

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## H50V Lyse, RFID

Version	Revision Date:	SDS Number:	Date of last issue: -
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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : H50V Lyse, RFID

Product code : 1440110 H50V Lyse 200 mL, RFID 1440109 H50V Lyse 500 mL, RFID

Unique Formula Identifier (UFI) : 8300-UOKY-8006-8MJG

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : For Veterinary In Vitro Diagnostic Use

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : Boule Medical AB  
Domnarvsgatan 4  
163 53 Spånga

Telephone : +46 8 7447700

E-mail address of person responsible for the SDS : product-stewardship@boule.com

#### 1.4 Emergency telephone number

Access Code: 60262  
(Europe Non-Specific) +1 760 476 3962  
+351 800 250 250

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Cat-	H411: Toxic to aquatic life with long lasting effects.

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### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H360FD May damage fertility. May damage the unborn child.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.  
**Storage:**  
P405 Store locked up.

#### Hazardous components which must be listed on the label:

Boric acid  
Borax

#### Additional Labelling

EUH205 Contains epoxy constituents. May produce an allergic reaction.

Restricted to professional users.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Dodecyltrimethylammonium chloride	112-00-5 203-927-0 01-2120766653-46	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 1  Acute toxicity estimate  Acute oral toxicity: 681 mg/kg	$\geq 2,5 - < 10$
Boric acid	10043-35-3 233-139-2 005-007-00-2	Repr. 1B; H360FD	$\geq 0,3 - < 1$
Tetradonium bromide	1119-97-7 214-291-9	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 STOT SE 3; H336 STOT RE 2; H373 (Gastrointestinal tract) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1  Acute toxicity esti-	$\geq 0,25 - < 1$

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		mate	
		Acute oral toxicity: 390 mg/kg	
Borax	1303-96-4 005-011-01-1	Eye Irrit. 2; H319 Repr. 1B; H360FD	>= 0,1 - < 0,3

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : No information available.
- Risks : May damage fertility. May damage the unborn child.

#### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Not applicable  
Will not burn

Unsuitable extinguishing media : Not applicable  
Will not burn

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Nitrogen oxides (NOx)

#### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate contain-

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ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- |                         |   |  |
|-------------------------|---|--|
| Technical measures      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.  |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe vapours or spray mist.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures        | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.   |

### 7.2 Conditions for safe storage, including any incompatibilities

- |   |   |   |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage                      | : | Do not store with the following product types:<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases       |

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### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Boric acid	10043-35-3	VLE-MP (Inhalable fraction)	2 mg/m <sup>3</sup> (Borate)	PT OEL
	Further information: Substances that are not classified as carcinogenic for humans.			
		VLE_CD (Inhalable fraction)	6 mg/m <sup>3</sup> (Borate)	PT OEL
	Further information: Substances that are not classified as carcinogenic for humans.			
Borax	1303-96-4	VLE-MP (Inhalable fraction)	2 mg/m <sup>3</sup> (Borate)	PT OEL
	Further information: Substances that are not classified as carcinogenic for humans.			
		VLE_CD (Inhalable fraction)	6 mg/m <sup>3</sup> (Borate)	PT OEL
	Further information: Substances that are not classified as carcinogenic for humans.			

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Tetradonium bromide	Workers	Inhalation	Long-term local effects	0,05 mg/m <sup>3</sup>
	Workers	Inhalation	Acute local effects	0,05 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	0,4 mg/kg bw/day
	Workers	Skin contact	Long-term local effects	0,05 mg/cm <sup>2</sup>
	Workers	Skin contact	Acute local effects	0,25 mg/cm <sup>2</sup>
Boric acid	Workers	Inhalation	Long-term systemic effects	8,3 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	392 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	4,15 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	196 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,98 mg/kg bw/day
Borax	Workers	Inhalation	Long-term systemic	6,7 mg/m <sup>3</sup>

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			effects	
	Workers	Inhalation	Long-term local effects	11,7 mg/m3
	Workers	Inhalation	Acute local effects	11,7 mg/m3
	Workers	Skin contact	Long-term systemic effects	316,4 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	3,4 mg/m3
	Consumers	Inhalation	Long-term local effects	11,7 mg/m3
	Consumers	Inhalation	Acute local effects	11,7 mg/m3
	Consumers	Skin contact	Long-term systemic effects	159,5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,79 mg/kg bw/day
	Consumers	Ingestion	Acute local effects	0,79 mg/kg bw/day

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Tetradonium bromide	Fresh water	0,026 µg/l
	Freshwater - intermittent	0,54 µg/l
	Marine water	0,003 µg/l
	Sewage treatment plant	0,19 mg/l
Boric acid	Fresh water	2,9 mg/l
	Freshwater - intermittent	13,7 mg/l
	Marine water	2,9 mg/l
	Sewage treatment plant	10 mg/l
	Soil	5,7 mg/kg dry weight (d.w.)
Borax	Fresh water	2,02 mg/l
	Marine water	2,02 mg/l
	Intermittent use/release	13,7 mg/l
	Sewage treatment plant	10 mg/l
	Soil	5,4 mg/kg

## 8.2 Exposure controls

### Engineering measures

Minimize workplace exposure concentrations.  
If sufficient ventilation is unavailable, use with local exhaust ventilation.

### Personal protective equipment

Eye/face protection : Wear the following personal protective equipment:  
Safety glasses  
Equipment should conform to NP EN 166

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub-

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stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to NP EN 143

Filter type : Particulates type (P)

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	: liquid
Form	: liquid
Colour	: transparent
Odour	: odourless
Odour Threshold	: No data available
Melting point/freezing point	: 0 °C
Initial boiling point and boiling range	: 100 °C
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: Will not burn
Upper explosion limit / Upper flammability limit	: No data available

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Lower explosion limit / Lower flammability limit : No data available

Flash point : boils before flash

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 2,20 - 3,20  
Concentration: 100 %

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : completely soluble

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : 0,1 hPa

Relative density : No data available

Density : 1,004 g/cm<sup>3</sup>

Relative vapour density : 1,004

Particle characteristics  
Particle size : Not applicable

### 9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

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Evaporation rate : No data available

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### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : None known.

#### 10.4 Conditions to avoid

Conditions to avoid : None known.

#### 10.5 Incompatible materials

Materials to avoid : None.

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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### SECTION 11: Toxicological information

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg  
Method: Calculation method

#### Components:

#### Dodecyltrimethylammonium chloride:

Acute oral toxicity : LD50 (Rat, female): 681 mg/kg  
Method: OECD Test Guideline 401  
Remarks: The test was conducted equivalent or similar to guideline

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### **Boric acid:**

Acute oral toxicity : LD50 (Rat): 3.450 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 2,03 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

### **Tetradonium bromide:**

Acute oral toxicity : LD50 (Rat): 390 mg/kg  
Method: OECD Test Guideline 401  
Remarks: The test was conducted equivalent or similar to guideline

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg  
Remarks: Based on data from similar materials

### **Borax:**

Acute oral toxicity : LD50 (Rat): 3.450 - 4.080 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 2,03 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **Dodecyltrimethylammonium chloride:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Skin irritation  
Remarks : The test was conducted according to guideline

#### **Boric acid:**

Species : Rabbit  
Result : No skin irritation

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### **Tetradonium bromide:**

Species : Rabbit  
Result : Skin irritation

### **Borax:**

Species : Rabbit  
Result : No skin irritation

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Components:**

#### **Dodecyltrimethylammonium chloride:**

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irritation to eyes, reversing within 21 days  
Remarks : The test was conducted according to guideline

#### **Boric acid:**

Species : Rabbit  
Result : No eye irritation

#### **Tetradonium bromide:**

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irreversible effects on the eye  
Remarks : The test was conducted according to guideline  
Based on data from similar materials

#### **Borax:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

### **Components:**

#### **Dodecyltrimethylammonium chloride:**

Test Type : Direct Peptide Reactivity Assay (DPRA)  
Method : OECD Test Guideline 442C  
Result : negative  
Remarks : The test was conducted according to guideline

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Test Type : KeratinoSens assay  
Method : OECD Test Guideline 442D  
Result : negative  
Remarks : The test was conducted according to guideline

### **Boric acid:**

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

### **Tetradonium bromide:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : The test was conducted according to guideline  
Based on data from similar materials

### **Borax:**

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **Dodecyltrimethylammonium chloride:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

### **Boric acid:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

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Test Type: In vitro mammalian cell gene mutation test  
Result: equivocal

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### **Tetradonium bromide:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

### **Borax:**

Genotoxicity in vitro : Test Type: In vitro sister chromatid exchange assay in mammalian cells  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Boric acid:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 103 weeks  
Result : negative

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### **Borax:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative  
Remarks : Based on data from similar materials

### **Reproductive toxicity**

May damage fertility. May damage the unborn child.

### **Components:**

#### **Dodecyltrimethylammonium chloride:**

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Ingestion  
Result: negative

#### **Boric acid:**

Effects on fertility : Test Type: Three-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: positive

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Ingestion  
Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

#### **Tetradonium bromide:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

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### **Borax:**

- Effects on fertility : Test Type: Three-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: positive
- Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: positive
- Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments., Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.

### **STOT - single exposure**

Not classified based on available information.

#### **Components:**

##### **Tetradonium bromide:**

- Assessment : May cause drowsiness or dizziness.  
Remarks : Based on data from similar materials

### **STOT - repeated exposure**

Not classified based on available information.

#### **Components:**

##### **Tetradonium bromide:**

- Target Organs : Gastrointestinal tract  
Assessment : Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.
- Exposure routes : Ingestion  
Target Organs : Gastrointestinal tract  
Assessment : Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

### **Repeated dose toxicity**

#### **Components:**

##### **Dodecyltrimethylammonium chloride:**

- Species : Rat  
LOAEL : > 25 mg/kg  
Application Route : Ingestion  
Exposure time : 1 yr  
Remarks : No test guideline followed  
Based on data from similar materials

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### **Boric acid:**

Species	: Rat
NOAEL	: 100 mg/kg
LOAEL	: 334 mg/kg
Application Route	: Ingestion
Exposure time	: 2 yr

### **Tetradonium bromide:**

Species	: Rat
NOAEL	: > 30 - 300 mg/kg
Application Route	: Skin contact
Exposure time	: 28 Days
Method	: Regulation (EC) No. 440/2008, Annex, B.7
Remarks	: The test was conducted according to guideline Based on data from similar materials

### **Borax:**

Species	: Rat
NOAEL	: 100 mg/kg
LOAEL	: 334 mg/kg
Application Route	: Ingestion
Exposure time	: 2 yr

### **Aspiration toxicity**

Not classified based on available information.

## **11.2 Information on other hazards**

### **Endocrine disrupting properties**

Not classified based on available information.

### **Product:**

Assessment	: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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## **SECTION 12: Ecological information**

### **12.1 Toxicity**

#### **Components:**

##### **Dodecyltrimethylammonium chloride:**

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,1 - 1 mg/l Exposure time: 96 h
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Method: OECD Test Guideline 203

Remarks: The test was conducted equivalent or similar to guideline

Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,46 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Scenedesmus capricornutum (fresh water algae)): 0,036 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline

NOEC (Scenedesmus capricornutum (fresh water algae)): 0,01 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: The test was conducted according to guideline

M-Factor (Acute aquatic toxicity) : 10

Toxicity to microorganisms : EC50 (activated sludge): > 10 - 100 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1

### **Boric acid:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 74 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 102 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 52,4 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 17,5 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 : 35,4 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

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Toxicity to fish (Chronic toxicity) : NOEC: 6,4 mg/l  
Exposure time: 34 d  
Species: Danio rerio (zebra fish)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 10,8 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)

### **Tetradonium bromide:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 1,81 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: The test was conducted according to guideline

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 22 µg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic plants : EC10 (Raphidocelis subcapitata (freshwater green alga)): 2,16 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline

ErC50 (Raphidocelis subcapitata (freshwater green alga)): 5,38 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline

M-Factor (Acute aquatic toxicity) : 100

Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): 0,28 mg/l  
Exposure time: 30 min

M-Factor (Chronic aquatic toxicity) : 1

### **Borax:**

Toxicity to fish : LC50 (Oncorhynchus kisutch (coho salmon)): 447 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 133 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : NOEC (Dunaliella tertiolecta (marine algae)): 50 mg/l  
Exposure time: 10 d

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Toxicity to microorganisms : EC50 : > 175 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 13 mg/l  
Exposure time: 96 d  
Species: Danio rerio (zebra fish)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 18 mg/l  
Exposure time: 14 d  
Species: Daphnia magna (Water flea)

### 12.2 Persistence and degradability

#### Components:

##### **Dodecyltrimethylammonium chloride:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 64,5 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B  
Remarks: The test was conducted equivalent or similar to guideline

##### **Tetradonium bromide:**

Biodegradability : Result: Readily biodegradable.  
Remarks: Based on data from similar materials

### 12.3 Bioaccumulative potential

#### Components:

##### **Dodecyltrimethylammonium chloride:**

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)  
Bioconcentration factor (BCF): < 500  
Remarks: No test guideline followed  
Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: 1,22  
Remarks: Calculation

##### **Boric acid:**

Bioaccumulation : Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): <= 3,2  
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: -1,09

##### **Tetradonium bromide:**

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Partition coefficient: n-octanol/water : log Pow: 2,2  
Remarks: Calculation

### **Borax:**

Partition coefficient: n-octanol/water : log Pow: -1,53

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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## SECTION 14: Transport information

### 14.1 UN number or ID number

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**ADN** : UN 3082  
**ADR** : UN 3082  
**RID** : UN 3082  
**IMDG** : UN 3082  
**IATA** : UN 3082

### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Dodecyltrimethylammonium chloride, Tetradonium bromide)  
**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Dodecyltrimethylammonium chloride, Tetradonium bromide)  
**RID** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Dodecyltrimethylammonium chloride, Tetradonium bromide)  
**IMDG** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Dodecyltrimethylammonium chloride, Tetradonium bromide)  
**IATA** : Environmentally hazardous substance, liquid, n.o.s.  
(Dodecyltrimethylammonium chloride, Tetradonium bromide)

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	: 9	
<b>ADR</b>	: 9	
<b>RID</b>	: 9	
<b>IMDG</b>	: 9	
<b>IATA</b>	: 9	

### 14.4 Packing group

**ADN**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9  
**ADR**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9  
Tunnel restriction code : (-)

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### RID

Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

### IMDG

Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

### IATA (Cargo)

Packing instruction (cargo aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

## 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

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### SECTION 15: Regulatory information

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 3  
  
Number on list 30: Boric acid  
  
Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.  
  
Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.
- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Boric acid  
Borax
- Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable
- Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
- Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
- REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national

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regulations, where applicable.

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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## SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

### Full text of H-Statements

H302 : Harmful if swallowed.  
H315 : Causes skin irritation.  
H318 : Causes serious eye damage.  
H319 : Causes serious eye irritation.  
H336 : May cause drowsiness or dizziness.  
H360FD : May damage fertility. May damage the unborn child.  
H373 : May cause damage to organs through prolonged or repeated exposure.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Aquatic Acute : Short-term (acute) aquatic hazard  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Eye Dam. : Serious eye damage  
Eye Irrit. : Eye irritation  
Repr. : Reproductive toxicity  
Skin Irrit. : Skin irritation  
STOT RE : Specific target organ toxicity - repeated exposure  
STOT SE : Specific target organ toxicity - single exposure  
PT OEL : Portugal. Security and Health at the Workplace - Occupational exposure limits of chemical agents  
PT OEL / VLE-MP : Time Weighted Average  
PT OEL / VLE\_CD : Short Term Exposure Limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonised System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships car-

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rying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Repr. 1B	H360FD
Aquatic Acute 1	H400
Aquatic Chronic 2	H411

### Classification procedure:

Calculation method
Calculation method
Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

PT / EN