

# Safety data sheet

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



## ROTIPHORESE® 5x TBE Buffer

article number: **1L9K**

Version: **3.0 en**

Replaces version of: 01.04.2022

Version: (2)

date of compilation: 10.08.2021

Revision: 21.09.2024

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Identification of the substance **ROTIPHORESE® 5x TBE Buffer**  
Article number 1L9K  
Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory and analytical use  
Laboratory chemical  
Uses advised against: Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household). Food, drink and animal feeding-stuffs.

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

Carl Roth GmbH + Co. KG  
Schoemperlenstr. 3-5  
D-76185 Karlsruhe  
Germany

**Telephone:**+49 (0) 721 - 56 06 0

**Telefax:** +49 (0) 721 - 56 06 149

**e-mail:** sicherheit@carlroth.de

**Website:** www.carlroth.de

Competent person responsible for the safety data sheet: Department Health, Safety and Environment

**e-mail (competent person):** sicherheit@carlroth.de

### 1.4 Emergency telephone number

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.7	Reproductive toxicity	1B	Repr. 1B	H360FD

For full text of abbreviations: see SECTION 16

### 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

**Signal word** Danger

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### Pictograms

GHS08



### Hazard statements

H360FD May damage fertility. May damage the unborn child

### Precautionary statements

#### Precautionary statements - prevention

P280 Wear protective gloves

#### Precautionary statements - response

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

For professional users only

**Hazardous ingredients for labelling:** Boric acid

#### Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Hazard pictogram(s):



H360FD May damage fertility. May damage the unborn child.

P280 Wear protective gloves.  
P308+P313 IF exposed or concerned: Get medical advice/attention.

contains: Boric acid

#### Labelling of packages where the contents do not exceed 10 ml

Signal word: Not required

Hazard pictogram(s):



Hazard statements: Not required

Precautionary statements: Not required

### 2.3 Other hazards

#### Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of  $\geq 0,1\%$ .

#### Endocrine disrupting properties

Contains an endocrine disruptor (ED) at a concentration of  $\geq 0,1\%$ .

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

not relevant (mixture)

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### 3.2 Mixtures

#### Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
TRIS	CAS No 77-86-1  EC No 201-064-4  REACH Reg. No 01-2119957659- 16-xxxx	5 – < 10			
Boric acid	CAS No 10043-35-3  EC No 233-139-2  Index No 005-007-00-2  REACH Reg. No 01-2119486683- 25-xxxx	2 – < 5	Repr. 1B / H360FD		11 GHS-HC
Ethylenediamine tetraacetic acid disodium salt dihydrate	CAS No 6381-92-6  EC No 205-358-3  REACH Reg. No 01-2119486775- 20-xxxx	< 1	Acute Tox. 4 / H332 STOT RE 2 / H373	 	

#### Notes

11: The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual boron compounds that are classified as reproductive toxicant in the mixture as placed on the market is  $\geq 0,3\%$ .

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/2008/EC, Annex VI)

Name of substance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Ethylenediamine tetraacetic acid disodium salt dihydrate	CAS No 6381-92-6  EC No 205-358-3	-	-	>1 mg//4h	inhalation: dust/mist

#### Substance of Very High Concern (SVHC)

Name of substance	Name acc. to inventory	CAS No	EC No	Listed in	Remarks
Boric acid	boric acid	10043-35-3	233-139-2	Candidate list	Repr. A57c

#### Legend

Candidate list Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV list

Repr. A57c Toxic for reproduction (article 57c)

#### Remarks

For full text of abbreviations: see SECTION 16

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### SECTION 4: First aid measures

#### 4.1 Description of first aid measures



##### General notes

Take off contaminated clothing.

##### Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

##### Following skin contact

Rinse skin with water/shower.

##### Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

##### Following ingestion

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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

Adverse effects on fertility

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

none

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media



##### Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings!  
water spray, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO<sub>2</sub>)

##### Unsuitable extinguishing media

water jet

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

Ingredients of the mixture combustible. The product itself does not burn.

##### Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NO<sub>x</sub>), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

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### SECTION 6: Accidental release measures

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



##### For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe vapour/spray.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

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

##### Advice on how to contain a spill

Covering of drains.

##### Advice on how to clean up a spill

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

##### Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Avoid exposure.

##### Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

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

Keep container tightly closed.

##### Incompatible substances or mixtures

Observe hints for combined storage. Incompatible materials: see section 10.

##### Consideration of other advice:

##### Specific designs for storage rooms or vessels

Recommended storage temperature: 15 – 25 °C

#### 7.3 Specific end use(s)

No information available.

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### National limit values

##### Occupational exposure limit values (Workplace Exposure Limits)

This information is not available.

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Relevant DNELs of components						
Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
TRIS	77-86-1	DNEL	117,5 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects
TRIS	77-86-1	DNEL	166,7 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Boric acid	10043-35-3	DNEL	8,3 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects
Boric acid	10043-35-3	DNEL	392 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	DNEL	1,5 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	DNEL	3 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	acute - local effects

Relevant PNECs of components						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
TRIS	77-86-1	PNEC	300 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Boric acid	10043-35-3	PNEC	2,9 mg/l	aquatic organisms	freshwater	short-term (single instance)
Boric acid	10043-35-3	PNEC	2,9 mg/l	aquatic organisms	marine water	short-term (single instance)
Boric acid	10043-35-3	PNEC	10 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Boric acid	10043-35-3	PNEC	5,7 mg/kg	terrestrial organisms	soil	short-term (single instance)
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	PNEC	2,2 mg/l	aquatic organisms	freshwater	short-term (single instance)
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	PNEC	0,22 mg/l	aquatic organisms	marine water	short-term (single instance)
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	PNEC	43 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)

## 8.2 Exposure controls

### Individual protection measures (personal protective equipment)

#### Eye/face protection



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Use safety goggles with side protection.

### Skin protection



#### • hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 °C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

#### • type of material

NBR (Nitrile rubber)

#### • material thickness

>0,11 mm

#### • breakthrough times of the glove material

>480 minutes (permeation: level 6)

#### • other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

### Respiratory protection



Respiratory protection necessary at: Aerosol or mist formation. Type: A-P2 (combined filters against particles and organic gases and vapours, colour code: Brown/White). Usually no personal respiratory protection necessary.

### Environmental exposure controls

Keep away from drains, surface and ground water.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	clear - colourless
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	100 °C at 1.013 hPa
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined

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Decomposition temperature	not relevant
pH (value)	8,2 – 8,5 (20 °C)
Kinematic viscosity	not determined
<u>Solubility(ies)</u>	
Water solubility	miscible in any proportion
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	this information is not available
Vapour pressure	23 hPa at 20 °C
<u>Density and/or relative density</u>	
Density	1,031 g/cm <sup>3</sup> at 20 °C
Relative vapour density	Information on this property is not available.
Particle characteristics	not relevant (liquid)
<u>Other safety parameters</u>	
Oxidising properties	none
<b>9.2 Other information</b>	
Information with regard to physical hazard classes:	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics:	
Miscibility	completely miscible with water

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

### 10.5 Incompatible materials

There is no additional information.

### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

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### SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

##### Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

##### Classification according to GHS (1272/2008/EC, CLP)

##### Acute toxicity

Shall not be classified as acutely toxic.

##### Acute toxicity estimate (ATE) of components

Name of substance	CAS No	Exposure route	ATE
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	inhalation: dust/mist	>1 mg/l/4h

##### Acute toxicity of components

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
TRIS	77-86-1	oral	LD50	>5.000 mg/kg	rat
TRIS	77-86-1	dermal	LD50	>5.000 mg/kg	rat
Boric acid	10043-35-3	oral	LD50	3.450 mg/kg	rat
Boric acid	10043-35-3	dermal	LD50	>2.000 mg/kg	rabbit
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	oral	LD50	2.800 mg/kg	rat

##### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

##### Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

##### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

##### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

##### Carcinogenicity

Shall not be classified as carcinogenic.

##### Reproductive toxicity

May damage the unborn child. May damage fertility.

##### Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

##### Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

##### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

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### Symptoms related to the physical, chemical and toxicological characteristics

- **If swallowed**

vomiting, nausea, gastrointestinal complaints

- **If in eyes**

Data are not available.

- **If inhaled**

Data are not available.

- **If on skin**

Data are not available.

- **Other information**

none

### 11.2 Endocrine disrupting properties

Contains an endocrine disruptor (ED) at a concentration of  $\geq 0,1\%$ .

Endocrine disrupting chemicals (EDC)				
Name of substance	CAS No	Combined category	Human health category	Wildlife category
Boric acid	10043-35-3	CAT1	CAT1	CAT2

#### Legend

CAT1 Category 1 - evidence of endocrine disruption in at least one species using intact animals  
CAT2 Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption

### 11.3 Information on other hazards

There is no additional information.

## SECTION 12: Ecological information

### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute) of components					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
TRIS	77-86-1	EC50	$>980 \text{ mg/l}$	aquatic invertebrates	48 h
TRIS	77-86-1	ErC50	$473 \text{ mg/l}$	algae	48 h
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	LC50	$41 \text{ mg/l}$	bluegill ( <i>Lepomis macrochirus</i> )	96 h
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	EC50	$610 \text{ mg/l}$	daphnia magna	24 h

Aquatic toxicity (chronic) of components					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
TRIS	77-86-1	EC50	$>1.000 \text{ mg/l}$	microorganisms	3 h
Ethylenediamine tetraacetic acid disodium	6381-92-6	EC50	$56 \text{ mg/l}$	<i>Pseudomonas putida</i>	8 h

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### Aquatic toxicity (chronic) of components

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
salt dihydrate					
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	NOEC	25,7 mg/l	zebra fish (Danio rerio)	35 d
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	LOEC	50 mg/l	daphnia magna	21 d

## 12.2 Persistence and degradability

### Degradability of components

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
TRIS	77-86-1	biotic/abiotic	89 %	28 d		
TRIS	77-86-1	oxygen depletion	100,7 %	28 d		ECHA
TRIS	77-86-1	carbon dioxide generation	65,9 %	28 d		ECHA
TRIS	77-86-1	DOC removal	97,1 %	28 d		ECHA

## 12.3 Bioaccumulative potential

Data are not available.

### Bioaccumulative potential of components

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
TRIS	77-86-1		-1,56 (20 °C)	
Boric acid	10043-35-3		-1,09 (pH value: 7,5, 22 °C)	
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	1,8		

## 12.4 Mobility in soil

Data are not available.

## 12.5 Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of  $\geq 0,1\%$ .

## 12.6 Endocrine disrupting properties

Contains an endocrine disruptor (ED) at a concentration of  $\geq 0,1\%$ .

### Endocrine disrupting chemicals (EDC)

Name of substance	CAS No	Combined category	Human health category	Wildlife category
Boric acid	10043-35-3	CAT1	CAT1	CAT2

#### Legend

CAT1 Category 1 - evidence of endocrine disruption in at least one species using intact animals  
CAT2 Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption

## 12.7 Other adverse effects

Data are not available.

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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

##### **Sewage disposal-relevant information**

Do not empty into drains.

##### **Waste treatment of containers/packagings**

Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

#### 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

##### **Properties of waste which render it hazardous**

**HP 10** toxic for reproduction

#### 13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions. Non-contaminated packages may be recycled.

### SECTION 14: Transport information

- |                                                                                           |                                                                       |
|-------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| 14.1 UN number or ID number                                                               | not subject to transport regulations                                  |
| 14.2 UN proper shipping name                                                              | not assigned                                                          |
| 14.3 Transport hazard class(es)                                                           | none                                                                  |
| 14.4 Packing group                                                                        | not assigned                                                          |
| 14.5 Environmental hazards                                                                | non-environmentally hazardous acc. to the dangerous goods regulations |
| 14.6 Special precautions for user                                                         | There is no additional information.                                   |
| 14.7 Maritime transport in bulk according to IMO instruments                              | The cargo is not intended to be carried in bulk.                      |
| 14.8 <u>Information for each of the UN Model Regulations</u>                              |                                                                       |
| <b>International Maritime Dangerous Goods Code (IMDG) - Additional information</b>        | Not subject to IMDG.                                                  |
| <b>International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information</b> | Not subject to ICAO-IATA.                                             |

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### SECTION 15: Regulatory information

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

##### Relevant provisions of the European Union (EU)

##### Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
ROTIPHORESE® 5x TBE Buffer	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
Boric acid	toxic for reproduction		R28-30	30
Boric acid	substances in tattoo inks and permanent make-up		R75	75

##### Legend

- R28-30 1. Shall not be placed on the market, or used,  
- as substances,  
- as constituents of other substances, or,  
- in mixtures,  
for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:  
- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,  
- the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008.  
Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:  
'Restricted to professional users'.  
2. By way of derogation, paragraph 1 shall not apply to:  
(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;  
(b) cosmetic products as defined by Directive 76/768/EEC;  
(c) the following fuels and oil products:  
- motor fuels which are covered by Directive 98/70/EC,  
- mineral oil products intended for use as fuel in mobile or fixed combustion plants,  
- fuels sold in closed systems (e.g. liquid gas bottles);  
(d) artists' paints covered by Regulation (EC) No 1272/2008;  
(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date;  
(f) devices covered by Regulation (EU) 2017/745.
- R3 1. Shall not be used in:  
- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,  
- tricks and jokes,  
- games for one or more participants, or any article intended to be used as such, even with ornamental aspects,  
2. Articles not complying with paragraph 1 shall not be placed on the market.  
3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:  
— can be used as fuel in decorative oil lamps for supply to the general public, and  
— present an aspiration hazard and are labelled with H304.  
4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).  
5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:  
(a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage";  
(b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: "Just a sip of grill lighter fluid may lead to life threatening lung damage";  
(c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.;
- R75 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:  
(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;  
(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;  
(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser cat-

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- egory 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
- (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
- (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
- (ii) 0,01 % by weight, in all other cases;
- (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
- (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:
- (i) "Rinse-off products";
- (ii) "Not to be used in products applied on mucous membranes";
- (iii) "Not to be used in eye products";
- (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
- (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
- (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
- (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
- (a) the statement "Mixture for use in tattoos or permanent make-up";
- (b) a reference number to uniquely identify the batch;
- (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
- (d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
- (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;
- (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;
- (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.
- The information shall be clearly visible, easily legible and marked in a way that is indelible.
- The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.
- Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.
- Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.
8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.
9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).
10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

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### List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Substance of Very High Concern (SVHC)						
Name acc. to inventory	CAS No	Listed in	Remarks	Latest application date	Sunset date	Date of inclusion
boric acid	10043-35-3	Candidate list	Repr. A57c			18.06.2010

#### Legend

Candidate list Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV  
Repr. A57c Toxic for reproduction (article 57c)

### Seveso Directive

2012/18/EU (Seveso III)			
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes
	not assigned		

### Deco-Paint Directive

VOC content	0 %
VOC content (Water content was discounted)	0 g/l

### Industrial Emissions Directive (IED)

VOC content	0 %
VOC content (Water content was discounted)	0 g/l

### Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

### Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

### Water Framework Directive (WFD)

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Boric acid	Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment		a)	
Ethylenediamine tetraacetic acid disodium salt dihydrate	Metals and their compounds		a)	

#### Legend

a) Indicative list of the main pollutants

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### Regulation on the marketing and use of explosives precursors

none of the ingredients are listed

### Regulation on drug precursors

none of the ingredients are listed

### Regulation on substances that deplete the ozone layer (ODS)

none of the ingredients are listed

### Regulation concerning the export and import of hazardous chemicals (PIC)

none of the ingredients are listed

### Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

### National inventories

Country	Inventory	Status
AU	AIIC	all ingredients are listed
CA	DSL	all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
EU	REACH Reg.	all ingredients are listed
JP	CSCL-ENCS	all ingredients are listed
JP	ISHA-ENCS	not all ingredients are listed
KR	KECI	all ingredients are listed
MX	INSQ	all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	not all ingredients are listed
VN	NCI	all ingredients are listed

#### Legend

AIIC	Australian Inventory of Industrial Chemicals
CICR	Chemical Inventory and Control Regulation
CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
DSL	Domestic Substances List (DSL)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
ISHA-ENCS	Inventory of Existing and New Chemical Substances (ISHA-ENCS)
KECI	Korea Existing Chemicals Inventory
NCI	National Chemical Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg.	REACH registered substances
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act

## 15.2 Chemical safety assessment

According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.

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### SECTION 16: Other information

#### Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.2		Hazard pictogram(s):	yes
2.2		Hazard pictogram(s):: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 10 ml	yes
2.2		Signal word: Not required	yes
2.2		Hazard pictogram(s):	yes
2.2		Hazard pictogram(s):: change in the listing (table)	yes
2.2		Hazard statements: Not required	yes
2.2		Precautionary statements: Not required	yes
2.3	Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance at a concentration of $\geq 0,1\%$ .	yes
2.3		Endocrine disrupting properties: Contains an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$ .	yes
14.8	Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information: Not subject to ADR, RID and ADN.		yes
15.1		Substance of Very High Concern (SVHC): change in the listing (table)	yes
15.1	VOC content: 0 % , 0 g/l	VOC content: 0 %	yes
15.1		VOC content (Water content was discounted): 0 g/l	yes
15.1		National inventories: change in the listing (table)	yes
15.2	Chemical Safety Assessment: Chemical safety assessments for substances in this mixture were not carried out.	Chemical safety assessment: According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.	yes

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### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
LOEC	Lowest Observed Effect Concentration
log KOW	n-Octanol/water
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Repr.	Reproductive toxicity
STOT RE	Specific target organ toxicity - repeated exposure
SVHC	Substance of Very High Concern

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Abbr.	Descriptions of used abbreviations
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

### Classification procedure

Physical and chemical properties. The classification is based on tested mixture.

Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

### List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H332	Harmful if inhaled.
H360FD	May damage fertility. May damage the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.

### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.