



## Safety Data Sheet

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

Betahistine Dihydrate USP

30-4260

### Section 1: Identification

**Product Name** Betahistine Dihydrate USP  
**Commercial Name** Not available.  
**Product Use** diamino - oxydase inhibitor  
**Restrictions On Use** N/A

**Product Code** 30-4260

**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:** Skin Irrit. 2 Eye Irrit. 2  
**CFR 1910.1200**

**Signal Word** WARNING

**Hazard Statement(s)** Causes skin irritation. Causes serious eye irritation.

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



**Precautionary Statement(s):**

<b>Prevention</b>	Wash thoroughly after handling Wear eye protection/face protection. Wear protective gloves.
<b>Response</b>	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/ attention. Take off contaminated clothing and wash before reuse.
<b>Storage</b>	Store in a closed container
<b>Disposal</b>	Dispose of contents/container in a site approved for chemical and hazardous waste or burned in a specialised burning centre

### Section 3: Composition/Information on Ingredients

**Substance/Mixture** Substance  
**Components** 2- Pyridine ethanamine ,N - methyl - ,dihydrochloride  
**% By Weight** 100%  
**CAS#** 5579-84-0  
**Molecular Weight** 209.12 g/mole  
**Chemical Formula** C8-H12-N2.2HCl  
**Synonym(s)** Not available.

#### Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Betahistine Dihydrate USP	5579-84-0	100		

**Section 4: First-Aid Measures**

<b>Inhalation</b>	Allow the victim to rest in a well ventilated area. Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. In severe cases or if symptoms persists, seek medical attention
<b>Skin Contact</b>	After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. If irritation persists, seek medical attention. Wash contaminated clothing before reusing
<b>Eye Contact</b>	Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention
<b>Ingestion</b>	Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention
<b>Symptoms/Effects</b>	
<b>Acute</b>	N/A
<b>Delayed</b>	N/A
<b>Immediate Medical Attention</b>	N/A

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

water, chemical type foam, carbon dioxide, dry chemical. Prevent run off of water from entering drains

**Unsuitable Extinguishing Media**

N/A

**Products of Combustion**

The substance evolves toxic fumes due to the presence of CO, CO<sub>2</sub>, NO<sub>x</sub>, HCl

**Firefighters Special Equipment and Precautions**

Wear: -Gas masks scuba -Complete protective equipment composed by: helmet whit face shield and neck protection, fireproof jacket and trousers with straps around arms, legs and waist. As not expected at this point, refer to the personal protective equipment recommended in Section 8 of this sheet

**Section 6: Accidental Release Measures**

Personal precautions, protective equipment and emergency procedures: Keep away any ignition source. Wear protective equipment. Keep unprotected persons away. Use respiratory protective device against the effects of fumes. Ensure adequate ventilation. Methods and materials for containment and cleaning up: Absorb spillage in earth or sand. Sweep or shovel-up spillage and remove to a safe place. Damp down to avoid dust generation. Environmental precautions: Do not allow to penetrate the ground/soil. Prevent seepage into sewage system, workpits and cellars. Inform respective authorities in case of seepage into water course or sewage system

**Section 7: Handling and Storage**

Precautions for safe handling: This product should be handled only by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals, who should take into account the fire, health and chemical hazard data given on this sheet. It should always be handled in an efficient fume hood or equivalent system and, if necessary, wear protective equipment. Care should be taken to prevent the chemical from coming into contact with the skin or eyes and from contaminating personal clothing. Conditions for safe storage, including any incompatibilities: Avoid contact with oxidising substances For safety purposes, the substance does not require any special storage conditions. As an indication, the information provided by official monographs are: USP: Preserve in well-closed containers. EP: Store in an airtight container. For storage of the substance for pharmaceutical use, or for registration purposes please refer to the stability data conducted in-house and reported in the document regulatory "Active Substance Master File" (ASMF or DMF). Specific end uses: Laboratory investigations, testing of pharmaceutical technology. Formulation in pharmaceutical preparations

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

<b>Exposure Limits</b>	Not available.
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**Engineering Controls****Personal Protection**

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with skin, eyes and clothing. Eye/face protection: Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Hand protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Skin and body protection: The type of protective equipment (es. Tyvek suit) must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Complete suit protecting against chemicals, flame retardant antistatic protective clothing. Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (EN 143) with cartridges P1 (inert substances) P2 (harmful substances) P3 (toxic substances). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**Section 9: Physical and Chemical Properties**

<b>Appearance</b>	crystalline powder, white or light yellow, very hygroscopic		
<b>Odor</b>	odourless		
<b>Odor Threshold</b>	N/A		
<b>Melting Point</b>	152-154°C	<b>pH</b>	N/A
<b>Freezing Point</b>	N/A	<b>Vapor Pressure</b>	Not available.
<b>Boiling Point/Range</b>	Not available.	<b>Vapor Density</b>	Not available.
<b>Decomposition temperature</b>	N/A	<b>Viscosity</b>	Not available.
<b>Partition Coefficient: n-octanol/water</b>	N/A	<b>Evaporation Rate</b>	N/A
<b>Flash Point</b>	Not available.	<b>Autoignition temperature</b>	N/A
<b>Flammability</b>	N/A	<b>Flammability or Explosive Limits:</b>	
		<b>Lower</b>	N/A
		<b>Upper</b>	N/A
<b>Solubility(ies)</b>	Not available.		
<b>Other</b>	N/A		

**Section 10: Stability and Reactivity**

<b>Reactivity</b>	N/A
<b>Chemical Stability</b>	The product is stable at room temperature and in usual working conditions
<b>Hazardous Polymerization</b>	Hazardous polymerization will not occur.
<b>Conditions to Avoid</b>	Heat, flames and sparks
<b>Incompatible Materials</b>	Strong oxidising agents. Alkali metals, bases, strong acids, halogens
<b>Hazardous Decomposition Products</b>	The substance evolves toxic fumes due to the presence of CO, CO <sub>2</sub> , NO <sub>x</sub> , HCL

**Section 11: Toxicological Information****RTECS** UT2969000**Acute Toxicity**

Acute Oral LD 50 rat mg/kg 3000

**Skin Corrosion/Irritation**

N/A

**Serious Eye Damage/Irritation**

N/A

**Respiratory or Skin Sensitization**

N/A

**Germ Cell Mutagenicity**

N/A

**Carcinogenicity**

N/A

**Reproductive Toxicity**

N/A

**Routes of Entry**

Not available.

**Symptoms Related to Exposure**

N/A



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### Potential Health Effects

May be harmful if inhaled. May be harmful if swallowed. May cause skin irritation May cause eye irritation

Target Organ(s) N/A

### Section 12: Ecological Information

#### Ecotoxicity

Not available.

#### Persistence and Degradability

N/A

#### Bioaccumulative Potential

N/A

#### Mobility in Soil

N/A

#### Other Adverse Effects

N/A

### Section 13: Disposal Considerations

#### Waste Disposal

Do not empty into drains. Use appropriate containment to avoid environmental contamination. Disposal should be in accordance with local, state or national regulation.

#### Disposal of Container

The containers and packing materials contaminated with dangerous substances or preparations, have the same treatment products.

#### Other Considerations

N/A

### 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

N/A

#### Other

N/A

### Section 16: Other Information

N/A