

Revised: 2 May 2023

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**SAFETY DATA SHEET**

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

A safety data sheet is not required for this product under Article 31 of REACH. This safety data sheet has been created on a voluntary basis to communicate relevant information.

**1.1 Product identifier**

Product Name: Salts No-Sting Stoma Paste  
Product Description: Soft adhesive paste 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: No information available

**1.3 Details of the supplier of the safety data sheet**

Name of Supplier: Salts Healthcare  
Address of Supplier: Richard Street  
Aston  
Birmingham  
B7 4AA  
United Kingdom  
Telephone: +44 (0) 121 333 2000  
Fax: +44 (0) 121 359 0830  
Email: hello@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**

Hazard pictograms: None  
Signal Word: None

**Hazard statements**

None

**Precautionary statements**

None

**Supplemental Hazard information (EU)**

None

**2.3 Other hazards**

Not a PBT according to REACH Annex XIII  
Not a vPvB according to REACH Annex XIII  
Does not contain any substances with endocrine disrupting properties

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**SECTION 3: Composition/information on ingredients**

## 3.1 Substances

Not applicable

## 3.2 Mixtures

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

Rescuers should put on approved personal protective equipment (PPE) before administering first aid

## Contact with eyes

No hazard expected under normal conditions of use  
If substance has got into eyes, immediately wash out with plenty of water

## Contact with skin

No hazard expected under normal conditions of use  
If skin irritation or rash occurs: gently wash with soap and water

## 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

## Contact with eyes

No hazard expected under normal conditions of use  
May cause mild eye irritation

## 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

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

No hazard expected under normal conditions of use

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**SECTION 5: Firefighting measures**

## 5.1 Extinguishing media

Suitable extinguishing media: In case of fire use water, alcohol resistant foam, carbon dioxide or dry agent

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**SECTION 5: Firefighting measures (....)**

Unsuitable extinguishing media: No information available

**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**

Collect contaminated fire extinguishing water separately. This MUST not be discharged into drains.  
Prevent fire extinguishing water from contaminating surface or ground water.  
Clothing for firefighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

No action shall be taken involving any personal risk or without suitable training  
Only trained and authorised personnel should carry out emergency response  
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(s): 7, 8 & 13

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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  
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**

Selection and use of personal protective equipment should be based on a risk assessment of exposure potential

**Engineering controls**

Engineering controls are not required for normal handling

**Respiratory protection**

No respiratory protection is needed during normal handling

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**SECTION 8: Exposure controls/personal protection (....)**

In case of fire: Wear suitable respiratory protection

Skin protection

None required for normal handling of product

Eye/face protection

None required for normal handling of product

Thermal hazards

Not applicable

Hygiene measures

Use good personal hygiene practices

Environmental exposure controls

Do not allow to enter public sewers and watercourses

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**SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Physical state: Solid (paste)

Colour: Beige

Odour: None

Melting point/freezing point: Not determined

Boiling point or initial boiling point and boiling range: Not applicable

Flammability: Not flammable

Lower and upper explosion limit: Not applicable

Flash point: Not applicable

Auto-ignition temperature: Not determined

Decomposition temperature: Decomposes above 50 °C

pH: Not applicable

Kinematic viscosity: No information available

Solubility: No information available

Partition coefficient n-octanol/water (log value): No information available

Vapour pressure: Not applicable

Density and/or relative density: No information available

Relative vapour density: No information available

Particle characteristics: 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

Avoid overheating

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**SECTION 10: Stability and reactivity (....)**

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 hazard classes as defined in Regulation (EC) No 1272/2008**

Reviewed in accordance with ISO 10993-1:2018 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

May cause mild eye irritation

**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

**11.2 Information on other hazards**

Does not contain any substances with endocrine disrupting properties

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**SECTION 12: Ecological information****12.1 Toxicity**

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**SECTION 12: Ecological information (....)**

- 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 Endocrine disrupting properties
    - Does not contain any substances with endocrine disrupting properties
  - 12.7 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)
    - Hazardous Property Code(s): None assigned
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**SECTION 14: Transport information**

- Not classified as hazardous for transport
  - 14.1 UN number or ID 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
  - 14.4 Packing group
    - Packing Group: Not applicable
  - 14.5 Environmental hazards
    - Presents little or no hazard to the environment
  - 14.6 Special precautions for user
    - No special precautions are required for this product
  - 14.7 Maritime transport in bulk according to IMO instruments
    - 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  
Tunnel Code: Not applicable

**14.9 Sea (IMDG)**

Proper Shipping Name: Not applicable  
IMDG UN No.: Not applicable  
IMDG Hazard Class: Not applicable  
IMDG Packing 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**

A safety data sheet is not required for this product under Article 31 of REACH. This safety data sheet has been created on a voluntary basis to communicate relevant information.

This safety data sheet is provided in compliance with REACH Regulation (EC) No 1907/2006 (as amended by Regulation (EU) 2020/878) and UK REACH

The GB Classification, Labelling and Packaging Regulation (GB CLP) applies in Great Britain Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) applies in Europe

This product is covered by the Medical Devices Regulation (EU) 2017/745 (MDR)

Reviewed in accordance with ISO 10993-1:2018 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.

Sources of data: Information from company data, published literature and supplier safety data sheets

Created by ChemRegs (UK) Ltd May 2014

Revision No. 2.0.0. Revised January 2017.

Changes made: Revised to conform to latest version of REACH. Minor changes to layout.

Revision No. 3.0.0. Revised May 2023.

Changes made: Updated to conform to the latest version of REACH Annex II and the Medical Devices Regulation (EU) 2017/745 (MDR)

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Not classified as hazardous for supply

Text not given with phrase codes where they are used elsewhere in this safety data sheet:

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**SECTION 16: Other information (....)**

None assigned

Acronyms

ATE: Acute Toxicity Estimate  
CAS: Chemical Abstracts Service  
DNEL: Derived No-Effect Level  
EC: European Community  
EC<sub>50</sub>: Effective Concentration, 50%  
GHS: Globally Harmonised System  
LC<sub>50</sub>: Lethal Concentration, 50%  
LD<sub>50</sub>: Lethal Dose, 50%  
NOAEC: No Observed Adverse Effect Concentration  
NOAEL: No Observed Adverse Effect Level  
OEL: Occupational Exposure Limit  
PBT: Persistent, Bioaccumulative and Toxic  
PNEC: Predicted No-Effect Concentration  
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals  
SCL: Specific Concentration Limit  
STOT RE: Specific Target Organ Toxicity Repeated Exposure  
STOT SE: Specific Target Organ Toxicity Single Exposure  
SVHC: Substances of Very High Concern  
vPvB: very Persistent and very Bioaccumulative  
WEL: Workplace Exposure Limit