

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE AND COMPANY

Product Name **ProCure Calcium Alginate Wound Dressing**
Product Code PCHCA12, PCHCA22, PCHCA44, PCHCA48
Company Name Twin Med LLC.
(Supplier of SDS)
Address 11333 Greenstone Ave. • Santa Fe Springs, CA 90670
Contact 1-877-TwinMed (894-6633)
Emergency 1-877-TwinMed (894-6633)
Relevant Use Use on exudation wounds, keeps wounds moist

2. HAZARD IDENTIFICATION

2.1 Overview of emergency: None
2.2 Risk category: None
2.3 Labeling elements: None
2.4 Physical and chemical hazards: None
2.5 Health hazards: None
Dermal exposure: None
Eye contact: None
Ingestion: ingestion has potential chronic health hazardous.
Inhalation: None
2.6 Environmental hazards: Impact on the water environment
2.7 Other hazards: None

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Material: ☒ Mixture: ☐

3.2 Composition:

Ingredient	Content	C.A.S. No.
Calcium Alginate	100%	9005-35-0

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4. FIRST AID MEASURES

4.1 First aid:

Skin contact: Usually not a health hazard, such as the occurrence of irritation or allergic symptoms, requiring medical observation.

Eye contact: Wash eyes with low pressure water, if irritation is still persistent, see medical attention.

Inhalation: Wash with low pressure water.

Ingestion: Seek medical attention immediately, emetic treatment.

4.2 The most important symptoms and health effects: Skin irritation or allergic reaction may occur.

4.3 Advice for the protection of rescuers: None

4.4 Special tips for doctors: The physician should be informed that there is no allergic or irritating reaction to the product itself and that there are a small number of special constitution people who will develop allergic or irritating symptoms to the Calcium Alginate Wound Dressing.

5. FIRE FIGHTING MEASURES

This product is a water-based non-combustible substance, and the product package will generate carbon dioxide or carbon monoxide gas when it encounters fire.

5.1 Extinguishing agent: Dry powder, Foam, Water, Carbon dioxide.

5.2 Special hazard: Under normal conditions, there will be no dangerous reaction and explosion, and the outer packaging of the product will burn to produce CO and CO₂

5.3 Precautions and protective measures for fire fighting:

- a) Personal protection of firefighters: fire and gas resistant clothing
- b) No prohibited extinguishing agent

6. ACCIDENTAL RELEASE MEASURES

6.1 Personnel protection measures, protective equipment and emergency response procedures: eliminate all ignition sources; Adequate ventilation.

6.2 Environmental protection measures: collect the leakage and deal with it according to local regulations.

6.3 The storage and removal methods of leaked chemicals and the disposal materials used: collect and store the leaked materials, and do not confuse them with normal products; Use non-sparking tools and equipment.

6.4 Preventive measures to prevent secondary disasters: eliminate ignition sources and prevent leakage from entering sewers and basements.

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7. HANDLING AND STORAGE

7.1 Precautions for safe handling: Read the instructions carefully before use to avoid misuse of the product.

7.2 Conditions for safe storage, including any incompatibilities: This product shall be stored in a well ventilated room with a temperature of less than 40°C and humidity of less than 80%, without corrosive gas or harmful substances in the environment, with good ventilation, and should not be stored together with harmful substances. No special precautions are required. Keep away from open fire, strong alkali, strong acid, strong oxidant and highly flammable substances. Prevent rain or moisture.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 maximum allowable concentration :/

8.2 Exposure detection method: /

8.3 Exposure control: /

8.4 Respiratory protection: /

8.5 Eye protection : /

8.6 Body protection:/

8.7 Hand protection : Not required for normal conditions of use.

Other protection: personal hygiene requirements, regular physical examination

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Dressing color should be white or light yellow, soft texture, no external foreign matter, no stains, no odor.

Melting point: /	Boiling point: /
Relative density (Water=1) :/	Relative vapor density (Air=1) :/
Saturated vapor pressure (kPa) :/	Combustion value (KJ/mol) :/
Critical temperature (°C) :/	Critical pressure (MPa) :/
Logarithmic value of octanol/water partition coefficient: /	
Flash point(°C) :/	Upper explosion limit%(V/V) :/
Ignition temperature(°C) :/	Lower explosive limit%(V/V) :/

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Solubility: Insoluble
Other physical and chemical properties: 1、 Mass per unit area: The mass per unit area of the dressing should be $\geq 110\text{g/cm}^2$. 2、 Calcium content: The content of calcium is 5.0%-10.0%. 3、 Acid-base: The pH of the dressing should be between 5.0 and 7.5. 4、 Loss on drying: The weight loss of the dressing is $\leq 25\%$ when baked at $105.0\text{ }^{\circ}\text{C}$. 5、 Heavy metal content: The heavy metal content of the dressing should be $\leq 20\mu\text{g/g}$. 6、 Fluorescent substance: At 365nm UV light, there is no strong blue fluorescence. 7、 Residue on ignition: Calculated as dry product, residual residue should be 18.0% ~ 24.0%. 8、 Tensile strength: Longitudinal tension $\geq 1.15\text{N}$, lateral tension $\geq 0.58\text{N}$. 9、 Sterility test: The dressing should be sterile.

10. STABILITY AND REACTIVITY

10.1 Reactivity: Hazardous reactions will not occur under normal conditions.

10.2 Stability: Product is stable.

10.3 Possibility of hazardous reactions: None

10.4 Conditions to avoid: Avoid freezing or heating.

10.5 Incompatible materials: None

10.6 Hazardous decomposition products: The product is easy to lose moisture and become dry.

11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity: None

11.2 Skin irritation: None

11.3 Eye damage/irritation: None

11.4 Respiratory or skin allergy: None

11.5 Germ cell mutagenicity: None

11.6 Carcinogenicity: None

11.7 Reproductive toxicity: None

11.8 Specific target organ toxicity - single exposure: None

11.9 Specific target organ toxicity - repeated exposure: None

11.10 Inhalation hazard: None

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12. ECOLOGICAL INFORMATION

- 12.1 Ecotoxicity: None
- 12.2 Persistence and degradability: None
- 12.3 Bioaccumulative potential: None
- 12.4 Mobility in soil: None
- 12.5 Other adverse effects: None

13. DISPOSAL CONSIDERATIONS

- 13.1 Nature of waste: this product is not a hazardous waste determined by RCRA.
- 13.2 Waste disposal method: Dispose in accordance with relevant local regulations on medical waste treatment.
- 13.3 Precautions for disposal: If the product has been used, it shall be treated as medical device waste.

14. TRANSPORT INFORMATION

- 14.1 UN code: None
- 14.2 UN proper shipping name: None
- 14.3 UN classification (transport hazard category): None
- 14.4 Packing classification: None
- 14.5 Whether it is a marine pollutant: No
- 14.6 Precautions for transportation: Protection from freezing, crushing, sun exposure, rain and drenching should be maintained during shipment.

15. REGULATORY INFORMATION

EUROPEAN/INTERNATIONAL REGULATIONS

All Labelling in Accordance with EC Directives Not considered as Hazardous

US FEDERAL

TSCA

Health & Safety Reporting List:

None of the chemicals are on the Health & Safety Reporting List.

Chemical Test Rules:

None of the chemicals in this product are under a Chemical Test Rule.

Section 12b:

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None of the chemicals are listed under TSCA Section 12b.

TSCA Significant New Use Rule:

None of the chemicals in this material have a SNUR under TSCA.

SARA

CERCLA Hazardous Substances and RQs:

None of the chemicals in this material have an RQ.

SARA Section 302 Extremely Hazardous Subs:

None of the chemicals in this product have a TPQ.

Section 313:

No chemicals are reportable under Section 313.

Clean Air Act:

This material does not contain any hazardous air pollutants.

This material does not contain any Class 1 Ozone depleters.

This material does not contain any Class 2 Ozone depleters.

Clean Water Act:

None of the chemicals in this product are listed as Hazardous Substances under the CWA.

None of the chemicals in this product are listed as Priority Pollutants under the CWA.

None of the chemicals in this product are listed as Toxic Pollutants under the CWA.

OSHA:

None of the chemicals in this product are considered highly hazardous by OSHA.

16. OTHER INFORMATION

16.1 Be careful! Do not use the product or material in vivo or directly with blood access, as this product does not have further clinical validation with respect to scope of applicability for in vivo or blood access; Nor is there any warranty as to in vivo transplantation.

16.2 References: None