

Document Title:

Product:

Issue:

Date:

Safety Data Sheet

BurnSoothe Burn Gel Dressings

V5

27/03/2024



Safety Data Sheet

According to Regulation (EC) No 1907/2006 of the European Parliament

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Identification of the substance or preparation

Product name: **BurnSoothe/CoolTherm Burn Gel and Dressings**

Product codes: 391 - 396 / 399 – 402 / 2399 / 5920-5923 / 5925 / 5926 / 5928

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

First aid. No uses against identified.

1.3. Details of the supplier of the safety data sheet

Reliance Medical Ltd.

West Avenue,

Talke, Stoke-on-Trent,

Staffordshire ST7 1TL

T: +44 8456 448808

E: sales@reliancemedical.co.uk

1.4. Emergency telephone

National Poisons Information Service (UK) 0844 8920111 (Health Professionals only)

National Health Service (UK) 111

SECTION 2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

The product is exempt from the requirements of the CLP regulation.

2.2. Label elements

The label elements in accordance with CLP Regulation do not apply for this medical device product.

2.3. Other hazards

No data available.

SECTION 3. COMPOSITION/ INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable.

3.2. Composition

Substance	CAS No.	EINECS	%	Hazard Statements ((EC) No 1272/2008)
Polyacrylic Acid	9003-01-4	618-347-7	0.5	H302, H318, H335, H410
Tris(Hydroxyethyl)amine	102-71-6	203-049-8	0.2	H302, H315, H318, H319, H373

See Section 16 for full text of the H statements declared above.

Non-hazardous ingredients: Water, glycerol.



SECTION 4. FIRST AID MEASURES

4.1. Description of first aid measures

Eye contact: Flush eyes with water.

Skin contact: Wash with water and soap.

Ingestion: Do not induce vomiting. Get medical attention.

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

Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Use extinguishing agent suitable for local conditions and the surrounding environment such as dry powder or CO₂.

5.2. Special hazards arising from the substance or mixture

No further relevant information available.

5.3. Advice for firefighter

Wear self-contained respirator. Wear fully protective impervious suit.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Normal use does not require special measures; for industrial production in the long term, refer to the following:

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

Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation.

6.2. Environmental precautions

Do not allow material to be released to the environment without proper governmental permits.

6.3. Methods and material for containment and cleaning up

All waste must refer to the United Nations, the national and local regulations for disposal.

6.4. Reference to other sections

See Section 7 for safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7. HANDLING AND STORAGE

Normal use does not require special measures; for industrial production in the long term, refer to the following:

7.1. Precautions for safe handling

Store in a cold, dry, well-ventilated environment. Store away from food and water supplies. Wash your hands thoroughly before eating and drinking. Storage of chemicals needed to prevent the generation and

Document Title:
Product:
Issue:
Date:

Safety Data Sheet
BurnSoothe Burn Gel Dressings
V5
27/03/2024



accumulation of static electricity when handling the container. Stay away from taboo, such as strong oxidising agents.

7.2. Conditions for safe storage, including any incompatibilities

Store in a cool place. Keep container closed. Store in a dry and ventilated place. Keep container tightly sealed.

7.3. Specific end use(s)

No specific uses identified.

SECTION 8. EXPOSURE CONTROL

8.1. Control parameters

No data available.

8.2. Exposure controls

Based on the composition shown in section 3, the following measures re suggested for occupational safety measure.

Appropriate Engineering Controls:

Keep away from foodstuffs, beverages, and feed. Remove all soiled and contaminated clothing immediately. Wash hands before breaks and at the end of work.

Personal Protective Equipment:

- Hand protection: Wear appropriate protective gloves to reduce skin contact.
- Eye protection: Wear safety goggles or eye protection combined with respiratory protection.
- Respiratory Protection: Wear suitable protective mask in order to reduce the respiratory system. With a large leakage, wear chemical protective clothing, including self-contained breathing apparatus.
- Clothing: Wear suitable protective clothing to minimise contact with skin. The type of protective equipment must be according to the concentration and the content of certain hazardous substances in the workplace.

Environmental exposure controls:

Control measures must be made in accordance with community environmental protection legislation.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Gel
Odour	Odourless
Odour threshold	Not determined.
pH	4.9 (25.3 °C)
Melting point/ Freezing point	Not determined.
Initial boiling point and range	Not determined.
Flash point	100 °C (closed cup)
Evaporation rate	Not determined.



Flammability (solid, gas)	Not determined.
Upper/lower flammability or explosive limits	Product does not present an explosion hazard.
Vapour pressure	Not determined.
Vapour density	Not determined.
Relative density	Not determined.
Solubility	soluble in water
Partition coefficient: n-octanol/ water	Not determined.
Auto-ignition temperature	Not determined.
Decomposition Temperature	Not determined.
Viscosity [Pa·s]	Not determined.
Explosive properties	Not determined.
Oxidising properties	Not determined.

9.2. Other information

Not determined.

SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity

There are no known reactivity hazards associated with this product.

10.2. Stability

Stable at normal ambient temperatures and when used as recommended.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

No further relevant information available.

10.5. Incompatible materials

No further relevant information available.

10.6. Hazardous decomposition products

Carbon oxide.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory or skin sensitization:	Not available.
Germ cell mutagenicity:	Not available.
Reproductive toxicity:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration hazard:	Not available.

Document Title:

Product:

Issue:

Date:

Safety Data Sheet

BurnSoothe Burn Gel Dressings

V5

27/03/2024



SECTION 12. ECOLOGICAL INFORMATION

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bio accumulative potential

No data available on bioaccumulation.

12.4. Mobility in soil

The product is soluble in water.

12.5. Results of PBT and vPvB assessment

Not determined.

12.6. Other adverse effects

None known.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Consult state, local or national regulations to ensure proper disposal.

SECTION 14. TRANSPORT INFORMATION

14.1. UN number

Not regulated.

14.2. UN proper shipping name

Not regulated.

14.3. Transport hazard class(es)

Not regulated.

14.4. Packing group

Not regulated.

14.5. Environmental hazards

No data available.

14.6. Special precautions for user

None.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable.

Document Title:
Product:
Issue:
Date:

Safety Data Sheet
BurnSoothe Burn Gel Dressings
V5
27/03/2024



SECTION 15. REGULATORY INFORMATION

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

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) (as amended).

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 (as amended).

Commission Directive 91/322/EEC of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical, and biological agents at work.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (as amended).

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16. OTHER INFORMATION

General information Always read the label and product information before use.

Key literature references and sources for data

Approved Supply List Dangerous Substances Directive Dangerous Preparations Directive

Revision comments SDS created in line with REGULATION (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (as amended). Additional product codes added.

Revision V5

Supersedes date 01.11.22

Relevant hazard statements

H302 Harmful if swallowed
H315 Causes skin irritation
H318 Causes serious eye damage
H319 Causes serious eye irritation
H335 May cause respiratory irritation
H373 Causes damage to organs through prolonged or repeated exposure
H410 Very toxic to aquatic life with long lasting effect

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