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SAFETY DATA SHEET

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

1.1 Product identifier

- Product Name: Harmony Duo Flange
(HD, HDF)
- Chemical Name: Hydrocolloid Adhesive

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 and hydrophilic polysaccharides. 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
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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

- 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 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, well ventilated 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

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: 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
- Explosive Properties: 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

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

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

- 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

- 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)

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SECTION 14: Transport information (....)

- Hazard Class: Not applicable
 - 14.4 Packing group
 - Packing Group: Not applicable
 - 14.5 Environmental hazards
 - Not Classified
 - 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
 - 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.

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SECTION 16: Other information (....)

--- end of safety datasheet ---
