

# Product Assessment Report

## *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*

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**Biocidal product assessment report related to national  
authorisation under Biocidal Product Regulation 528/2012**



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# 1 General information about the product application

## 1.1 Applicant

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### 1.1.1 Person authorised for communication on behalf of the applicant

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<b>Function:</b>	Quality Assurance Manager
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## 1.2 Information about the product application

<b>Application received:</b>	30 August 2011
<b>Application reported complete:</b>	17 April 2012
<b>Type of application:</b>	National authorisation
<b>Further information:</b>	No

## 1.3 Information about the biocidal product

### 1.3.1 General information

<b>Trade name:</b>	<i>Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT</i>
<b>Manufacturer's development code number(s), if appropriate:</b>	–
<b>Product type:</b>	8 (wood preservatives)
<b>Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):</b>	Boric acid 15.0% Disodium tetraborate 5.0%
<b>Formulation type:</b>	Powder
<b>Ready to use product (yes/no):</b>	No
<b>Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); If yes: authorisation/registration no. and product name: or Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):</b>	No

**1.3.2 Information on the intended use**

<b>Overall use pattern (manner and area of use):</b>	<ul style="list-style-type: none"> <li>▪ <u>Use classes:</u> <ul style="list-style-type: none"> <li>– UC 1 (wood or wood-based product under cover and fully protected from the weather, not exposed to wetting)</li> <li>– UC 2 (wood or wood-based product under cover and fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting)</li> </ul> </li> <li>▪ <u>Application method:</u> <ul style="list-style-type: none"> <li>– Painting/brushing</li> <li>– Dipping</li> <li>– Vacuum pressure</li> </ul> </li> </ul>
<b>Target organisms:</b>	<ul style="list-style-type: none"> <li>▪ Wood destroying <i>Basidiomycetes</i>: <ul style="list-style-type: none"> <li>- <i>Coniophora puteana</i>,</li> <li>- <i>Gloeophyllum trabeum</i>,</li> <li>- <i>Poria placenta</i></li> </ul> </li> <li>▪ Wood boring beetle: <ul style="list-style-type: none"> <li>- <i>Hylotrupes bajulus</i>, larvae</li> </ul> </li> </ul>
<b>Category of users:</b>	Professional Industrial
<b>Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:</b>	<ul style="list-style-type: none"> <li>▪ superficial treatment <ul style="list-style-type: none"> <li>– 500 g/m<sup>2</sup> of 20% working solution (100 g/m<sup>2</sup> of concentrate)</li> </ul> </li> <li>▪ penetrating treatment <ul style="list-style-type: none"> <li>– 25 kg/m<sup>3</sup> of 20% working solution (5 kg/m<sup>3</sup> of concentrate).</li> </ul> </li> </ul> <p>These doses are effective for prevention of against the wood rooting fungi and wood boring insects together</p>
<b>Potential for release into the environment (yes/no):</b>	Yes
<b>Potential for contamination of food/feeding stuff (yes/no)</b>	No
<b>Proposed Label:</b>	-
<b>Use Restrictions:</b>	Please referee to section 2.9

**1.3.3 Information on active substances**

<b>Active substance chemical name:</b>	Boric acid	Disodium tetraborate
<b>CAS No:</b>	1043-35-3	1330-43-4
<b>EC No:</b>	233-139-2	215-540-4
<b>Purity (minimum, g/kg or g/l):</b>	> 990 g/kg	> 990 g/kg
<b>Inclusion directive:</b>	2009/94/EC	2009/91/EC
<b>Date of inclusion:</b>	01.09.2011	01.09.2011
<b>Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):</b>	Yes	Yes

**Manufacturer of active substance used in the biocidal product**

<b>Company Name:</b>	US Borax Inc	ETI MADEN ISLETMELERI
<b>Address:</b>	14486 Borax Road	Korkutreis Mah., Cihan Sok. No:2
<b>City:</b>	Boron, CA	Sıhhiye Çankaya, Ankara
<b>Postal Code:</b>	93516-2000	06430
<b>Country:</b>	USA	Turkey
<b>Telephone:</b>	+ 1 760 762 7000	-
<b>Fax:</b>	-	-
<b>E-mail address:</b>	-	-

**1.3.4 Information on the substance(s) of concern**

<b>Substance chemical name</b>	benzyl-C12-14-alkyldimethyl, chlorides
<b>CAS No:</b>	85409-22-9
<b>EC No :</b>	287-089-1
<b>Purity (minimum, g/kg or g/l):</b>	≥99%
<b>Typical concentration (minimum and maximum, g/kg, or g/l):</b>	0.66% wag
<b>Relevant toxicological/ecotoxicological information:</b>	H302, H314, H400 P273, P280, P305 + P351 + P338, P 310
<b>Original ingredient (trade name):</b>	<i>Barquat MS-100</i>

## **1.4 Documentation**

### **1.4.1 Data submitted in relation to product application**

Please see to Annex 2.

### **1.4.2 Access to documentation**

Dekspol P.P.H. Iwona Oleszak has letter of access (dated on 18 August 2011) to data held by European Borates Association A.I.S.B.L. which was used to supports the Annex I listing of the active substances boric acid and disodium tetraborate according to Directive 98/8/EC .

## **2 Summary of the product assessment**

### **2.1 Identity related issues**

The biocidal product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* contains two active substances – boric acid (15%) (purity > 990 g/kg) and disodium tetraborate (5%) (purity > 990 g/kg).

The source of active substances used in the biocidal product is identical to the active substances that is listed in Annex I of 98/8/EC.

### **2.2 Classification, labelling and packaging**

#### **2.2.1 Harmonised classification of the biocidal product**

T- Toxic

R60, R61

#### **2.2.2 Labelling of the biocidal product**

The current Classification of Boric acid under Dir 67/548/EEC is:

T- Toxic

R60, R61

The current Classification of Boric acid under EC 1272/2008 is:

Repr. 1B, H360FD



The current Classification of Disodium tetraborate under Dir 67/548/EEC is:

T- Toxic

R60, R61

The current Classification of Disodium tetraborate under EC 1272/2008 is:

Repr. 1B, H360FD

Classification and labelling of the product under Dir 67/548/EEC is:

R-phrases

T: R60, R61

S-phrases

S2 – Keep out of the reach of children.

S36/39 – Wear suitable protective clothing and eye/face protection

S45 – In case of accident or if you feel unwell, seek medical advice immediately (show the label whenever possible).

S53 – Avoid exposure – obtain special instructions before use.

Classification and labelling of the product under EC 1272/2008 is:

Hazard statements:

Repr. 1B, H360FD

Precautionary statements:

P102 – Keep out of the reach of children.

P103 – Read label before use.

P280 – Wear suitable protective clothing and eye/face protection.

P308+P313 – IF exposed or concerned: Get medical advice/attention.

### 2.2.3 Packaging of the biocidal product

The packaging details for the biocidal product, *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*, are outlined below for professional and industrial users.

Packing type	Pack sizes for professional and industrial users
Buckets made of HDPE	1 kg
Buckets made of HDPE	5 kg
Buckets made of HDPE	10 kg
Buckets made of HDPE	20 kg
Bags made of polyethylene	10 kg
Bags made of polyethylene	20 kg

## 2.3 Physical-chemical properties and analytical methods

The product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is a powder, which is used to prepare the working solution (20% water solution) of biocidal product.

*Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is whitish powder with characteristic odour with no oxidizing nor explosive properties. It is also not fulfilling a criterion for highly flammable and is not self igniting up to 400°C. Tap density of the product is equal to 0.77 kg/m<sup>3</sup>. Water suspension of the product gives slightly-acetic pH (1%, pH = 6.58 to 6.57 – after storage stability test). Product is highly soluble in water. Due to test results, creation of persistent foam is expected to occur.

Taking into consideration results from the accelerated storage stability test and also stability of technical characteristics, the shelf life of the product is considered acceptable up to two years in ambient conditions.

The colorimetric method according to method described in AOAC. vol. 10 number 31.049, 31.050 and 31.051 with rules of GLP and SANCO/3030/99. rev.4 guide is acceptable for determination of the active substance content in the product.

**2.3.1 Physical-chemical properties****Physical-chemical properties of the active substance:**

The letter of access from European Borates Association A.I.S.B.L in short “EBA”, granted to Dekspol P.P.H. Iwona Oleszak, has been submitted for the active substance therefore no additional information for this point is needed.

**Physical-chemical properties of the biocidal product:**

	<b>Method</b>	<b>Purity/ Specification</b>	<b>Results</b>	<b>Reference</b>
<b>Physical state and nature</b>	Polish Pharmacopoeia VI Edition (2002) and according to EPA Product Properties Test Guideline OPPTS 830.6302	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT, partia nr (lot No.) DP.10.05.11.P 94.	Solid particles	EMC Nr 373800019, BF-25/11
<b>Colour</b>	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guideline OPPTS 830.6303	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT, partia nr (lot No.) DP.10.05.11.P 94.	whitish	EMC 373800019 study code: BF-25/11
<b>Odour</b>	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guidelines OPPTS 830.6304	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT, partia nr (lot No.) DP.10.05.11.P 94.	characteristic	EMC Nr 373800019, BF-25/11
<b>Explosive properties</b>	n.a.	n.a.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT does not possess explosive properties	n.a.
<b>Oxidizing properties</b>	n.a.	n.a.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT does not possess oxidizing properties	n.a.
<b>Flash point</b>	n.a.	n.a.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT is	n.a.

**Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT**

	Method	Purity/ Specification	Results	Reference
			not highly flammable	
<b>Autoflammability</b>	n.a.	n.a.	The self-ignition of Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT did not occur up to 400 °C	n.a.
<b>Other indications of flammability</b>	n.a.	n.a.	n.a.	n.a.
<b>Acidity / Alkalinity</b>	CIPAC MT 75	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT, partia nr (lot No.) DP.10.05.11.P 94.	pH of 1% water suspension is 6.58 before and 6.57 after accelerated storage stability test	EMC 373800019 study code: BF-25/11
<b>Relative density / bulk density</b>	CIPAC MT 186	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT, partia nr (lot No.) DP.10.05.11.P 94.	Tap density is 0.77 g/l	EMC 373800019 study code: BF-25/11
<b>Storage stability – stability and shelf life</b>	CIPAC MT 46 (2 weeks 54 °C)	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT, partia nr (lot No.) DP.10.05.11.P 94.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT is stable for two weeks in 54 °C	EMC 373800019 study code: BF-25/11
<b>Effects of temperature</b>	n.a.	n.a.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT is stable for two weeks in 54 °C	n.a.
<b>Reactivity towards container material</b>	CIPAC MT 46	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT, partia nr (lot No.) DP.10.05.11.P 94.	the weight, colour and shape of container as well as physical-chemical properties of product did not change during storage stability test	EMC 373800019 study code: BF-25/11
<b>Technical characteristics in dependence of the formulation type</b>  <i>Wettability</i>		Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT,	0 sec, the powder is wettable immediately	EMC 373800019 study code: BF-25/11

**Wood Protector przeciwoogniowy impregnat do drewna FIRESTOP KONCENTRAT**

	Method	Purity/ Specification	Results	Reference
<b>Persistence of foaming</b>	CIPAC MT 47	partia nr (lot No.) DP.10.05.11.P 94. Wood Protector przeciwoogniowy impregnat do drewna FIRESTOP KONCENTRAT partia nr (lot No.) DP.10.05.11.P 94.	After 12 min. 8 ml of foam	EMC 373800019 study code: BF-25/11
<b>Compability with other products</b>	n.a.	n.a.	Wood Protector przeciwoogniowy impregnat do drewna FIRESTOP KONCENTRAT will not be used with other products (expecially biocidal products)	n.a.
<b>Surface tension</b>	n.a.	n.a.	n.a.	n.a.
<b>Viscosity</b>	n.a.	n.a.	n.a.	n.a.
<b>Particle size distribution</b>	CIPAC MT 59	Wood Protector przeciwoogniowy impregnat do drewna FIRESTOP KONCENTRAT partia nr (lot No.) DP.10.05.11.P 94.	22.49% $\geq$ 1400 $\mu$ m 1000 $\mu$ m $\leq$ 10.23 % < 1400 $\mu$ m 710 $\mu$ m $\leq$ 15.48 % < 1000 $\mu$ m 500 $\mu$ m $\leq$ 29.06 % < 710 $\mu$ m 250 $\mu$ m $\leq$ 22.03 % < 500 $\mu$ m 125 $\mu$ m $\leq$ 0.72 % < 250 $\mu$ m 63 $\mu$ m $\leq$ 0 % < 125 $\mu$ m	EMC 373800019 study code: BF-25/11

**2.3.2 Analytical methods**

	Principle of method
<b>Technical active substance as manufactured:</b>	–
<b>Impurities in technical active substance:</b>	–
<b>Active substance in the formulation:</b>	<p>Specific analytical method with validation data was established for determination of content of the active substance in the product.</p> <p>The colorimetric method according to method described in AOAC. vol. 10 number 31.049, 31.050 and 31.051 with rules of GLP and SANCO/3030/99. rev.4 guide.</p> <p>In this method the total content of borates was determined by spectrophotometer in UV in water solutions containing colour complex - product of reaction of borates with curcumin in acidic solution.</p>

## **2.4 Risk assessment for physical-chemical properties**

Based on the physical-chemical data submitted for *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* Polish Competent Authority can conclude that there are no additional, specific physical-chemical risks for the product. The product has no explosive nor oxidizing properties. The product is not highly flammable and there are not autoflammability indications up to 400°C. Due to test results, creation of persistent foam is expected to occur. Technical properties characteristics of the product are done before and after accelerated storage stability test. No additional risks are found based on technical characteristics of a product (e.g. no potential inhalation danger since particles size < 125 µm are present as trace (0.72 % < 250 µm)).

Taking into consideration results from the accelerated storage stability test, the shelf life of the product is considered acceptable up to two years in ambient conditions.

## **2.5 Effectiveness against target organisms**

### **2.5.1 Function**

Product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is concentrated wood preservative to preserve against wood destroying basidiomycetes and wood boring beetles. The biocidal product concentrate is diluted with water to a 20% working solution. Certain efficacy data have been generated for the product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*.

### **2.5.2 Field of usage**

The product contains 15% boric acid and 5% disodium tetraborate. The final concentration of active substances in working solution is 3% of boric acid 1% of disodium tetraborate. The product is intended to be used on wood above-ground in use classes 1 and 2<sup>1</sup>.

According to label claims the product is efficient against wood destroying basidiomycetes and wood boring beetles.

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<sup>1</sup> According to EN 335-1:2006, *Durability of wood and wood-based products. Definition of use classes. Part 1:General*

The product is applied by professional and industrial users by superficial treatment (painting/brushing and dipping) to give an application rate of:

- 40 g product m<sup>2</sup> (200 g/m<sup>2</sup> of 20% solution of concentrate) in 2 or more coats against wood destroying basidiomycetes (6 g boric acid m<sup>2</sup> and 2 g disodium tetraborate m<sup>2</sup>)
- 100 g product m<sup>2</sup> (500 g/m<sup>2</sup> of 20% solution of concentrate) in 4 or more coats against wood boring beetles and wood destroying basidiomycetes (15 g boric acid m<sup>2</sup> and 5 g disodium tetraborate m<sup>2</sup>)

and by penetrating process (by vacuum pressure):

- 2.5 kg product m<sup>3</sup> (12.5 kg/m<sup>3</sup> of 20% solution of concentrate) to protect against the attack of wood destroying basidiomycetes (0.38 kg boric acid m<sup>3</sup> and 0.13 kg/disodium tetraborate m<sup>3</sup>),
- 5 kg product m<sup>3</sup> (25 kg/m<sup>3</sup> of 20% solution of concentrate) is effective for prevention against the attack of beetle and wood destroying basidiomycetes (0.75 kg boric acid/m<sup>3</sup> and 0.25 kg disodium tetraborate/m<sup>3</sup>).

### **2.5.3 Effect of target organisms**

#### **2.5.3.1 Wood destroying basidiomycetes**

##### **Study 1**

In study conducted according to test standard PN-ENV 839:2008, efficacy of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* was tested against wood destroying basidiomycetes.

The blocs used in the test were artificially aged according to PN-EN 73:1993.

**Table 2.1 Percentage of mass loss of virulence specimens**

Test fungus/wood species	Mass loss		Average loss [%]	Requested minimal value according to PN-ENV 839 [%]
	[g]	[%]		
<i>Coniophora puteana</i> BAM Ebw. 15 Scotch pine sapwood	3.67	42.77	39.1	20.0
	3.30	39.90		
	2.57	29.61		
	2.86	34.05		
	3.50	40.89		
	3.74	47.10		
<i>Gloeophyllum trabeum</i> BAM Ebw. 109 Scotch pine sapwood	1.85	22.26	28.1	20.0
	2.22	27.07		
	2.42	28.57		
	2.73	31.89		
	2.91	33.45		
	2.07	25.37		
<i>Poria placenta</i> FPRL 280 Scotch pine sapwood	1.92	21.69	25.0	20.0
	2.21	27.18		
	1.72	21.55		
	2.80	31.67		
	1.80	21.95		
	2.11	25.86		

Toxic threshold concentrations in superficial application were determined as follows:

- *Coniophora puteana* 200 g/m<sup>2</sup> of ready for use product (40 g/m<sup>2</sup> of concentrate) assuming wood density 0.51 g/cm<sup>3</sup>
- *Gloeophyllum trabeum* 200 g/m<sup>2</sup> of ready for use product (40 g/m<sup>2</sup> of concentrate) assuming wood density 0.51 g/cm<sup>3</sup>
- *Poria placenta* 200 g/m<sup>2</sup> of ready for use product (40 g/m<sup>2</sup> of concentrate) assuming wood density 0.51 g/cm<sup>3</sup>

Biological reference value against basidiomycetes after evaporation is 200 g/m<sup>2</sup>.

## Study 2

In a second study conducted according to a standard PN-EN 113:2000/A1:2005, efficacy of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* was tested against wood destroying basidiomycetes.

In this study serial dilutions of product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* was tested.

The blocs used in the test were artificially aged according to PN-EN 73:1993.



**Table 2.2 Toxic values for Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT (arithmetic means of 6 replicates).**

Test fungus/wood species	Concentration of preservative solution [% (w/w)]	Preservative absorption [kg/m <sup>3</sup> ]	Average of the adjusted mass loss of the highest concentration without protective effectiveness [%]
<i>Coniophora puteana</i> BAM Ebw. 15 Scotch pine sapwood	0.25 – 0.40	1.49 – 2.42	23.7
<i>Gloeophyllum trabeum</i> BAM Ebw. 109 Scotch pine sapwood	0.25 – 0.40	1.51 – 2.43	6.2
<i>Poria placenta</i> FPRL 280 Scotch pine sapwood	0.25 – 0.40	1.53 – 2.45	6.4

**Table 2.3 Percentage of mass loss of virulence specimens**

Test fungus/wood species	Mass loss [%]	Average loss [%]	Requested minimal value according to PN-EN 113:2000 [%]
<i>Coniophora puteana</i> BAM Ebw. 15 Scotch pine sapwood	34.58 44.89 37.16 43.56 33.49 39.09	38.8	20.0
<i>Gloeophyllum trabeum</i> BAM Ebw. 109 Scotch pine sapwood	35.26 31.61 32.07 25.06 27.07 32.16	30.5	20.0
<i>Poria placenta</i> FPRL 280 Scotch pine sapwood	24.26 23.05 20.81 20.99 25.65 26.67	23.6	20.0

The test results showed that the *b.r.v* (*biological reference value*) were 2.42 kg of product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* against *C. puteana*, 2.42 kg/m<sup>3</sup> against *G. trabeum* and 2.43 kg/m<sup>3</sup> against *P. placenta*

### 2.5.3.2 Wood boring beetles

#### Study 1

In this study conducted according to a test standard PN-EN 46-1:2009 *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* was tested for efficacy against wood boring beetles (recently hatched larvae of *Hylotrupes bajulus*).

The blocs used in the test were artificially aged according to PN-EN 73:1993.

As 90 – 100% of the larvae exposed to the untreated control test specimens and of those exposed to control test specimens treated with the solvent survived, therefore the test is valid.

**Table 2.4 Summary results for *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* (6 replicates)**

Concentration tested [% (w/w)]	Solution retention [g/m <sup>2</sup> ]	Number of larvae			Number of larvae not recovered [n]
		Dead		Alive [n]	
		Not gnawed [n]	Gnawed [n]		
20	498.4	6	4	0	0
	500.0	9	1	0	0
	498.4	4	6	0	0
	500.0	7	3	0	0
	499.2	6	4	0	0
	499.2	8	2	0	0

The test results indicated that, following treatment at an application rate of 500 g/m<sup>2</sup> of ready to use product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* all larvae are dead.

#### Study 2

In this study conducted according to a test standard EN 47:2005, *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* was tested for efficacy against wood boring beetles (recently hatched larvae of *Hylotrupes bajulus*).

The blocs used in the test were artificially aged according to PN-EN 73:1993.

**Table 2.5 Determination of the toxic values against *Hylitrupes bajulus* (L.) according to EN 47**

Concentration of product tested [% m/m]	Retention of wood preservative Mean [kg/m <sup>3</sup> ]	Number of larvae			
		Dead		Alive [n]	Not discovered [n]
		Not gnawed [n]	Gnawed [n]		
<i>Examination after 4 weeks</i>					
2.78	20.5	1	29	0	0
2.08	15.3	2	28	0	0
1.39	10.2	0	0	1 <sup>a)</sup>	0
<i>Examination after 12 weeks</i>					
1.39	10.2	2 <sup>b)</sup>	27 <sup>b)</sup>	0	0
0.97	7.1	0	30	0	0
0.69	5.1	0	30	0	0
0.00 (water)	0.0	0	0	29	1
control	-	1	0	29	0

<sup>a)</sup> No further splitting up after 4 weeks of testing

<sup>b)</sup> Referring to the remaining test blocks after 12 weeks

Study results showed that toxic values after 12 weeks test duration are < 5.1 kg/m<sup>3</sup>, product concentration 0.69 %

## 2.5.4 Discussion

### 2.5.4.1 Wood destroying basidiomycetes

The study conducted according to CEN/TS 839:2008 was carried out at rate 200 g/m<sup>2</sup> and 250 g/m<sup>2</sup> of 20% solution of product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*.

The study showed that product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is efficient in rate 200 g/m<sup>2</sup> of 20% working solution.

The superficial application rate against wood destroying basidiomycetes for the product is 200 g/m<sup>2</sup> of 20% working solution (6 g boric acid m<sup>2</sup> and 2 g disodium tetraborate m<sup>2</sup>).

Dipping application method used in the test is the superficial treatment. Brushing is also a superficial method and in the Polish Competent Authority view, the results support label claims for all requested superficial application methods.

The study conducted according to CEN/TS 839:2008 was carried out at rate 200 g/m<sup>2</sup> and 250 g/m<sup>2</sup> of ready to use product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP*.

According to European standard EN 599-1, the critical value (*c.v.*) is the highest *b.r.v* from all of the biological tests carried out on the product. Therefore the *c.v.* derived in the test study conducted according to PN-EN 113:2000 on product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is 2.43 kg/m<sup>3</sup> which correspond with 12.15 kg/m<sup>3</sup> of 20% working solution (0.37 kg boric acid/m<sup>3</sup> and 0.11 kg disodium tetraborate/m<sup>3</sup>).

The application rate against wood destroying basidiomycetes is 2.5 kg product/m<sup>3</sup>, 12.5 kg/m<sup>3</sup> of 20% working solution of concentrate (0.38 kg boric acid m<sup>3</sup> and 0.13 kg disodium tetraborate/m<sup>3</sup>)/

Therefore, the data supports declared by Applicant application rate for penetrating treatment against wood destroying basidiomycetes with *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*.

For the above reasons Polish Competent Authority considers the data to be acceptable in support of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*.

#### **2.5.4.2 Wood boring beetles**

The EN 46-1:2009 study demonstrated the efficacy of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* as a preventive wood preservative against wood boring beetles at a superficial application rate of 100 g product/m<sup>2</sup> – 500 g/m<sup>2</sup> of 20% working solution (15 g boric acid/m<sup>2</sup> and 5 g disodium tetraborate/m<sup>2</sup>).

The Applicant has indicated that the superficial application rate of the product against wood boring beetles is 500 g product/m<sup>2</sup> (15 g boric acid/m<sup>2</sup> and 5 g disodium tetraborate/m<sup>2</sup>). Therefore the results support proposed application rate of the product.

The brush application method used in the test is the superficial treatment. Dipping is also a superficial method and in the Polish Competent Authority view, the results support label claims for all requested superficial application methods.

The EN 47:2005 study demonstrated the efficacy of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* as a preventive wood preservative against wood boring beetles at a penetrative application rate of >5.1 kg product/m<sup>3</sup> – 25.5 kg/m<sup>3</sup> of 20% working solution (0.76 kg boric acid/m<sup>3</sup> and 0.26 kg disodium tetraborate/m<sup>3</sup>).

The Applicant has indicated that the penetrative application rate of the product against wood boring beetles is 5 kg of product/m<sup>3</sup> (0.75 kg boric acid/m<sup>3</sup> and 0.25 kg disodium tetraborate/m<sup>3</sup>). Although this is lower than the rate shown in the test to be effective, the difference is minimal. The Polish Competent Authority does not consider this difference to be an issue, and is satisfied that the results support declared by Applicant application rates for penetrative treatment with *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*. Therefore the results support proposed application rate of the product.

The Applicant has declared that the product is intended for use in 1 and 2-wood use classes. On the basis on *TNsG on Product Authorisation, Appendices to Chapter 7, Product Type 8, Section 2.2.1*, the submitted data meet the required criteria for use classes 1 and 2.

For the above reasons Polish Competent Authority considers the data to be acceptable in support of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*.

## **2.5.5 Conclusion**

Sufficient data confirming efficacy in declared field of use have been generated on the product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*.

## 2.6 Exposure assessment

### 2.6.1 Description of the intended use

*Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is a wood preservative for preventive use against wood destroying basidiomycetes and wood boring beetles. Biocidal product is intended to use in use class 1 (UC1 – wood or wood-based product under cover and fully protected from the weather, not exposed to wetting) and in use class 2 (UC2 – wood or wood-based product under cover and fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting).

The biocidal product is intended for professional and industrial users, recommended method of application is painting/brushing, dipping and vacuum pressure.

The product contains 15% w/w of boric acid and 5% w/w disodium tetraborate and it is used to prepare the product ‘ready to use’ (20% water solution of the concentrate) which contains 3% w/w of boric acid and 1% w/w of disodium tetraborate. Both substances are relevant for the risk assessment of the biocidal product. The toxic effects of them are similar and in both cases due to the content of boron. Therefore, in the exposure calculations the active substances will be expressed as B (boron) equivalents; the conversion factors for boric acid and disodium tetraborate into equivalent doses of boron are 0.175 and 0.215, respectively.

### 2.6.2 Assessment of exposure to humans and the environment

The biocidal product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* contain two active substance: boric acid and disodium tetraborate and one substance of concern – quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides (CAS 85409-22-9), trade name *Barquat MS 100*, classified and labelled under CLP regulation 1272/2008. The *Barquat MS 100* concentration in the product is very low (0.66%) and does not affect on overall classification of product. Please see Document IIIB6.5 for details.

New exposure studies have not been submitted and the risk assessment was performed based on the information presented in Competent Authority Reports for boric acid and disodium tetraborate<sup>2</sup>.

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<sup>2</sup> Competent Authority Reports available at <https://circabc.europa.eu>

## 2.7 Risk assessment for human health

The biocidal product *Wood Protector przeciwożniowy impregnat do drewna FIRESTOP KONCENTRAT* has been tested from toxicological point of view. However, information about toxicokinetics, critical endpoints and assessment factors presented in this section are taken from the final CARs on boric acid and disodium tetraborate to which the letter of access form the EBA A.I.S.B.L. has been submitted.

### 2.7.1 Hazard potential

#### 2.7.1.1 Toxicology of the active substance

##### Critical endpoints and assessment factors

###### Overall NOAEL

The toxicological data base reveals that the major targets for toxicity of borates are the testes and the blood. In the repeated dose studies with mouse, rat and dog, consistently effects on the testes and on blood parameters were found. In a 90 days study in the mouse the animals appeared to be more sensitive to the effects on the haematopoietic system than on the testes. In the rat effects on both the testes and on the blood were observed at dose levels of 334 mg boric acid/kg b.w./day. The NOAEL in this study was 100 mg/kg b.w./day (17.5 mg B/kg b.w./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 b.w./day (9.6 mg B/kg b.w./day) the overall NOAEL is 9.6 mg B/kg b.w./day.

###### Total assessment factor

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.

###### AOEL (acceptable operator exposure level)

Using the standard assessment factor of 100 (10 for interspecies- and 10 for intraspecies variation) an oral AOEL of 0.096 mg B/kg b.w./day can be derived based on the NOAEL

for embryotoxic/teratogenic effects of boric acid of 9.6 mg B/kg b.w./day. Based on the NOAEL of 17.5 mg B/kg b.w./day in a 2-year study in the rat and an assessment factor of 300 due to serious effects and based on the NOAEL of 21.8 mg B/kg b.w./day in a teratogenicity study in the rabbit and an assessment factor of 300 due to serious effects AOEL values can be derived of 0.06 and 0.07 mg B/kg b.w./day, respectively. For the risk assessment, a rounded (systemic) AOEL value of 0.1 mg B/kg b.w./day was used, even though values of 0.06 and 0.07 mg B/kg b.w./day could be derived from the critical effects.

#### MOE (margin of exposure)

For the risk assessment of borates the systemic NOAEL of 9.6 mg/kg b.w./day will be used. A MOE of 100 would be considered acceptable, on the basis of the standard assessment factors of 100 ( $10 \times 10$ ) for interspecies and intraspecies variability.

#### **2.7.1.2 Toxicology of the substance(s) of concern**

The biocidal product contains one substance of concern – quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides (CAS 85409-22-9), trade name *Barquat MS 100*, classified and labeled under CLP regulation 1272/2008. The *Barquat MS 100* concentration in the product is very low (0.66%) and does not affect on overall classification.

#### **2.7.1.3 Toxicology of the biocidal product**

##### Toxicokinetics

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. 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.

##### Acute toxicity

The biocidal product is of low acute toxicity: LD<sub>50</sub> oral rat > 2000 mg/kg; LD<sub>50</sub> dermal rat >2000 mg/kg.



**Irritation and Corrosivity**

The biocidal product is not a skin irritant or an eye irritant.

**Sensitization**

The biocidal product is non sensitizer, on the basis of a guinea pig maximization test.

**2.7.2 Exposure**

The exposure to borates is calculated by using the selected models and default values for wood preservatives from the *User Guidance TNsG*<sup>3</sup> as a guideline. In the calculations the process information given by the notifier is used as a base for the calculation.

**Main paths of human exposure:**

Route of exposure	Industrial use	Professional user	Via the environment
inhalation	Yes	Yes	No
dermal	Yes	Yes	No
oral	No	No	No

The crucial exposure is connected with mixing process, because the product ready to use is not classified and no adverse health effects are expected.

Direct contact with concentrated formulations of biocidal product should be avoided at each step. Where possible, use a container which avoids splashing, and/or small hand transfer pumps and/or pouring cradles. Concentrate should be diluted to 20% water solution ready to use where controlled conditions can be maintained and not where the public have access. Containers for diluted products must be suitably labelled. To minimize the exposure by inhalation and through the skin to concentrate appropriate protective clothing (gloves, coveralls, and foot protection) and respiratory protection should be provided and worn by worker when at each step of using the product. The secondary (indirect) exposure occurs after the actual use or application of the biocidal product. Secondary exposure to the non-

<sup>3</sup> *Technical Notes for Guidance (TNsG). Human Exposure to Biocidal Products – Guidance on Exposure Estimation. Contract B4-3040/2000/291079/MAR/E2. DG Environment June 2002. User Guidance, Version 1 belonging to Report Human Exposure to Biocidal Products (TNsG June 2002). Available from <http://ecb.jrc.it>*

users results from contact with treated timber/wood; e.g. adults using preserved timber in construction.

The treated wood is not placed on the market until it is dry. Use of biocidal product on wood, which is likely to come into prolonged direct contact with foodstuffs or feedstuffs is not expected.

Indirect exposure via the environment is considered not relevant based upon the rapid environmental degradation of biocidal product ingredients.

### 2.7.2.1 Exposure of industrial and professional users

Assumptions used in the estimations of exposure:

- the total content of active substances in *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is 20% w/w and in product ready to use is 4% w/w,
- the total content of active substances in *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* expressed as B equivalents is  $15\% \text{ boric acid} \times 0.175 + 5\% \text{ disodium tetraborate} \times 0.215 = 0.037 \text{ B equivalents}$
- the total content of active substances in product ready to use expressed as B equivalents is  $3\% \text{ boric acid} \times 0.175 + 1\% \text{ disodium tetraborate} \times 0.215 = 0.0074 \text{ B equivalents}$
- default factor 0.1 for the use of PPE
- rate and extent of dermal absorption: 0.5%
- rate and extent of inhalation absorption: 100%
- body weight 60 kg

#### 2.7.2.1.1 Vacuum pressure

*Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is diluted to 20% water solution as a product ready to use. Exposure is related to the following steps:

##### **Step 1a. Mixing and loading(the dose effective to protect wood against insects and fungi)**

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline. Exposure is assessed based on the model 'Mixing and Loading: Model 5' (95<sup>th</sup> percentile; *TNsG*):

- potential dermal exposure for powder – 14.3 mg a.s./kg a.s.
- potential inhalation exposure for powder – 0.55 mg a.s./kg a.s.

- application rate – 5 kg of product /m<sup>3</sup> wood = 0.185 kg B/m<sup>3</sup> wood (recommended by the Applicant)
- treated wood – 30 m<sup>3</sup> wood/day ESD<sup>4</sup>,
- in ‘Mixing and Loading: Model 5’ no information about exposure with PPE is given, therefore the default factor for exposure with and without PPE of 0.1, which is common practice in the UE, is used for both the dermal and the inhalation exposure with PPE.

Chronic systemic exposure during mixing and loading:

- without PPE  
dermal exposure: 79.37mg B/day × 0.005 = 0.40 mg B/day = 0.0067 mg B/kg b.w./day  
inhalation exposure: 3.05 mg B/day × 1 = 3.05 mg B/day = 0.0508 mg B/kg b.w./day
- with PPE  
dermal exposure: 0.00067 mg B/kg b.w./day  
inhalation exposure: 0.00508 mg B/kg b.w./day.

**Step 1b. Mixing and loading (the highest dose proposed by the applicant for this type of application)**

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline. Exposure is assessed based on the model ‘Mixing and Loading: Model 5’ (95<sup>th</sup> percentile; *TNsG*):

- potential dermal exposure for powder – 14.3 mg a.s./kg a.s.,
- potential inhalation exposure for powder – 0.55 mg a.s./kg a.s.,
- application rate – 40 kg of product /m<sup>3</sup> wood = 1.48 kg B/m<sup>3</sup> wood (recommended by the Applicant),
- treated wood – 30 m<sup>3</sup> wood/day ESD,
- in ‘Mixing and Loading: Model 5’ no information about exposure with PPE is given, therefore the default factor for exposure with and without PPE of 0.1, which is common practice in the UE, is used for both the dermal and the inhalation exposure with PPE.

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<sup>4</sup> *Emission Scenario Documents, number 2, Emission Scenario Document for Wood Preservatives, Part I* OECD 2003

Chronic systemic exposure during mixing and loading:

- without PPE

dermal exposure:  $634.92 \text{ mg B/day} \times 0.005 = 3.17 \text{ mg B/day} = 0.053 \text{ mg B/kg b.w./day}$

inhalation exposure:  $24.42 \text{ mg B/day} \times 1 = 24.42 \text{ mg B/day} = 0.407 \text{ mg B/kg b.w./day}$

- with PPE

dermal exposure:  $0.0053 \text{ mg B/kg b.w./day}$

inhalation exposure:  $0.0407 \text{ mg B/kg b.w./day}$

## **Step 2. Application and post-application**

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline. Exposure is assessed based on the model 'Handling: Model 1' (water based; 75<sup>th</sup> percentile; *TNsG*).

- potential dermal exposure – 8570 mg of product ready to use/cycle,
- for vacuum pressure process: daily use 3 cycles/day and 3 hours/cycle ,
- probability of exposure by inhalation – 1.9 mg of product ready to use/m<sup>3</sup>,
- inhalation rate – 0.021 m<sup>3</sup>/min,
- during the application and post-application phase gloves, coverall and respiratory protective equipment are used. In 'Handling: Model 1' the dermal exposure inside gloves and inside shoes is described, which is approximately 18% of the potential dermal exposure. The exposure inside gloves and inside shoes certainly isn't the total dermal exposure with PPE. Therefore, the default factor of 0.1, which is common practice in the UE and stated in the *TNsG*.

Chronic systemic exposure:

- without PPE

dermal exposure:  $190.25 \text{ mg B/day} \times 0.005 = 0.95 \text{ mg B/day} = 0.016 \text{ mg B/kg b.w./day}$

inhalation exposure:  $0.16 \text{ mg B/day} \times 1 = 0.16 \text{ mg B/day} = 0.0026 \text{ mg B/kg b.w./day}$

- with PPE

dermal exposure:  $0.0016 \text{ mg B/kg b.w./day}$

inhalation exposure:  $0.00026 \text{ mg B/kg b.w./day}$

### **2.7.2.1.2 Dipping**

Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT is diluted to 20% water solution as a product ready to use. Exposure is related to the following steps:

#### **Step 1. Mixing and loading (the dose effective to protect wood against insects and fungi)**

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline.

Exposure is assessed based on the model 'Mixing and Loading: Model 5' (95<sup>th</sup> percentile; *TNsG*):

- potential dermal exposure for powder – 14.3 mg a.s./kg a.s.,
- potential inhalation exposure for powder – 0.55 mg a.s./kg a.s.,
- application rate – 5 kg of product /m<sup>3</sup> wood = 0.185 kg B/m<sup>3</sup> wood (recommended by the Applicant),
- treated wood – 100 m<sup>3</sup> wood/day ESD,
- in 'Mixing and Loading: Model 5' no information about exposure with PPE is given, therefore the default factor for exposure with and without PPE of 0.1, which is common practice in the UE, is used for both the dermal and the inhalation exposure with PPE.

Chronic systemic exposure during mixing and loading:

- without PPE  
dermal exposure:  $264.55 \text{ mg B/day} \times 0.005 = 1.32 \text{ mg B/day} = 0.022 \text{ mg B/kg b.w./day}$   
inhalation exposure:  $10.18 \text{ mg B/day} \times 1 = 10.18 \text{ mg B/day} = 0.17 \text{ mg B/kg b.w./day}$
- with PPE  
dermal exposure: 0.0022 mg B/kg b.w./day  
inhalation exposure: 0.017 mg B/kg b.w./day

#### **Step 2a. Application and post-application (manual dipping)**

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline. Exposure is assessed based on the model 'Dipping: Model 1' (75<sup>th</sup> percentile; *TNsG*).

- potential dermal exposure – 178 mg of product ready to use/min,
- for dipping process: up to 30 min immersion/batch,

- 5 cycles/day (according to Applicant),
- during the application and post-application phase gloves and a coverall are used and no respiratory protective equipment. In ‘Dipping: Model 1’ the exposure with PPE is not stated, only the exposure inside gloves and inside shoes, which is approximately 9.9% of the potential dermal exposure. The exposure inside gloves and inside shoes certainly isn’t the total dermal exposure with PPE. Therefore, the default factor of 0.1, which is common practice in the UE and stated in the *TNsG*,
- in ‘Dipping: Model 1’ no range of non-zero values is given for the exposure by inhalation; all 5 data for inhalation were zero values.

Chronic systemic exposure:

- without PPE

$$197.58 \text{ mg B/day} \times 0.005 = 0.99 \text{ mg B/day} = 0.017 \text{ mg B/kg b.w./day}$$

- with PPE

$$0.0017 \text{ mg B/kg b.w./day}$$

### **Step 2b. Application and post-application (automated dipping)**

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline. Exposure is assessed based on the model ‘Handling: Model 1’ (water based; 75<sup>th</sup> percentile; *TNsG*).

- potential dermal exposure – 8570 mg of product ready to use/cycle,
- for automated dipping process: daily use 4 cycles/day and 1 hour/cycle,
- during the application and pos-application phase gloves and a coverall are used and no respiratory protective equipment. In ‘Handling: Model 1’ the dermal exposure inside gloves and inside shoes is described, which is approximately 18% of the potential dermal exposure. The exposure inside gloves and inside shoes certainly isn’t the total dermal exposure with PPE. Therefore, the default factor of 0.1, which is common practice in the UE and stated in the *TNsG*.

Chronic systemic exposure:

- without PPE

$$\text{dermal exposure: } 253.67 \text{ mg B/day} \times 0.005 = 1.27 \text{ mg B/day} = 0.021 \text{ mg B/kg b.w./day}$$

- with PPE

$$\text{dermal exposure: } 0.0021 \text{ mg B/kg b.w./day}$$

**2.7.2.1.3 Painting/brushing:****Step 1a. Mixing and loading (the dose effective to protect wood against insects and fungi)**

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline. Exposure is assessed based on the model 'Mixing and Loading: Model 5' (95<sup>th</sup> percentile; *TNsG*). However, due to the fact that certain value (for which the applicant did not submitted the access) was used in the calculation by RMS, full calculations were placed in Annex 8 as a confidential.

Chronic systemic exposure during mixing and loading:

- without PPE

dermal exposure:  $0.53 \text{ mg B/day} \times 0.005 = 0.0027 \text{ mg B/day} = 0.000045 \text{ mg B/kg b.w./day}$

inhalation exposure:  $0.02 \text{ mg B/day} \times 1 = 0.02 \text{ mg B/day} = 0.00033 \text{ mg B/kg b.w./day}$

- with PPE

dermal exposure:  $0.000045 \text{ mg B/kg b.w./day}$

inhalation exposure:  $0.000033 \text{ mg B/kg b.w./day}$

**Step 1b. Mixing and loading (the highest dose proposed by the applicant for this type of application)**

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline. Exposure is assessed based on the model 'Mixing and Loading: Model 5' (95<sup>th</sup> percentile; *TNsG*). However, due to the fact that certain value (for which the applicant did not submitted the access) was used in the calculation by RMS, full calculations were placed in Annex 9 as a confidential.

Chronic systemic exposure during mixing and loading:

- without PPE

dermal exposure:  $1.058 \text{ mg B/day} \times 0.005 = 0.0053 \text{ mg B/day} = 0.000088 \text{ mg B/kg b.w./day}$

inhalation exposure:  $0.0407 \text{ mg B/day} \times 1 = 0.0407 \text{ mg B/day} = 0.00068 \text{ mg B/kg b.w./day}$

- with PPE

dermal exposure:  $0.000088 \text{ mg B/kg b.w./day}$

inhalation exposure:  $0.000068 \text{ mg B/kg b.w./day}$





**Step 2. Application**

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline. There are no exposure models for professional painters, therefore, the exposure is assessed based on the model 'Consumer Product Painting: Model 3' (75<sup>th</sup> percentile; *TNsG*).

- potential dermal exposure is 16.9 mg product/min,
- use 4 hours/day (see: *User Guidance TNsG*), the use of preservative by professionals is less than half the time spent at the job),
- potential inhalation exposure – 4.15 mg of product ready to use/m<sup>3</sup>,
- inhalation rate – 0.021 m<sup>3</sup>/min,
- during the application and post-application phase gloves, coverall and respiratory protective equipment are used. In 'Consumer Product Painting: Model 3' the exposure with PPE is not stated, only the exposure inside gloves and inside shoes, which is approximately 5.8 % of the potential dermal exposure. The exposure inside gloves and inside shoes certainly isn't the total dermal exposure with PPE. Therefore, the default factor of 0.1, which is common practice in the UE and stated in the *TNsG*, is used as reduction factor.

Chronic systemic exposure:

- without PPE

dermal exposure:  $30.1 \text{ mg B/day} \times 0.005 = 0.15 \text{ mg B/day} = 0.0025 \text{ mg B/kg b.w./day}$

inhalation exposure:  $0.15 \text{ mg B/day} \times 1 = 0.15 \text{ mg B/day} = 0.0025 \text{ mg B/kg b.w./day}$

- with PPE

dermal exposure:  $0.00025 \text{ mg B/kg b.w./day}$

inhalation exposure:  $0.00025 \text{ mg B/kg b.w./day}$

**2.7.2.2 Non-professional exposure**

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

### **2.7.2.3 Indirect exposure as a result of use of the active substance in biocidal product**

Indirect exposure to borates as a result of use can occur during cutting and sanding and during handling treated timber. Exposure can take place due to inhalation of sawdust and due to contact with the treated wood.

Industrial treatment of timber occurs in large industrial installations. The indirect exposure does not occur at these industrial sites but elsewhere. In fact, this is exposure to a treated product. Here the exposure during cutting and sanding industrial treated timber will be described for professionals and non-professionals.

In the *User Guidance TNsG* the example Wood Preservatives' provides 'reference scenarios' for calculating exposure during cutting and sanding by professionals and non-professionals. These 'reference scenarios' are used as starting point for the exposure assessment.

Besides when handling timber, exposure could as well occur during the use of timber treated with wood preservatives. Treated timber could be used for playground structures outdoors but under cover where high environmental humidity can lead to occasional wetting. Children playing at these constructions could be exposed to borates by contacting the wood. In the *User Guidance TNsG* a 'reference scenario' for children playing on playground structures outdoors is described. This scenario will be starting point of the exposure assessment.

The 'indirect exposure as a result of use' is mainly based on assumptions and not on measurements nor on default values derived from measurements. Therefore the result of the exposure assessment must be seen as an indication of the order of magnitude.

#### **2.7.2.3.1 Exposure during cutting and sanding by professionals**

**Scenario:** Adult (-professional) sanding (powered sander) wooden posts (4 cm × 4 cm × 2.5 m) for one hour. The posts have been treated with wood preservative solution by the vacuum process (200 kg of product ready to use/m<sup>3</sup> wood). Sanding of treated wood occurs every work day.

##### **Inhalation exposure**

Active substance in the posts = 200 kg of product ready to use/m<sup>3</sup> wood = 1.48 kg B/m<sup>3</sup> wood  
= 1.48 mg B/cm<sup>3</sup> wood

Wood density: 0.5 g/cm<sup>3</sup> (according to *Assessment Report* for boric acid)

In the posts: 1.48 mg B/cm<sup>3</sup> wood/0.5 g/cm<sup>3</sup> = 2.96 mg B/g wood = 0.00296 mg B/mg wood

Inhalation rate:  $1.25 \text{ m}^3 \text{ air /hour}$

If the inhalation exposure were to be  $5 \text{ mg/m}^3$  (equal to the occupational exposure limit for wood dust) the inhalation exposure =  $5 \text{ mg/m}^3 \times 1.25 \text{ m}^3 \text{ /hour} \times 1 \text{ hour/day} = 6.25 \text{ mg wood dust/day}$ .

Inhalation exposure:

$6.25 \text{ [mg wood dust/day]} \times 0.00296 \text{ mg B/mg wood} = 0.0185 \text{ mg B/day of exposure}$

Inhalation absorption factor 1

Internal chronic inhalation exposure:  $0.0185 \text{ mg [B / day of exposure]} \times 1 \text{ [absorption factor]} / 60 \text{ [kg b.w.]} = 0.00031 \text{ mg B/(kg b.w.} \times \text{ day)}$ .

### **Dermal exposure**

Active substance residue on surface =  $1 \text{ mg/cm}^2 = 0.0074 \text{ mg B/cm}^2$

Hand surface area =  $420 \text{ cm}^2$

Assume 20% of hand ( $84 \text{ cm}^2$ ) contaminated at 100% of surface concentration

Dermal exposure =  $0.0074 \times 84 = 0.62 \text{ mg B/day of exposure}$

Dermal absorption factor: 0.005

Internal chronic dermal exposure =  $0.62 \text{ [mg B/day of exposure]} \times 0.005 \text{ [absorption factor]} / 60 \text{ [kg b.w.]} = 0.000052 \text{ mg B/(kg b.w.} \times \text{ day)}$ .

### **2.7.2.3.2 Exposure during cutting and sanding by non-professionals**

**Scenario:** Adult (non-professional) sanding (powered sander) wooden posts ( $4 \text{ cm} \times 4 \text{ cm} \times 2.5 \text{ m}$ ) for one hour. The posts have been treated with wood preservative solution by the vacuum process ( $200 \text{ kg of product ready to use/m}^3 \text{ wood}$ ). Sanding of treated wood by non-professional occurs once a year.

### **Inhalation exposure**

Active substance in the posts =  $200 \text{ kg of product ready to use/m}^3 \text{ wood} = 1.48 \text{ kg B/m}^3 \text{ wood} = 1.48 \text{ mg B/cm}^3 \text{ wood}$

Wood density:  $0.5 \text{ g/cm}^3$  (according to *Assessment Report* for boric acid)

In de posts:  $1.48 \text{ mg B/cm}^3 \text{ wood} / 0.5 \text{ g/cm}^3 = 2.96 \text{ mg B/g wood} = 0.00296 \text{ mg B/mg wood}$

Inhalation rate:  $1.25 \text{ m}^3 \text{ air /hour}$

If the inhalation exposure were to be  $5 \text{ mg/m}^3$  (equal to the occupational exposure limit for wood dust) the inhalation exposure =  $5 \text{ mg/m}^3 \times 1.25 \text{ m}^3/\text{hour} \times 1 \text{ hour/day} = 6.25 \text{ mg wood dust/day}$ .

Inhalation exposure:

$6.25 \text{ [mg wood dust/day]} \times 0.00296 \text{ mg B/mg wood} = 0.0185 \text{ mg B/day of exposure}$

Inhalation absorption factor 1

Internal inhalation exposure (acute):  $0.0185 \text{ mg [B / day of exposure]} \times 1 \text{ [absorption factor]} / 60 \text{ [kg b.w.]} = 0.00031 \text{ mg B/(kg b.w.} \times \text{day)}$ .

### **Dermal exposure**

Active substance residue on surface =  $1 \text{ mg/cm}^2 = 0.0074 \text{ mg B/cm}^2$

Hand surface area =  $420 \text{ cm}^2$

Assume 20% of hand ( $84 \text{ cm}^2$ ) contaminated at 100% of surface concentration

Dermal exposure =  $0.0074 \times 84 = 0.62 \text{ mg B/day of exposure}$

Dermal absorption factor: 0.005

Internal dermal exposure (acute) =  $0.62 \text{ [mg B/day of exposure]} \times 0.005 \text{ [absorption factor]} / 60 \text{ [kg b.w.]} = 0.000052 \text{ mg B/(kg b.w.} \times \text{day)}$ .

### **2.7.2.3.3 Exposure of a child playing on playground structure outdoors**

**Scenario:** Child playing on playground structure outdoors but under cover where high environmental humidity can lead to occasional wetting. The structures are made of wood, which has been treated with wood preservative and there is prolonged and repeated contact of wood with hands, which causes dermal exposure. Oral exposure may occur via hand-to-mouth transfer. It is assumed that 10% of the dermal exposure to borates is ingested orally due to hand-to-mouth transfer.

Child, 2-5 years of age, 16.7 kg.

### **Exposure hands**

Surface loading of boron in treated wood:  $0.01 \text{ mg/cm}^2 \text{ wood} \times 0.0074 \text{ B equivalents} = 0.000074 \text{ mg B/cm}^2$

Hand surface area =  $200 \text{ cm}^2$

Assume 20% of hand ( $40 \text{ cm}^2$ ) contaminated at 100% of surface concentration

Total exposure on the hands =  $0.000074 \times 40 = 0.003$  mg B/day

It is assumed that 10% of the total exposure that ends up on the skin of a child is taken in orally due to hand-mouth contact.

Dermal exposure  $0.9 \times 0.003 = 0.0027$  mg B/day

Dermal absorption factor: 0.005

Internal chronic dermal exposure =  $0.0027 \text{ [mg B/day of exposure]} \times 0.005 / 16.7 \text{ [kg b.w.]} = 0.00000081 \text{ mg B/(kg b.w.} \times \text{day)}$ .

Oral exposure due to hand-mouth contact:  $0.1 \times 0.003 = 0.0003 \text{ mg B/day}$

Oral absorption factor: 1

Internal chronic oral exposure =  $0.0003 \text{ [mg B/day of exposure]} / 16.7 \text{ [kg b.w.]} = 0.000018 \text{ mg B/(kg b.w.} \times \text{day)}$

### 2.7.3 Risk Characterisation

The risk characterization was performed in accordance with the recommendations of the technical guidelines *TNsG* (Annex I Inclusion Revision of Charter 4.1: Quantitative Human Health Risk Characterisation), based on the determined values of MOE and AEL.

#### 2.7.3.1 Risk for industrial and professional users

**Table 2.6 Risk assessment of biocidal product**

Exposure	Estimated exposure [mg B/kg b.w./day]		AOEL systemic [mg B/kg b.w./day]	Risk index	
	without PPE	with PPE		without PPE	with PPE
Vacuum pressure impregnation (the dose effective to protect wood against insects and fungi)	0.0761	0.00761	0.1	0.761	0.0761

Vacuum pressure impregnation (the highest dose proposed by the applicant for this type of application)	0.4786	0.04786	0.1	4.786	0.4786
Manual dipping	0.209	0.0209	0.1	2.09	0.209
Automated dipping	0.213	0.0213	0.1	2.13	0.213
Painting/brushing (the dose effective to protect wood against insects and fungi)	0.005375	0.0005375	0.1	0.05375	0.005375
Painting/brushing (the highest dose proposed by the applicant for this type of application)	0.005768	0.0005768	0.1	0.05768	0.005768

**Table 2.7 Risk assessment of biocidal product**

Exposure	Estimated exposure [mg B/kg b.w./day]		NAOEL systemic [mg B/kg b.w./day]	MOE	
	without PPE	with PPE		without PPE	with PPE
Vacuum pressure impregnation (the dose effective to protect wood against insects and fungi)	0.0761	0.00761	9.6	126	1261
Vacuum pressure impregnation (the highest dose proposed by the applicant for this type of application)	0.4786	0.04786	9.6	20	201
Manual dipping	0.209	0.0209	9.6	46	4595
Automated dipping	0.213	0.0213	9.6	45	451
Painting/brushing (the dose effective to protect wood against insects and fungi)	0.005375	0.0005375	9.6	1786	17860



Painting/brushing (the highest dose proposed by the applicant for this type of application)	0.005768	0.0005768	9.6	1664	16644
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It can be concluded that adverse health effects for the unprotected industrial and professional users due to combined dermal and respiratory exposure of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*, as a result of the processes as described in the Table 2.6 and Table 2.7 cannot be excluded in the case of vacuum pressure impregnation (the highest dose proposed by the applicant for this type of application), manual and automated dipping processes. Protective clothing (gloves, coveralls, and foot protection) and respiratory protection are necessary to reduce the exposure to get risk indices  $< 1$  and the MOEs  $> 100$ .

In connection with above, PPE are required in the case of vacuum pressure impregnation (the highest dose proposed by the applicant for this type of application), manual and automated dipping processes, however in case of other processes using the PPE is also recommended.

### 2.7.3.2 Indirect exposure as a result of use of the active substance in biocidal product

**Table 2.8 Risk assessment of biocidal product without PPE**

Exposure	Estimated exposure [mg B/kg b.w./day]	AOEL systemic [mg B/kg b.w./day]	Risk index
Exposure during cutting and sanding by professionals	0.000362	0.1	0.00362
Exposure during cutting and sanding by non-professionals	0.000362	0.1	0.00362
Exposure of a child playing on playground structure outdoors	0.0000188	0.1	0.000188

**Table 2.9 Risk assessment of biocidal product without PPE**

Exposure	Estimated exposure [mg B/kg b.w./day]	AOEL systemic [mg B/kg b.w./day]	Risk index
Exposure during cutting and sanding by professionals	0.000362	9.6	26519
Exposure during cutting and sanding by non-professionals	0.000362	9.6	26519
Exposure of a child playing on playground structure outdoors	0.0000188	9.6	510367

No adverse health effects for the non-professional user and the professional user due to indirect exposure are expected. For child playing on a playground structure outdoors (but under cover where high environmental humidity can lead to occasional wetting) a health risk as a consequence of exposure to borates can be excluded.

## 2.8 Risk assessment for the environment

*Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is used as a wood preservative against wood destroying basidiomycetes and wood boring beetle.

Biocidal product is intended to use in use class 1 (UC1 – timber under cover and fully protected from the weather, not exposed to wetting) and in use class 2 (UC2 – timber under cover and fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting).

### **2.8.1 Fate and distribution in the environment**

The biocidal product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* contains two active substances: 15% w/w of boric acid and 5% w/w disodium tetraborate and is dissolved with water to final concentration of 20% which contains 3% w/w of boric acid and 1% w/w of disodium tetraborate

Biocidal product contain also one substance of concern – quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides (CAS 85409-22-9), trade name *Barquat MS 100*, classified and labelled under CLP regulation 1272/2008. The *Barquat MS 100* concentration in the product is very low (0.66%) and does not affect on overall classification of product. Therefore only active substances are considered as of concern for environment and the risk characterisation can be performed only for these substances. Data necessary to assess risk for these substances were derived from the Competent Authority Report for boric acid and disodium tetraborate.

The characteristics of active substances including lists of endpoints are available in Competent Authority Reports for boric acid and disodium tetraborate. Applicant confirmed access to those data by the Letter of Access for boric acid and disodium tetraborate.

### **2.8.2 Emission to environmental compartments**

The product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is intended to used in UC1 and UC2. No emission scenarios are available for these Use Classes, since the potential risk from treated wood to the outer environment is considered negligible. Therefore, there is no necessity to assess the environmental risk.

In the case of application and storage of treated wood prior to shipment, the Annex I inclusion directives for both boric acid<sup>5</sup> and disodium tetraborate<sup>6</sup> include the following specific provision:

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

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<sup>5</sup> Commission Directive 2009/94/EC

<sup>6</sup> Commission Directive 2009/91/EC

Since for UC1 and UC2 the potential emission to the environment from treated wood in service is considered negligible and losses from storage of treated wood must be prevented, treatment process is the only phase considered in estimation of emission.

Emission, fate and behaviour in the environment were considered jointly for boric acid and disodium tetraborate because disodium tetraborate are converted into boric acid/borate upon dissolution in water. The same way as in Competent Authority Reports for active substances it is assumed that boric acid will be the predominant species in environmental compartments. Predicted Environmental Concentrations of active substances in environmental compartments (PEC's) were converted to boron concentration (for further explanation see Document IIB). These values were compared to Predicted No Effect Concentrations (PNEC's) derived from Competent Authority Reports for boric acid and disodium tetraborate. PNEC's values for both active substances were also expressed as concentration of boron.

It has to be noted that boron is present in natural environments. Therefore the PEC's and PNEC's mentioned in this document are  $PEC_{add}$ 's and  $PNEC_{add}$ 's, added concentrations on top of the background concentration, due to emission of boric acid to the environment.

In penetrating methods retention 2.5 kg of concentrate/m<sup>3</sup> prevents the attack of rotting destroying fungi. The application rate 5kg/m<sup>3</sup> (25 kg/m<sup>3</sup> 20% water solution) is effective for prevention of softwood against the fungi and insects together. Therefore application rate 5kg/m<sup>3</sup> was used to calculate the emission.

Application rates for product containing boron compounds are expressed as boron equivalents. Application rate 185 g of boron per m<sup>3</sup> of wood was used to calculate the emission.

According to declaration of Applicant biocidal product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is a fire retardant. This is not evaluated by Polish Competent Authority because it is not biocidal activity. However for sake of completeness the highest declared by Applicant application rate (40 kg of product per m<sup>3</sup> of wood) was considered in assessment. Application rate 1480 g of boron per m<sup>3</sup> of wood was also used to calculate the emission. Moreover according to Applicant declaration only vacuum treatment is used to protect wood against fire. Therefore additional application rate is considered only in emission estimation during vacuum treatment.

There are no available scenarios for industrial painting/brushing. According to calculation performed by Polish Competent Authority emission during professional application is not

higher than during automated processes. Exposure estimation for vacuum and dipping treatment covers emission for painting/brushing.

## 2.8.3 Environmental risk assessment

### 2.8.3.1 Aquatic compartment

#### 2.8.3.1.1 Surface water and sediment

According to the *ESD* industrial application of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* leads to exposure of surface water (for further explanation see Document IIB). Therefore risk must be estimated for this compartment.

A  $PNEC_{add, water}$  of 180  $\mu\text{g B/L}$  was derived from Competent Authority Reports for boric acid and disodium tetraborate. This value is compared with values of  $PEC_{add, water}$  to estimate risk for surface waters.

**Table 2.10  $PEC_{add, water}/PNEC_{add, water}$  ratio for surface water and sediment**

	$PEC_{add, water}$ [ $\mu\text{g B/L}$ ]	$PNEC_{add, water}$ [ $\mu\text{g B/L}$ ]	$PEC/PNEC$
<b>Vacuum pressure</b>	8.3	180	0.046
<b>Vacuum pressure (fire retardant)</b>	66.4	180	0.369
<b>Automated dipping</b>	27.7	180	0.154

$PEC_{add, water}/PNEC_{add, water}$  ratios for surface water associated with industrial application of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* are  $< 1$  for all scenarios and application rates. Therefore, no aquatic risks are expected.

No  $PEC_{add, sediment}/PNEC_{add, sediment}$  values have been determined because the Polish Competent Authority has concluded that boron does not pose any significant threat to the sediment compartment. Boron has a low adsorption potential. Therefore this atom remains predominantly in the water phase and does not adsorb to sediment. Risk assessment for the sediment compartment is not needed, risk assessment for the aquatic compartment should sufficiently cover any sediment dwelling organisms as the route of exposure will be predominantly aquatic. Therefore, taking into consideration risk assessment for surface water, the Polish Competent Authority has concluded that the proposed use patterns would not result in an unacceptable risk to the sediment compartment.

**2.8.3.1.2 Sewage treatment plant**

A  $PEC_{add,STP}$  of 1.8 mg B/L was derived from Competent Authority Reports for boric acid and disodium tetraborate. This value is compared with values of  $PEC_{add,STP}$  to estimate risk for STP.

**Table 2.11  $PEC_{add,STP}/PNEC_{add,STP}$  ratio for sewage treatment plant**

	$PEC_{add,STP}$ [ $\mu\text{g B/L}$ ]	$PNEC_{add,STP}$ [mg B/L]	PEC/PNEC
Vacuum pressure	83	1.8	0.046
Vacuum pressure (fire retardant)	664	1.8	0.369
Automated dipping	277	1.8	0.154

$PEC_{add,STP}/PNEC_{add,STP}$  ratios for sewage treatment plant associated with industrial application of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* are  $< 1$  for all scenarios and application rates. Therefore, no risk for STP is expected.

**2.8.3.2 Atmosphere**

Due to the low volatility of the inorganic borates, emission to air is very low. Therefore estimation of risk for atmosphere is considered to be not necessary.

**2.8.3.3 Terrestrial compartment**

*Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* is intended to be applied by industrial application processes vacuum, dipping and painting/brushing. According to ESD proposed application method and use of the biocidal product and taking into consideration fate and behavior of boric acid there is no potential exposure of terrestrial compartment and risk for soil.

**2.8.3.4 Groundwater**

According to Annex I, part B of the Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, there is a limit value for boron (as a representative for boric acid and tetraborates) is 1 mg B /l.

According to proposed use the biocidal product, *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*, there is no potential exposure, therefore consideration of risk for groundwater is not necessary.

#### **2.8.4 Non compartment specific effects relevant to the food chain (secondary poisoning)**

Boron is an essential micronutrient for all plants and is applied as an agricultural fertiliser. Borates are therefore part of an everyday diet of fresh fruit and vegetables. While boron may accumulate in plants and some animals relative to their immediate environment, there is evidence from field studies that boron is not bioconcentrated or bioaccumulated along the food chain (for further explanation please see Competent Authority Reports for boric acid and disodium tetraborate).

## 2.9 Measures to protect man, animals and the environment

Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying the following appropriate and available risk mitigation measures:

1. Authorisation is granted for Use Class 1 (wood or wood-based product under cover and fully protected from the weather, not exposed to wetting) and Use Class 2 (wood or wood-based product under cover and fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting).
2. Treated timber must not be permanently exposed to weather or used in external situations where it is in contact with the ground or in permanent contact with fresh or salt water.
3. The preserved wood must be used only indoor or outdoor under cover and fully protected from the weather.
4. Preserved wood must be protected from leaching until the roofing.
5. Always read the label before use and follow the instructions provided.
6. Avoid contact with skin and eyes.
7. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
8. After contact with skin wash immediately with plenty of water.
9. Avoid contact with clothing. Take off dirty cloth immediately.
10. Contaminated gloves should be cleaned or disposed. Do not allow that water used for cleaning gloves get into the soil, surface water or sanitary sewer system.
11. In the case of application by painting/brushing suitable personal protective equipment (coveralls, gloves, foot protection, eye protection glasses and respiratory protective equipment) are recommended when applying the product and when handling freshly treated timber. Avoid excessive contamination of protective equipment.



12. In the case of application techniques as vacuum pressure impregnation, dipping and automated dipping suitable personal protective equipment (coveralls, gloves, foot protection, eye protection glasses and respiratory protective equipment) are required when applying the product and when handling freshly treated timber. Avoid excessive contamination of protective equipment.
13. In case of accident (e.g. if swallowed) or if you feel unwell seek medical advice immediately (show packaging and the label).
14. Wash hands and exposed skin before meals, drinking, smoking and after use.
15. Do not mix with other products.
16. The working area should be ventilated adequately by natural or mechanical means.
17. Freshly treated wood should be stored in areas with good ventilation.
18. The treated wood is not placed on the market until it is dry.
19. Eating, drinking and smoking should be prohibited in areas where this product is handled, stored and processed.
20. Do not use for wood in direct contact with food, feeding stuffs and drinking water.
21. Biocidal product should not be used and stored where food, feeding stuffs or drinking water could be contaminated.
22. Do not contaminate ground, waterbodies or watercourses with biocidal product or used container.
23. Avoid release to the environment. Refer to special instructions/safety data sheet.
24. Avoid contamination of soil, surface water or sanitary sewer system from product or packaging the product.
25. In case of accidental release of product into the environment, it should be collected with non-combustible, absorbent material e.g. sand, earth, vermiculite and place in labeled and colder container for disposal and deliver to authorised company which are empowered to utilization of hazardous wastes and their disposal. During collect avoid direct contact with the skin.

26. Do not empty into drains.
27. If the product contaminates lakes, rivers, or sewers, inform the appropriate authorities in accordance with local regulations.
28. Product contains substances potentially dangerous to bat.
29. Product should be stored in original, labelled and closed containers in cool, dry and well-ventilated area.
30. Keep in a safe place.
31. Keep out of the reach of children.
32. Containers that have been opened should be tightly closed and stored in vertical position.
33. This material and its container must be disposed of in a safe way
34. Packaging of the product, any contaminated materials (i.e. water used for cleaning of contaminated surface, protection foil, cleaning solvents), unused product, the remains of the product after use (closed in a labeled container) and the out-of-service treated wood must be treated as hazardous waste and delivered to authorised company which are empowered to utilization of hazardous wastes and their disposal.
35. Package cannot be reused and be used for any other purpose.
36. Application processes must be carried out within a contained area, situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump). Any leachates collect for reuse or recycling.
37. Freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing with bunding and a recovery system in place (e.g. sump) to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

### 3 Proposal for decision

#### 1. Product Formulation

Active substance content	% w/w	Manufacturer of active substance
Boric acid	15	please referee to PAR section: <i>Manufacturer of active substance used in the biocidal product</i>
Disodium tetraborate	5	

<b>2. Formulation type</b>	powder
<b>3. Product type</b>	PT8
<b>4. User</b>	<ul style="list-style-type: none"> <li>▪ professional</li> <li>▪ industrial</li> </ul>
<b>5. Packaging</b>	please see to section 2.2.3
<b>6. Application</b>	<ul style="list-style-type: none"> <li>▪ painting/brushing</li> <li>▪ dipping</li> <li>▪ vacuum pressure</li> </ul>
<b>7. Application Rate</b>	<ul style="list-style-type: none"> <li>▪ superficial treatment               <ul style="list-style-type: none"> <li>– 500 g/m<sup>2</sup> of 20% working solution (100 g/m<sup>2</sup> of concentrate)</li> </ul> </li> <li>▪ penetrating treatment               <ul style="list-style-type: none"> <li>– 25 kg/m<sup>3</sup> of 20% working solution (5 kg/m<sup>3</sup> of concentrate).</li> </ul> </li> </ul> <p>These doses are effective for prevention of against the wood rooting fungi and wood boring insects together</p>
<b>8. Organism controlled</b>	<ul style="list-style-type: none"> <li>▪ Wood destroying basidiomycetes:               <ul style="list-style-type: none"> <li>- <i>Coniophora puteana</i>,</li> <li>- <i>Gloeophyllum trabeum</i>,</li> <li>- <i>Poria placenta</i></li> </ul> </li> <li>▪ Wood boring beetle:               <ul style="list-style-type: none"> <li>- <i>Hylotrupes bajulus</i>, larvae</li> </ul> </li> </ul>
<b>9. Shelf life</b>	up to 2 years
<b>10. Expiry data of the authorisation</b>	10 years after the date of authorisation granting
<b>11. Any other specific conditions:</b>	please see section 2.9.

**Annex 1: List of studies reviewed***List of new data submitted in support of the evaluation of the biocidal product*

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
IIIB	3.1.1 3.1.2 3.1.3 3.5 3.6 3.7 3.8 3.12	Al Amin Idris	2011	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT. Determination of physicochemical properties. Institute of Industrial Organic Chemistry, Warsaw Report No. EMC Nr 373800019, Study code No. BF-25/11,	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB		Al Amin Idris	2012	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT. Determination of wettability. Institute of Industrial Organic Chemistry, Warsaw Report No. EMC Nr 333200019, Study code No. BF-25/11,	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

*Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB	4.1	Drożdżewska Katarzyna	2011	Badania analityczne “Przeciwogniowego Impregnatu do drewna FIRESTOP Koncentrat” Instytut Przemysłu Organicznego, Warszawa Report No EMC Nr 373800023 Study code No BA-12/11	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB	5.10-01	Abram Alicja	2011	Wood Protector przeciwogniowy impregnat do drewna Firestop koncentrat Instytut Techniki Budowlanej, Warszawa, 2011 Test Report No LM 02-2265/10/Z00NM	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB	5.10-02	Abram Alicja	2011	Wood Protector przeciwogniowy impregnat do drewna Firestop koncentrat Instytut Techniki Budowlanej, Warszawa, 2011 Test Report No LM 01-2265/10/Z00NM	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT**

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
III-B	5.10-03	Fennert Eva-Maria, Doblinski M.	2010	Determination of the preventive action against recently hatched larvae of <i>Hylotrupes bajulus</i> (L.) according to EN 46-1 (2009) after evaporative ageing procedure according to EN 73 (1988). Wood Protector Firestop Koncentrat MPA Eberswalde, Test report No. 32/10/9443/02A	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
III-B	5.10-04	Fennert Eva-Maria, Doblinski M.	2010	Determination of the toxic values against recently hatched larvae of <i>Hylotrupes bajulus</i> (L.) according to EN 47 (06/2005) in combination with evaporative ageing procedure according to EN 73 (04/90) Wood Protector Firestop Koncentrat MPA Eberswalde, Test report No. 32/10/9443/03	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB	6.1.1	Kupny Joanna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Acute oral toxicity study – fixed dose method on rats according to the OECD Guideline No 420/EU Method B.1.BIS. Institute of Industrial Organic Chemistry Branch Pszczyna, Study code: PO-8/11,	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

*Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB	6.1.2	Kupny Joanna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Acute dermal toxicity study on rats according to the OECD Guideline No 402/EU Method B.3. Institute of Industrial Organic Chemistry Branch Pszczyna Study code: DER-8/11	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB	6.2.1-1	Gruszka Katarzyna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. <i>In vitro</i> skin corrosion: Transcutaneous electrical resistance test (TER) according to the OECD Guideline No 430/EU Method B.40. Institute of Industrial Organic Chemistry Branch Pszczyna Study code:OES-4/11	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB	6.2.1-2	Krupny Joanna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Acute skin irritation/corrosion study on rabbits according to the OECD Guideline No 404/EU Method B.4. Institute of Industrial Organic Chemistry Branch Pszczyna Study code: DDR-10/11,	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

*Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB	6.2.2-1	Gruszka Katarzyna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants according to the OECD Guideline No 438/EU Method B.48. Institute of Industrial Organic Chemistry Branch Pszczyna Study code: ICE-1/11	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB	6.2.2-2	Kupny Joanna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Acute eye irritation/corrosion study on rabbits according to the OECD Guideline No 405/EU Method B.5. Institute of Industrial Organic Chemistry Branch Pszczyna Study code:ODR-12/11	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IIIB	6.3	Kupny Joanna, Fochtman Przemysław	2012	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Skin sensitization study according to the OECD Guideline No 406/EU Method B.6. Institute of Industrial Organic Chemistry Branch Pszczyna Study code:Al-7/11	Dekspol P.P.H. Iwona Oleszak	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



**Annex 2: Analytical methods residues – active substance**

**< Boric acid >**  
**< Disodium tetraborate >**

No new data for the active substances residues was submitted. For detailed information please see the Competent Authority Reports for active substances boric acid and disodium tetraborate.

**Annex 3: Toxicology and metabolism –active substance**

<p style="text-align: center;"><b>&lt; Boric acid &gt;</b> <b>&lt; Disodium tetraborate &gt;</b></p>
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No new data for the active substances was submitted. For detailed information please see the Competent Authority Reports for active substances boric acid and disodium tetraborate.

**Annex 4: Toxicology – biocidal product****< Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT >****General information**

Formulation Type:	powder
Active substance(s) (incl. content)	15% boric acid, 5% disodium tetraborate
Category	PT 8 – wood preservatives

**Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)**

Rat LD <sub>50</sub> oral (OECD 420)	> 2 000 mg/kg b.w
Rat LD <sub>50</sub> dermal (OECD 402)	> 2 000 mg/kg b.w.
Rat LC <sub>50</sub> inhalation (OECD 403)	-
Skin irritation (OECD 404)	Non irritat
Eye irritation (OECD 405)	Non irritat
Skin sensitisation (OECD 429; LLNA)	Non sensitiser

**Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)**

Short-term toxicity studies	Not required
Toxicological data on active substance(s) (not tested with the preparation)	For detailed information please see the Competent Authority Reports for active substances boric acid and disodium tetraborate.
Toxicological data on non-active substance(s) (not tested with the preparation)	The biocidal product contains one substance of concern – quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides (CAS 85409-22-9), trade name <i>Barquat MS 100</i> , classified and labeled under CLP regulation 1272/2008. The <i>Barquat MS 100</i> concentration in the product is very low (0.66%) and does not affect on overall classification of product. Please see Doc.IIIB6.5 for details.
Further toxicological information	Not required

**Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)**

**Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT**

Directive 1999/45/EC	T- Toxic R60, R61
Regulation EC 1272/2008	Repr. 1B, H360FD

**Annex 5: Safety for professional operators**

< *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* >

See point 2.7.3.1 above

**Annex 6: Safety for non-professional operators and the general public**

*< Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT >*

Biocidal product is intended to only to professional and industrial users.

**Annex 7: Residue behaviour**

<p style="text-align: center;"><b>&lt; Boric acid &gt;</b> <b>&lt; Disodium tetraborate &gt;</b></p>
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No new data for the active substances was submitted. For detailed information please see the Competent Authority Reports for active substances boric acid and disodium tetraborate.

**Annex 8: Confidential information – ONLY FOR RMS INFORMATION, NOT FOR APPLICANT**

This part of the Product Assessment Report contains data submitted NOT by applicant.

Applicant did not submitted the access for certain value which was used in the calculation by Polish Competent Authority, therefore **information contained in this Annex are NOT intended for the applicant but for the Member States only.**