

Section 1: Identification

Product Name Buprenorphine Hydrochloride
Commercial Name Not available
Product Use Active Pharmaceutical Ingredient
Restrictions On Use Not available

Product Code 23-1012

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: GHS Classification Acute toxicity. Oral: Category 3 Acute toxicity. Dermal: Category 3 Acute toxicity.
CFR 1910.1200 Inhalation: Category 3 Skin sensitisation: Category 1 Specific target organ toxicity-single exposure:
 Category 3 narcotic effects

Signal Word DANGER

Hazard Statement(s) May form combustible dust concentrations in air. Harmful if swallowed. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children. Causes damage to organs. May cause drowsiness or dizziness.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention	Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Prevent dust accumulation to minimize explosion hazard. Keep container tightly closed. Ground/bond container and receiving equipment. Avoid breathing dust/fume/gas/mist/vapors/spray. Observe good industrial hygiene practices. Avoid breathing 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 thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.
Response	In case of fire: Use appropriate media to extinguish. If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off immediately all contaminated clothing and wash it before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Buprenorphine Hydrochloride
% By Weight >=90 - <=100
CAS# 53152-21-9
Molecular Weight 504.17 g/mole
Chemical Formula C29-H41-N-O4.HCl
Synonym(s) Not available

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
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Section 4: First-Aid Measures

Inhalation	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. Call a physician or poison control center immediately.
Skin Contact	Remove contaminated clothing immediately and wash skin with soap and water. Get medical advice/attention if you feel unwell. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash clothing separately before reuse.
Eye Contact	Do not rub eyes. 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. Call a physician or poison control center immediately. Continue rinsing.
Ingestion	If swallowed: Immediately call a poison center/doctor. Rinse mouth. 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. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Symptoms/Effects	
Acute	Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. May cause allergic skin reaction. Dermatitis. Rash
Delayed	Not available

Immediate Medical Attention

Treat symptomatically. In case of shortness of breath, give oxygen. Keep victim warm. Symptoms may be delayed. Take off immediately all contaminated clothing. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

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

Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable Extinguishing Media

Not available.

Products of Combustion

Explosion hazard: 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. During fire, gases hazardous to health may be formed such as: Carbon Monoxide. Carbon dioxide. Nitrogen Oxides (NO_x). Hydrogen Chloride (HCl).

Firefighters Special Equipment and Precautions

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Wear full protective clothing, including helmet, self-contained positive pressure or pressure demand breathing apparatus, protective clothing and face mask. Use water spray to cool unopened containers. In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

Section 6: Accidental Release Measures

Personal precautions: Immediately evacuate personnel to safe areas. 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. Local authorities should be advised if significant spillages cannot be contained. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7). For personal protection, see section 8 of the SDS. 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. Never return spills to original containers for re-use. 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 handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not use in areas without adequate ventilation. Minimize dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Do not breathe dust. Keep formation of airborne dusts to a minimum. Provide appropriate exhaust ventilation at places where dust is formed. 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. Do not ingest. Use personal protective equipment as required. Wash thoroughly after handling. Wash contaminated clothing before reuse. Observe good industrial hygiene practices. Storage: For storage condition, see finished product label. Protect from light. Store locked up. Keep container tightly closed. Store in a cool, dry place. Store in a well-ventilated place. Guard against dust accumulation of this material. Keep away from heat and sources of ignition. Store in accordance with local/regional/national/international regulation. Store away from incompatible materials (see Section 10 of the SDS).

Section 8: Exposure Controls/Personal Protection**Exposure Limits**

OEB 3 OEB OEG 1 µg/m³ 8-hour time-weighted average

Engineering Controls

To prevent contamination and overexposure, no open handling of powder should be allowed. Powder handling operations are to be done in a powder weighing hood, a glove box, or other equivalent ventilated containment system. In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used. Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs. See Section 7 for additional information on proper handling and venting requirements for potent compounds. 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.

Personal Protection

Eye/face protection: Chemical goggles are recommended. Provide eyewash station and safety shower. Skin protection Hand protection: Wear appropriate chemical resistant gloves. Impervious nitrile, rubber or latex gloves are recommended. Other: Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended. Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Respiratory protection: An air-purifying respirator (P95 or other type providing a higher level of protection) should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.). If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use. See Section 7 for additional information on proper handling and respirator recommendations for potent compounds. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene consideration: When using, do not eat, drink or smoke. Do not get in eyes. Do not get this material in contact with skin. Do not get this material on clothing. 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. See Section 7 for additional information on occupational control measures appropriate for OEB-3 potent compounds.

Section 9: Physical and Chemical Properties

Appearance	White. Crystalline. Powder.		
Odor	Odorless		
Odor Threshold	Not available		
Melting Point	500 °F (260 °C)	pH	4 - 6 (1% aqueous solution)
Freezing Point	Not available	Vapor Pressure	Not available
Boiling Point/Range	Not available	Vapor Density	Not available
Decomposition temperature	Not available	Viscosity	Not available.
Partition Coefficient: n-octanol/water	Not available	Evaporation Rate	Not available
Flash Point	Not available.	Autoignition temperature	Not available
Flammability	Not available	Flammability or Explosive Limits:	
		Lower	Not available
		Upper	Not available
Solubility(ies)	Slight in water. Soluble in alcohol		
Other	Explosive properties Molecular formula C29H41NO4.ClH Molecular weight 504.1 Not oxidizing.		

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Material is stable under normal conditions
Hazardous Polymerization	Hazardous polymerization does not occur.
Conditions to Avoid	Contact with incompatible materials. Avoid conditions which create dust. Moisture. Sunlight. Heat, flames and sparks.
Incompatible Materials	Not available.
Hazardous Decomposition Products	May decompose upon heating to produce corrosive and/or toxic fumes.

Section 11: Toxicological Information**RTECS** Not available**Acute Toxicity**

Toxic if inhaled. Toxic in contact with skin. Toxic if swallowed. Narcotic effects. Oral: LD50 Mouse 260 mg/kg

Skin Corrosion/Irritation

Dust or powder may irritate the skin. May produce narcotic effects if absorbed through skin. Symptoms may parallel ingestion. May cause sensitization by skin contact

Serious Eye Damage/Irritation

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.

Respiratory or Skin Sensitization

Prolonged inhalation may be harmful. Narcotic effect. May cause typical symptoms of narcosis (see Ingestion.) Dust irritates the respiratory system, and may cause coughing and difficulties in breathing.

Germ Cell Mutagenicity

Not available

Carcinogenicity

Animal testing did not show any carcinogenic effects.

Reproductive Toxicity

Limited evidence of reprotoxicity in animal studies and/or human studies.

Routes of Entry

Inhalation. Skin, Eye. Ingestion.

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 an allergic skin reaction. Dermatitis. Rash

Potential Health Effects

Toxic if swallowed. Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Dizziness. Causes central nervous system effects. Large doses can lead to respiratory or cardiac arrest and death.

Target Organ(s) Prolonged inhalation may be harmful. May cause central nervous system disorder (e.g., narcosis involving a loss of

Section 12: Ecological Information**Ecotoxicity**

Aquatic Chronic Algae: NOEC Algae 3.6 mg/l Aquatic Plants- Growth rate Crustacea: NOEC Crustacea 0.26 mg/l, 21 days Fish: NOEC Fathead minnow (Pimephales promelas) 0.13 mg/l, 28 days

Persistence and Degradability

Not available

Bioaccumulative Potential

Not available

Mobility in Soil

Not available

Other Adverse Effects

Not available

Section 13: Disposal Considerations**Waste Disposal**

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Notify site Controlled Substance Compliance officer and local DEA office or competent authority 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-3 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**

IDOT UN3288UN number Toxic solid, inorganic, n.o.s. (BUPRENORPHINE HYDROCHLORIDE)UN proper shipping name 6.1(PGIII)Class Transport hazard class(es) -Subsidiary risk 6.1Label(s) III Packing group Read safety instructions, SDS and emergency procedures before handling.Special precautions for user IB8, IP3, T1, TP33Special provisions 153Packaging exceptions 213Packaging non bulk 240Packaging bulk

Section 15: Regulatory Information**Regulations**

