

Revised: 2 May 2023

SAFETY DATA SHEET

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 Mouldable Seals with Aloe
Product Description: Mouldable hydrocolloid rings that form a secure seal around the base of the stoma, helping to prevent leaks that cause sore skin

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

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

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Consisting of elastomers and tackifiers, white soft paraffin and carbohydrate mixture, with Aloe Oil. Latex free.

This product does not contain any hazardous ingredients at levels above the relevant thresholds or any ingredients with a workplace exposure limit.

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

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

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

Unsuitable extinguishing media: No information available

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SECTION 5: Firefighting measures (....)

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

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

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.

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	Solid (putty)
Colour:	Brown
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

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

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

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

SECTION 12: Ecological information**12.1 Toxicity**

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

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

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

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

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 July 2017

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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:

None assigned

Acronyms

SECTION 16: Other information (....)

ATE: Acute Toxicity Estimate
CAS: Chemical Abstracts Service
DNEL: Derived No-Effect Level
EC: European Community
EC₅₀: Effective Concentration, 50%
GHS: Globally Harmonised System
LC₅₀: Lethal Concentration, 50%
LD₅₀: 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