

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE AND COMPANY

Product Name **ProCure Hydrocolloid Dressing**
Product Code PCHH3204, PCHH3206, PCHH3102, PCHH3104, PCHH3106, PCHH3107, PCHH3355
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 Used for surgical or injured wound covering, keep the wound moist, and absorb the wound exudate.

2. HAZARD IDENTIFICATION

- 2.1 Hazard category: In accordance with GHS, no hazards.
2.2 Intrusive way: Skin Contact, Eye Contact, Inhalation, Ingestion
2.3 Health hazard:
Skin Contact: No specific symptoms noted.
Eye Contact: No specific symptoms noted.
Inhalation: ingestion has potential chronic health hazardous.
Ingestion: No specific symptoms noted.
2.4 Environmental hazards: Not regarded as dangerous for the environment.
2.5 Hazard of combustion and explosion: No information found.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Material: ☐ Mixture: ☒

3.2 Composition:

material name	Composition/Chemical name	Content	CAS
Hydrocolloid	Sodium carboxymethyl cellulose /CMC	20%-35%	9004-32-4
	Medical Hot melt adhesive	44%-60%	/
PU film	Polyurethane	1%-5%	51852-81-4
Isolation paper	Glassine release paper	15% -20%	25038-59-9

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4. FIRST AID MEASURES

4.1 Skin contact: Usually there is no health hazard, such as irritation or allergy symptoms, which require medical attention.

Eye contact: Wash the eyes with low-pressure water, if irritation persists, seek medical attention.

Inhalation: Wash with low pressure water

Ingestion: Induce vomiting and seek immediate medical attention

4.2 The most important symptoms and health effects: Allergy

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 Hydrocolloid Wound Dressing.

5. FIRE FIGHTING MEASURES

5.1 Special hazards that may be encountered in fire extinguishing: Smoke stimulation

5.2 Fire extinguishing method and extinguishing agent: Dry powder, foam, carbon dioxide and mist water

5.3 Harmful combustion product: CO

5.4 Fire extinguishing precautions:

a) Personal protection for firefighters: Fire and gas resistant clothing

b) No prohibited fire extinguishing agent

6. ACCIDENTAL RELEASE MEASURES

6.1 Personnel protection measures, protective equipment and emergency response procedures: collect and preserve spills, not to be confused with normal products.

6.2 Environmental protection measures: collect them as much as possible and deal with them according to local laws and regulations. If the leakage is omitted, the polymer products cannot be degraded and will cause pollution to the environment.

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 Precautions of Storage :

0°C ≤ Storage temperature ≤ 40°C, humidity ≤ 80%, no corrosive gas ventilation room. No special precautions are required. Keep away from open flame, strong alkali and acid, strong oxidant.

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

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): 199°C	Upper explosion limit%(V/V) : /
Ignition temperature(°C) : /	Lower explosive limit%(V/V) : /
Solubility: Insoluble in water	
Other physical and chemical properties: 1. pH: 4.0-7.0 2. Peeling strength: The peeling strength of the dressing should be no less than 1.0N/cm 3. Heavy metal content: ≤10 mg/kg 4. Liquid Absorption Transmittance: The liquid permeability of 24h should be no less than 1.0g/10cm squared. The permeability of liquid at 48h should be no less than 2.0g/10cm squared 5. Holding Power: The top of the tape should not fall more than 2.5mm 6. Sterility test: The dressing should be sterile.	

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10. STABILITY AND REACTIVITY

- 10.1 Stability: Product is stable.
- 10.2 Possibility of hazardous reactions: None
- 10.3 Conditions to avoid: keep from heat
- 10.4 Incompatible materials: None
- 10.5 Decomposition products: when the product is heated decomposition should avoid inhalation of smoke, carbon monoxide, carbon dioxide, nitrogen dioxide and water after combustion.

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

12. ECOLOGICAL INFORMATION

- 12.1 Ecotoxicity: /
- 12.2 biodegradability : /
- 12.3 Non-biodegradability: /
- 12.4 Biological enrichment or accumulation: /
- 12.5 Other harmful effects: /

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.

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14. TRANSPORT INFORMATION

14.1 UN code: None

14.2 UN proper shipping name: None

14.3 UN classification (transport hazard category): None

14.5 Packing classification: None

14.6 Whether it is a marine pollutant: Yes

14.7 Precautions for transportation: Measures should be taken to prevent rain, sun and high temperature during transportation

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:

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.

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16. OTHER INFORMATION

16.1 Note! Do not use the product or material in vivo or directly with blood pathways as the product has not been further clinically validated in vivo or in the scope of blood pathways; Nor does it provide any expressive, promise or implied warranty with respect to in vivo transplantation.

16.2 References: None