

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 2023-02-20

Version number 1.0

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

1.1. Product identifier

Trade name	Cederroth Burn Gel 100 ml
Article number	51011005

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

Identified uses	Medical Device
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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

Aerosol 3, H229

(See section 16)

2.2. Label elements

Hazard pictogram	Not applicable
Signal word	Warning
Hazard statement	
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	Do not pierce or burn, even after use
P410+P412	Protect from sunlight. Do not expose to temperatures exceeding 50 °C

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures

The product contains no substances, nor concentration levels thereof, that require marking or that need to be declared.

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

Fresh air and rest. If symptoms persist seek medical advice.

Upon eye contact

For safety reasons, flush eyes with water; If symptoms occur, seek medical advice.

Upon skin contact

No special measures are considered to be necessary.

Upon ingestion

Rinse nose, mouth and throat with water.

Get medical attention if you feel unwell.

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

No further relevant information available.

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

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Recommended extinguishing agents

Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

Unsuitable extinguishing agents

May not be extinguished with water dispersed under high pressure.

5.2. Special hazards arising from the substance or mixture

Aerosols may explode when heated to temperatures above 50°C.

Gases detrimental to health can be spread in case of fire.

5.3. Advice for firefighters

Protective measures should be taken regarding other material at the site of the fire.

Wear full protective clothing.

In case of fire use proper breathing apparatus.

Cool closed containers that were exposed to fire with water.

The containers should be moved away from the place of fire, if this can take place without risks.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Switch off equipment which has an exposed flame, glows, or has a heat source of some other kind.

Switch off power at the main switch. Do not use the power switch in the room where the spillage has occurred.

Note, risk for formation of sparks due to static electricity. Do not remove clothing in a room where spillage has occurred.

Note the risk of ignition.

Keep unauthorized and unprotected people at a safe distance.

Ensure good ventilation.

Use breathing apparatus when oxygen levels are low or unknown.

6.2. Environmental precautions

Avoid release to drains, soil or watercourses.

Prevent from entering sewers, basements and pits, or any place where gas accumulation could be dangerous.

Notify rescue services for larger spillage.

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.

Ensure good ventilation after sanitation.

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.

Open fire, hot items, sparks or other ignition sources must not be present in the environment used for handling this product.

Pressure containers: do not puncture or burn, not even empty containers. Protect from sunlight. Do not expose to temperatures in excess of 50 °C.

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

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

Wash your hands after using the product.

Keep away from incompatible products.

Use recommended safety equipment, see section 8.

Implement appropriate engineering controls if necessary, see Section 8.

7.2. Conditions for safe storage, including any incompatibilities

Take the necessary preventive and protective measures for safe storage.

The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.

Keep out of reach for children.

Store separately from food and animal fodder, incl. utensils or surfaces which have been in contact with these things.

Keep away from heat and sunlight.

Store at maximum 50 °C.

Keep well closed.

Store in a well-ventilated space.

Do not store close to incompatible materials (see section 10.5).

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

All ingredients (cf. Section 3) lack occupational exposure limit values.

DNEL

No data available.

PNEC

No data available.

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

Protective gloves are normally not needed due to the properties of this product, but may be necessary for other reasons, e.g. mechanical risks, temperature conditions or microbiological risks.

During continuous contact use gloves with a minimum breakthrough time of at least 240 minutes, preferably over 480 minutes.

The most suitable protective glove should be chosen in consultation with the glove supplier, taking into account the risk assessment for the specific task and the properties of the chemicals involved. Note that the breakthrough time of the material is affected by the duration of the exposure, temperature conditions, abrasion, etcetera.

Based on the chemical properties of the product, the following glove materials are recommended (EN 374):.

– Nitrile rubber.

Respiratory protection

Use appropriate respiratory protective equipment in case of insufficient ventilation.

The most appropriate respiratory protective equipment should be decided in consultation with the appointed safety representative, taking into account the risk assessment for the specific task.

Based on the physical and chemical properties of the product, the following filter type(s) and/or filter combination(s) are recommended:.

– A.

Note that a breathing mask with a filter does not protect against lack of oxygen in the air.

Breathing apparatus may be required.

8.2.3. Environmental exposure controls

Work with the product should take place in such a way that the product does not get into drains, waterways, soil and air.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

(a) Physical state	liquid Form: gel
(b) Colour	Clear
(c) Odour	scentless
(d) Melting point/freezing point	Not indicated
(e) Boiling point or initial boiling point and boiling range	≈100 °C
(f) Flammability	Not indicated
(g) Lower and upper explosion limit	Not indicated
(h) Flash point	>65 °C
(i) Auto-ignition temperature	Not indicated
(j) Decomposition temperature	Not indicated
(k) pH	When supplied, pH is: 6 - 7.5
(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

Hazardous reactions not expected to occur under normal conditions.

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

Avoid heat, sparks and open flames.

Protect from heat and direct sunlight.

Do not expose to temperatures above 50 °C.

10.5. Incompatible materials

None known.

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.

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 criteria for classification cannot be considered fulfilled based on available data.

High concentrations can displace the normal air and cause suffocation from lack of oxygen.

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

No information is available.

11.2.2. Other information

Not indicated.

SECTION 12: Ecological information

12.1. Toxicity

Prevent release on land, in water and drains.

No ecological damage is known or expected in the event of normal use.

12.2. Persistence and degradability

There is no information regarding persistence or degradability.

12.3. Bioaccumulative potential

Neither this product, nor its contents, accumulates in nature.

12.4. Mobility in soil

Information about mobility in nature is not 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

No information is available.

12.7. Other adverse effects

No known effects or hazards.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste handling of the product

Avoid discharge into sewers.

May not be disposed of with household waste.

Pressurized container: Do not pierce or burn, even after use.

Product as well as packaging must be disposed of as hazardous waste.

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

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

1950

14.2. UN proper shipping name

AEROSOLS

14.3. Transport hazard class(es)

Class

2: Gases

Classification code (ADR/RID)

5A: Aerosols, asphyxiant

Labels



14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Tunnel restrictions

Tunnel category: E

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

14.8 Other transport information

Transport category: 3; Maximum total quantity per transport unit: 1000 kgs or litres (ADR 1.1.3.6)

Stowage category A (IMDG)

Emergency Schedule (EmS) for FIRE (IMDG) F-D

Emergency Schedule (EmS) for SPILLAGE (IMDG) S-U

SECTION 15: Regulatory information

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

Not indicated.

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

Aerosol 3 Aerosols, Hazard Category 3 - Aerosol 3, H229 - Pressurised container: May burst if heated

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

Tunnel restriction code: E; Passage through category E tunnels is strictly forbidden

Transport category: 3; Maximum total quantity per transport unit: 1000 kgs or litres (ADR 1.1.3.6)

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 2023-02-20.

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

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