

SAFETY DATA SHEET

In accordance with 1907/2006 annex II and 1272/2008
(All references to EU regulations and directives are abbreviated into only the numeric term)
Issued 2024-12-12
Version number 1.0



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

1.1. Product identifier

Trade name Cederroth Eye Wash

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

Identified uses Medical device
Eye wash

1.3. Details of the supplier of the safety data sheet

Company Orkla Wound Care AB
Svetsarvägen 15, Box 1336
SE-171 26 Solna
Sweden
Telephone +46 (0) 10 142 64 00
E-mail firstaid@cederroth.com

1.4. Emergency telephone number

Phone number for emergencies: 999 or 112. The numbers are available 24/7.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Upon assessment, this mixture is not classified as hazardous according to 1272/2008

2.2. Label elements

Hazard pictogram Not applicable
Signal word Not applicable
Hazard statement Not applicable

Supplemental hazard information

EUH210 Safety data sheet available on request.

2.3. Other hazards

This product does not contain any substances that are assessed to be a PBT or a vPvB
The product does not contain any substances identified as having endocrine disruptive properties in accordance with the criteria set out in (EU) 2017/2100 or (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

Constituent	Classification	Concentration
BORIC ACID		
CAS No: 10043-35-3 EC No: 233-139-2 Index No: 005-007-00-2	Repr. 1B; H360FD	<0.3 %

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture, see Section 16b.

SECTION 4: First aid measures

4.1. Description of first aid measures

Generally

In case of concern, or if symptoms occur, call a doctor/physician.

Upon breathing in

No special measures are considered to be necessary.

Upon eye contact

No special measures are considered to be necessary.

Upon skin contact

No special measures are considered to be necessary.

Upon ingestion

Rinse nose, mouth and throat with water.

If symptoms persist contact a doctor.

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

Upon ingestion

Indisposition.

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

Symptomatic treatment.

Upon contact with a doctor, make sure to have this safety data sheet with you.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Extinguish with materials intended for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

Not flammable.

In case of fire, substances hazardous to health, or substances harmful in other respects, may be dispersed.

5.3. Advice for firefighters

Protective measures to be taken with regard to other materials at the scene of the fire.

In case of fire use proper breathing apparatus.

Wear full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No special measures are considered to be necessary.

6.2. Environmental precautions

No specific measures need to be taken in the event of normal use.

6.3. Methods and material for containment and cleaning up

Small spills can be wiped up with a cloth or similar. Then flush the spill site with water. Larger spills should first be covered with sand or earth and then be collected. Collected material should be disposed according to Section 13.

6.4. Reference to other sections

See section 8 and 13 for personal protection equipment and disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Take the necessary preventive and protective measures for safe handling.

Work in order to avoid spillage. If spillage does occur, address it immediately in accordance with the directions specified in Section 6 of this safety data sheet.

Store this product separately from food items and keep it out of the reach of children and pets.

Do not eat, drink or smoke in premises where this product is handled.

Keep away from incompatible products.

7.2. Conditions for safe storage, including any incompatibilities

Take the necessary preventive and protective measures for safe storage.

Keep out of reach for children.

To be stored away from food and animal fodder and away from devices or surfaces that are in contact with those items.

Store only in the original package.

Store at 0-40°C.

7.3. Specific end use(s)

See identified uses in Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National limit values

DISODIUM TETRABORATE DECAHYDRATE

United Kingdom (EH40/2005)

Time-weighted-average exposure limit (TWA) 5 mg/m³

DNEL

BORIC ACID

	Type of exposure	Route of exposure	Value
Consumer	Chronic Systemic	Inhalation	4.15 mg/m ³
Worker	Chronic Systemic	Dermal	3924.8 g/d
Worker	Chronic Systemic	Inhalation	8.3 mg/m ³
Consumer	Acute Systemic	Oral	0.98 mg/kg bw/d
Consumer	Chronic Systemic	Oral	0.98 mg/kg bw/d
Consumer	Chronic Systemic	Dermal	196 mg/kg bw/d

PNEC

BORIC ACID

Environmental protection target	PNEC value
Fresh water	1.35 mg/l
Freshwater sediments	1.8 mg/kg
Marine water	1.35 mg/l
Marine sediments	1.8 mg/kg
Microorganisms in sewage treatment	1.75 mg/l
Soil (agricultural)	5.7 mg/kg dw
Intermittent	13.7 mg/L

8.2. Exposure controls

The risks posed by the product or its constituents must be considered in the task specific risk assessment, in accordance with current working environment legislation. The risk assessment should be reviewed regularly and updated if necessary.

8.2.1. Appropriate engineering controls

The ventilation in the workplace must ensure an air quality that meets the requirements of the current working environment legislation. Local exhaust ventilation should be used to remove airborne contaminants at the source.

Eye/face protection

Eye protection is not necessary during normal use.

Skin protection

It is generally not necessary to use protective gloves.

Respiratory protection

Respiratory protective equipment is not normally required when working with this product.

8.2.3. Environmental exposure controls

For limiting environmental exposure, see section 12.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

(a) Physical state	liquid
	Form: liquid
(b) Colour	colourless
(c) Odour	characteristic
(d) Melting point/freezing point	Not indicated
(e) Boiling point or initial boiling point and boiling range	Not indicated
(f) Flammability	Not indicated
(g) Lower and upper explosion limit	Not indicated
(h) Flash point	Not indicated
(i) Auto-ignition temperature	Not indicated
(j) Decomposition temperature	Not indicated
(k) pH	When supplied, pH is: ≈ 7
(l) Kinematic viscosity	Not indicated
(m) Solubility	Solubility in water: Soluble
(n) Partition coefficient n-octanol/water (log value)	Not indicated
(o) Vapour pressure	Not indicated
(p) Density and/or relative density	Not indicated
(q) Relative vapour density	Not indicated
(r) Particle characteristics	Not indicated

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Not indicated

9.2.2. Other safety characteristics

Not indicated

SECTION 10: Stability and reactivity

10.1. Reactivity

The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability

The product is stable at normal storage and handling conditions.

10.3. Possibility of hazardous reactions

No hazardous reactions known during normal use.

10.4. Conditions to avoid

There are no known conditions to avoid.

10.5. Incompatible materials

There are no known incompatible materials.

10.6. Hazardous decomposition products

None under normal conditions.

SECTION 11: Toxicological information

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

Information on possible health hazards are based on experience and / or toxicological properties of several components in the product.

Acute toxicity

The product is not classified as acutely toxic.

BORIC ACID

LD50 rabbit 24h: > 2000 mg/kg Dermal

LC50 rat 4h: > 2 mg/l Inhalation

LD50 rat 24h: 2660 mg/kg Orally

Skin corrosion/irritation

The product is not classified for skin corrosion/irritation.

Serious eye damage/irritation

The product is not classified for serious eye damage/eye irritation.

Respiratory or skin sensitisation

The product is not classified as sensitising.

Germ cell mutagenicity

The product is not classified as mutagen.

Carcinogenicity

The product is not classified as carcinogenic.

Reproductive toxicity

The product is not classified as a reproductive toxicant.

STOT-single exposure

The product is not classified for specific organ toxicity after single exposure.

STOT-repeated exposure

The product is not classified for specific organ toxicity after repeated exposure.

Aspiration hazard

The product is not classified as being toxic for aspiration.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

The product does not contain any substances identified as having endocrine disruptive properties in accordance with the criteria set out in (EU) 2017/2100 or (EU) 2018/605.

11.2.2. Other information

Not indicated.

SECTION 12: Ecological information

12.1. Toxicity

The product is not to be labelled as an environmental hazard. However, it is not inconceivable that large emissions, or repeated small emissions, can have a harmful effect on the environment.

BORIC ACID

LC50 fathead minnow (*Pimephales promelas*) 96h: 456 mg/l

LC50 Freshwater water flea (*Daphnia magna*) 48h: 760 mg/l

EC50 Freshwater water flea (*Daphnia magna*) 48 h: 102 mg/l

EC50 Algae 72 h: > 66 mg/l

LC50 Fish 96h: > 80 mg/l

EC50 Algae (*Pseudokirchneriella subcapitata*) 72h: 229 mg/l

12.2. Persistence and degradability

No information is available.

12.3. Bioaccumulative potential

No information is available.

12.4. Mobility in soil

No information is available.

12.5. Results of PBT and vPvB assessment

This product does not contain any substances that are assessed to be a PBT or a vPvB.

12.6. Endocrine disrupting properties

The product does not contain any substances identified as having endocrine disruptive properties in accordance with the criteria set out in (EU) 2017/2100 or (EU) 2018/605.

12.7. Other adverse effects

No known effects or hazards.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste handling of the product

The product is not classified as hazardous waste.

Empty, rinsed packaging is sent for recycling where practicable.

See directive 2008/98/EC on waste. Observe national or regional provisions on waste management.

Classification according to 2008/98/EC

Recommended LoW-code: 20 03 01 Mixed municipal waste
15 01 01 Paper and cardboard packaging
15 01 02 Plasticpackaging

SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

14.1. UN number or ID number

Not classified as dangerous goods

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

14.8 Other transport information

Not applicable

SECTION 15: Regulatory information

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

Contains substance on the candidate list of Substances of Very High Concern.

Substances on the list of SVHC Candidate List for authorisation (substances that meet the criteria in Article 57 of the REACH Regulation):

BORIC ACID

CAS No: 10043-35-3

EC No: 233-139-2

Index No: 005-007-00-2

15.2. Chemical safety assessment

Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

SECTION 16: Other information

16a. Indication of where changes have been made to the previous version of the safety data sheet

Revisions of this document

This is the first version

16b. Legend to abbreviations and acronyms used in the safety data sheet

Full texts for Hazard Class and Category Code mentioned in section 3

Repr. 1B Reproductive toxicity, Hazard Category 1B - Repr. 1B, H360FD - May damage fertility. May damage the unborn child

Explanations of the abbreviations in Section 14

ADR European Agreement concerning the International Transport of Dangerous Goods by Road

RID Regulations concerning the International Transport of Dangerous Goods by Rail

IMDG International Maritime Dangerous Goods Code

ICAO International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)

IATA The International Air Transport Association

16c. Key literature references and sources for data

Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2024-12-12.

Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

Full texts for Regulations mentioned in this Safety Data Sheet

- 1907/2006 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 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
- 1272/2008 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
- 2008/98/EC DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives

16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

16e. List of relevant hazard statements and/or precautionary statements

Full texts for hazard statements mentioned in section 3

H360FD May damage fertility. May damage the unborn child

16f. Advice on any training appropriate for workers to ensure protection of human health and the environment

Warning for misuse

Not indicated.

Other relevant information

Not indicated

Editorial information



This material safety data sheet has been prepared and checked by KemRisk®, KemRisk Sweden AB, Platensgatan 8, SE-582 20 Linköping, Sweden, www.kemrisk.se