SAFETY DATA SHEET

According to Regulation (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

CEDERROTH EYE & WOUND CLEANSING SPRAY

Issue date: 2017-03-01

SECTION 1: IDENTIFICATION OF PRODUCT AND COMPANY

1.1 Product identifier

Trade name and product number:	Cederroth Eye&Wound Cleansing Spray REF 726000

1.2 Relevant identified uses of the mixture and uses advised against

Identified uses:	Medical device product, Intended to be used for cleansing dust and dirt from eyes and wounds.

1.3 Details of the supplier of the safety data sheet

Supplier:	Orkla Care AB Svetsarvägen 15, Box 1336 SE-171 26 Solna
Website:	www.salvequick.com
Phone:	+46 (0) 10 142 64 00

1.4 Emergency phone number (Sweden)

Emergency:	112
Non-emergency:	+46 (0)10-456 6700, www.giftinformationscentralen.se

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to 1272/2008:	Aerosol (category 3)

2.2 Label elements

Labelling according to 1272/2008

Hazard pictograms:	Not applicable
Signal word:	Warning

Hazard statements

H229	Pressurised container: May burst if heated.

Precautionary statements

P102	Keep out of reach of children.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P251	Pressurized container: Do not pierce or burn, even after use.
P410+P412	Protect from sunlight. Do not expose to temperatures exceeding 50°C /122°F.

2.3 Other hazards

None known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

The product is a non-flammable aerosol, containing an aqueous solution of sodium chloride.

3.2 Mixtures

Ingredient		Classification	Concentration
WATER			
CAS no	7732-18-5	-	
EC no	231-791-2		
NITROGEN COMPRESSED			
CAS no	7727-37-9	-	
EC no	231-783-9		
SODIUM CHLORIDE			
CAS no	7647-14-5	-	
EG no	231-598-3		

The product ingredients are not fulfilling the criteria for hazard labelling and concentration limits for declaration.
The product does not contain fluorinated hydrocarbons.
Full text of H- and P-phrases: see item 2.2.
The classification is based on data from chemical supplier and http://echa.europa.eu/

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information: No special first aid measures are considered necessary. In case symptoms still occur, contact medical expertise.
In case of accident call 112 for advice.

Following ingestion: Contact physician in case large quantities are ingested.

Following inhalation: Fresh air.

Following eye contact: Not relevant. Product is intended for use on eyes.

Following skin contact: Not relevant. Product is intended to be used on skin.

4.2 Most important symptoms and effects, both acute and delayed

Ingestion: No symptoms are expected
Inahalation: No symptoms are expected
Eye contact: No symptoms are expected
Skin contact: No symptoms are expected

4.3 Indication of any immediate attention and special treatment needed

Not relevant

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Extinguish with media suitable for surrounding fire; powder, sand, carbon dioxide, foam or water mist.

5.2 Special hazards arising from the substance or mixture

Aerosol. Pressurized container that may burst if heated.
During fire hazardous gas may form. Avoid inhalation of smoke from fire.

5.3 Advice for fire-fighters

Use breathing apparatus and protective clothing for firefighting.
Cool undamaged product containers that have been exposed to fire with water and remove from fire if possible without risk.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid sparks, flames, strong heat. Do not smoke.

6.2 Environmental precautions

No particular measures necessary during normal use.

6.3 Methods and material for containment and cleaning up

Wipe up minor spills with a cloth or similar.

6.4 Reference to other sections

Refer to section 7 about handling.
Refer to section 8 about personal protective equipment.
Refer to section 13 for waste handling.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Store in closed original package.
Handle according to good occupational hygiene and safety practice.
Do not expose to heat, hot surfaces, sparks, open flames or other ignition sources. No smoking.

7.2 Conditions for safe storage, including any incompatibilities.

Do not store above normal room temperature (< 30°C) or in direct sunlight.
No special requirements on ventilation.
The liquid remains sterile even after repeated use.

7.3 Specific end use

Not relevant.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Precautions:

None

Occupational exposure limits

Exposure limits are not relevant nor defined for the ingredients in this products (refer to section 3).

8.2 Exposure controls

The product is intended to be used for cleansing of eyes and injured skin.
Personal protective equipment is not needed for handling of this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Liquid in aerosol bottle
Colour:	Transparent, no colour
Odour:	No odour
Density:	1 kg/L
Odour threshold:	Not applicable
pH-value (concentrate):	5-8
Melting/freezing point (°C):	Not applicable
Boiling point (°C):	~100
Flash point (°C):	Not applicable
Evaporation rate:	Not applicable
Flammability (solid, gas):	Not applicable

Upper/lower flammability or explosive limits:	Not applicable
Vapour pressure (°C):	5 bar ± 0,5
Vapour density (Air=1):	Not applicable
Solubility in water:	Soluble
Solubility in organic solvents:	Not applicable
Partition coefficient: n-oktanol/ water:	Not applicable
Auto-ignition temperature (°C):	Not applicable
Decomposition temperature (°C):	Not applicable
Viscosity (°C)	Not applicable
Explosive properties:	Not applicable
Oxidising properties:	Not applicable

9.2 Other information

No other information

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	The product contains no substances that can cause dangerous reactions when handled and used as recommended.
10.2 Chemical stability	The product is stable when stored and handled as recommended.
10.3 Possibility of hazardous reactions	No known hazardous reactions
10.4 Conditions to avoid	Direct sunlight. Open fire.
10.5 Incompatible materials	No known incompatible materials.
10.6 Hazardous decomposition products	No known hazardous decomposition products.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

General or unspecified toxicity:	The product is not classified as toxic.
Health hazards:	The product is not classified as hazardous to health.
Corrosivity and irration:	The product has not caused any skin irritation
Sensitization:	The product is not classified as skin sensitizer.
CMR (Cancerogenicity, Mutagenicity and toxicity for Reproduction)	The product is not classified as CMR
Relevant toxicological properties:	SODIUM CHLORIDE LD50 rabbit (Dermal) 24h > 10000 mg/kg dermal LD50 rat (Oral) 24h = 3000 mg/kg oral
Possible route for exposure:	Inhalation, skin, eyes, ingestion
Other information:	-

SECTION 12: ECOLOGICAL INFORMATION

The product is not classified as hazardous to the environment.

12.1 Toxicity SODIUM CHLORIDE
EC50 Daphnia magna 48h = 1000mg/l
LC50 Fish 96h = 17,9 mg/l
No ecological hazards are known nor expected from normal use.

12.2 Persistence and degradability Not relevant

12.3 Bioaccumulative potential The product (liquid) does not accumulate in the environment.

12.4 Mobility in soil No information available

12.5 Results of PBT- and vPvB-assessment The product (liquid) is not considered to meet the PBT/vPvB criteria of REACH, annex III.
No chemical safety report is available.

12.6 Other hazardous effects No

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Seek advice from local authorities regarding waste handling.
Pressurized container; The packaging may not be exposed to heat nor be discarded in household waste.
Waste transport : Class J(0) – Not hazardous to environment or health

SECTION 14: TRANSPORT INFORMATION

Classified as dangerous goods according to transport regulations (ADR/RID, DGR and IMDG-cod).

14.1 UN-number: 1950

14.2 Proper shipping name (IMDG, IATA/CAO): AEROSOLS

14.3 Hazard class for transport: 2: Gas, code 5A (label 2,2)

14.4 Packing group: Not applicable

14.5 Environmental hazards Not applicable

14.6 Special precautions: Tunnel restrictions, tunnel category: E

14.7 Bulk transport acc. to annex II of MARPOL 73/78 and IBC-kcde: Not applicable

14.8 Other transport information LQ, 1L
The product contains less than 1 liter.
Limited quantity (LQ) is therefore recommended for transport.
Transport category: 3 ; total quantity per transport unit maximum 1000 kg or liter.

SECTION 15: REGULATORY INFORMATION

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

The product is classified as a sterile medical device product, class IIa, according to the Medical device directive MDD 93/42/EEC.
Other classifications according to Regulations CLP (EC) No 1272/2008, REACH (EC) No 1907/2006, AFS 2014:43, AFS 2015:7, Avfallsförordningen (SFS 2011:927)

15.2 Chemical safety assessment

Assessment and chemical safety report according to 1907/2006 Annex 1 is currently not available.

SECTION 16: OTHER INFORMATION

16a. Information regarding this document

This Safety Data Sheet is issued in accordance with the REACH-regulation 1907/2006/EG and EG 830/2015.

Revision history

Earlier versions; -

Translation from Swedish version, dated 2017-02-17

16b. Abbreviations and acronyms

Tunnel restriction code: E	Passage forbidden through tunnels of category E
Transport category: 3	Maximum total volume/mass per transport unit: 1000 L/ kg
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bio Concentration Factor
CAS-nr	Chemical Abstracts Service number
EC50	Effect concentration
EG-nr	Substance number in Einecs, Elincs or in No-Longer polymers list
IMDG	International Maritime Dangerous Goods Code
LC50	Lethal concentration
LD50	Lethal dose
PBT-substance	Persistent, Bio accumulative and Toxic substances
vPvB-substance	Very persistent and Very Bio accumulative substances

16c. Full text hazard and precautionary statements

Refer to item 2.2

16d. Key literature references and sources for data

The information in this safety data sheet is mainly based on documentation from raw material suppliers and current European legislation.

16e. Full text for regulations referenced in this safety data sheet

- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- 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
- AFS 2011:18 Arbetsmiljöverkets föreskrifter och allmänna råd om hygieniska gränsvärden
- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)
- 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

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

For external use only. Do not mix with any other liquid, unless otherwise instructed.
Do not use for injection.

Warning regarding misuse

This product is not expected to cause serious harm to humans or the environment. The manufacturer, distributor or supplier can however be responsible for any unusual, non-intended or criminal use of the product.