

SAFETY DATA SHEET

1. Identification

Product Identifier:	Opium Tincture, 2% (Paregoric, USP) CIII
Synonyms:	7,8-didehydro-4,5-epoxy-17-methylmorphinan-3,6-diol sulfate pentahydrate; Morphine Sulfate,
National Drug Code (NDC):	50383-855-16
Recommended Use:	Pharmaceutical.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards:	Flammable liquid and vapor	Category 3
Health Hazards:	Not classifiable.	

Symbol(s):**Signal Word:**

Warning.

Hazard Statement(s):

H226 Flammable liquid and vapor.

Precautionary Statement(s):

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P241 Use explosion – proof electrical/ ventilating/ lighting/ equipment.

P242 Use only non – sparking tools.

P243 Take precautionary measures against static discharge.

P353 Rinse skin with water/shower.

P361 Take off immediately all contaminated clothing.

P370 + P378 In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary.

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P303 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 +
 P361 water/shower.
 +
 P353

P403 Store in a well-ventilated place. Keep cool.
 +
 P235

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Anhydrous Morphine	64-31-3	7,8-didehydro-4,5-epoxy-17-methylmorphinan-3, 6-diol sulfate pentahydrate; Morphine Sulfate,	$(C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O$	758.85	2%
Alcohol	64-17-5	Ethyl alcohol	C_2H_5OH	46.07	47%

*The formula also contains Anise Oil, Benzoic Acid, Camphor, Glycerin, and Purified Water.

4. First Aid Measures

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter 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.

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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.
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.
Signs and Symptoms:	<p>Material is a liquid drug dosage form intended for human use. Always follow prudent laboratory practices. Consult the package insert for further information. See Ingestions for information.</p> <p>OVERDOSE: Serious overdosage of morphine is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and, sometimes, bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest, and death may occur.</p>
Medical Conditions Aggravated by Exposure:	<p>Some individuals may become sensitized from exposure and develop skin rashes, coughs, stuffy nose, asthma, and other allergic complaints. Sensitivity may develop soon after immediate contact or after years of exposure.</p> <p>TREATMENT: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. The narcotic antagonist naloxone hydrochloride is a specific antidote against the respiratory depression that may result from overdosage or unusual sensitivity to narcotics. Therefore, an appropriate dose of the antagonist should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. Since the duration of action of morphine may exceed that of the antagonist, the patient should be kept under continued surveillance, and repeated doses of the antagonist should be administered as needed to maintain adequate respiration. Oxygen, intravenous fluids, vasopressors, and other supportive measures should be employed as indicated.</p>
Other Health Warnings:	This preparation should be used in diarrhea caused by poisoning until the toxic material is eliminated from the gastrointestinal tract.

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Notes to Physician: Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or foam as necessary.

Unsuitable Extinguishing Media: With small quantities, use carbon dioxide extinguisher. For large fires, use ample quantities of water with dry chemicals or foam as necessary.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: None, however, observe usual precautions for hand care of flammable liquid.

Other Specific Hazards: Not determined.

Special Protective Equipment Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

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.

Methods for Cleaning Up: Small spills can be absorbed with appropriate material, e.g., rags, paper towels. Large spills should be assessed and documented. All clean-up operations should be witnessed by more than one individual.

Other Information: Provide adequate ventilation to keep vapor levels as low as possible. Use proper personal protective equipment to avoid overexposure. Shut off ignition sources and stop leak if you can do without risk.

Environmental Precautions: No data available.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Keep container tightly closed. Store between 59°F – 86°F. 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: Protect from light. Avoid excessive heat. Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Anhydrous Morphine	Not established.
Alcohol	Not established.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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.

9. Physical and Chemical Properties

Physical State/Color: Light yellow solution.
Odor: Camphor odor.
Odor Threshold: No data available.
pH: No data available.
Melting Point: No data available.
Freezing Point: No data available.
Boiling Point: 73.3°C.
Flash Point: 24°C.
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): Miscible in water.

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.
Possibility of Hazardous Reactions:	Will not occur.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Strong oxidizer. Avoid excessive heat.
Hazardous Decomposition Products:	Does not undergo explosive decomposition.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	No data available.
Ingestion:	No data available.
Skin Contact:	No data available.
Eye Contact:	No data available.

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 – Oral:	No data available.
Acute Toxicity – Dermal:	No data available.
Acute Toxicity – Inhalation:	No data available.
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.

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.

Mutagenicity: No data available.
Aspiration Hazard: No data available.

12. Ecological Information

Ecotoxicity

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.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local 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

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

California Proposition 65: Not listed.

16. Other Information**NFPA Rating:**

Health:	1
Flammability:	3
Reactivity:	0

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