


SAFETY DATA SHEET

Paregoric, USP 2 mg/5 mL 

1. IDENTIFICATION

Product Identifier: Paregoric, USP 2 mg/5 mL 

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. Paregoric is useful for the treatment of diarrhea.

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

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

Hazards Not Otherwise Classified:
Supplementary Information:

Not classifiable.
None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Morphine Sulfate	7,8-didehydro-4,5-epoxy-17-methylmorphinan -3, 6-diol sulfate pentahydrate; Morphine Sulfate	64-31-3	$(C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O$	758.85	0.04%
Alcohol	Ethyl alcohol	64-17-5	C_2H_5OH	46.07	45%

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.

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: 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.

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.

Medical Conditions Aggravated by Exposure: Not determined.

Notes to Physician: Treat supportively and symptomatically. Morphine can produce drug dependence and, therefore, has the potential for being abused. Patients receiving therapeutic dosage regimens of 10 mg every 4 hours for 1 to 2 weeks have exhibited mild withdrawal symptoms. Development of the dependent state is recognizable by an increased tolerance to the analgesic effect and the appearance of purposive phenomena (complaints, pleas, demands, or manipulative actions) shortly before the time of the next scheduled dose. A patient in withdrawal should be treated in a hospital environment. Usually, it is necessary only to provide supportive care with administration of a tranquilizer to suppress anxiety. Severe symptoms of withdrawal may require administration of a replacement narcotic.

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

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: Keep ignition sources away - do not smoke. Protect against electrostatic charges. Toxic gases and vapors may be released if involved in a fire.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment and 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: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling: Paregoric is a Schedule III narcotic. 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: Store at controlled room temperature 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Protect from Light. Avoid excessive heat. This product may deposit a sediment if exposed to low temperatures. Filter if necessary. Store away from oxidizing agents and acids.

Specific End Use: Pharmaceuticals.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Morphine Sulfate	Mallinckrodt OEG	25 µg/m ³ , 8 hour TWA
Morphine Sulfate	Mallinckrodt STEG	75 µg/m ³ , 15 minute average
Alcohol	OSHA PEL	1,000 ppm; 1,900 mg/m ³
	NIOSH IDLH	3,300 ppm
	NIOSH REL	1,900 mg/m ³
	ACGIH TWA	1,000 ppm
	ACGIH TLV STEL	1,000 ppm

OSHA: Occupational Safety and Health Administration; PEL: Permissible Exposure Limits; NIOSH: National Institute for Occupational Safety and Health; REL: Recommended Exposure Limits. ACGIH: American Conference of Governmental Industrial Hygienists; TLV: Threshold Limit Value; STEL: Short Term Exposure Limit; TWA: Time Weighted Average; OEG: Occupational Exposure Guideline; STEG: Short-Term Exposure Guideline.

Engineering Controls:

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

Respiratory Protection:

None required for normal use. 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:

None required for normal use. 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:

None required for normal use. Chemically compatible gloves are recommended for bulk handling. 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.

General Hygiene Considerations:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

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:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Keep away from heat, spark, flames, and other sources of ignition.
Incompatible Materials:	Oxidizing substances. Avoid excessive heat.
Hazardous Decomposition Products:	Does not undergo explosive decomposition.

11. TOXICOLOGICAL INFORMATION**Information on the Likely Routes of Exposure**

Inhalation:	May cause irritation to the respiratory tract.
Ingestion:	Narcotic. Serious overdose of morphine is characterized by respiratory depression.
Skin Contact:	May cause skin irritation.
Eye Contact:	May cause 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

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Morphine Sulfate (anhydrous)	Mouse	Oral	LD ₅₀	600 mg/kg
	Rat	Oral	LD ₅₀	461 mg/kg
Alcohol	Rat	Oral	LD ₅₀	2,404 mg/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Effect(s)
Morphine Sulfate	Reproductivity	Rat	No route specified	10-70 mg/kg/day	Caused embryotoxicity, but did not increase the incidence of birth defects
Morphine Sulfate	Reproductivity	Mouse	Subcutaneous	100-500 mg/kg/day	Maternal and embryo toxicity and skeletal defects in offspring
Morphine Sulfate	Reproductivity	Rabbit	Subcutaneous	100 mg/kg/day	Maternally toxic and embryotoxic but, not increase malformations
Morphine Sulfate	Reproductivity	Hamster	No route specified	>88 mg/kg/day	Increased malformations of the skull

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Morphine Sulfate	In vitro chromosomal aberration	Mouse splenocytes	Negative
Morphine Sulfate	In vivo chromosomal aberration	Mouse lymphocytes	Positive
Morphine Sulfate	In vitro direct DNA damage	Human lymphocytes	Positive
Morphine Sulfate	In vivo mouse micronucleus test	Mouse	Positive

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Aspiration Hazard: No data available.
Toxicokinetics/Metabolism: No data available.
Target Organ Effects: No data available.
Systemic Effects: No data available.

Reproductive Effects: Pregnancy Category C. Animal reproduction studies have not been conducted with morphine. It is not known whether morphine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Paregoric should be given to a pregnant woman only if clearly needed.

Carcinogenicity: Paregoric has no known carcinogenic or mutagenic potential. However, no long-term animal studies are available to support this observation.

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 Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Morphine Sulfate	No data available	No data available	No data available	No data available
Alcohol	Water flea (<i>Daphnia magna</i>)	EC ₅₀	7.7-11.2 mg/l	48 hours
Alcohol	Fathead minnow (<i>Pimephales promelas</i>)	LC ₅₀	>100 mg/l	96 hours

Terrestrial Toxicity: 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.

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14. TRANSPORT INFORMATION

Department of Transportation (DOT):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Ethanol Solution	UN1170	Class 3	III

International Air Transport Association (IATA):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Ethanol Solution	UN1170	Class 3	III

International Maritime Dangerous Good (IMDG):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Ethanol Solution	UN1170	Class 3	III

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Morphine Sulfate	No
Alcohol	Yes

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Morphine Sulfate	Listed	Listed	Not Listed
Alcohol	Listed	Listed	Listed

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California Proposition 65:

Alcohol is listed to cause cancer, birth defects and other reproductive harm.

16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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