

## 1. Identification

**Product identifier** Buprenorphine System Suitability Mixture

**Other means of identification**

**Catalog number** 1078722

**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

#### Manufacturer

**Company name** U. S. Pharmacopeia

**Address** 12601 Twinbrook Parkway  
Rockville  
MD  
20852-1790  
United States

**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

**Environmental hazards** Not classified.

**OSHA defined hazards** Not classified.

#### Label elements



**Signal word** Warning

**Hazard statement** Harmful if swallowed. May cause drowsiness or dizziness.

**Precautionary statement**

**Prevention** Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.

**Response** If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.

**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.

**Hazard(s) not otherwise classified (HNOC)** None known.

**Supplemental information** None.

## 3. Composition/information on ingredients

#### Mixture

Chemical name	Common name and synonyms	CAS number	%
BUPRENORPHINE		52485-79-7	99.5
Ethenobuprenorphine		No Data	0.5

## 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.
<b>Most important symptoms/effects, acute and delayed</b>	Narcotic effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically.
<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>	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO <sub>2</sub> .
<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>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Methods and materials for containment and cleaning up</b>	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. 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. Use of a designated area is recommended for handling of potent materials.
<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

#### Exposure limit values

##### Industrial Use Components

	Type	Value
BUPRENORPHINE (CAS 52485-79-7)	STEL	0.012 mg/m <sup>3</sup>
	TWA	0.0015 mg/m <sup>3</sup>

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

<b>Appropriate engineering controls</b>	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.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	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.
<b>Skin protection</b>	
<b>Hand protection</b>	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. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
<b>Other</b>	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
<b>Respiratory protection</b>	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).
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Crystalline powder.
<b>Color</b>	White.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	Not available.
<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>	None known.
<b>Incompatible materials</b>	None known.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Due to lack of data the classification is not possible.
<b>Skin contact</b>	Due to lack of data the classification is not possible.
<b>Eye contact</b>	Due to lack of data the classification is not possible.
<b>Ingestion</b>	Harmful if swallowed.

**Symptoms related to the physical, chemical, and toxicological characteristics**      Gastrointestinal disturbances. Vision loss. Weakness. Headache. Dizziness. Convulsions.

### Information on toxicological effects

<b>Acute toxicity</b>	Harmful if swallowed.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Due to lack of data the classification is not possible.

### Local effects

BUPRENORPHINE	Irritancy test (0.001%) Result: Irritant. Species: Human Organ: Skin. Severity: Mild.
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### Respiratory or skin sensitization

<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.
<b>Skin sensitization</b>	Based on available data, the classification criteria are not met.
BUPRENORPHINE	Sensitization test Result: Non-sensitizing. Species: Guinea pig Organ: Skin.

**Germ cell mutagenicity**      Due to lack of data the classification is not possible.

**Carcinogenicity**      Due to lack of data the classification is not possible.

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

### Reproductivity

BUPRENORPHINE	< 5 mg/kg Reproductivity study Result: Intramuscular doses during organogenesis in rats and rabbits had no adverse fetal effects. > 0.05 mg/kg/day Reproductivity study Result: Fetal growth retardation was observed but no defects up to 5 mg. Species: Rat
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**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

<b>Ecotoxicity</b>	No ecotoxicity data noted for the ingredient(s).
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	Not available.
<b>Mobility in soil</b>	Not available.
<b>Other adverse effects</b>	Not available.

## 13. Disposal considerations

<b>Disposal instructions</b>	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.
<b>Hazardous waste code</b>	Not regulated.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. 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).
<b>Contaminated packaging</b>	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 dangerous goods.

### IATA

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not available.

## 15. Regulatory information

**US federal regulations** CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

### **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)**

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

### **SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** No

### **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.

**Safe Drinking Water Act (SDWA)** 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.

**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

**US. Pennsylvania RTK - Hazardous Substances**

Not regulated.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

Not Listed.

**International Inventories**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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)

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**

**Issue date** 06-23-2015

**Revision date** 05-20-2016

**Version #** 02

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**Revision information** Composition / Information on Ingredients: Additional Components  
Physical and chemical properties: Appearance  
Physical and chemical properties: Color  
Physical and chemical properties: Form  
Stability and reactivity: Conditions to avoid  
Regulatory Information: United States