



SAFETY DATA SHEET

Morphine Sulfate Oral Solution USP

1. IDENTIFICATION

Product identifier: Morphine Sulfate Oral Solution USP

Product Codes: 0121-4955-05, 0121-4955-94

Supplier Name and Address: PAI Pharma
1700 Perimeter Road
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug – treatment of pain

Restrictions on use: Prescription use only.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Reproductive Toxicity Category 2

Label Elements:
Warning!



Hazard statement(s)

Suspected of damaging fertility or the unborn child.

Precautionary statement(s)

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves.
IF exposed or concerned: Get medical attention.
Store locked up.
Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Morphine Sulfate	6211-15-0	0.1-1%
Citric Acid	77-92-9	<1%
Edetate Disodium	6381-92-6	Proprietary
Sodium Benzoate	532-32-1	Proprietary
Glycerin	56-81-5	Proprietary
Sorbitol Solution	Mixture	Proprietary

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Sodium Citrate	6132-04-3	Proprietary
Water	7732-18-5	Proprietary
FD&C Green No 3	2353-45-9	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation or symptoms of exposure develop, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintentional ingestion or overdose, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Swallowing large amounts causes central nervous system depression with drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, sweating, and constipation. Severe overdose may result in respiratory depression and, to a lesser degree, circulatory depression, respiratory arrest, shock, and cardiac arrest. Codeine phosphate can cause physical and psychological dependence. Overdose of acetaminophen may cause gastrointestinal effects, nervousness, dizziness and sleeplessness.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is recommended for unintended ingestion or overdose.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: Product is not classified as flammable but will burn in a fire after the water has evaporated.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

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Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging in a secure location.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Morphine Sulfate	None Established
Citric Acid	None Established
Edetate Disodium	None Established
Sodium Benzoate	2.5 mg/m ³ (inhalable) skin
Glycerin	5 mg/m ³ (respirable particulate) TWA OSHA PEL 15 mg/m ³ (total particulate) TWA OSHA PEL
Sorbitol Solution	None Established
Sodium Citrate	None Established
FD&C Green No 3	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid	Color: Clear, blue-green
Odor: Not available	pH: 3.0-3.5
Melting point/freezing point: Not determined	Boiling Point: Not determined

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Flash point: Not applicable	Particle Characteristics: Not applicable
Flammability: Not flammable	VOC: Not determined
Flammable limits: LEL: Not determined	UEL: Not determined
Vapor pressure: Not determined	Relative Vapor density: Not determined
Relative density: ~1.1	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Kinematic Viscosity: Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon and sulfur oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and symptoms similar to ingestion.

Ingestion: Swallowing large amounts causes central nervous system depression with drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, sweating, and constipation. Severe overdosage may result in respiratory depression and, to a lesser degree, circulatory depression, respiratory arrest, shock, and cardiac arrest. Morphine sulfate can cause physical and psychological dependence.

Skin contact: May cause mild irritation. Absorption through the skin is possible with effects similar to ingestion.

Eye contact: May cause mild irritation with redness and tearing.

Chronic Effects: Prolonged use of morphine sulfate may lead to dependence and withdrawal symptoms when use stops.

Sensitization: Not classified.

Germ Cell Mutagenicity: In the published literature, morphine was found to be mutagenic *in vitro* increasing DNA fragmentation in human T-cells. Morphine was reported to be mutagenic in the *in vivo* mouse micronucleus assay and positive for the induction of chromosomal aberrations in mouse spermatids and murine lymphocytes. Mechanistic studies suggest that the *in vivo* clastogenic effects reported with morphine in mice may be related to increases in glucocorticoid levels produced by morphine in this species. In contrast to the above positive findings, *in vitro* studies in the literature have also shown that morphine did not induce chromosomal aberrations in human leukocytes or translocations or lethal mutations in *Drosophila*.

Reproductive Toxicity: Chronic use of opioids may cause reduced fertility in females and males of reproductive potential. Several nonclinical studies from the literature have demonstrated adverse effects on male fertility in the rat from exposure to morphine. One study in which male rats were administered morphine sulfate subcutaneously prior to mating (up to 30 mg/kg twice daily) and during mating (20 mg/kg twice daily) with untreated females, a number of adverse reproductive effects including reduction in total pregnancies and higher incidence of pseudopregnancies at 20 mg/kg/day were reported. Studies from the literature have also



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reported changes in hormonal levels in male rats (i.e. testosterone, luteinizing hormone) following treatment with morphine at 10 mg/kg/day or greater. Female rats that were administered morphine sulfate intraperitoneally prior to mating exhibited prolonged estrous cycles at 10 mg/kg/day. Prolonged use of opioid analgesics during pregnancy can cause neonatal opioid withdrawal syndrome. In published animal reproduction studies, morphine administered subcutaneously during the early gestational period produced neural tube defects (i.e., exencephaly and cranioschisis) in hamsters and mice, respectively, lower fetal body weight and increased incidence of abortion in the rabbit, growth retardation in the rat, and axial skeletal fusion and cryptorchidism in the mouse. Administration of morphine sulfate to pregnant rats during organogenesis and through lactation resulted in cyanosis, hypothermia, decreased brain weights, pup mortality, decreased pup body weights, and adverse effects on reproductive tissues.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5,000 mg/kg

Morphine sulfate: Oral rat LD50 461 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No data available

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT	-	Not Regulated	-	-	No
TDG	-	Not Regulated	-	-	No
IMDG	-	Not Regulated	-	-	No
IATA	-	Not Regulated	-	-	No

Transport in bulk according to IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

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Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA Hazard Classification

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: New SDS

Disclaimer : The information provided on this SDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.