



Safety Data Sheet

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

Hydroxyzine Pamoate USP

55-2316

Section 1: Identification

Product Name Hydroxyzine Pamoate USP
Commercial Name Not available.
Product Use Active pharmaceutical ingredient for the preparation of drugs. Professional use only
Restrictions On Use There are no uses advised against.
Product Code 55-2316
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 4 Specific target organ toxicity, single exposure Category 3 narcotic effects
CFR 1910.1200

Signal Word WARNING

Hazard Statement(s) Harmful if swallowed.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention Avoid breathing dust/fume/gas/mist/vapors/spray. 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

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Hydroxyzine Pamoate
% By Weight 100
CAS# 10246-75-0
Molecular Weight 763.29 g/mole
Chemical Formula C₂₁H₂₇ClN₂O₂.C₂₃H₁₆O₆
Synonym(s) Hydroxyzine Embonate

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
1) Hydroxyzine Pamoate	10246-75-0	100	Not Available.	Not Available.

Section 4: First-Aid Measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Do not use mouth-to-mouth method if the substance is inhaled. 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 if symptoms develop or persist
Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye Contact	Rinse with water. Get medical attention if irritation develops and persists
Ingestion	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
Symptoms/Effects	
Acute	Central nervous system effects. Narcotic effects. Pharmacologically active material. Occupational exposure may cause physiological effects
Delayed	Central nervous system effects. Narcotic effects. Pharmacologically active material. Occupational exposure may cause physiological effects

Immediate Medical Attention

Provide general supportive measures and treat symptomatically. Perform gastric lavage. Administer a saline cathartic or sorbitol to promote excretion. For circulatory depression, administer a vasopressor and intravenous fluids. Do not use epinephrine. Administer oxygen. Avoid the use of stimulants (analeptic agents); they may cause seizures

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

Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable Extinguishing Media

Not available.

Products of Combustion

No unusual fire or explosion hazards noted

Firefighters Special Equipment and Precautions

Wear suitable protective equipment As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

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. Methods and materials for containment and cleaning up: 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. Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

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. TWA 0.3 mg/m ³
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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.

Personal Protection

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.

Section 9: Physical and Chemical Properties

Appearance	Light Yellow Powder. solid.		
Odor	Almost Odorless		
Odor Threshold	Not available.		
Melting Point	Not available	pH	Not available.
Freezing Point	Not available.	Vapor Pressure	< 0.0000001 kPa at 25 °C
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)	Practically insoluble in water.		
Other	Chloroform: Very slightly soluble. Dimethylformamide: Freely soluble. Methanol: Practically insoluble Chemical family Piperazine derivative. Molecular formula C ₂₁ H ₂₇ CIN ₂ O ₂ . C ₂₃ H ₁₆ O ₆ Molecular weight 763.29 Percent volatile < 5 %		

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	No dangerous reaction known under conditions of normal use
Conditions to Avoid	Contact with incompatible materials
Incompatible Materials	Strong oxidizing agents
Hazardous Decomposition Products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. Cl-

Section 11: Toxicological Information**RTECS** QL2200000**Acute Toxicity**

Harmful if swallowed Oral LD50 Rat 1740 mg/kg

Skin Corrosion/Irritation

Not available

Serious Eye Damage/Irritation

Not available

Respiratory or Skin Sensitization

Not available.

Germ Cell Mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive Toxicity

Knowledge about health hazard is incomplete A review of limited human pregnancy data has not demonstrated an increase in adverse developmental effects.

Routes of Entry

Inhalation, Ingestion.

Symptoms Related to Exposure

For antihistamines: Gastrointestinal disturbances. Drowsiness. Dizziness. Weakness. Trouble sleeping. Clumsiness. Blurred vision. Confusion. Dry mouth. Irregular heart beat. Urination sleeping. Clumsiness. Blurred vision. Confusion. Dry mouth. Irregular heart beat. Urination problems.

Potential Health Effects

Pharmacologically active material. Occupational exposure may cause physiological effects.

Target Organ(s)

May cause drowsiness and dizziness

Section 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

Not available.

Bioaccumulative Potential

Not available

Mobility in Soil

Not available.

Other Adverse Effects

Not available.

Section 13: Disposal Considerations**Waste Disposal**

Dispose of contents/container in accordance with local/regional/national/international 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. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. 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)

Disposal of Container

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Other Considerations

Not available.

Section 14: Transport Information**DOT Classification**

Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

Section 15: Regulatory Information**Regulations**

US federal regulations: 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) Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Hazard categories SARA 302 Extremely hazardous substance Not listed. YesSARA 311/312 Hazardous chemical 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. Not regulated.Safe Drinking Water Act (SDWA) 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

Other

Not available.

Section 16: Other Information

DISCLAIMER This document aims to provide guidance for appropriate handling and precaution of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for purposes other than those mentioned in section 1, unless they are given adequate written information received on how to handle the material. The provider of this document can not provide any warnings about the dangers of ' use or interaction with other chemicals or materials. And 'the user's safe use of the product, the product suitability for the purpose for which it is applied and proper disposal. The information below should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with Annex I of Regulation No 453/2010/EU.