
SAFETY DATA SHEET

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

1.1 Product identifier

- Product Name: Conformable Seals
- Product Part Number: 900222 and 900444
- Product Description: Hydrocolloid washers of varying sizes
- Chemical Name: A beige to brown, inherently tacky pressure sensitive adhesive

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

- Use of the substance/mixture: As an adhesive for ostomy collection devices
- 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
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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

- Symbols: None
- Signal Word: None
- Hazard statements
None
- Precautionary statements
None
- Supplemental Hazard Information (EU)
None

2.3 Other hazards

- None
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SECTION 3: Composition/information on ingredients

3.1 Substances

3.2 Mixtures

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

- Contains synthetic elastomers and hydrophilic polysaccharides. Latex Free.
 - Glycerol; glycerine
 - Concentration: <5%
 - CAS Number: 56-81-5
 - EC Number: 200-289-5
 - Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]: Not Classified
 - Substance with a workplace exposure limit, see Section 8
-

SECTION 4: First aid measures

4.1 Description of first aid measures

- 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
 - If swallowed, rinse mouth with water (only if the person is conscious)
- Inhalation
 - Not applicable in supplied form
 - Inhalation is unlikely to occur

4.2 Most important symptoms and effects, both acute and delayed

- Mildly irritating to eyes

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

- In case of fire: use water, alcohol resistant foam or dry agent to extinguish.

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

- Wear protective clothing as per section 8
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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- 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

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SECTION 6: Accidental release measures (...)

- Do not allow to enter public sewers and watercourses
- 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 & 8
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SECTION 7: Handling and storage

- 7.1 Precautions for safe handling
- No special precautions are required for this product
 - See Section 8
- 7.2 Conditions for safe storage, including any incompatibilities
- Keep in a cool, dry place
 - Protect from heat
- 7.3 Specific end use(s)
- As an adhesive for ostomy collection devices
-

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- Glycerol; glycerine
The exposure limit is for mists. Exposure by inhalation is unlikely to occur for this product during normal handling.
WEL (long term) (mist) 10 mg/m³ (UK)
DNEL (inhalational) 56 mg/m³ Industry, Long Term, Local Effects
DNEL (inhalational) 33 mg/m³ Consumer, Long Term, Local Effects
DNEL (oral) 229 mg/kg (bw/day) Consumer, Long Term, Systemic Effects
PNEC aqua (freshwater) 885 ug/l
PNEC aqua (marine water) 88.5 ug/l
PNEC (STP) 1000 mg/l
PNEC sediment (freshwater) 3.3 mg/kg
PNEC sediment (marine water) 330 ug/kg
PNEC terrestrial (soil) 141 ug/kg

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.
In case of inadequate ventilation wear respiratory protection.



Gloves



Suit



Goggles



Respirator

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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SECTION 9: Physical and chemical properties (....)

- Appearance: Brown; malleable; putty; in annular form between two silicone coated release films
- Odour: No information available
- Odour threshold: No information available
- Melting point/freezing point: No information available
- Initial boiling point and boiling range: No information available
- Flashpoint: No information available
- Evaporation Rate: No information available
- Flammability (solid,gas): No information available
- Upper/lower flammability or explosive limits: No information available
- Vapour Pressure: No information available
- Vapour Density: No information available
- Relative Density: No information available
- Solubility(ies): No information available
- Partition Coefficient (n-Octanol/Water): No information available
- Autoignition Temperature: No information available
- Decomposition temperature: Decomposes above 50 °C
- Viscosity: No information available
- Explosive Properties: No information available
- Oxidising Properties: 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

10.6 Hazardous decomposition products

- Decomposition products may include carbon oxides
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SECTION 11: Toxicological information**11.1 Information on toxicological effects**

- Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices

- Acute Toxicity
Based on available data, the classification criteria are not met

SECTION 11: Toxicological information (....)

- 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
No information available
- Specific target organ toxicity (STOT) - repeated exposure
No information available
- Aspiration hazard
No information available
- Contact with eyes
No hazard expected under normal conditions of use
May cause 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

SECTION 12: Ecological information

12.1 Toxicity

- Based on available data, the classification criteria are not met
- Glycerol; glycerine
LC50 (fish) 54 g/l (4 days)
EC50 (aquatic invertebrates) 10 g/l (24 hr)

12.2 Persistence and degradability

- Will degrade

12.3 Bioaccumulative potential

- No information available

12.4 Mobility in soil

- Insoluble in water

12.5 Results of PBT and vPvB assessment

SECTION 12: Ecological information (....)

- 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

Not classified as hazardous for transport

- 14.1 UN 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 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 Code: Not applicable
- 14.9 Sea (IMDG)
- Proper Shipping Name: Not applicable
 - IMDG UN No.: Not applicable
 - IMDG Hazard Class: Not applicable
 - IMDG Pack Group.: Not applicable
- 14.10 Air (ICAO/IATA)
- Proper Shipping Name: Not applicable
 - ICAO UN No.: Not applicable
 - ICAO Hazard Class: Not applicable

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SECTION 14: Transport information (....)

- ICAO Packing Group: Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- This Safety Data Sheet is provided in compliance with REACH Regulation (EC) No 1907/2006 as amended by Regulation (EU) 2015/830
- Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) applies in Europe
- 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

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

--- end of safety datasheet ---
