SAFETY DATA SHEET

1. Identification

Product identifier **Acepromazine Maleate**

Other means of identification

Catalog number 1001502

Chemical name Ethanone, 1-[10-[3-(dimethylamino)propyl]-10H-phenothiazin-2-yl]-, (Z)-2-butenedioate (1:1)

Synonym(s) Acetylpromazine maleate (1:1)

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 1 (heart)
Specific target organ toxicity, repeated exposure	Category 1 (nervous system)

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

Hazard statement Harmful if swallowed. Causes damage to organs (heart). Causes damage to organs (nervous system) through prolonged or repeated exposure.

Precautionary statement

Prevention Wash thoroughly after handling.

Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed: Call a poison center/doctor.

Storage 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	%
Acepromazine Maleate	Acetylpromazine maleate (1:1)	3598-37-6	100

4. First-aid measures

Inhalation	Move to fresh air. 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	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
Most important symptoms/effects, acute and delayed	Drowsiness. Dizziness. Heart rhythm abnormalities. Decrease in motor functions.
Indication of immediate medical attention and special treatment needed	Treatment of phenothiazine overdose should be symptomatic and supportive. 1. Do NOT induce vomiting. Perform gastric lavage. Administer activated charcoal as a slurry. 2. Control cardiac arrhythmias with intravenous phenytoin. Treat ventricular tachydysrhythmias with sodium bicarbonate. 3. For Torsades de Pointes, treat hemodynamically unstable patients with electrical cardioversion. Treat stable patients with magnesium and/or atrial overdrive pacing. Correct electrolyte abnormalities. 4. Treat hypotension with positioning, intravenous fluids, and norepinephrine or phenylephrine. Do NOT use epinephrine. 5. Treat convulsions with a benzodiazepine and phenytoin. Monitor ECG. Do NOT use barbiturates that may potentiate respiratory and CNS depression. 6. For parkinsonian effects or dystonia, administer benztropine or diphenhydramine. 7. Treat neuroleptic malignant syndrome with cooling and bromocriptine. 8. Monitor acid-base status, fluid and electrolyte balance, hepatic enzymes, renal function, urine output, and cardiac function. 9. Most phenothiazines are not removed by dialysis. [Meditext; USP DI]
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	Yellow crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	275 - 276.8 °F (135 - 136 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
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	Soluble.
Partition coefficient (n-octanol/water)	2.3 = Log P
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Phenothiazine.
Molecular formula	C19H22N2OS.C4H4O4
Molecular weight	442.53

pH in aqueous solution	4 - 5.5 (1% solution)
Solubility (other)	Soluble in ethanol and in chloroform; slightly soluble in ether.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Oxidizing agents. Acids.
Hazardous decomposition products	SOx, NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

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 phenothiazines: Abnormal heartbeat. Sudden death. Involuntary movement (muscle spasms; uncontrolled body movements; difficulty breathing, speaking, or swallowing; loss of balance; trembling or shaking hands and fingers; shuffling walk; unusual facial expressions; eyelid spasms; twisting of neck, trunk, arms, or legs). Rigidity. Weakness. Incoordination. Dizziness. Drowsiness. Disorientation. Pinpoint pupils. Yellow eyes and/or skin. Dry mouth. Constipation. Nasal congestion. Decreased sweating. Difficulty urinating. Increased sensitivity of skin or eyes to sunlight. Skin rash. Skin discoloration. Changes in menstrual period. Swelling or pain in breasts or milk secretion. Weight gain. Vomiting. Convulsions. Coma.
Delayed and immediate effects of exposure	For phenothiazines: Extrapyramidal effects. Motor restlessness. Vision changes. Low blood pressure. Hypothermia or hyperthermia. Central nervous system toxicity. Cardiac toxicity. Respiratory depression.
Cross sensitivity	Persons sensitive to any other phenothiazine may be sensitive to this material also.
Medical conditions aggravated by exposure	For phenothiazines: Active alcoholism. Blood, liver, kidney, respiratory, or cardiovascular disorders. Pheochromocytoma. History of convulsive disorders, brain damage, neuroleptic malignant syndrome, or dermatoses. Acquired immune deficiency syndrome (AIDS). Glaucoma. Parkinson's disease. Reye's syndrome. Breast cancer. Hypocalcemia. Exposure to extreme heat or phosphorus insecticides.
Acute toxicity	Harmful if swallowed.

Product	**Species**	**Test Results**
Acepromazine Maleate (CAS 3598-37-6)		
Acute		
Oral		
LD50	Mouse	257 mg/kg
	Rat	400 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.
Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA. Phenothiazines produce an elevation in prolactin concentrations. In vitro studies show about 1/3 of human breast cancers are prolactin-dependent. Studies in rodents found an increase in mammary tumors after long-term administration of antipsychotic medications. Early epidemiological studies did not show an association between chronic administration of antipsychotics and breast cancer in women. A later study found a modest dose-related increased risk of breast cancer in women using antipsychotic dopamine antagonists. The available evidence is inconclusive.
Reproductive toxicity	Due to lack of data the classification is not possible. There have been reports of prolonged jaundice, under or overactive reflexes, movement disorders, and withdrawal effects (runny nose, vomiting, difficulty breathing) in newborns exposed to phenothiazines in utero.

Specific target organ toxicity - single exposure	Causes damage to organs (heart).
Specific target organ toxicity - repeated exposure	Causes damage to organs (nervous system) through prolonged or repeated exposure.
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. One or more components are not listed on TSCA.

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

Country(s) or region	Inventory name	On inventory (yes/no)*
China	Inventory of Existing Chemical Substances in China (IECSC)	No
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	No

*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 07-16-2004

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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.