

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE AND COMPANY

Product Name **ProCure CalmaPlex Anorectal Ointment**
Product Code PCS004, PCS005
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 to relieve pain, itching, burning, and swelling associated with
 anorectal disorders such as hemorrhoids and anal fissures.

2. HAZARD IDENTIFICATION

Physical Hazards: Not classifiable.
Health Hazards: Irritation of contaminated eyes and contaminated skin.
Flammability Hazards: If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, and hydrogen chloride).
Reactivity Hazards: This product is not reactive.
Environmental Hazards: Large quantities released to the environment may have an adverse effect.
Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Composition:

Active Ingredient:

Ingredient Name	CAS	Composition (%)
Zinc Oxide	1314-13-2	20.625 %
Menthol	1490-04-6	0.44 %
White Petrolatum	8009-03-8	66.335%

Inactive Ingredient:

Ingredient Name	CAS
Calamine	8011-96-9
Glycerin	56-81-5
Phenol	108-95-2
Lanolin	8006-54-0
Mineral Oil	8042-47-5
Sodium Bicarbonate	144-55-8
Thymol	89-83-8

4. FIRST AID MEASURES

Ingestion: If a person vomits place them in the recovery position so that vomit will not re-enter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

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Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: External use only as per labelling information.

Other Health Warnings: For external use only. Avoid contact with eyes or lips.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Use Dry chemical powder for small fires and water spray, fog or foam for large fires. Do not use water jet.

Unsuitable Extinguishing Media: Wear full protective clothing and use self-contained breathing apparatus (SCBA).

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Carbon oxides (CO, CO₂), Nitrogen oxides (NO, NO₂)

Other Specific Hazards: Not determined.

Special Protective Equipment Precautions for Fire fighters: Wear full protective clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Cleanup Procedure: Pick up in the most efficient manner. Contain or absorb small spills. Larger spills must be contained to prevent spreading and absorption. Residue must be placed in a non-reactive container. Area should be washed well with water. If appropriate, use protective equipment during spill clean-up.

Environmental Precautions: Not available.

Containment Method: Disposal of waste in accordance with State and Local regulations

7. HANDLING AND STORAGE

Precautions for Safe Handling:

Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities:

- Keep container tightly closed.
- Store below 30°C.
- Do not refrigerate.

Store according to label and/or product insert information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Local exhaust ventilation or other engineering control to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limits.

Personal Protective Measures

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Light pink colour homogenous ointment
Odor:	Fragrance Free
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	No data available.
Partition Coefficient (n-octanol/water):	No data available
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Hazardous Decomposition Products:	Carbon oxides (CO, CO ₂), Nitrogen oxides (NO, NO ₂)
Possibility of Hazardous Reactions:	Will not occur.

11. TOXICOLOGICAL INFORMATION

Inhalation:	No data available.
Ingestion:	No data available.
Skin Contact:	Possible skin irritation.
Eye Contact:	Possible eye irritation.

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Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity – Dermal: LD50 Dose = 500 mg/kg

Corrosivity: No data available.

Dermal Irritation: No data available.

Eye Irritation: No data available.

Sensitization: No data available.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: No data available.

Reproductive Effects: No data available.

Carcinogenicity: No data available.

Mutagenicity: No data available.

Aspiration Hazard: No data available.

National Toxicology Program (NTP):

Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC):

Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA):

Not considered to be a carcinogen

12. ECOLOGICAL INFORMATION

Aquatic: No data available.

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Mobility in Environment: No data available.

Other Adverse Effects: No data available.

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13. DISPOSAL CONSIDERATIONS

Waste to be disposed of in accordance with federal, state and local environmental control regulations

14. TRANSPORT INFORMATION

UN Number: Not applicable.
UN Proper Shipping Name: Not applicable.
Transport Hazard Class(es): Not applicable.
Packing Group: Not applicable.
Department of Transportation: Not regulated as a hazardous material.
International Air Transport Association (IATA): Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good

15. REGULATORY INFORMATION

Toxic Substance Control Act (TSCA):	Not listed.
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16. OTHER INFORMATION

Sources of Information:

The Hazard Communication Standard (HCS) (29 CFR 1910.1200(g));
NIOSH Pocket Guide to Chemical Hazards (1993);
Occupational Health Guidelines for Chemical Hazards;
NIH U.S. National Library of Medicine;
Drugbank

Disclaimer: While reasonable care has been taken to ensure the accuracy and completeness of the information regarding the material described herein, it is the purchaser's responsibility to ensure the suitability of such information as it applies to the purchaser's intended use of the material.