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SAFETY DATA SHEET

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

1.1 Product identifier

- Product Name: SecuPaste
- Chemical Name: Soft adhesive paste
- Product Description: SecuPaste has been specifically designed to be used as an effective filler where scar tissue or gaps are present around the stoma

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

- Use of the substance/mixture: Application to skin as part of an adhesive device.
- Use advised against: Not for internal use.

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

- Symbols: None
- Signal Word: None
- Hazard statements
None
- Precautionary statements
None
- Supplemental Hazard Information (EU)
None

2.3 Other hazards

- None
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SECTION 3: Composition/information on ingredients

3.1 Substances

3.2 Mixtures

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SECTION 3: Composition/information on ingredients (....)

A soft adhesive paste containing elastomers, a combination of hydrocolloid particles and isoalkanes.

- This product does not contain any hazardous ingredients at levels above the relevant thresholds or any ingredients with a workplace exposure limit.
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SECTION 4: First aid measures

4.1 Description of first aid measures

- Contact with eyes
If substance has got into eyes, immediately wash out with plenty of water
Remove contact lenses, if present and easy to do. Continue rinsing.
- Contact with skin
No hazard expected under normal conditions of use
If skin irritation or rash occurs: gently wash with soap and water
- Ingestion
Rinse mouth with water (do not swallow)
IF exposed or concerned: Call a doctor.
- Inhalation
Inhalation is unlikely to occur

4.2 Most important symptoms and effects, both acute and delayed

- Mildly irritating to eyes

4.3 Indication of any immediate medical attention and special treatment needed

- No hazard expected under normal conditions of use
-

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

- Wear protective clothing as per section 8
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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

- No special precautions are required for this product

6.3 Methods and material for containment and cleaning up

- No special precautions are required for this product

6.4 Reference to other sections

- See Section 7 and 8
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SECTION 7: Handling and storage

7.1 Precautions for safe handling

- No special precautions are required for this product
- See Section 8

7.2 Conditions for safe storage, including any incompatibilities

- Keep in a cool, dry, well ventilated place
- Protect from heat

7.3 Specific end use(s)

- Application to skin as part of an adhesive device.
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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- No exposure limits have been set for this product

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.
Wear safety glasses approved to standard EN 166.
In case of inadequate ventilation wear respiratory protection.



Gloves



Suit



Goggles



Respirator

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance: Beige, viscous, paste
- Odour: None
- Odour threshold: Not applicable
- pH: No information available
- Melting point/freezing point: No information available
- Initial boiling point and boiling range: No information available
- Flashpoint: No information available
- Evaporation Rate: No information available
- Flammability (solid,gas): No information available
- Upper/lower flammability or explosive limits: No information available
- Vapour Pressure: No information available
- Vapour Density: No information available
- Relative Density: No information available
- Solubility(ies): No information available
- Partition Coefficient (n-Octanol/Water): No information available

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SECTION 9: Physical and chemical properties (....)

- Autoignition Temperature: No information available
- Decomposition temperature: Decomposes above 50 °C
- Viscosity: Viscous
- Explosive Properties: No information available
- Oxidising Properties: No information available

9.2 Other information

- Hydrophilic
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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

- Avoid overheating
- 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
No information available

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SECTION 11: Toxicological information (....)

- Specific target organ toxicity (STOT) - repeated exposure
No information available
 - Aspiration hazard
Based on available data, the classification criteria are not met
 - Contact with eyes
Mildly irritating to eyes
 - Contact with skin
No hazard expected under normal conditions of use
 - Ingestion
The ingestion of significant quantities may cause nausea/vomiting
The ingestion of significant quantities may cause diarrhoea
 - Inhalation
Inhalation is unlikely to occur
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SECTION 12: Ecological information

12.1 Toxicity

- No information available

12.2 Persistence and degradability

- Will degrade

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

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

- UN No.: Not applicable

14.2 UN proper shipping name

- Proper Shipping Name: Not applicable

14.3 Transport hazard class(es)

- Hazard Class: Not applicable
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SECTION 14: Transport information (....)

14.4 Packing group

- 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)

- Proper Shipping Name: Not applicable
- ADR UN No.: Not applicable
- ADR Hazard Class: Not applicable
- ADR Packing Group: Not applicable
- Tunnel Code: 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
- Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) applies in Europe
- Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices

15.2 Chemical safety assessment

- A REACH chemical safety assessment has not been carried out
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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: Revised to conform to latest version of REACH. Minor changes to layout.

--- end of safety datasheet ---
