

Document Title:
Product:
Issue:
Date:

Safety Data Sheet
Hot Cold Packs
V5
18/03/2024



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: **Reusable Hot & Cold Packs** (This SDS is related to the liquid inside the product)
Product codes: 711, X001, X0055, X711, X123, X1951, X1952, X1953, X1955, X1964, X1975, X1976, X1977,
8801, 8802, LP711, LP712

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

Hot and Cold Therapy. 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)
Mixture of: 5-Chloro-2-methyl-3 (2H)-isothiazolone (CIT) with 2-Methyl-3 (2H)-isothiazolone (MIT) (3:1)	55965-84-9	911-418-6	0.02	H301, H311, H314, H317, H331, H400, H410
Indigo	482-89-3	207-586-9	0.002	H373

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

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Non hazardous ingredients: Water, glycerol, carboxymethyl cellulose, sodium salt.

SECTION 4. FIRST AID MEASURES

4.1. Description of first aid measures

Eye contact: Remove contact lenses. Rinse opened eye for several minutes under running water. If discomfort persists, contact doctor.

Skin contact: Wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

Ingestion: Rinse mouth with water. If symptoms persist consult doctor.

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

Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Use fire extinguishing methods suitable to surrounding conditions.

5.2. Special hazards arising from the substance or mixture

No further relevant information available.

5.3. Advice for firefighter

Special protective equipment: Mouth respiratory protective device. Wear fully protective suit.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Avoid contact with eyes and skin.

6.2. Environmental precautions

Do not allow to enter sewers/surface or ground water.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material.

6.4. Reference to other sections

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

SECTION 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. Avoid contact with eyes and skin. Prevent formation of aerosols. For the general occupational hygienic measures refer to section 8. Avoid long exposure to heat. Keep away from direct sunlight.

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7.2. Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles: Store in a cool location. Information about storage in one common storage facility: Store away from food. Further information about storage conditions: Store in cool, dry conditions in well-sealed receptacles.

7.3. Specific end use(s)

No specific uses identified.

SECTION 8. EXPOSURE CONTROL

8.1. Control parameters

Ingredients with limit values that require monitoring at the workplace: 56-81-5 glycerol (10.000%)	
AGW (Germany)	Long-term value: 200 E mg/m ³ 2 (I);DFG, Y
VME (France)	Long-term value: 10mg/ m ³
WEL (Great Britain)	Long-term value: 10mg/ m ³
55965-84-9 Mixture of: 5-Chloro-2-methyl-3 (2H)-isothiazolone (CIT) (CAS No.26172-55-4) with 2-Methyl-3(2H)-isothiazolone (MIT) (CAS No.2682-20-4) (3:1) (0.020%)	
MAK (Germany)	Long-term value: 0.2E mg/ m ³ Vgl.Abschn.Xc

8.2. Exposure controls

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

Appropriate Engineering Controls:

Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid close or long-term contact with the skin. See section 7 for information about design of technical facilities.

Personal Protective Equipment:

Hand protection: The glove material must be impermeable and resistant to the product, the substance, and the preparation. Due to missing tests no recommendation to the glove material can be given for the product, the preparation, or the chemical mixture. The selection of the suitable gloves does not only depend on the material but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and therefore must be checked prior to the application. The exact break through time must be found out by the manufacturer of the protective gloves and has to be observed

Eye protection: Tightly sealed goggles.

Respiratory Protection: In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device with independent circulating air.

**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	Not determined.
Melting point/ Freezing point	Not determined.
Initial boiling point and range	Not determined.
Flash point	Not Determined.
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	2.07 (Air=1).
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

VOC 0%

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

No dangerous decomposition products known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity: Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification: 55965-84-9 Mixture of: 5-Chloro-2-methyl-3(2H)-isothiazolone (CIT) (CAS No.26172-55-4) with 2-methyl-3(2H)-isothiazolone (MIT) (CAS No.2682-20-4) (3:1)		
Oral	LD50	60 mg/kg (mouse) 53 mg/kg (rat)
9004-32-4 carboxymethyl cellulose, sodium salt		
Oral	LD50	27000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
56-81-5 glycerol		
Oral	LD50	4090 mg/kg (mouse) 12600 mg/kg (rat) 27000 mg/kg (rabbit)
7732-18-5 Water		
Oral	LD50	>90000 mg/kg (rat)

Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization:	May cause an allergic skin reaction.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration hazard:	Based on available data, the classification criteria are not met.

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.

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12.6. Other adverse effects

None known.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Must not be disposed together with household waste. Do not allow product to reach sewage system.
Contaminated packaging recommendation: Disposal must be made according to official regulations.

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.

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).

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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 Additional hot and cold pack codes added.

Revision V5

Supersedes date 18/03/2024

Relevant hazard statements

- H301 Toxic if swallowed.
- H311 Toxic in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H331 Toxic if inhaled.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long-lasting effects.

Legal Disclaimer: This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability, or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.