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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 Convex with Flexifit & Aloe (XFHD)
- 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

#### 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, 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

- 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

- 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: 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
- 

### 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

- 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

- No exposure limits have been set 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.  
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
- Odour threshold: No information available
- pH: Not applicable
- Melting point/freezing point: No information available
- Initial boiling point and boiling range: No information available
- Flashpoint: No information available
- Flammability (solid,gas): No information available
- Upper/lower flammability or explosive limits: No information available
- Evaporation Rate: 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

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

- Autoignition Temperature: No information available
- Decomposition temperature: No information available
- 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
- 

## 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
- 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

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

- Specific target organ toxicity (STOT) - repeated exposure  
No information available
  - 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
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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

- Insoluble in water

### 12.5 Results of PBT and vPvB assessment

- No information available

### 12.6 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)
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## 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

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

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

--- end of safety datasheet ---

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