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**SAFETY DATA SHEET**

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

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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: Hydrocolloid Formulation 0952  
Chemical Name: Hydrocolloid Adhesive containing Aloe Vera Extract

**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  
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**

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

**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

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**SECTION 3: Composition/information on ingredients**

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**SECTION 3: Composition/information on ingredients (....)****3.1 Substances**

Not applicable

**3.2 Mixtures**

Contains synthetic elastomers, hydrophilic polysaccharides and Aloe Vera extract. 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

**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

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

**SECTION 5: Firefighting measures (....)**

## 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

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

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**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

## 10.6 Hazardous decomposition products

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

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**

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

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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

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**SECTION 12: Ecological information (....)**

## 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

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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

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

ADR Packing Group: Not applicable

Tunnel Code: Not applicable

## 14.9 Sea (IMDG)

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**SECTION 14: Transport information (....)**

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  
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

Created by ChemRegs (UK) Ltd June 2017

Revision No. 2.0.0. Revised March 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

**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

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

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  
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