
SAFETY DATA SHEET

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

1.1 Product identifier

- Product Name: Dermacol
- Chemical Name: Hydrocolloid Adhesive

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

- Use of the substance/mixture: Adhesive for ostomy pouches
- Use advised against: No information available

1.3 Details of the supplier of the safety data sheet

- Name of Supplier: Salts Healthcare
- Address of Supplier: Richard St,
Aston,
Birmingham
United Kingdom
B7 4AA
- Telephone: +44 (0) 121 333 2000
- Fax: +44 (0) 121 359 0830
- Email: salt@salts.co.uk

1.4 Emergency telephone number

- +44 (0) 121 333 2000
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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

- Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]: Not Classified

2.2 Label elements

- None

2.3 Other hazards

- No hazard expected under normal conditions of use
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SECTION 3: Composition/information on ingredients

3.1 Substances

3.2 Mixtures

- This product does not contain any hazardous ingredients at levels above the relevant thresholds or any ingredients with a workplace exposure limit.
 - Contains synthetic elastomers and hydrophilic polysaccharides. Latex Free.
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SECTION 4: First aid measures

4.1 Description of first aid measures

- Contact with eyes
No hazard expected under normal conditions of use
 - Contact with skin
No hazard expected under normal conditions of use
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SECTION 4: First aid measures (....)

If skin irritation occurs: Get medical advice/attention.

- Ingestion
No hazard expected under normal conditions of use
- Inhalation
Not applicable in supplied form

4.2 Most important symptoms and effects, both acute and delayed

- No hazard expected under normal conditions of use

4.3 Indication of any immediate medical attention and special treatment needed

- Treat symptomatically
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SECTION 5: Firefighting measures

5.1 Extinguishing media

- In case of fire: use water, alcohol resistant foam or dry agent to extinguish.

5.2 Special hazards arising from the substance or mixture

- Gives off irritating or toxic fumes (or gases) in a fire.
- Decomposition products may include carbon oxides

5.3 Advice for firefighters

- Special protective equipment: Wear self-contained breathing apparatus (SCBA). Wear full protective clothing including chemical protection suit.
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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions for non-emergency personnel: No special precautions are required for this product
- Personal precautions for emergency responders: Wear protective clothing as per section 8

6.2 Environmental precautions

- Do not allow to enter public sewers and watercourses

6.3 Methods and material for containment and cleaning up

- Absorb spillage in suitable inert material
- Place in sealable container

6.4 Reference to other sections

- See Section 8
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SECTION 7: Handling and storage

7.1 Precautions for safe handling

- No special precautions are required for this product

7.2 Conditions for safe storage, including any incompatibilities

- Keep in a cool, dry place
- Keep away from heat and sources of ignition

7.3 Specific end use(s)

- Application to skin as part of an Ostomy Device
 - Adhesive
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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- No exposure limits have been set for this product
- The UK HSE (EH40) recommends the following limits for dusts: 10 mg/m³ (8hr TWA) total inhalable dust; 4 mg/m³ (8hr TWA) total respirable dust

8.2 Exposure controls

- In case of fire:
Wear protective gloves/protective clothing/eye protection/face protection.
The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and standard EN 374.
The selection of a suitable glove depends on work conditions and whether the product is present on its own or in combination with other substances. Breakthrough time is dependent on the characteristics of the brand of glove used and the supplier should be consulted.
Wear safety glasses approved to standard EN 166.
Wear suitable respiratory equipment



Gloves



Suit



Goggles



Respirator

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance: Brown putty
- Odour: No information available
- Odour threshold: No information available
- pH: Not applicable
- Melting point/freezing point: Not applicable
- Initial boiling point and boiling range: Not applicable
- Flashpoint: No information available
- Evaporation Rate: Not applicable
- Flammability (solid,gas): No information available
- Upper/lower flammability or explosive limits: Not applicable
- Vapour Pressure: Not applicable
- Vapour Density: Not applicable
- Relative Density: No information available
- Solubility(ies): insoluble in water
- Partition Coefficient (n-Octanol/Water): No information available
- Autoignition Temperature: No information available
- Decomposition temperature: No information available
- Viscosity: Not applicable
- Explosive Properties: No information available
- Oxidising Properties: No information available

9.2 Other information

- No information available

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SECTION 10: Stability and reactivity

10.1 Reactivity

- No information available

10.2 Chemical stability

- Considered stable under normal conditions

10.3 Possibility of hazardous reactions

- No information available

10.4 Conditions to avoid

- Keep away from heat and sources of ignition

10.5 Incompatible materials

- No information available

10.6 Hazardous decomposition products

- Decomposition products may include carbon oxides
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SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices
- Acute Toxicity
Based on available data, the classification criteria are not met
- 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 sensitisation
Based on available data, the classification criteria are not met
- Germ cell mutagenicity
No evidence of mutagenic effects
- Carcinogenicity
No evidence of carcinogenic effects
- Reproductive toxicity
No evidence of reproductive effects
- Specific target organ toxicity (STOT) - single exposure
Based on available data, the classification criteria are not met
- Specific target organ toxicity (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
- Contact with eyes
No hazard expected under normal conditions of use
- Contact with skin
No hazard expected under normal conditions of use
- Ingestion
No hazard expected under normal conditions of use

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SECTION 11: Toxicological information (....)

- Inhalation
No hazard expected under normal conditions of use
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SECTION 12: Ecological information

- 12.1 Toxicity
 - No information available
 - 12.2 Persistence and degradability
 - No information available
 - 12.3 Bioaccumulative potential
 - No information available
 - 12.4 Mobility in soil
 - Insoluble in water
 - 12.5 Results of PBT and vPvB assessment
 - No information available
 - 12.6 Other adverse effects
 - No information available
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SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
 - Avoid release to the environment.
 - Disposal should be in accordance with local, state or national legislation
 - Dispose of contents/container to an authorised waste collection point
 - 13.2 Classification
 - The waste must be identified according to the List of Wastes (2000/532/EC)
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SECTION 14: Transport information

- Not classified as hazardous for transport
- 14.1 UN number
 - Not applicable
 - 14.2 UN proper shipping name
 - Not applicable
 - 14.3 Transport hazard class(es)
 - Not applicable
 - 14.4 Packing group
 - Not applicable
 - 14.5 Environmental hazards
 - Not Classified
 - 14.6 Special precautions for user
 - No special precautions are required for this product
 - 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
 - Not applicable
 - 14.8 Road/Rail (ADR/RID)

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SECTION 14: Transport information (....)

- Proper Shipping Name: Not applicable
- ADR UN No.: Not applicable
- ADR Hazard Class: Not applicable
- ADR Packing Group: Not applicable

14.9 Sea (IMDG)

- Proper Shipping Name: Not applicable
- IMDG UN No.: Not applicable
- IMDG Hazard Class: Not applicable
- IMDG Pack Group.: Not applicable

14.10 Air (ICAO/IATA)

- Proper Shipping Name: Not applicable
 - ICAO UN No.: Not applicable
 - ICAO Hazard Class: Not applicable
 - ICAO Packing Group: Not applicable
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SECTION 15: Regulatory information

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

- This Safety Data Sheet is provided in compliance with REACH Regulation (EC) No 1907/2006 as amended by Regulation (EU) 2015/830
- Exempt from the requirements of CLP as product is regulated as a medical device or an accessory to a medical device. Information is provided to inform users of the hazards associated with the use of the product.
- Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices

15.2 Chemical safety assessment

- A chemical safety assessment is not required under REACH
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SECTION 16: Other information

This information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contra-indications and precautions for the treatment of patients.

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Changes made: Updated sections to conform to latest version of REACH

--- end of safety datasheet ---
