

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: -
1.0	03.12.2025	11604509-00001	Date of first issue: 03.12.2025

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 Substance/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

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.

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Long-term (chronic) aquatic hazard, Category 2 H411: Toxic to aquatic life with long lasting effects.

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.

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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	$\geq 0,25 - < 1$

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		Acute toxicity estimate	
		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.

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.

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.
Do not breathe vapours or spray mist.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
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:
Self-reactive substances and mixtures
Organic peroxides
Explosives
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
Borax	1303-96-4	NDS (inhalable fraction)	0,5 mg/m ³	PL OEL
		NDSch (inhalable fraction)	2 mg/m ³	PL OEL

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 ³	
	Workers	Inhalation	Acute local effects	0,05 mg/m ³	
	Workers	Skin contact	Long-term systemic effects	0,4 mg/kg bw/day	
	Workers	Skin contact	Long-term local effects	0,05 mg/cm ²	
	Workers	Skin contact	Acute local effects	0,25 mg/cm ²	
Boric acid	Workers	Inhalation	Long-term systemic effects	8,3 mg/m ³	
	Workers	Skin contact	Long-term systemic effects	392 mg/kg bw/day	
	Consumers	Inhalation	Long-term systemic effects	4,15 mg/m ³	
	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 effects	6,7 mg/m ³
		Workers	Inhalation	Long-term local effects	11,7 mg/m ³
Workers		Inhalation	Acute local effects	11,7 mg/m ³	
Workers		Skin contact	Long-term systemic effects	316,4 mg/kg bw/day	
Consumers		Inhalation	Long-term systemic effects	3,4 mg/m ³	
Consumers		Inhalation	Long-term local effects	11,7 mg/m ³	
Consumers		Inhalation	Acute local effects	11,7 mg/m ³	
Consumers		Skin contact	Long-term systemic	159,5 mg/kg	

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			effects	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
Borax	Soil	5,7 mg/kg dry weight (d.w.)
	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 PN 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 substance 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).

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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 PN EN 143

Filter type : Particulates type (P)

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

Lower explosion limit / Lower flammability limit : No data available

Flash point : boils before flash

Auto-ignition temperature : No data available

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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/cm³

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.

Evaporation rate : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

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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.

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

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

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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

Tetradonium bromide:

Species : Rabbit
Result : Skin irritation

Borax:

Species : Rabbit
Result : No skin irritation

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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

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

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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 syn-
thesis in mammalian cells (in vitro)
Result: negative

Boric acid:

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

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)

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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 mam-
malian 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

Borax:

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

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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

Borax:

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

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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

Boric acid:

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

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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 Method: OECD Test Guideline 203 Remarks: The test was conducted equivalent or similar to guideline Based on data from similar materials
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Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0,46 mg/l Exposure time: 48 h
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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

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) : NOEC: 10,8 mg/l
Exposure time: 21 d

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ic toxicity) 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

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)

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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:

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

Borax:

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

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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

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.

SECTION 14: Transport information

14.1 UN number or ID number

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

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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
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 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 : (-)

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

IMDG
Packing group : III
Labels : 9

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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.

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

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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 regulations, where applicable.

Act of February 25, 2011 on chemical substances and their mixtures (i.e. Journal of Laws of 2020, item 2289)

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Official Journal of the European Union L 353 from 31.12.2008) with further adaptation to technical progress (ATP).

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and

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repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union L 396 from 30.12.2006, as amended).

Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Ordinance of the Minister of Family, Labour and Social Policy of 12 June 2018 concerning the highest allowable concentrations and levels of the agents harmful for health in the workplace (Dz.U 2018 pos 1286, with later amendments).

Ordinance of the Minister of Health of 2nd February 2011 concerning tests and measurement of agents harmful for health in the workplace (Dz. U. Nr. 33, item 166 with later amendments).

Ordinance of the Minister of Health of 30th December 2004 on the health and safety of workers related to chemical agents at work (consolidated text, Journal of Laws 2016 no. 0 item 1488)

Act of 14 December 2012. on Waste (Journal of Laws of 2013. pos. 21, as amended).

Act of 13 June 2013. On packaging and packaging waste (Journal. U. of 2013. Item. 888, as amended).

Ordinance of the Minister of Climate of 2nd January 2020 on Waste Catalog (Dz. U. 2020 item 10).

Ordinance of the Minister of Environment on the requirements for carrying out the process of thermal treatment of waste and how to deal with waste produced in the process. (Dz. U. of 2016., Pos. 108)

Act of 19 August 2011 on transport of dangerous goods (Dz. U. Nr. 227, item 1367, as amended).

Government Statement of February 15, 2021 on the entry into force of amendments to Annexes A and B to Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), drawn up in Geneva on September 30, 1957 (Journal of Laws 202 poz.874 as amended)

Act of July 29, 2005 on drug addiction prevention (Journal of Laws of 2005, No. 179, item 1485, with later amendments)

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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.

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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
PL OEL : Ordinance of the Minister of Family, Labour and Social Policy
of 12 June 2018 concerning the highest allowable concentra-
tions and levels of the agents harmful for health in the work-
place (Dz.U 2018 pos 1286, with later amendments)
PL OEL / NDS : Maximal Admissible Concentration
PL OEL / NDSch : Maximal Admissible Temporary Concentration

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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 carrying 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

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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.

PL / EN