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## SAFETY DATA SHEET

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

#### 1.1 Product identifier

- Product Name: Harmony Duo with Flexifit & Aloe Flange (FHD, FHDF)
- 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 a 2 piece 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 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
- Classification (67/548/EEC, 1999/45/EC) [CHIP]:
  - Not Classified

#### 2.2 Label elements

- None

#### 2.3 Other hazards

- None
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### SECTION 3 Composition/information on ingredients

#### 3.1 Substances

#### 3.2 Mixtures

Containing synthetic elastomers, hydrophilic polysaccharides and Aloe Vera extract. Latex Free.

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### SECTION 4 First aid measures

#### 4.1 Description of first aid measures

- IF ON SKIN: No action needed
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#### **SECTION 4 First aid measures (....)**

- IF INHALED: Not applicable
  - IF IN EYES: Not applicable
  - IF SWALLOWED: Not applicable
- 4.2 Most important symptoms and effects, both acute and delayed
- Not hazardous
- 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 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
- 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
- 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
  - 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)
- Application to skin as part of a 2 piece Ostomy Device
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#### **SECTION 8 Exposure controls/personal protection**

- 8.1 Control parameters
- WEL (inhalable dust) 10 mg/m<sup>3</sup>
  - WEL (respirable dust) 4 mg/m<sup>3</sup>
- 8.2 Exposure controls
- In case of fire:  
Wear protective gloves/protective clothing/eye protection/face protection.
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## **SECTION 8 Exposure controls/personal 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

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## **SECTION 9 Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

- Appearance: Brown, putty
- Odour: No information available
- pH: No information available
- Freezing point/Range: No information available
- Boiling Point/Range: No information available
- Melting point/Range: No information available
- Flashpoint: No information available
- Evaporation Rate: No information available
- Flammability: No information available
- Explosive Properties: No information available
- Vapour Pressure: No information available
- Vapour Density: No information available
- Density: No information available
- Solubility in water: No information available
- Solubility in Fat: No information available
- Viscosity: No information available
- Partition Coefficient (n-Octanol/Water): 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

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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 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

#### 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

- Not applicable

#### Contact with eyes

- Not applicable

#### Contact with skin

- Not hazardous

#### Ingestion

- Not applicable

#### Inhalation

- Not applicable
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## 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

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## SECTION 12 Ecological information (....)

- 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)
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## 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
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## SECTION 15 Regulatory information

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

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

- This Safety Data Sheet is provided in compliance with the EC Directive 1907/2006-453/2010
  - 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
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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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