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## SAFETY DATA SHEET

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

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 under Article 32.

#### 1.1 Product identifier

- Product Name: Confidence Natural Advanced Urostomy and Confidence Natural Soft Convex Urostomy
- Product Description: Healthcare device

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

- Use of the substance/mixture: Medical device or accessory to a medical device, 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
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### SECTION 2 Hazards identification

Exempt from the requirements of CLP as product is regulated as a medical device or an accessory to a medical device. Information is provided to inform users of the hazards associated with the use of the product.

#### 2.1 Classification of the substance or mixture

- Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]: Not Classified

#### 2.2 Label elements

- None

#### 2.3 Other hazards

- Contains combustible material
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### SECTION 3 Composition/information on ingredients

#### 3.1 Substances

#### 3.2 Mixtures

A pouch consisting of a hydrocolloid wafer and outer films of polyethylene non-woven or ethylene vinyl acetate perforated films, which can be in direct contact with skin. The inner films of the pouch consist of 5 layer coextruded laminate EVA/EVA/PVDC/EVA/EVA films and combinations of charcoal filters, EMA films, PET springs and polyamide hook and loop.

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## **SECTION 3 Composition/information on ingredients (....)**

SEBS/PE/EVA & PP taps.

On the basis of available information, the activated carbon component is not considered hazardous or dangerous goods.

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## **SECTION 4 First aid measures**

### 4.1 Description of first aid measures

- Contact with eyes  
If substance has got into eyes, immediately wash out with plenty of water
- Contact with skin  
If skin irritation or rash occurs: gently wash with plenty of soap and water
- Ingestion  
Give plenty of water to drink  
Get medical advice/attention.
- Inhalation  
Inhalation is unlikely to occur  
Seek medical advice if necessary

### 4.2 Most important symptoms and effects, both acute and delayed

- No hazard expected under normal conditions of use

### 4.3 Indication of any immediate medical attention and special treatment needed

- If skin irritation or rash occurs: Get medical advice/attention.
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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

- Contains combustible material
- Risk of burns from molten product
- Gives off irritating or toxic fumes (or gases) in a fire.
- Decomposition products may include nitrogen and carbon oxides
- Decomposition products may include hydrocarbons
- Decomposition products may include hydrogen chloride

### 5.3 Advice for firefighters

- Special protective equipment: Wear self-contained breathing apparatus (SCBA). Wear full protective clothing including chemical protection suit.
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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

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## **SECTION 6 Accidental release measures (....)**

- 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

### 7.2 Conditions for safe storage, including any incompatibilities

- Keep in a cool, dry, well ventilated place
- Protect from heat
- Contains combustible material

### 7.3 Specific end use(s)

- Medical device or accessory to a medical device
- as a collection device for ostomy output

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## **SECTION 8 Exposure controls/personal protection**

### 8.1 Control parameters

- There are no recommended or established controls 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.  
Wear suitable respiratory equipment



Gloves



Suit



Goggles



Respirator

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

### 9.1 Information on basic physical and chemical properties

- Appearance: Skintone plastic pouch
- Odour: Not applicable
- Odour threshold: Not applicable
- pH: Not applicable
- Melting point/freezing point: Not applicable
- Initial boiling point and boiling range: Not applicable
- Flashpoint: No information available
- Evaporation Rate: Not applicable
- Flammability (solid,gas): Combustible polymer material
- Upper/lower flammability or explosive limits: Not applicable
- Vapour Pressure: Not applicable
- Vapour Density: Not applicable
- Relative Density: No information available
- Solubility(ies): Insoluble in water
- 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: >200°C
- Viscosity: Not applicable
- Explosive Properties: Not applicable
- Oxidising Properties: Not applicable

### 9.2 Other information

Polymeric plastic films, chemically inert

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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

- Incompatible with strong acids
- Incompatible with strong oxidizing substances

### 10.6 Hazardous Decomposition Products

- Decomposition products may include nitrogen and carbon oxides
  - Decomposition products may include hydrocarbons
  - Decomposition products may include hydrogen chloride
  - Decomposition products may include aldehydes
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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

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

- 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  
Not hazardous
- Specific target organ toxicity (STOT) - repeated exposure  
Not hazardous
- Aspiration hazard  
Not applicable
- Contact with eyes  
No hazard expected under normal conditions of use  
Dust may be irritating to eyes
- Contact with skin  
No hazard expected under normal conditions of use  
Risk of burns from molten product
- Ingestion  
The ingestion of significant quantities may cause nausea/vomiting
- Inhalation  
No hazard expected under normal conditions of use  
Dust may cause respiratory irritation.

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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
  - 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)

## **SECTION 14 Transport information**

Not classified as hazardous for transport

### 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

- 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 73/78 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

- 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 under Article 32.
- Exempt from the requirements of CLP as product is regulated as a medical device or an accessory to a medical device. Information is provided to inform users of the hazards associated with the use of the product.
- Reviewed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices

### 15.2 Chemical Safety Assessment

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

- 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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