is intended to be used as wood preservative against wood boring beetles and mould with flame retardant effect in Use Classes 1, and 2, according to CEN 335-1 standard.

B. ORGANISMS TO BE CONTROLLED AND PRODUCTS, ORGANISMS OR OBJECTS TO BE PROTECTED

Wood boring insects: Pyrrhidiumsanguineum, Callidiumviolaceum, Hylecoetusdermestoides, Sirexgigas, Plagionotusarcuatus, Platypus cylindrus etc.
Wood-destroying or wood-disfiguring organisms, fungi: Coniphoraputeana, Coriolusversicolor, Gloeaphyllumtrobeum etc.
Considering the use pattern, no products, organisms or objects are in the surroundings of the biocidal product that should be protected against the adverse effect of the product.

C. EFFECTS ON TARGET ORGANISMS, INCLUDING UNACCEPTABLE SUFFERING

The active ingredients of the biocidal product act on wood boring insects as stomach poisons. Most of the borate salts have also effects on chitin exoskeleton.
Effects against fungi: The compounds containing boron inhibit the development of spores.
No information about unacceptable suffering effect.

D. MODE OF ACTION, INCLUDING TIME DELAY

TETOL FB Solution is a wood preservative product to prevent various wood destroying insect infestation, wood rot, fungus & mold, and it can be applied as flame retardant. The active ingredients of the biocidal product act on wood boring insects as stomach poisons. Most of the borate salts have also effects on chitin exoskeleton.
Effects against fungi: The compounds containing boron inhibit the development of spores.
The reapplication is necessary based on in-service experience in every 5-10 years.

E. EFFICACY DATA

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		Boric acid	Please refer to assessment report				Assessment report Finalised in the Standing Committee on Biocidal Products at its meeting on 20 February 2009 in view of its inclusion in Annex I to Directive 98/8/EC

		Disodium tetraborate	Please refer to assessment report				Assessment report Finalised in the Standing Committee on Biocidal Products at its meeting on 20 February 2009 in view of its inclusion in Annex I to Directive 98/8/EC

Conclusion on the efficacy of the product
TETOL FB Solution is a wood preservative product to prevent various wood destroying insect infestation, wood rot, fungus & mold, and it can be applied as flame retardant. The active ingredients of the biocidal product act on wood boring insects as stomach poisons. Most of the borate salts have also effects on chitin exoskeleton. Effects against fungi: The compounds containing boron inhibit the development of spores. Considering the use pattern, no products, organisms or objects are in the surroundings of the biocidal product that should be protected against the adverse effect of the product. Tetol FB Solution does not contain any repellent, which keeps away the non-target organisms. The product is used indoors as preservative of wooden structure of the buildings, roofing, therefore the possibility of mass poisoning of non-target organisms is negligible.

F. OCCURRENCE OF RESISTANCE AND RESISTANCE MANAGEMENT

No data available for the biocidal product Tetol FB Solution. For the active ingredients please refer to Boric acid Assessment report finalised in the Standing Committee on Biocidal Products at its meeting on 20 February 2009 in view of its inclusion in Annex I to Directive 98/8/EC, and Disodium tetraborate Assessment report finalised in the Standing Committee on Biocidal Products at its meeting on 20 February 2009 in view of its inclusion in Annex I to Directive 98/8/EC.

G. KNOWN LIMITATIONS

The use of TETOL FB Solution is not recommended:

1. in open space that is exposed to rain resulting in emission into groundwater
2. in rooms above the 75% relative humidity
3. use as preservatives of children's toys
4. as wood preservative of bee-hives
5. as preservative of wood equipment and containers that can be in contact with food and feed (e.g. fruit containers)
6. for preventive maintenance of wooden frames of greenhouses
7. the use of the biocidal product together with other (biocidal) product is not recommended.

H. EVALUATION OF THE LABEL CLAIMS

TETOL FB Solution is a wood preservative product to prevent various wood destroying insect infestation, wood rot, fungus & mold, and it can be applied as flame retardant.
The labeling of the product corresponds to the relevant regulation (CLP Regulation (EC) No. 1272/2008**)**

I. RELEVANT INFORMATION IF THE PRODUCT IS INTENDED TO BE AUTHORISED FOR USE WITH OTHER BIOCIDAL PRODUCT(S)

The use of the biocidal product together with other (biocidal) products is not recommended.

1.3.5 Risk assessment for human health

The toxicokinetics and toxicological effects of boric acid, disodium tetraborate, boric oxide (B_2O_3) and disodium octaborate tetrahydrate are likely to be similar on a boron equivalents basis. Therefore, the data obtained from studies with different borates can be read across in the human health assessment for each individual substance.

For hazard assessment of the active substances please refer to boric acid Assessment report finalised in the Standing Committee on Biocidal Products at its meeting on 20 February 2009 in view of its inclusion in Annex I to Directive 98/8/EC, and disodium tetraborate Assessment report finalised in the Standing Committee on Biocidal Products at its meeting on 20 February 2009 in view of its inclusion in Annex I to Directive 98/8/EC.

A. ASSESSMENT OF EFFECTS ON HUMAN HEALTH

Skin corrosion and irritation

The acute skin irritation study of the test item Tetol FB solution was performed in New Zealand White rabbits. The irritation effects of the test item were evaluated according to the Draize method (OECD No.: 404, 2002). The test item was administered in pure state, in a single dose of 0.5 ml to the hairless skin of all experimental rabbits. The untreated skin of each animal served as control. After 4 hours the rest of the test item was removed with water of body temperature. The animals were examined at 1, 24, 48 and 72 hours after the patch removal.
No irritation symptoms (erythema and oedema) or other signs occurred 1 hour after the patch removal and during the 72-hour observation period, so the study was terminated at the 72nd hour after patch removal) The individual scores for erythema and oedema were 0.00, 0.00 and 0.00 respectively.
During the study the behaviour and general state of animals were normal. There were no notable body weight changes during the contact and observation period.

According to EC directive 2001/59/EC, the test item Tetol FB solution has not been classified as irritating for the skin.
According to Regulation (EC) No. 1272/2008, the test item has not been classified into any category.

Summary table of animal studies on skin corrosion /irritation

Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score(24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major devia-tions)*	**Reference**
OECD Guidelines for Testing Chemicals, N° 404, GLP	Male Albino rabbit (Oryctolagus-cuniculus), New Zealand white, 3/group	Tetol FB Solution, 0.5 ml, 4 h	The test item is not irritating to rabbit skin (Directive 2001/59/EC criteria). According to CLP criteria		Kuthy, PM (2011c) Acute Skin Irritation Study of Test Item Tetol FB Solution In Rabbits Toxi-Coop ZRT, Hungary

			(Regulation (EC) 1272/2008) the test item is not classified into any Category.		Report No.: 664.550.2802 20 May, 2011. Unpublished

No human data is available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Erythema: The animals' individual mean scores (considering readings at 24, 48 and 72 hours after patch removal) for erythema was 0.00, 0.00, 0.00. Edema: The animals' individual mean scores (considering readings at 24, 48 and 72 hours after patch removal) for erythema was 0.00, 0.00, 0.00. Reversibility: Since animals did not develop dermal lesions the observation stopped at 72 h according to OECD guideline. The duration of the study was sufficient to evaluate fully the reversibility or irreversibility of the effects observed. Other examinations: General state and behaviour of all animals was normal during the test. No notable body weight changes during contact and observation period.
Justification for the value/conclusion	No irritation symptoms (erythema, oedema) occurred at any time during the 72h observation period.
Classification of the product according to CLP and DSD	The test item is not irritating to rabbit skin (Directive 2001/59/EC criteria). According to CLP criteria (Regulation (EC) 1272/2008) the test item is not classified into any Category.

Eye irritation

The acute eye irritation study of the test item Tetol FB solution was performed in New Zealand White rabbits. The irritation effect of the test item was evaluated according to the Draize method (OECD No.: 405, 2002). The test item was placed into the conjunctival sac of left eye of each animal. The untreated right eye served as control. 0.1 ml of the test item was used for the study in pure state, as a single dose. The eyes of the test animals were not washed out after the application of test item. The eyes were examined at 1, 24, 48 and 72 hours after the application. 1 hour after the single application of test item Tetol FB solution into the eye of the rabbits, slight redness occurred. 24 hours after treatment animals were symptom-free. 72 hours after treatment the study was terminated, as all animals free of symptoms of irritation. During the study the control eyes of animals were symptom-free. General state and the behaviour of animals were normal throughout the study period. There were no notable body weight changes during the contact and observation period.

In conclusion, test item Tetol FB solution applied to the rabbits' eye mucosa, caused slight conjunctival irritant effects, fully reversible within 24 hours. According to the EC criteria for classification and labelling requirements for dangerous substances and preparations, the test item does not have to be classified and has no obligatory labelling requirement for eye irritation. According to Regulation (EC) No. 1272/2008, the test item has not been classified into any category.

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major devia-tions)*	**Reference**
OECD guidelines for testing of chemicals, N° 405; GLP; 1	Male Albino rabbit (Oryctolagus-cuniculus); New Zealand white; 3/group	Tetol FB Solution, 0.1 ml	The test item caused slight conjunctival irritant effects, fully reversible within 24h. The test item is not irritating to rabbit eyes (Directive 2001/59/EC criteria). According to CLP criteria (Regulation (EC) 1272/2008) the test item is not classified into any Category.	-	Kuthy, PM (2011d): Acute Eye Irritation Study of Test Item Tetol FB Solution In Rabbits Toxi-Coop ZRT, Hungary Report No.: 664.550.2803 27 May, 2011. Unpublished

No human data is available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Clinical signs: No treatment related clinical signs other than eye irritation were observed in the rabbits throughout the experimental period. Cornea opacity: The animals' individual mean scores were 0.00 at 24 h, 0.00 at 48 h and 0.00 at 72 h Iris: The animals' individual mean scores were 0.00 at 24 h, 0.00 at 48 h and 0.00 at 72 h Redness: The animals' individual mean scores were 0.00 at 24 h, 0.00 at 48 h and 0.00 at 72 h Chemosis: The animals' individual mean scores were 0.00 at 24 h, 0.00 at 48 h and 0.00 at 72 h Reversibility: Yes Other examinations: General state and behaviour of all animals was normal during the test. No notable body weight changes during contact and observation period
Justification for the value/conclusion	72 hours after treatment the study was terminated, since no primary irritation symptoms occurred.Test item is not irritating to rabbit eyes.
Classification of the product according to CLP and DSD	The test item is not irritating to rabbit eyes (Directive 2001/59/EC criteria). According to CLP criteria (Regulation (EC) 1272/2008) the test item is not classified into any Category.

Respiratory tract irritation

The product is not volatile, and the components have low acute toxicity, therefore no respiratory tract irritation study was carried out.

Skin sensitisation

A skin sensitisation study was performed according to the Magnusson-Kligman method using Freund's complete adjuvant technique to evaluate the sensitisation potential of test item Tetol FB solution.

10 test animals were subjected to sensitisation procedures in a two-stage study, i.e. an intra-dermal treatment and a topical application. The test item was used at a concentration of 5 % for intra-dermal injections and in undiluted state for dermal sensitisation treatment. Before the dermal exposure the test area was treatedwith 0.5 ml of 10 % sodium dodecyl sulphate in Vaseline 24 h prior to the topical induction application, in order to create a local irritation. Two weeks following the last induction exposure, a challenge dose (at concentration of 75 %) was administered. Challenge was performed by dermal application of the test item.

5 control guinea pigs were simultaneously exposed to vehicle during the sensitisation phase and they were treated with the test item (at concentration of 75 %) only in the case of challenge.

Incidence Rate

No signs of contact sensitisation were detected in guinea pigs exposed previously to the test item during experiments.

Intensity of Sensitisation Response

In the control and treated animals the mean of the scores was 0.00 according to the 24th and 48th-hour results.

According to the EEC Directive 2001/59 EEC, 6 August 2001, the test item Tetol FB solution was classified as a non-sensitizer.

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guidelines for Testing Chemicals N° 406; GLP; 1	Male guinea pigs (Caviaporcellus); 10/group	Tetol FB Solution;			Stáhl J (2011e): Skin sensitisation study of Test Item Tetol FB Solution in guinea pigs Toxi-Coop ZRT Hungary, Study No: 664.552.2870 14 June, 2011 (Unpublished)

Summary table of human data on skin sensitisation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
1	Tetol FB Solution	The method was carried out according to the guidelines of OECD N° 406 (July 1992).	Incidence Rate: No signs of contact sensitisation were detected in guinea pigs exposed previously tothe test item during experiments. Intensity of Sensitisation Response: In the control and treated animals the mean of the scores was 0.00 according to the24th and 48th-hour results.	Stáhl J (2011e): Skin sensitisation study of Test Item Tetol FB Solution in guinea pigs Toxi-Coop ZRT Hungary, Study No: 664.552.2870 14 June, 2011 (Unpublished)

[Please insert/delete rows according to the number of studies.]

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	24h after challenge: Negative skin response 48h after challenge: Negative skin response
Justification for the value/conclusion	Challenge with Test Item Tetol FB Solutionat concentration of 75 % evoked no positive responses in the test animals sensitised previously. At the same time, none of the animals proved to be positive in the control group. The net response value represented an incidence rate of 0 % and the net score value of 0.00. According to the net percentage value of positively responded animals and to the net score value of the skin reactions, the Test Item Tetol FB Solutionwas classified as a non-sensitizer.

Classification of the product according to CLP and DSD	According to GHS criteria the test item is classified as a non-sensitizer.

Respiratory sensitization (ADS)

The product is not volatile, and the components have low acute toxicity, therefore no respiratory sensitization study was carried out.

Acute toxicity

Acute toxicity by oral route

The acute toxic class method (OECD Guideline No. 423) was carried out involving a stepwise procedure with the use of 2000 mg/kg bw as the starting dose in three female rats. No animal died in the first step at 2000 mg/kg bw dose level, so treatment with 2000 mg/kg bw was repeated on further three female rats. No animal died in the second step, too, so the test was finished, the stopping criteria of Annex 2d of OECD Guideline No. 423 was met. Animals were weighed, observed for lethality and toxic symptoms for 14 days after the treatment. Gross pathological examination was carried out on the 15th day after the treatment.
In the acute oral toxicity study (acute toxic class method) of test item Tetol FB Solution in rats (Kuthy, 2011a) the acute oral LD50 of the test item was found to be>2000 mg/kg bw.
According to GHS criteria the test item is classified to Category 5.

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline N°423, GLP, 1, Council Regulation (EC) No 440/2008 (30 May 2008), Regulation (EC) No. 1272/2008	female rats, Crl:(WI)Br, 3/group	Tetol FB Solution, 2000 mg/kg bw, oral gavage	No treatment related clinical symptoms were observed	>2000 mg/kg bw	According to GHS criteria the test item is classified to Category 5.	Kuthy, PM (2011a) Acute Oral Toxicity Study (Acute Toxic Class Method) of Test Item Tetol FB Solution In Rats ATRC, Hungary Report No.; 664.321.2800 13 May, 2011. Unpublished

No human data is available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	No deaths occurred following a single dose of 2000 mg/kg bw. No treatment related clinical symptoms were observed throughout the 14-day post-treatment period at any groups of the female animals. The mean body weight of the animals corresponded to their species and age throughout the study. No pathological changes were found related to the effect of the test item during the macroscopic examination of animals.
Justification for the selected value	The method used is not intended to allow the calculation of a precise LD50 value.The acute oral LD_{50} of the test item is >2000 mg/kg bw.

Classification of the product according to CLP and DSD	According to GHS criteria the test item is classified to Category 5.

Acute toxicity by inhalation

Based on the TECHNICAL GUIDANCE DOCUMENT IN SUPPORT OF THE DIRECTIVE 98/8/EC CONCERNING THE PLACING OF BIOCIDAL PRODUCTS ON THE MARKETGUIDANCE ON DATA REQUIREMENTS FOR ACTIVE SUBSTANCES AND BIOCIDAL PRODUCTS, biocidal products other than gases shall be administered in acute toxicity studies via at least two routes, one of which should be the oral route. The choice of the second route will depend upon the nature of the product and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.

The dermal route was selected as second route of administration of TETOL FB Solution for acute toxicity study, as the probability of human exposure by dermal route is much higher than by inhalation. The product is not volatile, and the components have low acute toxicity.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No study was carried out.
Justification for the selected value	The product is not volatile, and the components have low acute toxicity therefore no acute inhalation study was carried out.
Classification of the product according to CLP and DSD	As the acute inhalation study was considered as technically not feasible, the product did not get any classification.

Acute toxicity by dermal route

Limit test was performed on the basis of the result of a preliminary study (there were no deaths in the preliminary study at 5, 50, 300 and 2000 mg/kg dose levels). The objective of the study was to assess the toxicity of test item Tetol FB solution when administered in a single dermal dose to rats at one dose level (2000 mg/kg). The test item was applied in pure state and left in contact with the skin for 24 hours, followed by a 14-day observation period. No death occurred after the single 2000 mg/kg bw dermal dose of Tetol FB solution. There were no systemic toxic clinical signs at both sexes and no signs related to the effect of the test item found in body weights and body weight gains of males during the study. The observed body weight loss and reduced body weight in females was related to the effect of test item. Autopsy revealed no treatment related pathological changes.

The acute dermal LD50 value of the test item Tetol FB solution proved to be greater than 2000 mg/kg bw in male and female Crl:(WI)BR rats.

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, , Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area,**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major devia-tions)*	**Reference**
OECD Guideline No.: 402, Council Regulation (EC) No 440/2008 (30 May 2008), Regulation (EC) No. 1272/2008, Commission Directive 92/69 EEC (1992) and	male & female rats, Crl:(WI)Br, Preliminary study; 2 per dose Main study; 10	Tetol FB Solution, Preliminary study; 5, 50, 300, 2000 mg/kg bw. Main study; 2000 mg/kg bw.	No behavioral changes, dermal irritation symptoms or systemic toxic signs were noted during the study	>2000 mg/kg bw.	According to GHS criteria the test item is classified Category 5.	Kuthy, PM (2011b) Acute Dermal Toxicity Study of Test Item Tetol FB Solution In Rats ATRC, Hungary

EPA Health Effects Test Guidelines, OPPTS 870.1200, EPA 712-C-98-192 (August 1998).	per dose (5 males, 5 females)					Report No.; 664.321.2801 16 May, 2011. Unpublished

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Erythema: The animals' individual mean scores (considering readings at 24, 48 and 72 hours after patch removal) for erythema was 0.00, 0.00, 0.00. Edema: The animals' individual mean scores (considering readings at 24, 48 and 72 hours after patch removal) for erythema was 0.00, 0.00, 0.00. Reversibility: Since animals did not develop dermal lesions the observation stopped at 72 h according to OECD guideline. The duration of the study was sufficient to evaluate fully the reversibility or irreversibility of the effects observed. Other examinations: General state and behaviour of all animals was normal during the test. No notable body weight changes during contact and observation period.
Justification for the selected value	No primary irritation symptoms such as erythema and oedema, or other signs occurred during the observation period.
Classification of the product according to CLP and DSD	The test item is not irritating to rabbit skin (Directive 2001/59/EC criteria). According to CLP criteria (Regulation (EC) 1272/2008) the test item is not classified into any Category.

Information on dermal absorption

No study available with Tetol FB Solution. For the purpose of risk assessment the data from the inclusion dossier for boric acid were used.

Absorption of borates via the oral route is nearly 100%. For the respiratory route also 100% absorption is assumed. Dermal absorption through intact skin is very low. For risk assessment of borates a dermal absorption of 0.5% is used as a reasonable worst case approach. In the blood boric acid is the main species present. Boric acid is not further metabolised. Boric acid is distributed rapidly and evenly through the body, with concentrations in bone 2-3 higher than in other tissues. Boron is excreted relatively rapidly with elimination half-lives of 1h in the mouse, 3h in the rat and 21h in humans, and has low potential for accumulation. Boric acid is mainly excreted in the urine.

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Boric acid		
Value(s)	0.5%		
Justification for the selected value(s)	Endpoint value in a.s. inclusion dossier		

Data waiving	
Information requirement	Information on dermal absorption
Justification	Detailed results are presented in the final CAR. Toxicol Sci. 1998 Sep;45(1):42-51.

	In vivo percutaneous absorption of boric acid, borax, and disodium octaborate tetrahydrate in humans compared to in vitro absorption in human skin from infinite and finite doses. Wester RC1, Hui X, Hartway T, Maibach HI, Bell K, Schell MJ, Northington DJ, Strong P, Culver BD. Based on this article the percutaneous absorption was 0.226 (SD = 0.125) mean percentage dose.

B. EXPOSURE ASSESSMENT

Tetol FB is ready-to-use wood preservative intended for non-professional and professional users. Only manual application methods – brushing, spraying and dipping - are expected. Active substances are boric acid (4%) and disodium tetraborate decahydrate (2%). These ingredients are similar in their effectiveness and toxicological properties (in fact they can convert into each other, depending on the pH), therefore in the exposure assessment the boron content of the biocidal product will be taken into account. Boron content of Tetol FB is 0.93%.

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	n.a.	yes	yes	n.a.	yes	yes	no
Dermal	n.a.	yes	yes	n.a.	yes	yes	no
Oral	n.a	no	no	n.a.	no	yes	no

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Professional spraying	Primary	Professionals
2.	Mixing&loading for dipping	Primary	Professionals
3.	Manual dipping	Primary	Professionals
4.	Brushing	Primary	Professionals and non-professionals
5.	Brush cleaning	Primary	Professionals and non-professionals
6.	Non-professional spraying	Primary	Non-professionals
7.	Sanding treated wood	Secondary	Professionals and non-professionals
8.	Infant chewing wood	Secondary	Bystanders

Some scenarios cover the whole primary exposure during use activity, including mixing & loading, application and post-application phases. Others are complex scenarios where sub-phases are added up. See the following sections for the details.

Industrial exposure

The product has no industrial use.

Professional exposure

Professional users can be exposed to the biocidal product during application (primary exposure) or by handling treated wood (secondary exposure), for instance by sanding it.
In the following tables the exposure scenarios of Tetol FB, including the application methods and possible secondary exposure paths, are detailed:

Description of Scenario 1 (professional manual spraying)		
Professional worker applies wood preservatives by low-medium pressure spraying. Frequency of task is several times a week. Worker wears standard protective equipment: coverall and gloves. Concentration of a.s. in the product is 0.93%. Mixing and loading phase is included in the model (Spraying model No 2 inTNsG, recommended by User's Guidance).		
	Parameters	Value
Tier 1	Respiration rate	0.021 m^3/min
	Task duration	40 min
Tier 2	Protection factor (coated coverall)	80%
	Protection factor (gloves)	90%
	Dermal absorption of boron	0.5%

Description of Scenario 2 (mixing & loading for manual dipping)		
Pouring ready-to-use wood preservative solution into a tank before dipping. Frequency of task is one per day. Worker wears standard protective equipment: coverall and gloves. Concentration of a.s. in the product is 0.93%. (Mixing and Loading model 3 inTNsG, recommended by User's Guidance).		
	Parameters	Value
Tier 1	Hand exposure	20 mg/kg a.s.
	Hand deposit	400 mg
Tier 2		
	Protection factor (gloves)	90%
	Dermal absorption of boron	0.5%

Description of Scenario 3 (manual dipping)		
Non-industrial manual dipping of wood in a tank, filled with wood preservatives and handling the treated material. Frequency of task is once per day for 30 minutes. Worker wears standard protective equipment: coverall and gloves. Concentration of a.s. in the product is 0.93%. The model includes application and post-application activities (Dipping model 1inTNsG, recommended by User's Guidance).		
	Parameters	Value
Tier 1	Body exposure	178 mg/min
	Task duration	30 min
	Hand exposure (inside gloves)	12.7 mg/min
Tier 2	Protection factor (coated coverall)	80%
	Protection factor (gloves)	90%
	Dermal absorption of boron	0.5%

Description of Scenario 4 (brushing)		
Professional or amateur user apply wood preservative on a surface with a brush. Duration of the task is 155 min/day. The user doesn't wear any personal protective equipment. Concentration of a.s. in the product is 0.93%. Mixing and loading phase is not required, the product is supplied as ready-to-use (Consumer product painting model 3 in TNsG, recommended by User's Guidance).		
	Parameters	Value
Tier 1	Respiration rate	0.021 m^3/min
	Task duration	40 min
Tier 2	Protection factor (coverall)	75%
	Protection factor (gloves)	90%
	Dermal absorption of boron	0.5%

Description of Scenario 5 (brush cleaning)		
Professional or amateur user cleans a large brush after application of wood preservative. Washing the brush in water/solvent three times, squeezing it and wrapping in a cleaning rag. Frequency of task is once a day. Personal protective equipment is not considered. Concentration of a.s. in the product is 0.93%. (Exposure model: Primary exposure scenario – washing out of a brush which has been used to apply paint, HEEG opinion, 2011**)**.		
	Parameters	Value
Tier 1	Product in brush	25 ml
	% of residues remaining in brush after each washing step	10%
	% of residues squeezed out of brush	50%
	% of residues squeezed out of brush which are absorbed by the cloth	90%

Description of Scenario 7 (sanding treated wood)		
Professional or amateur user sands treated wood with a powered sander. Duration of the task is one hour per day. Personal protective equipment is not considered. Concentration of a.s. in the product is 0.93%. (User's Guidance, p 51. *Human Exposure to Wood Preservatives*).		
	Parameters	Value
Tier 1	Respiration rate	1.25 m^3/h
	Task duration	60 min
	OEL for wood dust	5 mg/m^3
	Product amount in wood	50 l/m^3
	Hand surface	420 cm^2
	Dermal absorption of boron	0.5%

Calculations for Scenarios

The following table contains the exposure of the professional users in the different scenarios by inhalation, oral and dermal pathways. For the details of calculation see Appendix 3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg bw/day**	**Estimated dermal uptake mg/kg bw/day**	**Estimated oral uptake mg/kg bw/day**	**Estimated total uptake mg/kg bw/day**
Scenario 1	with PPE	0.0099	0.0014	0	0.0113
Scenario 2	with PPE	0	0.000031	0	0.000031
Scenario 3	with PPE	0.000097	0.0011	0	0.0012
Scenario 4	without PPE	0.00082	0.0027	0	0.0035
Scenario 5	without PPE	0	0.000117	0	0.000117
Scenario 7	without PPE	0.000057	0.007	0	0.007

Combined scenarios
Combined scenarios for professionals include filling and emptying the containers before or after manual dipping (mixing & loading phase) and manual brushing and cleaning the brush thereafter.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 2+3	0.000097	0.00113	0	0.001227
Scenarios 4+5	0.00082	0.002817	0	0.003637

Non-professional exposure

Tetol FB is sold to non-professional users, who could be exposed to the biocidal product either primarily by applying it to wooden surfaces via manual brushing or spraying; or secondarily by handling treated wooden articles.

Description of Scenario 6 (non-professional spraying)		
Low pressure spraying of water-based wood preservative by a non-professional. Task frequency is one day per year; duration is 40 min. User doesn't wear any personal protection equipment, only standard clothing (long sleeve pants and shirt). Concentration of a.s. in the product is 0.93%. (Consumer spraying and dusting model 3 inTNsG, recommended by User's Guidance).		
	Parameters	Value
Tier 1	Body exposure	120 mg/min
	Hand exposure	176 mg/min
Tier 2	Clothing penetration	50%
	Dermal absorption of boron	0.5%

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 4	No PPE	0.00082	0.0027	0	0.0035
Scenario 5	No PPE	0	0.000117	0	0.000117
Scenario 6	No PPE	0.015	0.0073	0	0.0223
Scenario 7	No PPE	0.000057	0.007	0	0.007

Combined scenarios
One combined scenario should be considered for non-professionals: brushing and brush-washing.

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 4+5	0,00082	0.002817	0	0.003637

Exposure of the general public

Treated wooden articles are fairly common in households, workplaces, schools or playgrounds. Potentially the most dangerous exposure scenario (especially when differences between oral and dermal absorption are taken into account) is when an infant chews a piece of treated wood.

Description of Scenario 8 (infant chewing wood)		
A 10 kg infant picks up and chews wood off-cut (4 cm x 4 cm x1 cm), which has been treated with 0,93% wood preservative solution. (Users Guidance p 52.)		
	Parameters	Value
Tier 1	Wood volume	16 cm^3
	Product amount in wood	57.5 mg/cm^3
	Oral absorption of boron	100%
	Extracted amount	10%

Calculations for Scenario 8

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 8	No PPE	0	0	0.086	0.086

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake**
1. Professional spraying	Professionals	with PPE	0.0113
2+3. Manual dipping	Professionals	with PPE	0.001227
4+5. Manual brushing	Professionals and non-professionals	no PPE	0.003637
6. Non-professional spraying	Non-professionals	no PPE	0.0223
7. Sanding of treated wood	Professionals and non-professionals	no PPE	0.007
8. Infant chewing on wood	Bystanders	no PPE	0.086

C. RISK CHARACTERISATION FOR HUMAN HEALTH

Critical endpoints and assessment factors

According to the data presented in the assessment report for inclusion of borates, major targets for toxicity are the testes and the blood. In the repeated dose studies with mouse, rat and dog, effects on the testes and on blood parameters were found, consistently. In a 90-day study in mice, the animals appeared to be more sensitive to the effects on hematopoietic system than on the testes. In rats, effects on both the testes and on blood were observed at dose levels of 334 mg boric acid/kg bw/day. The NOAEL in this study was 100 mg/kg bw/day (17.5 mg B/kg bw/day). Similar results were obtained from studies with disodium tetraborate decahydrate at equimolar doses of boron. Based on the NOAEL for embryotoxic/teratogenic effects of boric acid of 55 mg/kg bw/day (9.6 mg B/kg bw/day) the overall NOAEL is 9.6 mg B/kg bw/day.

The available information on kinetics and dynamics does not allow refinement of the standard assessment factors (10 for interspecies variation and 10 for intraspecies variation). There are indications that the sensitivity for the effects on the testes does not differ markedly between subchronic and chronic exposure. Therefore the application of an additional assessment factor for extrapolation from subchronic to chronic exposure is not required.

Using the standard assessment factor of 100 (10 for interspecies- and 10 for intraspecies variation) an AEL of 0.096 mg B/kg bw/day can be derived based on the NOAEL for embryotoxic/teratogenic effects of boric acid of 9.6 mg B/kg bw/day.

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Correction for oral absorption**	**Value**
AELshort-term	Teratogenicity	9.6	100	100%	0.1
AELmedium-term	Teratogenicity	9.6	100	100%	0.1
AELlong-term	Teratogenicity	9.6	100	100%	0.1

Risk for industrial users

The product has no industrial use.

Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1		9.6	0.1	0.0113	11.3	yes
Scenario 2		9.6	0.1	0.000031	0.031	yes
Scenario 3		9.6	0.1	0.0012	1.2	yes
Scenario 4		9.6	0.1	0.0035	3.5	yes
Scenario 5		9.6	0.1	0.000117	0.117	yes
Scenario 7		9.6	0.1	0.007	7	yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 2+3		9.6	0.1	0.001227	1.227	yes
Scenarios 4+5		9.6	0.1	0.003637	3.637	yes

Local effects

The product does not have adverse effects in skin irritation and sensitization tests.

Conclusion

It can be concluded that adverse health effects for the professional user due to the combined dermal and respiratory exposure to boric acid and disodium tetraborate decahydrate, as a result of manual spraying, manual dipping, brushing or treated wood sanding can be excluded.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 4		9.6	0.1	0,0035	3.5	yes
Scenario 5		9.6	0.1	0.000117	0.117	yes
Scenario 6		9.6	0.1	0.0223	22.3	yes
Scenario 7		9.6	0.1	0.007	7	yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 4+5		9.6	0.1	0.003637	3.637	yes

Local effects

The product does not have adverse effects in skin irritation and sensitization tests.

Conclusion

It can be concluded that adverse health effects for the unprotected non-professional user due to the combined dermal and respiratory exposure to boric acid and disodium tetraborate decahydrate, as a result of spraying, brushing or treated wood sanding can be excluded.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake / AEL (%)	Acceptable (yes/no)
Scenario 8		9.6	0.1	0.086	86	yes

Local effects

The product does not have adverse effects in skin irritation and sensitization tests.

Conclusion

For a child-chewing on a piece of treated wood (most conservative scenario) a health risk as a consequence of exposure to borates can be excluded.

Risk for consumers via residues in food

Occurrence of Tetol FB Solution residues in food is not expected.

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

Toxicity of boric acid and disodium tetraborate decahydrate can be expressed on the basis of boric acid equivalents (BAE), as they have the same mode of action.

1.3.5 Risk assessment for animal health

Harm of Tetol FB Solution on animals is not expected.

1.3.6 Risk assessment for the environment

A. EFFECTS ASSESSMENT ON THE ENVIRONMENT

Neither new information in comparison with the assessment report of the active substances for Annex I inclusion, nor ecotoxicological data of the product are available.

The environmental effect assessment has been evaluated during the Annex I inclusion of boric acid and disodium tetraborate decahydrate.

Based on the lowest NOEC of 1.8 mg boron/L and an assessment factor of 10 the $PNEC_{add,aquatic}$ (add: added risk approach) for aquatic systems is set to 0.18 mg B/L. The $PNEC_{add,sed}$ of 0.24 mg B/kg wwt is calculated using the equilibrium partitioning from $PNEC_{add,aquatic}$.
Based on a submitted microbial inhibition test with micro-organisms in activated sludge, a $PNEC_{add,STP}$ of 1.8 mg B/L was calculated, based on a NOEC of 17.5 mg B/L and applying an assessment factor of 10.
The $PNEC_{add,terrestrial}$ is set to 0.4 mg B/kg dwt soil, equivalent to 0.35 mg B/kg wwt soil.
Boron is not bioconcentrated or bioaccumulated along the food chain in both aquatic and terrestrial ecosystems.

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

No further information is available.

Further Ecotoxicological studies

No further studies are required.

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

No further studies are required.

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

No trials are available.

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

No further studies are required.

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

Not relevant.

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

See section Fate and distribution in exposed environmental compartments.

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

No further studies are required.

Leaching behavior (ADS)

All information investigated by the CAR suggests that boron is rapidly lost from the treated wood. The daily average leaching rate used for the risk assessment is 92.1 mg B/m^2/d.

B. EXPOSURE ASSESSMENT

General information

Assessed PT	PT 8
Assessed scenarios	Scenario 1: Industrial preventive processes and storage of treated wood, dipping Scenario 2: In situ treatment (preventive): house Scenario 3: Treated wood in service: house
ESD(s) used	OECD series on emission scenario documents Number 2 Revised Emission Scenario Document for Wood Preservatives (OECD, 2013)
Approach	Scenario 1: Average consumption
Distribution in the environment	Calculated based on TGD 2003
Groundwater simulation	According to the ESD, the groundwater simulation is not needed in that case when risk mitigation measures are required because the risk for the soil was identified.
Confidential Annexes	NO
Life cycle steps assessed	Scenario 1: Production: No

	Formulation No Use: Yes Service life: Yes
Remarks	Emission scenarios for in situ treatment (preventive): house For indoor treatments by spraying and brushing, no scenarios are proposed because related emissions to the environment are considered to be negligible. Emission scenarios for treated wood in service: For wood of UC 1 and 2 emission pathways are presented but scenarios are not, since for these wood classes the potential emissions from treated wood to the outer environment are considered negligible.

The environmental exposure assessment is based on the *OECD series on emission scenario documents Number 2 Revised Emission Scenario Document for Wood Preservatives* (OECD, 2013) and *Technical Guidance Document on Risk Assessment* (TGD, 2003)

The following stages of the wood preservative life cycle are considered:

1. product application (or processing), covering:
   - industrial preventive wood preservation treatments (including storage)
   - preventive treatments performed in-situ by professionals and public
2. treated wood in service

Exposure during the formulation of the product has not been assessed since it is covered by other legislations and it is stated by the applicant that all losses are contained and collected for reuse or disposal.

Emissions of the product to the environment may occur during industrial application via dipping in sawmills, during storage after industrial treatment, during professional and non-professional in-situ applications and during service life of treated wood.

Emission estimation

Scenario 1a :**Industrial scale preventive processes and storage of treated wood: dipping**

According to the applicant, the used amounts of the product are 0.16 L/m^2 (0.184 kg/m^2) against wood boring beetles and mould and 1.2 L/m^2 (1.38 kg/m^2) for the flame retardant effect. In case of dipping application used in sawmills the amount applied can be controlled by weight measurement. In the OECD ESD the quantity of treated wood is expressed in m^3 rather than m^2. Wood area/wood volume ratio is set to 40 m^2/m^3. In terms of boric acid equivalent (BAE) the quantities applied per m^3 of wood (Q_{ai}) are (rounded up) 0.4 kg BAE/m^3 and 3 kg BAE/m^3. Emission to air is not relevant for the Tetol FB solution because of the lack of organic solvents, according to the ESD.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario:Industrial preventive processes and storage of treated wood: dipping			
Volume of wood treated per day (VOLUME)	100	*m^3/d*	
Quantity of a substance applied per m^3 of wood (Q_{ai})	0.07 0.525	*kg boron/m^3*	
Fraction released to facility drain ($F_{facilitydrain}$)	0.03	-	
Fraction released to air (F_{air})	0	-	

Calculations for Scenario 1a

$Elocal_{facilitydrain} = Q_{ai} \times VOLUME_{wood\text{-}treated} \times F_{facilitydrain}$

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg boron/d]**	**Remarks**
STP	0.21 (against wood boring beetles and mould) 1.6 (for flame retardant effect)	
Air	negligible	

Scenario 1b :**Industrial preventive processes and storage of treated wood: dipping**

Emissions can occur from a storage place, where treated wood is stored before shipment. According to the CARs, the average daily flux is 92.1 mg boron/m^2.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario:Industrial preventive processes and storage of treated wood: dipping			
Effective surface area of treated wood, considered to be exposed to rain, per 1 m^2 storage area (i.e. soil) ($AREA_{wood-expo}$)	11	*m^2/ m^2*	
Surface area of the storage place ($AREA_{storage}$)	700	*m^2*	
Duration of the initial assessment period (TIME1)	30	d	
Average daily flux i.e. the average quantity of a substance that is daily leached out of 1 m^2 of treated wood during 14 day storage period ($FLUX_{storage,dipp}$)	9.21 x 10^{-5}	*kg/m^2/d*	
Bulk density of wet soil (RHO_{soil})	1700	*kg/m3*	
Soil depth ($DEPTH_{soil}$)	0.5	*m*	
Fraction of rainwater running off the storage site (F_{runoff})	0.5	-	

Calculations for Scenario 1b

$Q_{leach,storage,time1}$: Cumulative quantity of a substance, leached due to rainfall from stored treated wood, over the initial assessment period

$Elocal_{surfacewater,time1}$: Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over the initial assessment period

$Clocal_{soil,time1}$: Local concentration in soil at storage place at the end of the initial assessment period

V_{soil}: Volume of (wet) soil

$Q_{leach,storage,time1} = FLUX_{storage,dipp} \times AREA_{wood-expo} \times AREA_{storage} \times TIME1$

$Elocal_{surfacewater,time1} = Q_{leach,storage,time1} \times F_{runoff} / TIME1$

$Clocal_{soil,time1} = Q_{leach,storage,time1} \times (1-F_{runoff})/(V_{soil} \times RHO_{soil})$

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg boron/d]**	**Remarks**
Freshwater	0.355	
Air	negligible	
Soil	17.88 mg/kg_{wwt}	local concentration in soil at storage place at the end of the initial assessment period

Scenario 2 :**In situ treatment (curative and preventive): house**

For indoor treatments by spraying and brushing, no scenarios are proposed because related emissions to the environment are considered to be negligible.

Scenario 3 : Treated wood in service: house

For wood of UC 1 and 2 emission pathways are presented but scenarios are not, since for these wood classes the potential emissions from treated wood to the outer environment are considered negligible.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air[1)]	Soil	Ground-water	Other
Scenario 1	*yes*				*yes*	*yes*	*yes*	*yes*	
Scenario 2[2)]	*yes*					*yes*	*yes*	*yes*	
Scenario 3[3)]	*yes*					*yes*	*yes*	*yes*	

1) Emission to air is not relevant because the lack of organic solvents
2) No scenarios are proposed because related emissions to the environment are considered to be negligible
3) Potential emissions to the environment are considered negligible for UC1 and UC2

Calculated fate and distribution in the STP *[if STP is a relevant compartment]*		
Compartment	Percentage [%]	Remarks
	Scenario 1a	
Air		
Water	99.9%	According to the CAR Doc IIB
Sludge		
Degraded in STP		

At lower concentrations of boron (B ≤ 0.025 M) in dilute aqueous solutions boric acid remains undissociated at pH < 7, at pH > 11 the metaborate ion is the main species in the solution. Both species are present between pH 7 and pH 11.

At higher boron concentrations (B >0.025 M) an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3 \leftrightarrow$polynuclear anions $\leftrightarrow B(OH)_4^-$. In acid solution at pH < 5, boron is mainly present as $B(OH)_3$ and in alkaline solution at pH > 12.5, boron is mainly present as $B(OH)_4^-$. At pH values (pH 5-12) polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$.

Biodegradation is not relevant because boric acid and disodium tetraborate decahydrate are inorganic substances. The actives are not subject to hydrolysis or photolysis.

Under environmentally relevant conditions disodium tetraborate decahydrate will dissolute to boric acid. Therefore, data on the sorption of boric acid can be used for disodium tetraborate decahydrate as well. The average K_F value is 2.6 L/kg with 1/n of 0.83. The soil-water partitioning coefficient is calculated as 4.16 m^3/m^3, according to the CARs. The vapour pressure is less than 10^{-5} Pa at ambient temperature.

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}** [1]	**PEC_{air}**
	[mg B/L]	[mg B/L]	[mg B/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg B/kg_{wwt}]	[mg B/L]	[mg/m^3]
Scenario 1a	0.1 0.8	0.01 0.08	0.014 0.11					
Scenario 1b		0.014	0.018			17.88	7.3	
[1] If the PEC_{GW} was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.								

Primary and secondary poisoning

Primary poisoning

According to the ESD, bats can be exposed to treated wood via contact with roof timbers, but no scenarios are available for bats. Boron compounds are adequate for preventive treatment of wood with regard to bats. *(Mitchell-Jones, A.J, & McLeish, A.P. Ed., (2004), 3rd Edition Bat Workers' Manual, 178 pages b/w photos, softback, ISBN 1 86107 558 8).*

Secondary poisoning

According to the CARs, the secondary poisoning in the aquatic and terrestrial food chain is not an issue.

C. RISK CHARACTERISATION

Atmosphere

Conclusion: Release of borates to the atmosphere is not to be expected. Emission to the air is not relevant because of the very low vapour pressure.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1a	0.06 0.44

Conclusion: Unacceptable risks for sewage treatment plants are not expected due to the industrial application in dipping baths. The amount applied can be controlled by weight measurement. The run-off during treatment processes must be collected via drip pads for reuse or disposal.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
Scenario 1a	0.06 0.44	0.06 0.46		
Scenario 1b	0.08	0.075		

Conclusion: Surface water can be exposed via the STP from dipping application and rain run-off from the storage place. The PEC/PNEC ratios do not exceed the trigger value of 1. Therefore the releases of the Tetol FB solution do not pose a risk to surface water.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1b	51

Conclusion: Emissions can occur to soil due to storage of treated wood after dipping application and prior to shipment. PEC/PNEC ratio is greater than one for this scenario. Therefore, risk mitigation measures are required to prevent losses to soil. Freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

Groundwater

The maximum permissible concentration is 1 mg boron/L for drinking water and groundwater, according to the Directive 98/83/EC. As a result of the risk mitigation measures required for the identified risk for the soil compartment from storage of freshly treated timber (see above), the exposure of groundwater in not expected.

Primary and secondary poisoning

Primary poisoning
According to the Agreement on the Conservation of Population of European Bats (EUROBATS), the parties to the agreement shall endeavour to replace timber treatment chemicals which are highly toxic to bats with safer alternatives.

Boron compounds are relatively non-toxic to mammals, and they are adequate for preventive treatment with regard to bats *(Mitchell-Jones, A.J, & McLeish, A.P. Ed., (2004), 3rd Edition Bat Workers' Manual, 178 pages b/w photos, softback, ISBN 1 86107 558 8).*

Secondary poisoning
Secondary poisoning is not relevant. According to the CARs, boron is not bioconcentrated or bioaccumulated along the food chain in both aquatic and terrestrial ecosystems.

Mixture toxicity

Under environmentally relevant conditions disodium tetraborate decahydrate will dissolute to boric acid. Boric acid and disodium tetraborate decahydrate are expressed on the basis of boron (B) equivalents. The conversion factors of boric acid and disodium tetraborate decahydrate are 1 and 0.649.

Aggregated exposure (combined for relevant emission sources)

Not relevant.

1.3.7 Measures to protect man, animals and the environment

A. RECOMMENDED METHODS AND PRECAUTIONS

Handling and use of the product

Use standard protective clothing and protective gloves during the manipulation with the product to prevent contamination of skin. The mixture does not contain volatile components, the using of personal protection equipment against inhalation is not necessary if the product does not generate an aerosol in the air.

Observe general principles of working hygiene, especially not to eat, not to drink and not to smoke after manipulation without washing hands before.

The run-off during the dipping application must be collected via drip pads for reuse or disposal. Freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

Storage

Should be kept in its closed, original container on a covered, dry space, away from radiating heat.

Transportation

The biocidal product is not classified as dangerous goods according to ADR.

B. IDENTITY OF RELEVANT COMBUSTION PRODUCTS IN CASES OF FIRE

C. SPECIFIC TREATMENT IN CASE OF AN ACCIDENT

No special first aid measures are necessary in case of accident or poisoning.

Ingestion:

Drink at least two glasses of water if swallowed. Seek medical advice immediately and show the container or label.

Inhalation:

The product does not contain volatile components. In case of aerosol inhalation, the mucous membranes or the respiratory tract might be irritated. Leave the contaminated area and stay in the fresh air as long as irritation disappears.

Eye contamination:

Immediately rinse eyes with water, when needed open eyelids by hand. If the affected person wears contact lens, remove them before rinsing. If eye irritation does not disappear even after 15 minutes, seek medical help.

Skin contamination:

Remove contaminated clothing or protective equipment. Wash the skin thoroughly with water or soap and water.

D. POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING RELEASE

Air:

The product is not volatile. It settles in the air quickly, more air cleaning is not required.

Water:

The product is soluble in water, it is diluted quickly. If a small amount of the product reaches the surface water or the groundwater, removal is unnecessary, because low concentrations do not pose a threat to wildlife. In case of a large contamination, the contaminated water body should be treated with lime, which precipitates the borate, sulphate and phosphate anions as well. Using this method the degree of contamination can be reduced to below 100 ppm.

Soil:

The borate salts are naturally present in a variety of rocks, soils and as microelements they play an important role in plant development. The components of the product can be removed from the contaminated soil by acid washing or by water.

E. PROCEDURES FOR WASTE MANAGEMENT OF THE BIOCIDAL PRODUCT AND ITS PACKAGING

The residues of the wood preservative (including the sawdust or sand used for absorption, along with the incidentally contaminated and collected environmental media) has to be transported to a hazardous waste incinerator or a hazardous waste dump site. The empty containers are considered hazardous waste, their disposal has to be done in accordance with waste management regulations and the local waste management plan. If the treated wood becomes waste, it also has to be handled as hazardous waste.

The Waste Catalogue code for the wood preservative waste:
EWC 06 13 01* inorganic plant protection products, wood-preserving agents and other biocides

The Waste Catalogue code for the packaging waste:
EWC 15 01 10* packaging containing residues of or contaminated by dangerous substances

The Waste Catalogue code for the treated wood waste:
EWC 17 02 04* glass, plastic and wood containing or contaminated with dangerous substances

F. PROCEDURES FOR CLEANING APPLICATION EQUIPMENT WHERE RELEVANT

The product is soluble in water, so the used equipment and tools can be cleaned by water. The cleaning water must be collected and must be treated as hazardous waste.

G. SPECIFY ANY REPELLENTS OR POISON CONTROL MEASURES INCLUDED IN THE PRODUCT

Not relevant.

1.3.8 Assessment of a combination of biocidal products

During the storage and use of the product the contact with alkalines, acids, and strong oxidizing agents should be avoided. The use of the product with other (biocidal) products was not tested, therefore separate usage is recommended.

2. ANNEXES

2.1. List of studies of the biocidal product
2.2. Output tables from exposure assessment tools
2.3. Confidential Annex

2.1 LIST OF STUDIES OF THE BIOCIDAL PRODUCT

Author(s)	Year	Title Source (where different from company), Company, Report No., GLP (where relevant) / (Un)published	Data Protection Claimed (Yes/No)	Owner
Kuthy, PM	2011a	Acute Oral Toxicity Study (Acute Toxic Class Method) of Test Item Tetol FB Solution In Rats ATRC, Hungary Report No.; 664.321.2800 GLP, 13 May, 2011. Unpublished	Yes	Tetol Ltd.
Kuthy, PM	2011b	Acute Dermal Toxicity Study of Test Item Tetol FB Solution In Rats ATRC, Hungary Report No.; 664.321.2801 GLP, 16 May, 2011. Unpublished	Yes	Tetol Ltd.
Kuthy, PM	2011c	Acute Skin Irritation Study of Test Item Tetol FB Solution In Rabbits Toxi-Coop ZRT, Hungary Report No.: 664.550.2802 GLP, 20 May, 2011. Unpublished	Yes	Tetol Ltd.
Kuthy, PM	2011d	Acute Eye Irritation Study of Test Item Tetol FB Solution In Rabbits Toxi-Coop ZRT, Hungary Report No.: 664.550.2803 27 May, 2011. Unpublished	Yes	Tetol Ltd.
Stáhl, J	2011e	Skin sensitisation study of Test Item Tetol FB Solution in guinea pigs Toxi-Coop ZRT Hungary, Study No: 664.552.2870 GLP, 14 June, 2011 (Unpublished)	Yes	Tetol Ltd.
Thomas, T	2013a	Determination of Explosive potential, TETOL FB Solution, CSR Regulatory Ltd., UK Report No.; 13/164-902AN 16 July, 2013. Unpublished	Yes	Tetol Ltd.
Thomas, T	2013b	Evaluation of Oxidising Potential, TETOL FB Solution, CSR Regulatory Ltd., UK Report No.; 13/164-903AN 16 July, 2013. Unpublished	Yes	Tetol Ltd.
Thomas, T	2013c	Flash point room temperature to 200°C closed cup method expert report (A9) for Tetol FB solution, CSR Regulatory Ltd., UK Report No.; 13/164-936AN 16 July, 2013. Unpublished	Yes	Tetol Ltd.
Thomas, T	2013d	Auto-ignition temperature (autoflam-mability) (A15) expert report for Tetol FB Solution CSR Regulatory Ltd., UK Report No.; 13/164-927AN GLP, 16 July, 2013. Unpublished	Yes	Tetol Ltd.
Thomas, T	2013e	Incompatibility Assessment Report for Tetol FB Solution, CSR Regulatory Ltd., UK Report No.; 13/164-920AN	Yes	Tetol Ltd.

Author(s)	Year	Title Source (where different from company), Company, Report No., GLP (where relevant) / (Un)published	Data Protection Claimed (Yes/No)	Owner
		16 July, 2013. Unpublished		
Ulbert, O.	2014a	Tetol FB Solution: Determinati-on of the accelerated storage stability, CiToxLAB Hungary Ltd. Report No: 13/164-314ANH, GLP, 27 January 2014, Unpublished	Yes	Tetol Ltd.
Ulbert, O.	2014b	Tetol FB Solution: Determinati-on of the Relative Density, CiToxLAB Hungary Ltd. Report No: 13/164-325AN, GLP, 20 January 2014, Unpublished	Yes	Tetol Ltd.

2.2 HUMAN EXPOSURE ASSESSMENT

Product	
Tetol-FB	
Intended use	
EXPOSURE ASSESSMENT (BRUSHING)	
Dermal exposure:	
Body exposure	16.9 mg/min
Duration	155 min
Potential body deposit	2620 mg
Hand exposure	5.9 mg/min
Potential hand deposit	915 mg
Total dermal exposure (product)	3535 mg
Concentration of the active substance	0.93% boron equivalent
Total dermal exposure (boron)	32.876 mg
Clothing penetration	100%
Dermal absorption	0.5%
Systemic exposure	0.164 mg
Systemic dose (dermal route)	0.0027 mg/kg bw/day
Inhalation exposure	
Indicative value	1.63 mg/m^3
Duration	155 min
Inhalation rate	0.021 m^3/min
Inhaled volume	3.26 m^3
Inhaled product	5,3 mg
Absorption	100%
Inhaled active substance	0,049 mg
Systemic dose (inhalation route)	0,00082 mg/kg bw/day
Total systemic dose	**0,0035 mg/kg bw/day**
EXPOSURE ASSESSMENT (BRUSH CLEANING)	
Brush volume	200 ml
Product in brush	25 ml
Product weight (rel. density 1.15)	28.75 g
Product available for absorption after 1st washing step	0.15 g
Product available after 2nd washing step	0.72 mg
Product available after 3rd washing step	0,0036 mg
Total exposure (product)	151 mg
Total exposure (boron)	1.4 mg
Systemic exposure	0.007 mg
Systemic dose	**0.000117 mg/kg bw/day**
EXPOSURE ASSESSMENT (MANUAL SPRAYING: PROFESSIONAL)	
(Mixing&loading included)	
Dermal exposure	
Body exposure	222 mg/min
Duration	40 min
Potential deposit	8880 mg
Clothing penetration	20%
Potential exposure	1776 mg
Hand exposure	7.8 mg/min
Potential deposit	312 mg
Gloves penetration	10%

Potential exposure	31.2 mg
Total exposure (product)	1807 mg
Total exposure (boron)	16.8 mg
Systemic exposure	0.084 mg
Systemic dose (dermal route)	0.0014 mg/kg bw/day
Inhalation exposure	
Indicative value	76 mg/ m^3
Duration	40 min
Inhalation rate	0.021 m^3/min
Inhaled volume	0.84 m^3
Inhaled product	63.84 mg
Inhaled active substance	0.59 mg
Systemic dose (inhalation)	0.0099 mg/kg bw/day
Total systemic dose	**0.0113 mg/kg bw/day**
EXPOSURE ASSESSMENT (SPRAYING: NON-PROFESSIONAL)	
Dermal exposure	
Body exposure	120 mg/min
Duration	40 min
Potential deposit	4800 mg
Clothing penetration	50%
Potential exposure	2400 mg
Hand exposure	176 mg/min
Hand deposit	7040 mg
Total exposure (product)	9440 mg
Total exposure (boron)	87.8 mg
Systemic exposure	0.439 mg
Systemic dose (dermal route)	0.0073 mg/kg bw/day
Inhalation exposure	
Indicative value	115 mg/ m^3
Duration	40 min
Inhalation rate	0.021 m^3/min
Inhaled volume	0.84 m^3
Inhaled product	96.6 mg
Inhaled active substance	0.898 mg
Systemic dose (inhalation)	0.015 mg/kg bw/day
Total systemic dose	**0.0223 mg/kg bw/day**
EXPOSURE ASSESSMENT (MANUAL DIPPING: PROFESSIONALS)	
Mixing&loading	
Hand exposure	20 mg/kg a.s.
Actual hand deposit	400 mg
Gloves penetration	10%
Dermal exposure (product)	40 mg
Dermal exposure (boron)	0.372 mg
Systemic exposure	0.00186
Systemic dose	0.000031 mg/kg bw/day
Dipping	
Dermal exposure	
Body exposure	178 mg/min
Duration	30 min
Potential deposit	5340 mg
Clothing penetration	20%

Actual deposit	1068 mg
Hand exposure (inside gloves)	12.7 mg/min
Hand deposit	381 mg
Total dermal deposit	1449 mg
Dermal exposure (boron)	13.5 mg
Systemic exposure	0.067 mg
Systemic dose (dermal route)	0.0011 mg/kg bw/day
Inhalation exposure	
Indicative value	1 mg/ m^3
Duration	30 min
Inhalation rate	0.021 m^3/min
Inhaled volume	0.63 m^3
Inhaled product	0.63 mg
Inhaled active substance	0.0059 mg
Systemic dose (inhalation route)	0.000097 mg/kg bw/day
Total systemic dose	**0.0012 mg/kg bw/day**
SECONDARY EXPOSURE ASSESSMENT: SANDING	
Inhalation exposure	
Duration	60 min
Inhalation rate	1.25m^3/h
OEL for wood dust	5 mg/m^3
Inhaled wood dust	6.25 mg (=7.8 µl)
Product amount in wood	50 l/m^3 (=57.5 kg/m^3)
Inhaled product	0.449 mg
Inhaled active substance	0.004 mg
Systemic dose	0.000069 mg/kg bw/day
Dermal exposure	
Active substance amount on wood surface	1 mg/cm^2
Hand surface	420 cm^2
Contaminated hand surface (20%)	84 cm^2
Dermal exposure	84 mg
Systemic exposure	0.42 mg
Systemic dose	0.007 mg/kg bw/day
Total systemic dose	**0.007 mg/kg bw/day**
SECONDARY EXPOSURE ASSESSMENT: INFANT CHEWING WOOD	
Wood volume	16 cm^3
Product amount in wood	57.5 mg/cm^3 (920 mg)
Active substance in wood	8.556 mg
Extracted amount	10% (0.86 mg)
Body weight	10 kg
Systemic dose	0.086 mg/kg bw/day

2.3 CONFIDENTIAL ANNEX

1. MANUFACTURER(S) OF THE ACTIVE SUBSTANCE(S)

Active substance	Boric acid
Name of manufacturer	
Address of manufacturer	
Location of manufacturing sites	

Active substance	Disodium tetraborate decahydrate
Name of manufacturer	
Address of manufacturer	
Location of manufacturing sites	

2. PRODUCT COMPOSITION AND FORMULATION

NB: This information is confidential and should not be disclosed to third parties

2.1 QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE PRODUCT/OF THE PRODUCTS OF THE FAMILY[4]

Ingredients of the product[5]					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Boric acid	Boric acid	Active substance	10043-35-3	233-139-2	4
Disodium tetraborate decahydrate	Sodium tetraborate decahydrate	Active substance	1330-43-4	215-540-4	2
[redacted]					
[redacted]					
[redacted]					
[redacted]					

3. INFORMATION ON THE SUBSTANCE(S) OF CONCERN

IUPAC name or other accepted chemical name	Boric acid
EC number	233-139-2
CAS number	10043-35-3
Concentration (minimum and maximum, g/kg or g/l)	4 w/w%
Classification and Labelling according to Regulation (EC) No 1272/2008:	Repr. 1B
Relevant toxicological/ecotoxicological information	

4 Please delete as appropriate.

5 Please give all ingredients, including the active substance(s).

Other grounds for concern[6]	-

IUPAC name or other accepted chemical name	Disodium tetraborate decahydrate
EC number	231-987-8
CAS number	1330-43-4
Concentration (minimum and maximum, g/kg or g/l)	2 w/w%
Classification and Labelling according to Regulation (EC) No 1272/2008:	Repr. 1B
Relevant toxicological/ecotoxicological information	
Other grounds for concern[7]	-

IUPAC name or other accepted chemical name	[redacted]
EC number	[redacted]
CAS number	[redacted]
Concentration (minimum and maximum, g/kg or g/l)	[redacted]
Classification and Labelling according to Regulation (EC) No 1272/2008:	[redacted]
Relevant toxicological/ecotoxicological information	
Other grounds for concern[8]	-

4. ASSESSMENT OF ENDOCRINE DISRUPTOR PROPERTIES

Active substances boric acid and disodium tetraborate decahydrate are classified under CLP as Toxic for reproduction (Repr 1B) and they are included in the list of substances of very high concern (SVHC). Their mode of action is unknown. The assessment of ED properties of the active substances that have already been evaluated and approved should be coordinated at EU level. Hence, HU CA should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures.

The concentration of the boron in the product is below the specific concentration limit, thus Tetol FB Solution is not classified as toxic for reproduction.

Since 7 June 2018, the assessment of endocrine disrupting properties of co-formulants are mandatory according to the Article 19 of the Regulation (EU) No 528/2012 and the Commission Delegated Regulation (EU) 2017/2100. In absence of harmonized method for assessment of co-formulants, it was performed according to a step-wise method proposed by BE and FR.

STEP 1: low concern	
Is this co-formulant defined as “food” under Article 2 of Regulation (EC) No 178/2002 ?	[redacted]
STEP 2: EU DECISIONS ON ED PROPERTIES and EU ON-GOING PROCESSES	

6 Please include PBT, vPvB, POP and ED properties, if relevant.
7 Please include PBT, vPvB, POP and ED properties, if relevant.
8 Please include PBT, vPvB, POP and ED properties, if relevant.

Has the co-formulant been assessed and identified as an ED under Art 57(f) of REACH and included in the Candidate List of SVHCs?	[redacted]
Is the co-formulant in active substance under the BPR of the PPPR?	[redacted]
STEP 3: AVAILABLE ED ASSESSMENTS	
Is/was the co-formulant under assessment under REACH because of an initial concern about potential endocrine disruption (PACT), including Substance evaluation ? https://echa.europa.eu/fr/pact	[redacted]
Has the co-formulant been assessed by a public organisation and assessment is available to sCA/rMS (for example "List of Endocrine Disrupting Chemicals" from the Danish Center of Endocrine Disrupters?)	[redacted]
Has the co-formulant been identified in the EU priority list of potential endocrine disrupters? http://ec.europa.eu/environment/chemicals/endocrine/documents/studies_en.htm?	[redacted]
STEP 4: indications of ED properties	
• Has the co-formulant been included in EASIS list ? • Has the co-formulant been screened in USEPA EDSP21 Program https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-21st-century? • Has the co-formulant been screened in USEPA ToxCast Dashboard https://www.epa.gov/chemical-research/toxcast-dashboard?	[redacted]
Has the co-formulant been assigned (harmonised or self-) classification for - reproductive toxicity - STOT-RE (May cause damage to the thyroid or pancreas or adrenals or other endocrine organs, through prolonged or repeated exposure) - Carcinogenicity under the CLP Regulation in the C&L inventory (https://echa.europa.eu/fr/information-on-chemicals/cl-inventory-database) or in the accompanying Safety Data Sheet (SDS)?	[redacted]

Conclusion

Based on the existing knowledge, there is no indication of concern regarding the ED properties of the co-formulants used in the biocidal product Tetol FB Solution.