



SAFETY DATA SHEET

1. Identification

Product identifier	Codeine Sulfate		
Other means of identification			
Catalog number	1145003		
Chemical name	Morphinan-6-ol, 7,8-didehydro-4,5-epoxy-3-methoxy-17- methy-, (5alpha, 6alpha)-, sulfate (2:1) (salt), trihydrate		
Synonym(s)	Methylmorphine sulfate trihydrate		
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. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US		
Telephone	RS Technical Services	301-816-8129	
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300	
	CHEMTREC outside US & Canada	+1 703-527-3887	

2. Hazard(s) identification

Physical hazards	Not classified.		
Health hazards	Acute toxicity, oral	Category 4	
	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.
Precautionary statement	
Prevention	Use only outdoors or in a well-ventilated area. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.
Response	If swallowed: Call a poison center/doctor// if you feel unwell. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor/. Rinse mouth.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container to an approved disposal site.
Hazard(s) not otherwise classified (HNOC)	Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Codeine Sulfate	Methylmorphine sulfate trihydrate	6854-40-6	100

4. First-aid measures

Inhalation	Call a POISON CENTER or doctor/physician if you feel unwell.
Skin contact	Get medical attention if irritation develops or persists.
Eye contact	Get medical attention if irritation develops or persists.
Ingestion	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. May cause irritation and toxicity. Flush out mouth with water. This material is absorbed from the gastrointestinal tract. Its onset of action is 30 to 45 minutes, and its duration of action is 4 to 6 hours.
Most important symptoms/effects, acute and delayed	Not available.
Indication of immediate medical attention and special treatment needed	Treatment for opioid overdose should be symptomatic and supportive and may include the following: 1. Do not induce vomiting. 2. Administer activated charcoal as a slurry. 3. Monitor vital signs, pulse oximetry, and cardiac function. Monitor for CNS and respiratory depression. 4. Administer oxygen and assist ventilation for respiratory depression. Protect airway with orotracheal intubation. 5. Naloxone reverses coma and respiratory depression. Administer intravenously, intramuscularly, intratracheally, intranasally, or subcutaneously. A continuous infusion might be needed for long-acting opioids. 6. Treat seizures with intravenous benzodiazepines; propofol or barbiturates may be administered if seizures persist. 7. Treat hypotension with an infusion of isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. 8. Hemodialysis and hemoperfusion are not recommended. [Poisindex 2010]
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	Use water spray to cool unopened containers. 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

Biological limit values	No biological exposure limits noted for the ingredient(s).
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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, needle-like crystals or crystalline powder, odorless.
Physical state	Solid.
Form	Solid.
Odor	Not available.
Odor threshold	Not available.
pH	5
Melting point/freezing point	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	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Morphinan derivative; phenanthrenic alkaloid
Molecular weight	750.85 (trihydrate)
Solubility (other)	Very slightly soluble in ethanol; insoluble in chloroform and in ether.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. SOx. NOx.

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	Dizziness. Drowsiness. Weakness. Behavior, mood, or mental changes. Euphoria. Confusion. Agitation. Nausea. Vomiting. Constipation. Sweating. Flushing. Itching. Skin rash.
Delayed and immediate effects of exposure	Change in blood pressure. Irregular heartbeat. Seizures. Hypothermia. Death.
Chronic effects	Psychological dependence. Tolerance.
Medical conditions aggravated by exposure	Impaired liver function. Impaired kidney function. History of seizures. Asthma. Respiratory disorders. Heart problems. Drug abuse. Gallbladder disorders. Inflammatory bowel disease. Gastrointestinal tract obstruction. Addison's disease.
Acute toxicity	Harmful if swallowed.

Product	Species	Test Results
Codeine Sulfate (CAS 6854-40-6)		
Oral		
LD50	Mouse	395 mg/kg, (anhydrous)
	Rat	430 mg/kg, (anhydrous)
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.	
Sensitization	Not classified.	
Germ cell mutagenicity	Due to lack of data the classification is not possible.	
Mutagenicity		
In vitro bacterial reverse mutation assay		
Result: Negative		
In vitro chromosome aberration assay (Chinese hamster ovary cells)		
Result: Negative		
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
400 mg/kg/day Two-year dietary study		
Result: No evidence of carcinogenicity (codeine)		
Species: Mouse		
80 mg/kg/day Two-year dietary study		
Result: No evidence of carcinogenicity (codeine)		
Species: Rat		
Reproductive toxicity	A study by the Collaborative Perinatal Project of 563 mothers exposed to codeine in the first four months of pregnancy and 2522 women exposed any time during pregnancy did not show the frequency of birth defects to be greater than expected. The Boston Collaborative Surveillance Program also found no increase in the frequency of birth defects in children of more than 630 women who used codeine-containing medications therapeutically in the first trimester of pregnancy. 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. Based on available data, the classification criteria are not met.	

Reproductivity

120 mg/kg/day Gestational study
Result: Increased fetotoxicity
Species: Rat
30 mg/kg Gestational study
Result: No maternal or fetal adverse effects
Species: Rabbit
300 mg/kg/day Gestational study
Result: Increase in cranial malformations
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 This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. 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 DEA Controlled Substance Schedule CII
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 - No
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

Safe Drinking Water Act (SDWA) Not regulated.

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		
Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No
*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)		

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

Issue date	09-29-2010
Revision date	11-30-2012
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.