

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 Collar

Product Description: 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 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

Revised: 2 May 2023

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

3.1 Substances

Not applicable

3.2 Mixtures

Contains synthetic elastomers and hydrophilic polysaccharides. 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

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

5.2 Special hazards arising from the substance or mixture

Revised: 2 May 2023

SECTION 5: Firefighting measures (....)

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 Ostomy Device. Adhesive.

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
In case of fire: Wear suitable respiratory protection

Skin protection

None required for normal handling of product

Revised: 2 May 2023

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

- 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 (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: Not determined
- 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
- Keep away from heat and sources of ignition

10.5 Incompatible materials

- No information available
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Revised: 2 May 2023

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

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

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

No information available

12.2 Persistence and degradability

No information available

Revised: 2 May 2023

SECTION 12: Ecological information (....)

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)

Proper Shipping Name: Not applicable

ADR UN No.: Not applicable

ADR Hazard Class: Not applicable

Revised: 2 May 2023

SECTION 14: Transport information (....)

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

Revision No. 2.0.0. Revised December 2016 by ChemRegs (UK) Ltd.

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

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:

None assigned

SECTION 16: Other information (....)

Acronyms

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