



## Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Hydrocodone Bitartrate USP Hydrate

20-1010

### Section 1: Identification

**Product Name** Hydrocodone Bitartrate USP Hydrate  
**Commercial Name** Hydrocodone bitartrate  
**Product Use** Medication: Analgesic agent.  
**Restrictions On Use** Not available.

**Product Code** 20-1010

**Company** PCCA  
9901 South Wilcrest  
Houston, TX 77099  
Phone: 1-800-331-2498  
Fax: 1-800-874-5760

In case of emergency contact:  
**CHEMTREC (24hr) 1-800-424-9300**

### Section 2: Hazard(s) Identification

**OSHA Haz Com:** Acute toxicity, oral Category 2 Acute toxicity, dermal Category 4 Acute toxicity, inhalation Category 2  
**CFR 1910.1200** Sensitization, respiratory Category 1 Sensitization, skin Category 1 Specific target organ toxicity, single exposure Category 3 narcotic effects

**Signal Word** DANGER

**Hazard Statement(s)** Harmful if swallowed. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause drowsiness or dizziness.

**Pictogram(s) or Symbol(s)**



**Precautionary Statement(s):**

#### Prevention

Do not breathe dust. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation wear respiratory protection. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing. Wash hands thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Dust accumulation from this product may present an explosion hazard in the presence of an ignition source.

#### Response

If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. Call a poison center/doctor if you feel unwell. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. If experiencing respiratory symptoms: Call a poison center/doctor. Take off contaminated clothing and wash it before reuse.

#### Storage

Store locked up. Store in a well-ventilated place. Keep container tightly closed.

#### Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

### Section 3: Composition/Information on Ingredients

**Substance/Mixture** Substance  
**Components** Hydrocodone Bitartrate  
**% By Weight** 100  
**CAS#** 34195-34-1  
**Molecular Weight** 494.5 g/mole  
**Chemical Formula** C<sub>18</sub>H<sub>21</sub>NO<sub>3</sub>.C<sub>4</sub>H<sub>6</sub>O<sub>6</sub>.2-1/2H<sub>2</sub>O  
**Synonym(s)** Not available.

#### Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Hydrocodone bitartrate	34195-34-1	100		Oral (LD50): Acute: 375 mg/kg (Rat)

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**Section 4: First-Aid Measures**

<b>Inhalation</b>	If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediately call a POISON CENTER or doctor/physician.
<b>Skin Contact</b>	Rinse skin with water/shower. For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing and shoes. If skin irritation or rash occurs: Get medical advice/attention. Wash clothing separately before reuse
<b>Eye Contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. If a contact lens is present, DO NOT delay irrigation or attempt to remove the lens. Get medical attention immediately.
<b>Ingestion</b>	If swallowed: Immediately call a poison center/doctor. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs
<b>Symptoms/Effects</b>	
<b>Acute</b>	Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. May cause allergic respiratory and skin reactions.
<b>Delayed</b>	Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. May cause allergic respiratory and skin reactions.

**Immediate Medical Attention**

In case of shortness of breath, give oxygen. Keep victim warm. Symptoms may be delayed.

**Section 5: Fire-Fighting Measures****Suitable Extinguishing Media**

Water. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**Unsuitable Extinguishing Media**

Not available.

**Products of Combustion**

During fire, gases hazardous to health may be formed. Dust may form explosive mixture with air. Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

**Firefighters Special Equipment and Precautions**

Wear full protective clothing, including helmet, self-contained positive pressure or pressure demand breathing apparatus, protective clothing and face mask. In case of fire and/or explosion do not breathe fumes. In the event of fire, cool tanks with water spray.

Move containers from fire area if you can do so without risk. As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Cool containers exposed to flames with water until well after the fire is out. Follow handling guidance appropriate for OEB-2 potent compounds, (see section 7).

**Section 6: Accidental Release Measures**

Personal precautions, protective equipment and emergency procedures: Ensure adequate ventilation. Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate protective equipment and clothing during clean-up. Avoid contact with spilled material. Avoid inhalation of dust from the spilled material. Ventilate closed spaces before entering them. Follow handling guidance appropriate for OEB-2 potent compounds, (see Section 7). Methods and materials for containment and cleaning up: Stop the flow of material, if this is without risk. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Prevent entry into waterways, sewer, basements or confined areas. Do not flush to sewer. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Collect dust using a vacuum cleaner equipped with HEPA filter. Use only non-sparking tools. Clean surface thoroughly to remove residual contamination. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. For waste disposal, see section 13 of the SDS Environmental precautions: Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

### Section 7: Handling and Storage

Handling: Do not use in areas without adequate ventilation. DO NOT handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not breathe dust. Keep formation of airborne dusts to a minimum. Provide appropriate exhaust ventilation at places where dust is formed. Use personal protective equipment as required. Do not ingest. Do not get this material in contact with eyes. Do not get this material in contact with skin. Do not get this material on clothing. Wash thoroughly after handling. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Ground and bond containers when transferring material. When using, do not eat, drink or smoke. Avoid release to the environment. Handle and open container with care. Storage: Store locked up. Keep container tightly closed. For storage condition, see finished product label. Store in a well-ventilated place. Guard against dust accumulation of this material. Keep away from heat and sources of ignition. This material can accumulate static charge which may cause spark and become an ignition source. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Use care in handling/storage. Store in accordance with local/regional/national/international regulation. Further information: CONTROLLED SUBSTANCE: Location of storage area must comply with all Drug Enforcement Agency regulations. Hydrocodone Bitartrate has potent pharmacological activity and is classified as an OEB-2\* material. Handling practices for OEB-2 substances are described below. LABORATORY: \*Wear appropriate gloves, lab coat, and safety glasses. Use good lab practices. \*No local exhaust ventilation required for transfer/handling of quantities of powder less than 100 g (total weight transferred or handled). However, if the source container contains 2 kg or more, pilot plant practices apply. \*No local exhaust ventilation required for solutions of these compounds. 'Quantities of solid above 100 g require use of a powders weighing hood or other approved containment/ventilation system. 'High-energy operations such as milling, particle-sizing, spraying or fluidizing should be done within an approved emission control or containment system. 'Develop cleaning procedures and techniques that limit potential exposure.

### Section 8: Exposure Controls/Personal Protection

<b>Exposure Limits</b>	HYDROCODONE BITARTRATE (CAS 34195-34-1)	OEB	2 OEB OEG	33 pg/m3	8-hour
	Time-Weighted Average STEG	100pg/m3	15-minute Average Biological limit values	- No biological exposure limits noted for the ingredient(s). Exposure guidelines	- No exposure standards allocated.
<b>Engineering Controls</b>	Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Ensure adequate ventilation, especially in confined areas.				

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**Personal Protection**

Eye/face protection: Chemical goggles are recommended. Provide eyewash station and safety shower. Skin protection Hand protection: Wear protective gloves. Other: Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Respiratory protection: See Section 7 for additional information on occupational control measures appropriate for OEB-2 potent compounds. Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene considerations: When using, do not eat, drink or smoke. Do not breathe dust. Avoid contact with eyes. Avoid contact with skin. Avoid contact with clothing. Wash hands after handling and before eating. Handle in accordance with good industrial hygiene and safety practice. See Section 7 for additional information on occupational control measures appropriate for OEB-2 potent compounds.

**Section 9: Physical and Chemical Properties**

<b>Appearance</b>	Solid. (Crystals solid.) White to Pale yellow		
<b>Odor</b>	Odorless.		
<b>Odor Threshold</b>	Not available.		
<b>Melting Point</b>	Not available.	<b>pH</b>	296.6 °F (147 °C)
<b>Freezing Point</b>	Not available.	<b>Vapor Pressure</b>	Not available.
<b>Boiling Point/Range</b>	Not available.	<b>Vapor Density</b>	Not applicable.
<b>Decomposition temperature</b>	Not available.	<b>Viscosity</b>	Not available
<b>Partition Coefficient: n-octanol/water</b>	Not available.	<b>Evaporation Rate</b>	Not available.
<b>Flash Point</b>	Not available.	<b>Autoignition temperature</b>	Not available.
<b>Flammability</b>	Not available.	<b>Flammability or Explosive Limits:</b>	
		<b>Lower</b>	Not available.
		<b>Upper</b>	Not available.
<b>Solubility(ies)</b>	Slight Soluble in water.		
<b>Other</b>	Dispersion properties: See solubility in water, methanol.		

**Section 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>Hazardous Polymerization</b>	Hazardous polymerization does not occur.
<b>Conditions to Avoid</b>	Contact with incompatible materials. Heat, flames and sparks.
<b>Incompatible Materials</b>	Strong acids, alkalies and oxidizing agents. Metal salts.
<b>Hazardous Decomposition Products</b>	Carbon monoxide. Carbon dioxide.

**Section 11: Toxicological Information**

<b>RTECS</b>	QD2840000	
<b>Acute Toxicity</b>	This material is toxic. Fatal if swallowed. Fatal if inhaled. Harmful in contact with skin. Oral LD50	Rat 375 mg/kg
<b>Skin Corrosion/Irritation</b>	Not available.	
<b>Serious Eye Damage/Irritation</b>	Not available	
<b>Respiratory or Skin Sensitization</b>	Not available	
<b>Germ Cell Mutagenicity</b>	Not available	
<b>Carcinogenicity</b>	Not available	
<b>Reproductive Toxicity</b>	This product is reported to have caused developmental abnormalities of the central nervous system in animals.	
<b>Routes of Entry</b>		

Inhalation: Fatal if inhaled. Narcotic effect. May cause typical symptoms of narcosis (see Ingestion.) Dust irritates the respiratory system, and may cause coughing and difficulties in breathing. Skin contact: Harmful in contact with skin. May produce narcotic effects if absorbed through skin. May cause sensitization by skin contact. May cause an allergic skin reaction. Symptoms may parallel ingestion. Eye contact: Dust or powder may irritate eye tissue. May have a strong narcotic effect (pupil constriction) and the eye may serve as an absorption route into the body. Ingestion: Fatal if swallowed. Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Dizziness. May cause central nervous system depression. Large doses can lead to respiratory or cardiac arrest and death.

**Symptoms Related to Exposure**

Narcotic. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. May cause allergic respiratory and skin reactions. Decrease in motor functions.

Respiratory disorder.

**Potential Health Effects**

May cause central nervous system disorder (e.g., narcosis involving a loss of coordination, weakness, fatigue, mental confusion and blurred vision) and/or damage.

**Target Organ(s)** Not available.

**Section 12: Ecological Information****Ecotoxicity**

This product has no known eco-toxicological effects.

**Persistence and Degradability**

Not available.

**Bioaccumulative Potential**

Not available.

**Mobility in Soil**

Not available.

**Other Adverse Effects**

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

**Section 13: Disposal Considerations****Waste Disposal**

Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Follow handling guidance appropriate for OEB-2 potent compounds, (see Section 7). Dispose of contents/container (in accordance with related regulations).

**Disposal of Container**

Not available.

**Other Considerations**

Not available.

**Section 14: Transport Information****DOT Classification**

Not available

**Section 15: Regulatory Information****Regulations**

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US federal regulations TSCA exempt status. 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. CERCLA (Superfund) reportable quantity None Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazardous substance Not listed. SARA 311/312 Hazardous Yes chemical 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. Safe Drinking Water Act Not regulated. (SDWA) Drug Enforcement Schedule II - 9193 Administration (DEA) (21 CFR 1308.11-15) 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. US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100) Not listed. US. Massachusetts RTK - Substance List Not regulated.

**Other**

Not available.

**Section 16: Other Information**

PCCA provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. PCCA MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION. Revision Information Product and Company Identification: Product and Company Identification First-aid measures: Most important symptoms/effects, acute and delayed Exposure controls/personal protection: Thermal hazards Stability and reactivity: Reactivity Toxicological Information: Toxicological Data Toxicological information: Symptoms related to the physical, chemical and toxicological characteristics Other information, including date of preparation or last revision: Further information