



## MATERIAL SAFETY DATA SHEET

### 1 PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Acepromazine Maleate Tablets

**Product No.:** NADA 117-532

**GHS Product Identifier:** Not applicable

**Synonyms:** Not available

**Molecular Formula:** Mixture, not applicable

**Molecular Weight:** Not applicable

**CAS Number:** Mixture, not applicable

**Chemical Family:** Phenothiazine Tranquilizer/Sedative

**Manufacturer:**

Boehringer Ingelheim Vetmedica, Inc.

2621 North Belt Hwy

St. Joseph, MO 64506-2002

**Emergency Telephone:**

Transportation Emergency: (800) 424-9300

Medical Emergency (24HR): (800)530-5432

**Intended Use:**

Tranquilization aid and preanesthetic agent in dogs and cats

**Non-emergency Telephone:** (800) 821-7467

### 2 HAZARDS IDENTIFICATION

**Emergency Overview**

**Physical State:** Solid, quarter scored tablets (0220 embossed on 10mg tablets and 0221 embossed on 25mg tablets)

**Color:** Pink -10mg; Yellow – 25mg

**Odor:** Odorless



**WARNING!**

**Harmful if swallowed-For dog and cat oral use only.**

**Not for human use.**

**May cause drowsiness or dizziness.**

**Precautionary Statements:**

Keep only in original container.

Keep at a temperature not exceeding 30° C.

Fire-fighting: Use foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Wear suitable gloves and eye/face protection.

Spills: Sweep spilled substance into appropriate waste containers.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed, seek medical advice immediately and show this container or label.

In case of contact with eyes, rinse immediately with plenty of water for at least 15 minutes. Get medical attention.

This material and its container must be disposed of in a safe way.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

**Acute effect:**

Hypotension can occur.

Tranquilizers are potent central nervous system depressants and they can cause marked sedation with suppression of the sympathetic nervous system.

May produce an additive action when given in conjunction with other depressants.

Will potentiate general anesthesia.

**Precautions/Contraindications:**

Should be avoided in pregnant or lactating animals. Should be used with caution in older animals, animals with liver disease, heart disease, injury or debilitation. Should not be used in animals with a history of epilepsy, those prone to seizures or those receiving a myelogram (lowers the seizure threshold). Should not be used in animals with tetanus or strychnine poisoning. Use with caution in giant dog breeds and greyhounds due to their increased sensitivity to acepromazine.

**Overdosage:**

A safety study using elevated dosages of Acepromazine Maleate Tablets demonstrated no adverse reactions even when administered at three times the upper limit of the recommended daily dosage (3.0 mg/lb body weight). The clinical observation for this high dose was mild depression which disappeared in most dogs 24 hours after termination of dosing.

Overdose can cause sedation, slow respiratory and heart rate, pale gums, unsteady gait, poor coordination, and inability to stand. May cause sudden collapse, unconsciousness, seizures and death. Phenylephrine and norepinephrine are the drugs of choice to treat acepromazine-induced hypotension. Barbiturates or diazepam may be used for the treatment of seizures associated with overdose.

**ADVERSE REACTIONS TO PRODUCT:** May cause marked sedation with suppression of the sympathetic nervous system. Can produce prolonged depression or motor restlessness when given in excessive amounts or when given to sensitive animals.

Idiosyncratic reactions may occur in dogs following oral or parenteral administration. Symptoms include potentially serious adverse reactions including behavioral disorders such as aggression, biting, chewing, and nervousness.

### **Potential Health Effects**

**Inhalation:** Not expected to be an inhalation hazard.

**Eye Contact:** Not expected to be a hazard to the eye with prescribed use. Contact with eye may cause irritation.

**Skin Contact:** Can cause hypersensitive reactions.

**Ingestion:** Harmful. Ingestion may cause vomiting, nausea, dizziness, drowsiness or other systemic effects.

**Chronic Health Effects:** Possible hypersensitization (development of abnormal sensitivity).

**Target Organ(s):** Central Nervous System

**Potential Physical Effects:** Decreases anxiety causes central nervous system depression, a drop in blood pressure and heart rate.

**OSHA Regulatory Status:** Nonhazardous, exempt

**Environment:** No data available

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Acepromazine maleate	2227489	3598-37-6	10 mg tablet 25 mg tablet	Xn; R22; R36	----
Microcrystalline cellulose	2326749	9004-34-6	proprietary	N/A	----
Dextrose, monohydrate, U.S.P.	200075 (glucose)	50-99-7	proprietary	N/A	25 mg tablets only
Starch, pregelatinized	2326796 (starch)	9005-25-8	proprietary	N/A	----
Magnesium stearate, N.F	89040*	557-04-0	proprietary	N/A	----
Dibasic calcium phosphate dihydrate	2318261	7757-93-9	proprietary	N/A	10 mg tablets only
D & C Red Lake Blend	N/A	mixture	proprietary	N/A	10 mg tablets only

\*EC Reference No.

The full texts for all R-Phrases are displayed in Section 16.

**4 FIRST AID MEASURES**

**General:** Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

**Inhalation:** Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

**Eye Contact:** Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

**Skin Contact:** Wash with soap and water. Get medical attention if symptoms occur.

**Ingestion:** Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

**Note to Physician:** For animal use only. Not for human use. 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.

**5 FIRE-FIGHTING MEASURES**

**Extinguishing Media:** Extinguish with foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** None known

**Special Fire Fighting Procedures:** Wear self-contained breathing apparatus and protective clothing.

**Unusual Fire & Explosion Hazards:** None known

**Hazardous Combustion Products:** Carbon monoxide, carbon dioxide

**Flammability Class:** 0

**6 ACCIDENTAL RELEASE MEASURES**

**Personal Precautions:** Wear appropriate personal protective equipment. (See Section 8).

**Spill Cleanup Methods:** STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF TABLETS ARE BROKEN: Wear an approved respirator, eye protection, personal protective coverings and gloves. Use HEPA filtered vacuum or wet sweeping to clean up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

**Environmental Precautions:** Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

<b>7</b>	<b>HANDLING AND STORAGE</b>
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**Handling:** HANDLING SIGNIFICANT QUANTITIES OF BROKEN TABLETS: Avoid contact with eyes, skin or clothing. Do not taste or swallow. Avoid generating dust. Wash hand thoroughly after handling.

**Storage:** Keep only in the original container. Store at 15°-30° C (59°-86° F). Keep from light. Store away from foodstuffs.

<b>8</b>	<b>EXPOSURE CONTROLS / PERSONAL PROTECTION</b>
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**Exposure Limits:**

Chemical Name	Source	Type	Exposure Limits	Notes
Acepromazine maleate	----	----	N/A	----
Cellulose, respirable fraction	OSHA Z-1	8-HR TWA	10 mg/m <sup>3</sup>	Irritation
Cellulose, total dust	OSHA Z-1	8-HR TWA	5 mg/m <sup>3</sup>	Irritation
Cellulose	Alberta	8-HR TWA	10 mg/m <sup>3</sup>	Irritation
Cellulose, respirable fraction	British Columbia	8-HR TWA	3 mg/m <sup>3</sup>	----
Cellulose, total dust	British Columbia	8-HR TWA	10 mg/m <sup>3</sup>	----
Cellulose (paper fibres), total dust	Quebec	8-HR TWA	10 mg/m <sup>3</sup>	----
Cellulose	Belgium	8-HR TWA	10 mg/m <sup>3</sup>	----
Cellulose	France	8-HR TWA	10 mg/m <sup>3</sup>	----
Cellulose, respirable dust	Ireland	8-HR TWA	4 mg/m <sup>3</sup>	----
Cellulose, total inhalable dust	Ireland	8-HR TWA	10 mg/m <sup>3</sup>	----
Cellulose	Italy	8-HR TWA	10 mg/m <sup>3</sup>	----
Cellulose	Portugal	8-HR TWA	10 mg/m <sup>3</sup>	----
Cellulosa	Spain	8-HR Daily exposure limit	10 mg/m <sup>3</sup>	----
Cellulose, poussières alvéolaires	Switzerland	TWA	3 mg/m <sup>3</sup>	----
Cellulose, inhalable dust	United Kingdom	TWA	10 mg/m <sup>3</sup>	----
Cellulose, respirable dust	United Kingdom	TWA	10 mg/m <sup>3</sup>	----
Dextrose, monohydrate, U.S.P.	----	----	N/A	----
Dibasic calcium phosphate dihydrate	----	----	N/A	----

D & C Red Lake Blend	----	----	N/A	----
Starch	ACGIH	8-HR TWA	10 mg/m <sup>3</sup>	Dermatitis, lung
Starch, respirable fraction	OSHA Z-1	PEL	5 mg/m <sup>3</sup>	----
Starch, total dust	OSHA Z-1	PEL	15 mg/m <sup>3</sup>	----
Starch	Alberta	8-HR TWA	10 mg/m <sup>3</sup>	----
Starch, (respirable fraction)	British Columbia	8-HR TWA	3 mg/m <sup>3</sup>	----
Starch, (total dust)	British Columbia	8-HR TWA	3 mg/m <sup>3</sup>	----
Starch (total dust)	Ontario	8-HR TWA	10 mg/m <sup>3</sup>	----
Starch (total dust)	Quebec	8-HR TWA	10 mg/m <sup>3</sup>	----
Starch	Belgium	8-HR TWA	10 mg/m <sup>3</sup>	----
Starch (inhalable)	Greece	8-HR TWA	10 mg/m <sup>3</sup>	----
Starch (respirable)	Greece	8-HR TWA	5 mg/m <sup>3</sup>	----
Starch, respirable dust	Ireland	8-hour OEL (TWA)	4 mg/m <sup>3</sup>	----
Starch, total inhalable dust	Ireland	8-hour OEL (TWA)	10 mg/m <sup>3</sup>	----
Starch	Italy	8-HR TWA	10 mg/m <sup>3</sup>	----
Starch	Portugal	8-HR TWA	10 mg/m <sup>3</sup>	----
Starch	Spain	8-hour Daily Exposure Limit	10 mg/m <sup>3</sup>	----
Starch	Switzerland	TWA	3 mg/m <sup>3</sup>	----
Starch, respirable	United Kingdom	TWA	4 mg/m <sup>3</sup>	----
Starch, total inhalable	United Kingdom	TWA	10 mg/m <sup>3</sup>	----
Starch, (respirable fraction)	British Columbia	8-HR TWA	3 mg/m <sup>3</sup>	----
Starch, (total dust)	British Columbia	8-HR TWA	10 mg/m <sup>3</sup>	----
Starch (total dust)	Ontario	8-HR TWA	10 mg/m <sup>3</sup>	----
Starch	Quebec	8-HR TWA	10 mg/m <sup>3</sup>	---
Magnesium Stearate (generic group name: stearates; except stearates of toxic metals)	ACGIH	8-HR TWA	10 mg/m <sup>3</sup>	Irritation
Stearates (excluding stearates of toxic metal)	Alberta	8-HR TWA	10 mg/m <sup>3</sup>	----
Stearates	Belgium	8-HR TWA	10 mg/m <sup>3</sup>	----
Stearates	Ireland	8-HR TWA	10 mg/m <sup>3</sup>	----
Stearates	Italy	8-HR TWA	5 mg/m <sup>3</sup>	----
Stearates	Netherlands	8-HR TWA	5 mg/m <sup>3</sup>	----
Stearates	Portugal	8-HR TWA	10 mg/m <sup>3</sup>	----

Stearates	Spain	8-HR TWA	10 mg/m <sup>3</sup>	----
Stearates	Sweden	8-HR TWA	5 mg/m <sup>3</sup>	----

**Engineering Controls:** Not generally required when handling containers or tablets. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If operations involve crushing or other processes that may release powder, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Respiratory Protection:** Not generally required when handling containers or tablets. If containers or tablets are broken and 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. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: Dust

**PERSONAL PROTECTIVE EQUIPMENT:** Not generally required when handling containers. If containers are compromised or exposure to the active ingredient or mixture is likely wear:

**Eye Protection:** Wear safety glasses with side shields (or goggles).

**Hand Protection:** Wear suitable gloves.

**Skin Protection:** It is a good industrial hygiene practice to minimize skin contact.

**Hygiene Measures:** Eye bath, washing facilities

## 9 PHYSICAL AND CHEMICAL PROPERTIES

**Color:** Pink: 10 mg tablet; Yellow: 25 mg tablet

**Odor:** Odorless

**Odor Threshold:** No data available

**Physical State:** Solid, quarter scored tablets (0220 embossed on 10mg tablets and 0221 on 25 mg tablets).

**pH:** No data available

**Melting Point:** No data available

**Freezing Point:** No data available

**Boiling Point:** No data available

**Flash Point:** No data available

**Flammability Limit – Upper (%):** No data available

**Flammability Limit – Lower (%):** No data available

**Evaporation rate:** No data available

**Vapor Pressure:** No data available

**Vapor Density (Air=1):** No data available

**Specific Gravity:** No data available

**Solubility:** Slight

**Partition Coefficient (n-Octanol/water):** No data available

**Autoignition Temperature:** Not applicable

**Decomposition Temperature:** No data available

**10 STABILITY AND REACTIVITY**

**Stability:** Stable

**Conditions to Avoid:** None known

**Incompatible Materials:** Strong oxidizing agents

**Hazardous Decomposition Products:** None known

**Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

**11 TOXICOLOGICAL INFORMATION****Specified Substances****Acute Toxicity**

Chemical Name	Test Results
Acepromazine maleate	Oral LD <sub>50</sub> (rat): 400 mg/kg Intravenous LD <sub>50</sub> (rat): 65 mg/kg Oral LD <sub>50</sub> (mouse): 270 mg/kg Subcutaneous LD <sub>50</sub> (mouse): 175 mg/kg

**Listed Carcinogens:** None

**12 ECOLOGICAL INFORMATION**

**Ecotoxicity:** No data available

**Persistence and degradability:** No data available

**Mobility in soil:** No data available

**Other adverse effects:** No data available

**13 DISPOSAL CONSIDERATIONS**

**General Information:** Dispose of in accordance with local, state and federal regulations.

**Disposal Methods:** No specific disposal method required. Do not empty into drains; dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by storage disposal.

**Container:** Since emptied containers retain product residue, follow label warnings even after container is emptied.

**14 TRANSPORT INFORMATION**

**DOT:** Not regulated

**TDG:** Not regulated

**ADR/RID:** Not regulated

**IATA:** Not regulated

**IMDG:** Not regulated

<b>15</b>	<b>REGULATORY INFORMATION</b>
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**Canadian Controlled Products Regulations:** This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

**WHMIS Classification:** Noncontrolled, exempt

**Inventory Status**

This material is **not** listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

This material is **not** listed on the DSL Inventory.

**US Regulations**

**FEDERAL LAW RESTRICTS THIS DRUG TO LICENSED VETERINARIANS.**

**State Regulations**

**California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):** None

**Massachusetts Right-To-Know List:** Cellulose, Starch Dust

**Minnesota Hazardous Substances List:** Cellulose, Starch

**New Jersey Right-To-Know List:** None

**Pennsylvania Right-To-Know List:** Cellulose, Starch

**European Regulations**

**Switzerland Toxins List 1:** alpha-Hydroxytoluol: Toxicity Category: 4; Starch: Toxicity Category: Not Categorized: G-8447; Calcium-Hydrogenphosphat: Toxicity Category: Not Categorized: G-7156

<b>16</b>	<b>OTHER INFORMATION</b>
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**Hazard Ratings**

	<b>Health Hazard</b>	<b>Fire Hazard</b>	<b>Reactivity Hazard</b>
<b>HMIS</b>	2	0	0

	<b>Health Hazard</b>	<b>Fire Hazard</b>	<b>Reactivity Hazard</b>	<b>Special Hazard</b>
<b>NFPA</b>	2	0	0	N/A

\*- Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

Xn - Harmful

R22 - Harmful if swallowed.

R36 - Irritating to eyes.

S25 - Avoid contact with eyes.

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S46 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

**ABBREVIATIONS:**

BIV - Boehringer Ingelheim Vetmedica, Inc.

AIHA- American Industrial Hygiene Association

mppcf – million particles/cubic foot

N/A - Not applicable

N/E - Not established

**References:**

1. Freedom of Information Summary. ANADA 200-361. Acepromazine Maleate Injection, Tranquilizer. Boehringer Ingelheim Vetmedica, Inc. April 2004.  
[www.fda.gov](http://www.fda.gov)
2. Freedom of Information Summary. ANADA 200-319. Acepromazine Maleate Injection 10mg/ml Phoenix Scientific, Inc., St. Joseph, MO. March 25, 2003.  
[www.fda.gov](http://www.fda.gov)
3. Acepromazine Maleate Injection and Tablets. Product Reference Information. Boehringer Ingelheim Vetmedica, Inc. [www.bi-vetmedica.com](http://www.bi-vetmedica.com)
4. Acepromazine Maleate Tablets. Product Label. Boehringer Ingelheim Vetmedica, Inc. [www.bi-vetmedica.com](http://www.bi-vetmedica.com)
5. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database. Benzyl Alcohol, Acepromazine Maleate.
6. RTECS – Benzyl Alcohol. RTECS No. DN3150000
7. GHS Manual

**Revision Information:** Updated all sections of the MSDS for ANSI, GHS and OSHA Compliance.

**Prepared by:** Boehringer Ingelheim Vetmedica, Inc.

**Issue Date:** 06/30/06

**Supersedes Date:** 3/29/05

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