SAFETY DATA SHEET

1. Identification

Product identifier **Pyrilamine Maleate**

Other means of identification

Catalog number 1588004

Chemical name 1,2-Ethanediamine, N-[(4-methoxyphenyl)methyl]-N', N'-dimethyl-N-2-pyridinyl-, (Z)-2-butenedioate (1:1)

Synonym(s) Diaminide maleate * Mepyramine maleate

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

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

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

OSHA hazard(s) Not classified.

Label elements

Signal word Warning

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

Precautionary statement

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

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

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) Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Pyrilamine Maleate	Diaminide maleate Mepyramine maleate	59-33-6	100

4. First-aid measures

Inhalation	Move to fresh air. Call a POISON CENTER or doctor/physician if you feel unwell.
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	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
Most important symptoms/effects, acute and delayed	Cardiovascular effects.
Indication of immediate medical attention and special treatment needed	For antihistamine overdose: Treatment should be symptomatic and supportive. Administer activated charcoal as an aqueous slurry. Consider gastric lavage if it can be administered within one hour of ingestion, unless contraindicated. Protect airway and control seizures before initiating. Sedation with benzodiazepines will control tachycardia. If severe, beta blocking agents such as esmolol may be used, but use with caution in patients with asthma or COPD. Ventricular arrhythmias may be treated with lidocaine. Dysrhythmias may respond to sodium bicarbonate. Monitor blood pH. Torsades De Pointes: Electrical cardioversion may be required in hemodynamically unstable patients; magnesium, isoproterenol, and/or atrial overdrive pacing may be used for stable patients. Treat seizures and agitation with a benzodiazepine IV. Dystonia may be treated with oral or IV diazepam. For hypotension, infuse isotonic fluid. Administer dopamine or norepinephrine if persistent. [Meditext]
General information	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

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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.
Methods and materials for containment and cleaning up	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.

7. Handling and storage

Precautions for safe 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.
Conditions for safe storage, including any incompatibilities	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

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.

Appropriate engineering controls	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.

Individual protection measures, such as personal protective equipment

Eye/face protection	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.
Skin protection	
Hand protection	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.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	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).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White or slightly yellowish crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless or faint odor.
Odor threshold	Not available.
pH	5.1 (100 g/L in water)
Melting point/freezing point	210.2 - 217.4 °F (99 - 103 °C)
Initial boiling point and boiling range	Not available.
Flash point	> 370.00 °F (> 187.78 °C) (S.P. Marten Closed Cup test)
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Very soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	> 680 °F (> 360 °C)
Decomposition temperature	Not available.
Viscosity	Not available.

Other information

Chemical family	Ethylenediamine derivative.
Molecular formula	C17H23N3O.C4H4O4
Molecular weight	401.47

Percent volatile	0.5 %
Solubility (other)	Slightly soluble in benzene and in ether; freely soluble in alcohol and in chloroform.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents. Bases.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	For antihistamines: Nausea. Diarrhea. Headache. Drowsiness. Dizziness. Sore throat. Fever. Bleeding or bruising. Tiredness. Weakness. Thickening of mucus. Change in appetite. Change in weight. Dry mouth, nose, or throat. Blurred vision. Changes in vision. Confusion. Difficult or painful urination. Sweating. Sensitivity to sunlight. Ringing or buzzing in ears. Stomach pain. Skin rash. Chills. Clay-colored stools. Dark urine. Burning, prickly sensations. Tingling. Trouble sleeping. Clumsiness. Unsteadiness. Flushing. Trouble breathing. Fast heartbeat. Irregular heartbeat. Fixed or dilated pupils. Fainting. Hallucinations. Seizures.
Delayed and immediate effects of exposure	For antihistamines: Coma. Death.
Cross sensitivity	Persons sensitive of other antihistamines may be sensitive of this material also.
Medical conditions aggravated by exposure	For antihistamines: Active alcoholism. Bronchial asthma. Hyperthyroidism. Heart disease. Hypertension. Urinary retention. Bladder neck obstruction. Prostate enlargement. Glaucoma. Peptic ulcer. Pyloric obstruction.
Acute toxicity	Harmful if swallowed.

Product	**Species**	**Test Results**
Pyrilamine Maleate (CAS 59-33-6)		
Oral		
LD50	Mouse	220 mg/kg
	Rat	365 mg/kg

Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity

Ames test (Salmonella)
Result: Negative.
In vitro mouse lymphoma assay
Result: Positive with metabolic activation; negative without.
In vivo micronucleus assay (mouse)
Result: Negative.

Carcinogenicity Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

2000 ppm 110-Week study (dietary)
Result: No evidence of carcinogenicity.
Species: Rat
300 - 3000 ppm Two-year study (dietary)
Result: No evidence of carcinogenicity.
Species: Rat

Reproductive toxicity Due to lack of data the classification is not possible.
Epidemiological studies are not sufficient to determine an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects.

Reproductivity

Reproduction study (1-2x human dose)
Result: No adverse fetal effects.
Species: Mouse
Reproduction study (10-20x human dose)
Result: Increased frequency of embryonic, fetal and perinatal death.
Species: Mouse

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

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions 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.

Local disposal regulations Not available.

Hazardous waste code Not available.

Waste from residues / unused products 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).

Contaminated packaging 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 a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

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

All components are on the U.S. EPA TSCA Inventory List.

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 No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA)	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.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
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	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date	05-07-2008
Revision date	06-09-2014
Version #	02
Further information	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.