

SECTION 1: IDENTIFICATION OF PRODUCT AND COMPANY

1.1 Product identifier

Trade name and product number: 51011005 Cederroth Burn Gel 100ml

1.2 Relevant identified uses of the mixture and uses advised against

Identified uses: Medical device product.
Intended to be used on minor burns, scalds, sunburn and radiation injured skin to cool and relieve.
For external use only.

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.cederroth.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

CLP 1272/2008: Product is not classified as dangerous according to CLP.
Not applicable, medical device (Art 1.5d).
75/324/EEG, 2013/10/EU Aerosol

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

This product is not considered to contain any substances that meet the criteria for classification as PBT or vPvB substances.

The product does not contain any fluorinated hydrocarbons. Not flammable.

For external use only. Do not mix with any other fluid if not directed.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

This product is a non-flammable aerosol.

3.2 Mixtures

Component	CAS no.	EG no.	Concentration (%)	Hazard classification
The product ingredients are not fulfilling the criteria for hazard labelling and concentration limits for declaration.	-	-	-	-

For the Hazard statement codes, see section 2.2.

The classification is based on data from chemical supplier and <http://echa.europa.eu/> (databases)

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

- General information:** In all cases of doubt, or when symptoms persist, seek medical expertise. Keep person warm and calm. Never give fluids or induce vomiting if patient is unconscious.
- Following ingestion:** Rinse your mouth and drink plenty of water. Do not induce vomiting. If symptoms persist consult a doctor.
- Following inhalation:** Fresh air.
- Following eye contact:** Rinse with (lukewarm) water for several minutes. Remove potential contact lenses. Keep your eyelids open. If symptoms persist consult a doctor.
- Following skin contact:** If irritation occurs; wash with water and rinse skin thoroughly.

4.2 Most important symptoms and effects, both acute and delayed

- Skin contact: No symptoms are expected
- Inhalation: No symptoms are expected
- Eye contact: May be irritating to the eye (redness, pain, tearing)
- Ingestion: Ingestion may cause nausea and discomfort.

4.3 Indication of any immediate attention and special treatment needed

No information available.

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 endangered product containers with water in case of fire and move from fire, if it can be done without risk.

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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

Prevent large amounts of product from flushing into surface water or sewage system.

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.

Smoking prohibited. Avoid inhalation of vapours/aerosol.

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.

7.3 Specific end use

Not relevant.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Precautions:

None

Occupational exposure limits (according to Swedish limits AFS 2015:7)

None established.

8.2 Exposure controls

General protective and hygiene measures

Wash hands before breaks and after work. Avoid inhalation of vapors/aerosols.

Handle in accordance with good professional tradition and safety practice.

Do not eat, drink or smoke when working with the product.

Individual protection measures, such as personal protective equipment

Always consult a competent person/supplier when selecting personal protective equipment.

Respiratory protection

In accordance with instructions: not required. In inadequately ventilated places or in case of creation of aerosols, wear suitable respiratory equipment approved for this purpose. (P2)

Eye protection

None required for normal use.

Hand protection

None required for normal use.

Body protection

None required for normal use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Gel
Colour:	Clear
Odour:	Neutral
Density:	Not determined
Odour threshold:	Not determined
pH-value (concentrate):	Not determined
Melting/freezing point (°C):	Not determined
Boiling point (°C):	~100
Flash point (°C):	> 65
Evaporation rate (°C):	Not flammable
Flammability (solid, gas):	Not determined
Upper/lower flammability or explosive limits:	Not determined
Vapour pressure (20°C):	Not determined
Vapour density (air = 1):	Not determined
Relative density:	Not determined
Solubility in water:	Soluble
Partition coefficient, n-octanol/ water:	Not determined
Auto-ignition temperature (°C):	Not determined
Decomposition temperature (°C):	Not determined
Viscosity (°C)	30 000 – 60 000 cP
Explosive properties:	Not determined
Oxidising properties:	Not determined

9.2 Other information

No further information

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	The product is stable for recommended handling and use.
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.
10.6 Hazardous decomposition products	No known.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Also refer to section 4. (Most important symptoms and effects, both acute and delayed)

Inhalation:	Not irritating.
Skin contact:	Not irritating.
Eye contact:	May be irritating.
Ingestion:	Ingestion may cause discomfort.
Toxicology data:	Information/data about this preparation is not available.
STOT-single exposure -repeated exposure:	None.
Routes of exposure:	Inhalation, eyes and skin, ingestion.
Allergic potential:	This product is not classified as allergenic by inhalation or skin contact.
Carcinogenicity, mutagenicity and toxicity for reproduction:	The product is not classified as carcinogen, mutagen and toxic for reproduction.
Aspiration hazard:	No aspiration hazard expected.
Other information:	-

SECTION 12: ECOLOGICAL INFORMATION

The product is not classified as hazardous to the environment.

Do not flush into surface water or sanitary sewer system

12.1 Toxicity	No toxicological data available for this product.
12.2 Persistence and degradability	No information available.
12.3 Bioaccumulative potential	Not expected to bioaccumulate.
12.4 Mobility in soil	No information available.
12.5 Results of PBT- and vPvB-assessment	This product is not considered to contain any substances that meet the criteria for classification as PBT or vPvB substances.
12.6 Other adverse effects	No known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment:	Product is not classified as hazardous waste (according to Swedish Waste Ordinance (Avfallsförordningen SFS 2011:927)). Consult local authority for disposal of waste.
Package:	Pressure vessel; The package may not be exposed to heat or disposed of in household waste. Well-emptied and cleaned packaging can be left for recycling.

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SECTION 14: TRANSPORT INFORMATION

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

14.1 UN-number:	1950
14.2 UN proper shipping name	AEROSOLS
14.3 Hazard class for transport:	2, (label 2,2)
14.4 Packing group:	Not applicable
14.5 Environmental hazards	Marine pollutant: No
14.6 Special precautions:	Tunnel restrictions, tunnel category: E
14.7 Bulk transport acc. to annex II of MARPOL 73/78 and IBC-code:	Not applicable
14.8 Other transport information	LQ, 1L The product contains less than 1 litre. Limited quantity (LQ) is therefore recommended for transport.

SECTION 15: REGULATORY INFORMATION

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

The product is classified as a medical device, class II a, according to MDD 93/42/EEC.

Classifications according to CLP (EC) No 1272/2008 – not relevant, medical device. (Art. 1.5d)

REACH (EC) No 1907/2006,

15.2 Chemical safety assessment

Not performed.

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 2018-11-09

16b. Abbreviations and acronyms

ADR/RID	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS no.	Chemical Abstracts Service number
CLP	Classification, Labelling and Packaging
DGR	Dangerous Goods Regulation
EG no.	Substance number in Einecs, Elincs or in No-Longer polymers list
IMDG	International Maritime Dangerous Goods Code
LQ	Limited Quantity
MDD	Medical Device Directive
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
P2	Classification of breathing mask
PBT-substance	Persistent, Bio accumulative and Toxic substances
Tunnel restriction code: E	Passage forbidden through tunnels of category E
vPvB-substance	Very persistent and Very Bio accumulative substances

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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.

Data sheet from manufacturer. CLP regulation, www.kemi.se (databases), AFS 2015:7, <http://echa.europa.eu/> (databases)

- 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
- COMMISSION DIRECTIVE 2013/10/EU of 19 March 2013 amending Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers in order to adapt its labelling provisions to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
- COMMISSION DIRECTIVE 2013/10/EU of 19 March 2013 amending Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers in order to adapt its labelling provisions to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

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.