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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.

**1.1 Product identifier**

- Product Name: Protective Wafer / Salts Protective Wafers
- Product Part Number: PW1010  
PW1515
- Chemical Name: Protective ostomy hydrocolloid square
- Product Description: For use in the management of stomas to protect the skin and provide a surface onto which other appliances may be attached. The wafer will also mould on skin which may be irregular due to skin folds, furrows etc

**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 an Ostomy Device
- Use advised against: Not for internal use.

**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

**SECTION 3: Composition/information on ingredients**

## 3.1 Substances

## 3.2 Mixtures

- 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  
Not applicable  
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  
IF exposed or concerned: Call a doctor.
- Inhalation  
Inhalation is unlikely to occur

## 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

- 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

- 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
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**SECTION 6: Accidental release measures (....)**

## 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 an 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: Beige, malleable, wafer
- Odour: None
- Odour threshold: Not applicable
- pH: Not applicable
- 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
- 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



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

- 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
- 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  
Not applicable in supplied form
- 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)
  - Hazard Class: Not applicable
- 14.4 Packing group

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

- 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
- 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.
  - 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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--- end of safety datasheet ---

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