

## 1. Identification

<b>Product identifier</b>	<b>Codeine Phosphate CII</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1144000	
<b>CAS number</b>	41444-62-6	
<b>Synonyms</b>	Methylmorphine phosphate	
<b>Chemical name</b>	Morphinan-6-ol, 7,8-didehydro-4,5-epoxy-3-methoxy-17- methyl-, (5alpha,6alpha)-, phosphate (1:1) (salt), hemihydrate	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	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 3
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Toxic if swallowed. May cause drowsiness or dizziness.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Wash thoroughly after handling. Avoid breathing dust. Use only outdoors or in a well-ventilated area.	
<b>Response</b>	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.	
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.	
<b>Supplemental information</b>	Pharmacologically active material.	

## 3. Composition/information on ingredients

**Substance**

Chemical name	Common name and synonyms	CAS number	%
Codeine Phosphate CII	Methylmorphine phosphate	41444-62-6	100

#### 4. First-aid measures

<b>Inhalation</b>	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.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
<b>Most important symptoms/effects, acute and delayed</b>	Narcotic effects. Pharmacologically active material. Occupational exposure may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Treatment for opioid overdose 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.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

#### 7. Handling and storage

<b>Precautions for safe handling</b>	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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
<b>Conditions for safe storage, including any incompatibilities</b>	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

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

Industrial Use Material	Type	Value
Codeine Phosphate CII (CAS 41444-62-6)	TWA	200 micrograms/m3

### Biological limit values

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

### Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

#### Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Chose respiratory protection appropriate to the task and the level of existing engineering controls.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

## 9. Physical and chemical properties

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Crystalline powder.

#### Color

White.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

428 - 455 °F (220 - 235 °C)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not available.

### 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(ies)

#### Solubility (water)

Freely soluble.

<b>Solubility (other)</b>	Ethanol: Slightly soluble.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Morphinan derivative; phenanthrenic alkaloid
<b>Molecular formula</b>	C18H21NO3.H3O4P.1/2H2O
<b>Molecular weight</b>	406.37 g/mol
<b>pH in aqueous solution</b>	4 to 5 Solution: 4%
<b>Specific gravity</b>	1.76

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	None known.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. POx.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Toxic if swallowed. Based on information from therapeutic use, this material may cause: Narcotic effects.

**Symptoms related to the physical, chemical, and toxicological characteristics**  
Opioids: Respiratory depression. Central nervous system depression. Gastrointestinal disturbances. Mood or mental changes. Pinpoint pupils. Muscle rigidity. Seizures.

### Information on toxicological effects

<b>Acute toxicity</b>	Toxic if swallowed.
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Product	Species	Test Results
Codeine Phosphate CII (CAS 41444-62-6)		
<b>Oral</b>		
LD50	Rat	266 mg/kg
<b>Skin corrosion/irritation</b>	Knowledge about health hazard is incomplete.	
<b>Serious eye damage/eye irritation</b>	Knowledge about health hazard is incomplete.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Skin sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.	
<b>Mutagenicity</b>		
Ames test (Salmonella typhimurium)		
Result: Negative (+/- activation)		
Mutagenicity, Chromosome aberration study (CHO cells)		
Result: Negative.		
Mutagenicity, Sister chromatid exchange (CHO cells)		
Result: Positive with and without activation.		
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.	
Two-year carcinogenicity study, Feed study with Codeine		
Result: Negative: No evidence of carcinogenicity.		
Species: Mouse		
Two-year carcinogenicity study, Feed study with Codeine		
Result: Negative: No evidence of carcinogenicity.		
Species: Rat		

## IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

## OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

## US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

### Reproductive toxicity

Knowledge about health hazard is incomplete.

In women with normal codeine metabolism (normal CYP2D6 activity), the amount of codeine secreted into human milk is low and dose-dependent. In ultra-rapid metabolizers of codeine, high serum levels of codeine's active metabolite, morphine, may cause high serum morphine levels in their breastfed infants. Fetal exposure to opioids may lead to respiratory difficulties and withdrawal symptoms in the newborn.

### Reproductivity

100 mg/kg Developmental Toxicity

Result: Delayed ossification.

Species: Mouse

120 mg/kg Developmental Toxicity

Result: Increase in embryo resorption.

Species: Rat

Developmental Toxicity

Result: No observed effect level for developmental toxicity 10

mg codeine/kg/twice a day. Reduced fetal body weight at

maternally nontoxic dose of 50 mg/kg/twice a day.

Species: Hamster

Developmental Toxicity

Result: No observed effects at 75 mg codeine/kg/twice a day.

Reduced fetal body weight at 150 mg/kg/twice a day.

Increased resorptions, increased maternal mortality, no increase in major fetal malformations at 300 mg/kg/twice a day.

Species: Mouse

### Specific target organ toxicity - single exposure

Narcotic effects.

### Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

### Aspiration hazard

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

### Further information

Pharmacologically active material. Occupational exposure may cause physiological effects.

## 12. Ecological information

### Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

### Persistence and degradability

No data is available on the degradability of this product.

### Bioaccumulative potential

No data available.

### Mobility in soil

No data available.

### Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

### Disposal instructions

Dispose in accordance with all applicable regulations. 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.

### Local disposal regulations

Dispose in accordance with all applicable regulations.

### Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

### 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

#### UN number

UN1544

#### UN proper shipping name

Alkaloid salts, solid, n.o.s. (Codeine Phosphate)

#### Transport hazard class(es)

#### Class

6.1

<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>IATA</b>	
<b>UN number</b>	UN1544
<b>UN proper shipping name</b>	Alkaloid salts, solid, n.o.s. (Codeine Phosphate)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Other information</b>	
<b>Passenger and cargo aircraft</b>	Allowed with restrictions.
<b>Cargo aircraft only</b>	Allowed with restrictions.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.
<b>DOT; IATA</b>	



<b>General information</b>	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.
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## 15. Regulatory information

<b>US federal regulations</b>	CERCLA/SARA Hazardous Substances - Not applicable.
	One or more components are not listed on TSCA.
	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - Yes
	Delayed Hazard - No
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard - No

### SARA 302 Extremely hazardous substance

Not listed.

<b>SARA 311/312 Hazardous chemical</b>	Yes
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### SARA 313 (TRI reporting)

Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

<b>Safe Drinking Water Act (SDWA)</b>	Not regulated.
<b>Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)</b>	Schedule II - 9050
<b>US state regulations</b>	WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
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	Yes
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)

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, including date of preparation or last revision

<b>Issue date</b>	10-20-2010
<b>Revision date</b>	04-27-2018
<b>Version #</b>	02
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