

Product name: Eakin Freeseal

Created: 11 Apr 2024



1. Identification of the substance/preparation and of the company/undertaking

1.1 Product identifier

This information covers the composition of the following products:

- Eakin Freeseal ostomy seals, product codes 839007, 839008, 839017, 839027, 839028
- Any of the above product codes prefixed by SP which denotes sample of the same item.
- Any of the above product codes prefixed by a 2-letter country code which denotes a language-specific version of the same item.

1.2 Relevant intended uses of the substances or mixture and uses advised against

Eakin Freeseal ostomy seals are made from a pale cream to pale tan - coloured hydrophilic medical adhesive mixture designed to assist in attaching medical devices such as ostomy pouches to human skin and for the protection of peristomal skin from bodily fluids.

1.3 Details of the supplier of the safety data sheet

Supplier

TG Eakin Limited

Street

15 Ballystockart Road

Postal code / city

Comber, BT23 5QY, Northern Ireland

Telephone / Telefax

T+44 2891 871000 F +44 2891 871111

Information Contact

Mark Stinson (E-Mail: mark.stinson@eakinhealthcare.com)

Emergency telephone number

+44 2891 871000 (only at office hours 9:00 - 16:30 GMT)

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Eakin Freeseal ostomy seals are not classified as hazardous under CLP Regulations.

2.2 Label elements

Labelling (67/548/EEC or 1999/45/EC)

Eakin Freeseal ostomy Seals are not classified as hazardous under the Dangerous Substances Directive or Dangerous Preparations Directive and do not require any hazard labelling as per Regulation (EC) No.1272/2008 [CLP].

2.3 Other hazards

There are no other hazards associated with Eakin Freeseal ostomy seals.

3. Composition/information on ingredients

Substances and Mixtures

Hazardous ingredients

There are no hazardous ingredients contained in Eakin Freeseal ostomy seals.

The main ingredients are:

- Polyolefins
- Carboxymethylcellulose
- Polysaccharide
- Carbohydrate

Additional information

No additional information is available

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**4. First-aid measures**

4.1 Description of first aid measures

• General Information

In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.

• After inhalation

Not applicable.

• In case of skin contact

No action required as product is designed for skin applications, however, if causing irritation, discontinue use and wash with soap and warm water.

• After eye contact

Remove contact lenses for better cleaning. Keep eyelids open. Irrigate well with plenty of water for at least 15 min. Contact a physician if necessary.

• After ingestion

Rinse mouth. Do not induce vomiting. If breathing has stopped, contact a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

No information available

4.3 Indication of any immediate medical attention and special treatment needed

No information available

5. Fire-fighting measures

5.1 Extinguishing media

- Suitable extinguishing media
Water spray, carbon dioxide, dry chemical powders.
- Unsuitable extinguishing media
Waterjet.

5.2 Special hazards arising from the substance or mixture - Hazardous combustion products

Combustion products are carbon dioxide, carbon monoxide, nitrogen and water. In case of fire do not breathe fumes

5.3 Special protective equipment and advice for firefighters

Appropriate breathing apparatus and clothing must be worn.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with eyes. Do not ingest. Remove contaminated clothing.

6.2 Environmental precautions

Due to high organic carbon content prevent contamination of drains, watercourses and vegetation.

6.3 Methods and material for containment and cleaning up

Sweep or scoop up and place in a suitable container for safe disposal.

6.4 References to other sections

Not applicable.

7. Handling and storage

7.1 Precautions for safe handling

Keep out of reach of children. Store flat in the carton in a cool dry place.

7.2 Conditions for safe storage, including any incompatibilities

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Do not refrigerate. Avoid high humidity.

- 7.3 Specific end uses
See Section 1 for Intended use.

8. Exposure controls/personal protection

- 8.1 Control Parameters
No information available. No CSR.
- 8.2 Exposure controls
No special handling requirements are necessary. In the event of a fire wear protective clothing, safety goggles (with side shields) and gloves. If ventilation is inadequate, use a respirator mask.

9. Physical and chemical properties

- 9.1 Basic physical and chemical properties
- | | |
|----------------------|---|
| Physical state: | Solid becoming viscous liquid when heated |
| Odour: | No information available |
| Colour: | Pale cream to pale tan |
| pH value: | Not determined |
| Flash point: | 190°C, 374° Fahrenheit |
| Density: | 1.1 g/cm ³ |
| Solubility in water: | Barely soluble |
| Stability: | Stable under normal conditions |
| Viscosity: | 1300-3520 cPs/1000 |
- 9.2 Other information
No further relevant information available.

10. Stability and reactivity

- 10.1 Reactivity
No information available.
- 10.2 Chemical stability
Stable under recommended storage and handling conditions (See Section 7).
- 10.3 Possibility of hazardous reactions
No information available.
- 10.4 Conditions to avoid
Extremes of temperature. Protect from frost. Keep away from heat, sparks or fire.
- 10.5 Incompatible materials
Strong oxidising agents, strong acids and bases.
- 10.6 Hazardous decomposition products
When exposed to high temperatures typical decomposition products are carbon monoxide, carbon dioxide, nitrogen and water.

11. Toxicological information

- 11.1 Information on toxicological effects
This product is a medical device and has been assessed in accordance with Regulation 2017/745 on medical devices. The product is considered to be non-toxic.
- **Acute effects**
 - **Acute oral toxicity**
Not classified as toxic if swallowed

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- **Acute dermal toxicity**
Not irritating to eyes and skin
Approved: Not a skin irritant, January 1980 - (Test - U.S.P. from Federal Register)
Approved: Not a skin irritant, August 1982 - (Test - U.S.P. from Federal Register)
Approved: Not a skin irritant, November 1983 - (Test - U.S.P. from Federal Register)
Primary Skin Irritation: slight (0.5), November 2002 - (ISO 10993 - 10, 5.2)
Delayed contact hypersensitivity: non-sensitising, November 2002 - (OECD #406, 1992)
- **Acute inhalation toxicity**
Not classified as toxic if inhaled
- **Toxicity**
Approved: Found to be non-toxic, November 1979 (Test - E.P.)
Approved: Found to be non-toxic, August 1982 (Test - U.S.P.)
Approved: Found to be non-toxic, November 1983 (Test - U.S.P.)
Approved: Found to be non-toxic, March 1986 (Test - U.S.P. XX1)
- **Cytotoxicity**
In vitro cytotoxicity: non-cytotoxic, October 2002 - (USP 25 (87) and ISO 10993-5)
In vitro cytotoxicity: non-cytotoxic August 2020
- **Pyrogen**
Not classified as pyrogenic

12. Ecological information

- 12.1 Toxicity / Aquatic toxicity
Not determined
- 12.2 Persistence and degradability
Not determined
- 12.3 Bio accumulative potential
Not determined
- 12.4 Mobility in soil
Not determined. However, product is barely soluble in water, therefore it is not expected to be highly mobile.
- 12.5 Results of PBT and vPvB assessment
Not determined
- 12.6 Other adverse effects
No information available
- 12.7 Further ecological information
No information available

13. Disposal considerations

The disposal should always comply with national, federal, state and local regulations. The product should not be discharged to the environment.

- 13.1 Waste treatment methods
Per The European Waste Catalogue (EWC), in accordance with EC Directive 75/422/EEC, the following Waste Code can be used: 18 01 06 wastes whose collection and disposal is not subject to special requirements in view of the prevention of infection (e.g. dressings, plaster casts, linen, disposable clothing, diapers). However, if the waste in view of the prevention of infection needs special requirements, other Waste Codes should be used.

14. Transport information

The material is not a hazardous good by any means for transportation. The product does not have any restricted classification.

- 14.1 UN Number
Not applicable / / Not Relevant
- 14.2 UN proper shipping name

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Land (ADR/RID), Sea (IMDG), Air transport (ICAO-TI/ IATA-DGR): Not Applicable / Not Relevant

14.3 Transport hazard class(es)

Land (ADR/RID, Sea (IMDG), Air transport (ICAO-TI/ IATA-DGR): Not Relevant / Non hazardous

14.4 Packing group

Land (ADR/RID, Sea (IMDG), Air transport (ICAO-TI/ IATA-DGR): Not Applicable / Not Relevant

14.5 Environmental hazards

None

14.6 Special precautions for user

None

15. Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

No further information available.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out. No CSR.

16. Other information

This data is based on our present knowledge. However, it shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.
