
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 under Article 32.

1.1 Product identifier

- Product Name: Salts Ostomy Pouches (Various)
- Product Description: Healthcare device

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

- Use of the substance/mixture: Medical device or accessory to a medical device, as a collection device for ostomy output
- 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 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

SECTION 2 Hazards identification

Exempt from the requirements of CLP as product is regulated as a medical device or an accessory to a medical device. Information is provided to inform users of the hazards associated with the use of the product.

2.1 Classification of the substance or mixture

- Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]: Not Classified

2.2 Label elements

- None

2.3 Other hazards

- Contains combustible material

SECTION 3 Composition/information on ingredients

3.1 Substances

3.2 Mixtures

A pouch consisting of a hydrocolloid wafer and outer films of polyethylene non-woven or ethylene vinyl acetate perforated films, which can be in direct contact with skin. The inner films of the pouch consist of 5 layer coextruded laminate EVA/EVA/PVDC/EVA/EVA films and combinations of charcoal filters, EMA films, PET springs and polyamide hook and loop.

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

On the basis of available information, the activated carbon component is not considered hazardous or dangerous goods.

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
- Contact with skin
If skin irritation or rash occurs: gently wash with plenty of soap and water
- Ingestion
Give plenty of water to drink
Get medical advice/attention.
- Inhalation
Inhalation is unlikely to occur
Seek medical advice if necessary

4.2 Most important symptoms and effects, both acute and delayed

- No hazard expected under normal conditions of use

4.3 Indication of any immediate medical attention and special treatment needed

- If skin irritation or rash occurs: Get medical advice/attention.
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SECTION 5 Fire-fighting measures

5.1 Extinguishing media

- In case of fire: use water, alcohol resistant foam or dry agent for extinction

5.2 Special hazards arising from the substance or mixture

- Contains combustible material
- Risk of burns from molten product
- Gives off irritating or toxic fumes (or gases) in a fire.
- Decomposition products may include nitrogen and carbon oxides
- Decomposition products may include hydrocarbons
- Decomposition products may include hydrogen chloride

5.3 Advice for firefighters

- Special protective equipment: Wear self-contained breathing apparatus (SCBA). Wear full protective clothing including chemical protection suit.
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SECTION 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- No special precautions are required for this product

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

7.2 Conditions for safe storage, including any incompatibilities

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

7.3 Specific end use(s)

- as a collection device for ostomy output

SECTION 8 Exposure controls/personal protection

8.1 Control parameters

- There are no recommended or established controls 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.

Wear suitable respiratory equipment



Gloves



Suit



Goggles



Respirator

SECTION 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance: Skintone plastic pouch
- Odour: Not applicable
- Odour threshold: Not applicable
- pH: Not applicable
- Melting point/freezing point: Not applicable
- Initial boiling point and boiling range: Not applicable
- Flashpoint: No information available
- Evaporation Rate: Not applicable
- Flammability (solid,gas): Combustible polymer material
- Upper/lower flammability or explosive limits: Not applicable
- Vapour Pressure: Not applicable
- Vapour Density: Not applicable
- Relative Density: No information available
- Solubility(ies): Insoluble in water
- 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: >200°C
- Viscosity: Not applicable
- Explosive Properties: Not applicable
- Oxidising Properties: Not applicable

9.2 Other information

Polymeric plastic films, chemically inert

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

- Incompatible with strong acids
- Incompatible with strong oxidizing substances

10.6 Hazardous Decomposition Products

- Decomposition products may include nitrogen and carbon oxides
 - Decomposition products may include hydrocarbons
 - Decomposition products may include hydrogen chloride
 - Decomposition products may include aldehydes
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SECTION 11 Toxicological information

11.1 Information on toxicological effects

- Acute Toxicity
Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices
Non-toxic
- Skin corrosion/irritation
Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices
Not hazardous
- Serious eye damage/irritation
Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices
Not hazardous
- Respiratory or skin sensitisation
Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices
Not hazardous

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SECTION 11 Toxicological information (....)

- 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
Not hazardous
- Specific target organ toxicity (STOT) - repeated exposure
Not hazardous
- Aspiration hazard
Not applicable
- Contact with eyes
No hazard expected under normal conditions of use
Dust may be irritating to eyes
- Contact with skin
No hazard expected under normal conditions of use
Risk of burns from molten product
- Ingestion
The ingestion of significant quantities may cause nausea/vomiting
- Inhalation
No hazard expected under normal conditions of use
Dust may cause respiratory irritation.

SECTION 12 Ecological information

- 12.1 Toxicity
 - No information available
- 12.2 Persistence and degradability
 - No information available
- 12.3 Bioaccumulation 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

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)

SECTION 14 Transport information

14.1 UN Number

- Not applicable

14.2 UN Proper Shipping Name

- Not applicable

14.3 Transport hazard class(es)

- Not applicable

14.4 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 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

- Not applicable

14.8 Road/Rail (ADR/RID)

- Proper Shipping Name: N/A
- ADR UN No.: N/A
- ADR Hazard Class: N/A
- ADR Packing Group: N/A

14.9 Sea (IMDG)

- Proper Shipping Name: N/A
- IMDG UN No.: N/A
- IMDG Hazard Class: N/A
- IMDG Pack Group.: N/A

14.10 Air (ICAO/IATA)

- Proper Shipping Name: N/A
- ICAO UN No.: N/A
- ICAO Hazard Class: N/A
- ICAO Packing Group: N/A

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 under Article 32.
- Exempt from the requirements of CLP as product is regulated as a medical device or an accessory to a medical device. Information is provided to inform users of the hazards associated with the use of the product.
- 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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