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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 Stoma Collar

Product Description: The Salts Stoma Collar consists of a hydrocolloid adhesive and a polyurethane collar

**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 Ostomy Device

Use advised against: No information available

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

Name of Supplier: Salts Healthcare UK

Address of Supplier: Richard Street  
Aston, Birmingham  
B7 4AA  
United Kingdom

Telephone: +44 (0) 121 333 2000

Email: hello@salts.co.uk

**1.4 Emergency telephone number**

Emergency Telephone: +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

Additional information: For full text of Hazard- and EU Hazard-statements: see section 16

**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**

Does not contain any substances considered to be PBT or vPvB at levels of 0.1% or higher

Does not contain any substances with endocrine disrupting properties at levels of 0.1% or higher

**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.

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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

## 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

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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 Ostomy 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**

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

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

**Eye/face protection**

None required for normal handling of product

**Thermal hazards**

Not applicable

**Hygiene measures**

Not applicable

**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
Colour:	Pale yellow
Odour:	No information available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	Not flammable
Lower and upper explosion limit:	Not applicable
Flash point:	Not applicable
Auto-ignition temperature:	Not applicable
Decomposition temperature:	No data available
pH:	No data available
Kinematic viscosity:	No data available
Solubility:	No data available
Partition coefficient n-octanol/water (log value):	No data available
Vapour pressure:	No data available
Density and/or relative density:	No data available
Relative vapour density:	No data available
Particle characteristics:	No data 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

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

**SECTION 11: Toxicological information (....)**

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 at levels of 0.1% or higher

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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**

No information available

**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 at levels of 0.1% or higher

**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

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 Restriction 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

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**SECTION 15: Regulatory information (....)**

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

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)

Revision No. 3.1.0. Revised February 2025.

Changes made: Name and product description changed

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**

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

IARC: International Agency for Research on Cancer

IOELV: Indicative Occupational Exposure Limit Value

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



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

PNEC: Predicted No-Effect Concentration

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

SCL: Specific Concentration Limit

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

WEL: Workplace Exposure Limit