

Safety Data Sheet

Issuing date: 07/24/2017

Revision date: 07/24/2017

Revision number: 00

1. Identification of the substance/preparation and the company/undertaking

Product Identifier	Morphine Sulfate Oral Solution USP
Other means of identification	
NDC Number(s)	0121-0825-01; 0121-0825-04; 0121-0825-08
Synonyms	None
Recommended Use/Restrictions	
Recommended Use	Morphine Sulfate Oral Solution indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
Uses advised against	Do not use except as recommended.
Supplier Information	
Company name	Pharmaceutical Associates, Inc.
Address	201 Delaware Street Greenville, SC 29605
Telephone	864 - 277 - 7282
Emergency telephone number	CHEMTREC: 800 - 424 - 9300

2. Hazards Identification

Classification	Not classified
Physical hazards	Not classified
Chemical Family	None
Label elements	
Hazard symbol	None
Signal word	Warning
Hazard statement	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
Additional hazard Information	
Short term	Serious adverse reactions associated with morphine use included: respiratory depression, apnea, and to a lesser degree, circulatory depression, respiratory arrest, shock and cardiac arrest.
Long term	No data available.

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Known Clinical Effects

Serotonergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue Morphine Sulfate Oral Solution if serotonin syndrome is suspected.

Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with Morphine Sulfate Oral Solution because they may reduce analgesic effect of Morphine Sulfate Oral Solution or precipitate withdrawal symptoms.

EU Indication of danger

Not classified.

Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

Precautionary statements

Prevention	Observe good industrial hygiene practices.
Skin Contact	Wash hands after handling
Storage	Protect from moisture. Store at 20 – 25 °C (68 - 77°F). Store away from incompatible materials.
Disposal	Incineration of waste at an approved USEPA incinerator is recommended.

3. Composition/Information on ingredients

Substances

Chemical name	CAS-No	mg/5 mL	Trade Secret
Morphine Sulfate	6211-15-0	100 mg	
Citric Acid Anhydrous	77-92-9		X
Edetate Disodium	6381-92-6		X
Sodium Benzoate	532-32-1		X
Glycerin USP	56-81-5		X
Sorbitol Solution	Mixture		X
Sodium Citrate	6132-04-3		X

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4. First aid measures

Eye contact	Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/ supportive care as necessary
Skin contact	Wash off with soap and water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/ supportive care as necessary
Inhalation	If signs of toxicity occur seek medical attention. Provide symptomatic/ supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Overdosage is characterized by respiratory depression with or without concomitant CNS depression. Since respiratory arrest may result either through direct depression of the respiratory center or as the result of hypoxia, primary attention should be given to the establishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. The narcotic antagonist, naloxone, is a specific antidote. Naloxone hydrochloride should be administered intravenously, simultaneously with respiratory resuscitation. As the duration of effect of naloxone is considerably shorter than that of morphine, repeated administration may be necessary. Patients should be closely observed for evidence of re-narcotization
Most important symptoms/effects, acute and delayed	Respiratory depression is the chief hazard. The most common symptoms include: drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, and sweating.
Indication of immediate medical attention and special treatment needed, if necessary	Immediate medical attention is required if overdose is suspected. In the case of overdose, the primary management should be the reestablishment of adequate ventilation with mechanical assistance of respiration, if required. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation. Treat symptomatically.
Indication of immediate medical attention and special treatment needed, if necessary	Immediate medical attention is required if overdose is suspected.
Notes to Physician	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Explosion data	No unusual fire or explosion data notes.

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Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

6. Accidental release measures

Personal precautions, protective equipment, and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and materials for containment and cleaning up

Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended. Controlled substances must be destroyed following DEA guidelines for witnessed destruction of the product beyond reclamation.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground

7. Handling and storage

Precautions for safe handling

Handling

No special handling required for hazard control under conditions of normal product use. In the US, morphine sulfate is a Schedule II controlled substance. Additional training may be required for handling this material.

Conditions for safe storage, including any incompatibilities

Storage

No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label or the product insert.

Incompatible products

As a precautionary measure, keep away from strong oxidizers.

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8. Exposure controls/personal protection

Control parameters

Exposure guidelines

The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Morphine Sulfate	Not Available	Not Available	Not Available
Citric Acid Anhydrous	10 mg/m ³ TWA	15 mg/m ³ TWA	Not Available
Edetate Disodium	Not Available	Not Available	Not Available
Sodium Benzoate	Not Available	Not Available	Not Available
Glycerin USP	10 mg/m ³ TWA	10 mg/m ³ TWA	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
Sodium Citrate	Not Available	Not Available	Not Available

Appropriate engineering controls

Engineering measures

Engineering controls should be used to limit exposure. Ventilation should be matched to conditions

Individual protection measures, such as personal protective equipment

Eye/face protection

None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin protection

Hand protection

For consumer use, no unusual precautions are necessary.

Other

None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

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Respiratory protection

None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

Hygiene measures

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

Appearance

Physical state	Solution
Appearance	Clear, colorless to slightly yellow solution, free of sedimentation
Odor	Not available.
Odor threshold	Not available.

Property	Values	Remarks/Method
pH	Not available.	
Melting point/range	Not available.	
Boiling point/boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability limits in air	Not available.	
-upper flammability limit	Not available.	
-lower flammability limit	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient: n-octanol/water	Not available.	
Autoignition temperature	Not available.	
Decomposition temperature	Not available.	
Viscosity	Not available.	
Flammable properties	Not available.	
Explosive properties	Not available.	
Oxidizing properties	Not applicable	

Other information

VOC content (%)	Not applicable
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10. Stability and reactivity

Reactivity	The product is non-reactive under normal conditions of use, storage and transport
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Exposure to light.
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	No Hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Not expected to be hazardous in final pharmaceutical form.
Eye contact	Not expected to be hazardous in final pharmaceutical form. Contact with eyes may cause temporary irritation.
Skin contact	Not expected to be hazardous in final pharmaceutical form.
Ingestion	Ingestion may cause irritation and malaise.

Information on toxicological effects

Acute toxicity May be harmful if swallowed in large quantities.
 The information in the table below is for the individual components and not the product.

Component	LD50 oral	LD50 dermal	LC50 inhalation
Morphine Sulfate	461 mg/kg Rat 600 mg/kg Mouse	Not Available	Not Available
Citric Acid Anhydrous	5400 mg/kg Rat	>2000 mg/kg Rabbit	Not Available
Edetate Disodium	>2000 mg/kg Rat	Not Available	Not Available
Sodium Benzoate	2100 mg/kg Rat	Not Available	Not Available
Glycerin USP	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
Sodium Citrate	Not Available	Not Available	Not Available

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Symptoms related to the physical, chemical and toxicological characteristic

Respiratory depression is the chief hazard. The most common symptoms include: drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, and sweating

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization	No data available
Mutagenic effects	This product is not expected to be mutagenic.
Carcinogenicity	Long-term studies in animals have not been conducted to evaluate carcinogenic potential.
Reproductive toxicity	Based on available data, the classification criteria are not met. Use of opioids during pregnancy may cause physical dependence in the fetus leading to respiratory difficulties and withdrawal symptoms (dehydration, irritability, tremors, excessive crying, diarrhea) in the newborn.
STOT – single exposure	Narcotic effects.
STOT – repeated exposure	Not classified.
Aspiration hazard	Not classified.
Numerical measures of toxicity	No data available.

12. Ecological information

Ecotoxicity	This product is not classified as environmentally hazardous.
Persistence and Degradability	No data available
Bioaccumulation	No data available
Other adverse effects	None

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Morphine Sulfate	Not Available	Not Available	Not Available	Not Available
Citric Acid Anhydrous	Not Available	440 mg/L 48 hr. <i>Leuciscus idus melanotus</i>	Not Available	1535 mg/L 24 hr.
Edetate Disodium	10 – 100 mg/L 72 hr	>500 mg/kg 96 hr <i>Leuciscus idus melanotus</i>	Not Available	>100 mg/L 24 hr.
Sodium Benzoate	Not Available	484 mg/L 96 hr. <i>Pimephales Promelas</i>	Not Available	Not Available
Glycerin USP	Not Available	58.5 ppm 96 hr Trout	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available	Not Available
Sodium Citrate	Not Available	Not Available	Not Available	Not Available

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13. Disposal considerations

Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations. In the U.S., morphine sulfate is a Schedule II controlled substance and may have additional requirements for proper disposal. Empty containers may retain some product residues. This material and its container must be disposed of in a safe manner.

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since empties containers may retain product residue, follow label warning even after container is empties.

14. Transport information

Notes:

Not regulated as a dangerous good under USDOT, IATA, TDG, IMDG or other regulations.

Transport in bulk according to Annex II of MARPOL 73/78 and IBC Code

15. Regulatory information

US federal regulations

This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

DEA: Morphine Sulfate Oral Solution, CII is a DEA scheduled II controlled substance.

FDA: Morphine Sulfate Oral Solution, CII is an approved prescription medication

US TSCA Section 12(b) Not listed.

US CERCLA Status Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard	Yes
Delayed Hazard	No
Fire Hazard	No
Pressure Hazard	No
Reactivity Hazard	No

US SARA 302 Not listed.

US SARA 311/312 Not a hazardous chemical.

US SARA 313 Not listed.

US PROP 65 (calif.) Not listed.

US EPA label information Not applicable.

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OSHA specifically Regulated Substances

Not listed.

Clean Water Act

Not regulated. (40 CFR 122.21 and 40 CFR 122.42)

U.S. state Right-to-Know regulations

"X" designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Morphine Sulfate					
Citric Acid Anhydrous	X		X		
Edetate Disodium					
Sodium Benzoate	X		X		
Glycerin USP	X	X	X	X	X
Sorbitol Solution	X		X		
Sodium Citrate	X		X		

International inventories

Country(s) or region	Inventory name	On inventory list (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
 A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Prepared by: Pharmaceutical Associates Regulatory Affairs Department
Issuing date: 07/24/2017
Revision date: NA
Revision note: NA



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Legal Disclaimer

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 construed as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet