Product name: Eakin Cohesive Paste Revised: 18 Aug 2021

SDS 2 Issue 4 eakin®

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 Cohesive Paste product codes 839010, S839010, SE839010, DE839010, PHC839010 and any of the above product codes prefixed by SP which denotes sample of the same item

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

Eakin Cohesive Paste is an ostomy paste designed as a pouching accessory for use around high output wounds, stomas and fistulae. It is a highly adhesive, absorptive and protective alcohol-free formulation which can be used directly on raw skin without discomfort to the patient. It requires no drying time, is easily removed and is compatible with hydrocolloids on wound drainage pouches allowing more rapid pouching applications thereby decreasing patient trauma and discomfort, and speeding up the pouching process. It is made from a pale cream to pale tan - coloured hydrophilic medical adhesive designed to attach medical devices such as ostomy pouches, wound drainage appliances, drains etc. to human skin.

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 Roisin Gilpin (E-Mail: roisin.gilpin@eakin.co.uk)

Emergency telephone number

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

2. Hazards identification

2.1 Classification of the substance or mixture Classification according to Regulation (EC) No. 1272/2008 [CLP]

Eakin Cohesive Paste is not classified as hazardous under CLP Regulations

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 (CLP) Eakin Cohesive Paste does not require any hazard labelling

2.3 Other hazards

There are no other hazards associated with Eakin Cohesive Paste.

3. Composition/information on ingredients Substances and Mixtures

Hazardous ingredients

There are no hazardous ingredients contained in Eakin Cohesive Paste. The main ingredients are:

- Polyolefin
- Sodium Carboxymethylcellulose
- Carbohydrate mixture

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. If irritation continues seek medical attention.
 - 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 vomiting occurs or 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

- Personal precautions, protective equipment and emergency procedures 6.1 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 in the carton in a cool dry place.
- 7.2 Conditions for safe storage, including any incompatibilities Do not refrigerate. Avoid high humidity.

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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: Odour: Colour: pH value: Flash point: Density: Solubility in water: Stability: Viscosity:

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 Directive 93/42/EEC on medical devices. The product is considered to be non-toxic
 - Acute effects
 - Acute oral toxicity
 - Not classified as toxic if swallowed
 - 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)

Solid becoming viscous liquid when heated No information available Pale cream to pale tan Not determined 190 °C, 374° Fahrenheit 1.1 g/cm³ Barely soluble Stable under normal conditions 1300-3520 cPs/1000

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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
- 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)
- Pyrogen
 Approved: October 1979

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 recommended disposal technology at any approved facility. 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 for transportation by any means. The product does not have any restricted classification.

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

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- 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.