

Safety Data Sheet

Product Name: Acepromazine Maleate Tablets

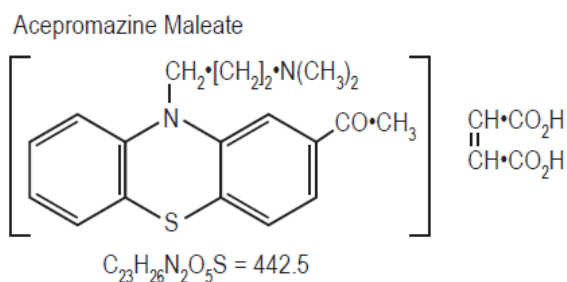
Strength : 10 and 25 mg

Revision No.: 00

Section 1: Identification

Product Name: Acepromazine Maleate Tablets

Chemical Name: 2-acetyl-10-(3-dimethylaminopropyl) phenothiazine hydrogen maleate.



Description: Acepromazine maleate, a potent neuroleptic agent with a low order of toxicity, is of particular value in the tranquilization of dogs. Its rapid action and lack of hypnotic effect are added advantages.

Dosage forms and strengths:

Acepromazine Maleate Tablets are available in 10 and 25 mg quarter-scored tablets and are supplied in bottles containing 100 and 500 tablets.

NDC Number	Tablet Size	Tablets/Bottle
86117-049-07	10mg	100 Tablets
86117-049-12	10mg	500 Tablets
86117-050-07	25mg	100 Tablets
86117-050-12	25mg	500 Tablets

Manufacturer / supplier identification

Company Zyclus Animal Health and Investments Limited,
Ahmedabad, India

Contact for information Tel.: +91 2717-683954

Emergency Telephone No Tel.: +91 2717-683951

Distributed by: ZyVet Animal Health Inc.
Pennington, NJ 08534

Section 2: Hazard (s) Identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

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Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	None known.

Section 3: Composition / information on ingredients

Mixtures

Chemical name	CAS number	%
Acepromazine maleate	3598-37-6	<15
Magnesium distearate	557-04-0	proprietary
Microcrystalline cellulose	9004-34-6	proprietary
Starch, pregelatinized	9005-25-8	proprietary

Section 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	Do not rub eyes. 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.
Most important symptoms/effects, acute and delayed	Dusts may irritate the respiratory tract, skin and eyes. Ingestion of a large quantity may cause vomiting, nausea, dizziness, drowsiness and other systemic effects.
Indication of immediate medical attention and special treatment needed	Not for human use. For use in animals only. Persons developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention. Epinephrine is contraindicated for treatment of acute hypotension caused by phenothiazine derivative tranquilizers since further depression of blood pressure can occur. Other pressor amines, such as norepinephrine or phenylephrine are the drugs of choice. Barbiturates or diazepam may be used for the treatment of seizures associated with overdose.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

Section 5: Fire-fighting measures

Suitable extinguishing media	Powder. Water spray. Foam. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from	During fire, gases hazardous to health may be formed. Combustion products may

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the chemical	include: carbon oxides, metal oxides, nitrogen oxides, sulfur oxides.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Collect dust using a vacuum cleaner equipped with HEPA filter. Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Avoid the generation of dusts during clean-up. Following product recovery, flush area with water. Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

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Section 7: Handling and Storage

Precautions for safe handling Avoid breaking or crushing tablets. Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid prolonged exposure. Practice good housekeeping.

Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Store away from foodstuffs. Store material between 15°C (59°F) and 30°C (86°F).

Section 8: Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	PEL	5 mg/m ³	Respirable fraction.
		Total dust.	
Starch, pregelatinized (CAS 9005-25-8)	PEL	5 mg/m ³	Respirable fraction.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
		15 mg/m ³	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
Magnesium distearate (CAS 557-04-0)	TWA	10 mg/m ³
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³
Starch, pregelatinized (CAS 9005-25-8)	TWA	10 mg/m ³

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total
Starch, pregelatinized (CAS 9005-25-8)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total

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

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure

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Limit (OEL), suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear suitable protective clothing.
Respiratory protection	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Section 9: Physical and chemical properties

Appearance	
Physical state	Solid.
Form	Solid, quarter scored tablets (0220 embossed on 10 mg tablets and 0221 on 25 mg tablets).
Color	Pink: 10 mg tablet; Yellow: 25 mg tablet
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Will burn if involved in a fire.
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	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	available.
Solubility (water)	Slight
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.

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Decomposition temperature Not available.

Viscosity Not available.

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.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of exposure

Inhalation Dust may irritate respiratory system. Prolonged inhalation may be harmful.

Skin contact Dust or powder may irritate the skin.

Eye contact Dust may irritate the eyes.

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Dusts may irritate the respiratory tract, skin and eyes. Ingestion of a large quantity may cause vomiting, nausea, dizziness, drowsiness and other systemic effects.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
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Acepromazine maleate (CAS 3598-37-6)

Acute

Oral

LD50	Mouse	270 mg/kg
	Rat	400 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. **Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation. **irritation**

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

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Specific target organ toxicity -Not classified.
single exposure

Specific target organ toxicity - Not
classified. **repeated exposure**

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful. Possible hypersensitization (development of abnormal sensitivity).

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** No data is available on the degradability of this product.

Bioaccumulative potential

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Section 13: Disposal consideration

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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.

Section 14: Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to

Not applicable. **Annex II of MARPOL 73/78 and the IBC Code**

Section 15: Regulatory information

US federal regulations One or more components are not listed on TSCA. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. **FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.**

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TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No

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

US. Massachusetts RTK - Substance List

Microcrystalline cellulose (CAS 9004-34-6)

Starch, pregelatinized (CAS 9005-25-8)

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

Microcrystalline cellulose (CAS 9004-34-6)

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

Microcrystalline cellulose (CAS 9004-34-6)

Starch, pregelatinized (CAS 9005-25-8)

US. Rhode Island

RTK Not regulated.

US. California Proposition 65

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)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No

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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

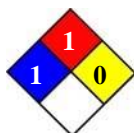
*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

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).

Section 16: Other information

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the American Coatings Association (ACA).

HMIS® ratings Health: 1
Flammability: 1
Physical hazard: 0



NFPA ratings

References: Nil.

Issue date: 04-09-2023

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.