
SAFETY DATA SHEET

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

1.1 Product identifier

- Product Name: Confidence Natural
- Chemical Name: Hydrocolloid wafer, with Aloe Vera Extract, and outer films of Polyethylene non-woven or Ethylene Vinyl Acetate perforated films

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

- Use of the substance/mixture: As a collection device for ostomy output
- 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

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

SECTION 3: Composition/information on ingredients

3.1 Substances

3.2 Mixtures

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

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

- This product does not contain any hazardous ingredients at levels above the relevant thresholds or any ingredients with a workplace exposure limit.

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
Inhalation is unlikely to occur

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

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 & 8

SECTION 7: Handling and storage

7.1 Precautions for safe handling

SECTION 7: Handling and storage (....)

- 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 a collection device for ostomy output
-

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: Ostomy device consisting of adhesive and polymer films
- 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: Not applicable
- Flashpoint: No information available
- Evaporation Rate: Not applicable
- Flammability (solid,gas): No information available
- Upper/lower flammability or explosive limits: No information available
- Vapour Pressure: Not applicable
- Vapour Density: Not applicable
- 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: No information available
- Viscosity: No information available
- Explosive Properties: No information available

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

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

SECTION 11: Toxicological information (...)

- 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

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
 - No information available
- 12.5 Results of PBT and vPvB assessment
 - 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

SECTION 14: Transport information (....)

- 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

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

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 ---
