SAFETY DATA SHEET

1. Identification

Product identifier Morphine Sulfate

Other means of identification
- Catalog number: 1448005
- Chemical name: Morphinan-3,6-diol, 7,8-didehydro-4,5-epoxy-17-methyl, (5alpha, 6alpha)-, sulfate (2:1) salt, pentahydrate

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information
- Company name: U. S. Pharmacopoeia
- Address: 12601 Twinbrook Parkway
- Rockville
- MD 20852-1790
- US
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300
- CHEMTREC outside US & Canada +1 703-527-3887
- E-mail: RSTECH@usp.org

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards
- Acute toxicity, oral: Category 4
- Germ cell mutagenicity: Category 2
- Specific target organ toxicity, single exposure: Category 3 narcotic effects

OSHA hazard(s) Not classified.

Label elements

Signal word Warning

Hazard statement Harmful if swallowed. May cause drowsiness or dizziness. Suspected of causing genetic defects.

Precautionary statement
- Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use only outdoors or in a well-ventilated area. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.
- Response: Rinse mouth. If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. If inhaled: Remove person to fresh air and keep comfortable for breathing. If exposed or concerned: Get medical advice/attention.
- Storage: Store in a well-ventilated place. Keep container tightly closed. Store locked up.
- Disposal: Dispose of contents/container to an approved disposal sites.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Substance

Material name: Morphine Sulfate
4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
Narcotic effects.

Indication of immediate medical attention and special treatment needed
Treatment for opioid overdose should be symptomatic and supportive and may include the following: Do not induce vomiting. Administer activated charcoal as a slurry. Monitor vital signs, pulse oximetry, and cardiac function. Monitor for CNS and respiratory depression. Administer oxygen and assist ventilation for respiratory depression. Protect airway with orotracheal intubation. Naloxone reverses coma and respiratory depression. Administer intravenously, intramuscularly, intratracheally, intranasally, or subcutaneously. A continuous infusion might be needed for long-acting opioids. Treat seizures with intravenous benzodiazepines; propofol or barbiturates may be administered if seizures persist. Treat hypotension with an infusion of isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. Hemodialysis and hemoperfusion are not recommended. [Poisindex]

General information
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media
Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire-fighting equipment/instructions
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
8. Exposure controls/personal protection

Exposure limit values

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine Sulfate (CAS 6211-15-0)</td>
<td>STEL</td>
<td>75 micrograms/m3</td>
<td>(15 minutes)</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>25 micrograms/m3</td>
<td></td>
</tr>
</tbody>
</table>

Biological limit values
No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection
Safety glasses with sideshields 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.

Skin protection
Hand protection
Chemically compatible gloves. 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 nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other
For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

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).

Thermal hazards
Not available.

General hygiene considerations
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance
White crystals, crystalline powder, or cubical mass of crystals.

Physical state
Solid.

Form
Powder.

Odor
Odorless.

Odor threshold
Not available.

Initial boiling point and boiling range
Not available.

Flash point
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
Not applicable.

Upper/lower flammability or explosive limits
Flammability limit - lower (%)
Not available.

Flammability limit - upper (%)
Not available.

Explosive limit - lower (%)
Not available.

Explosive limit - upper (%)
Not available.

Vapor pressure
Not available.

Vapor density
Not available.

Relative density
Not available.

Solubility in water
Freely soluble in hot water.

Partition coefficient (n-octanol/water)
1.42 (at physiological pH)
Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other information

Chemical family
Morphinan derivative; alkaloid.

Molecular formula
(C17H19NO3)2 . H2SO4 . 5H2O

Molecular weight
758.83

Solubility (other)
Slightly soluble in alcohol, but more soluble in hot alcohol; insoluble in chloroform and in ether.

Specific gravity
1.3

10. Stability and reactivity

Reactivity
No reactivity hazards known.

Chemical stability
Material is stable under normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
None known.

Incompatible materials

Hazardous decomposition products
NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion
Harmful if swallowed.

Inhalation
Due to lack of data the classification is not possible.

Skin contact
Due to lack of data the classification is not possible.

Eye contact
Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics

Delayed and immediate effects of exposure

Cross sensitivity
Persons sensitive to other opioids may be sensitive to this material as well.

Medical conditions aggravated by exposure

Acute toxicity
Harmful if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine Sulfate (CAS 6211-15-0)</td>
<td>Oral LD50</td>
<td>Rat 973 mg/kg 461 mg/kg, (anhydrous)</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Due to lack of data the classification is not possible.

Serious eye damage/eye irritation
Due to lack of data the classification is not possible.

Respiratory sensitization
Due to lack of data the classification is not possible.

Skin sensitization
Due to lack of data the classification is not possible.

Germ cell mutagenicity
Suspected of causing genetic defects.

Mutagenicity
In vitro chromosomal aberration in mice splenocytes.
Result: Negative.
In vivo chromosomal aberration in mouse lymphocytes
Result: Positive.
In vivo direct DNA damage in human lymphocytes
Result: Positive.
Mutagenicity
In vivo mouse micronucleus test
Result: Positive.

Carcinogenicity
Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. In repeated-dose toxicity studies in rats and dogs, there was no microscopic evidence of pre-neoplastic or neoplastic changes.

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.

Reproductivity
10 - 70 mg/kg/day Reproductivity test
Result: Caused embryotoxicity but did not increase the incidence of birth defects.
Species: Rat
100 - 500 mg/kg/day Reproductivity test (subcutaneous)
Result: Maternal and embryo toxicity and skeletal defects in offspring.
Species: Mouse
100 mg/kg/day Reproductivity test (subcutaneous)
Result: Maternally toxic and embryotoxic, but did not increase malformations.
Species: Rabbit
> 88 mg/kg/day Reproductivity test
Result: Increased malformations of the skull.
Species: Hamster

Specific target organ toxicity - single exposure
Narcotic effects.

Specific target organ toxicity - repeated exposure
Due to lack of data the classification is not possible.

Aspiration hazard
Based on available data, the classification criteria are not met.

12. Ecological information
Ecotoxicity
No ecotoxicity data noted for the ingredient(s).

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
Not available.

Mobility in soil
Not available.

Other adverse effects
Not available.

13. Disposal considerations
Disposal instructions
Dispose in accordance with all applicable regulations.

Local disposal regulations
Not available.

Hazardous waste code
Not regulated.

Waste from residues / unused products
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

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

14. Transport information
DOT
Not regulated as a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No information available.

15. Regulatory information
US federal regulations
CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.
Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance: No
SARA 311/312 Hazardous chemical: No

Other federal regulations
- Drug Enforcement Administration (DEA) (21 CFR 1308.11-15): Schedule II - 9300
- Food and Drug Administration (FDA): Not regulated.

US state regulations
- California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
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<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date: 09-27-2010
Revision date: 09-20-2013
Version #: 02
Further information: Not available.

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Revision Information
This document has undergone significant changes and should be reviewed in its entirety.