

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE AND COMPANY

Product Name **ProCure Honey Gel**
Product Code PCHNY07, PCHNY15
Company Name TwinMed 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 The product is suitable for covering damaged wounds on the body surface, and provides a moist environment for wound healing, such as unhealed wounds formed by trauma, surgical wounds, diabetic foot, first-degree and second-degree burns, pressure ulcers or venous ulcers.

2. HAZARD IDENTIFICATION

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Material: ☒ Mixture: ☐

3.2 Composition :

Composition/Chemical name	Content	CAS
Manuka honey	100%	8028-66-8

SAFETY DATA SHEET



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: Skin irritation or allergic reaction may occur.

4.3 Advice for the protection of rescuers: None

4.4 Special tips for doctors: The product itself should be informed that there is no allergy and irritation, a small number of people with special constitution to the product will produce allergy and irritation.

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 and CO₂

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: 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.

SAFETY DATA SHEET



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: Honey gel should be stored at room temperature, ventilated, dry and away from light, 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: Dust mask. Not required for normal conditions of use.

8.5 Eye protection: Safety goggles

8.6 Body protection:/

8.7 Hand protection: Rubber gloves

Other protection: personal hygiene requirements, regular physical examination

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: The gel is paste, yellow or yellowish brown in color, with no visible foreign bodies and impurities.

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): /

SAFETY DATA SHEET



solubility: Honey is very soluble in water.

Other physical and chemical properties:

- 1、Gram Weight: $\pm 5\%$
- 2、pH: 3.0-7.0
- 3、Viscosity: 8000~40000mPa $\cdot$ s($25 \pm 2^\circ\text{C}$)
- 4、Moisture Content: $\leq 18.6\%$
- 5、Ash Content: $\leq 0.4\%$
- 6、Heavy metal content: $\leq 20\text{ppm}$
- 7、Bacterial endotoxin: The maximum bacterial endotoxin should be $\leq 4.0\text{EU/ piece}$
- 8、Sterility check: The dressing should be sterile.

10. STABILITY AND REACTIVITY

- 10.1 Stability: Product is stable.
- 10.2 Possibility of hazardous reactions: None
- 10.3 Conditions to avoid: Avoid freezing or heating
- 10.4 Incompatible materials: None
- 10.5 Decomposition products: No data.

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: /
- 11.9 Specific target organ toxicity - repeated exposure: /
- 11.10 Inhalation hazard: /

12. ECOLOGICAL INFORMATION

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

SAFETY DATA SHEET



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
- 14.5 Packing classification: None
- 14.6 Whether it is a marine pollutant: Yes
- 14.7 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:

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

TSCA Significant New Use Rule:

SAFETY DATA SHEET



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 depletors.

This material does not contain any Class 2 Ozone depletors.

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 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

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.