

MATERIAL SAFETY DATA SHEET

Bromocriptine Mesylate Tablets 2.5 mg

Revision Date: 10/08/08

SECTION 1: PRODUCT IDENTIFICATION

Product Name	Bromocriptine Mesylate Tablets, 2.5 mg
Common Name/Trade Name	Bromocriptine Mesylate Tablets, 2.5 mg
Manufacturer	Paddock Laboratories, Inc.
Synonyms	NA
Chemical Name	Ergotaman-3',6',18-trione, 2-bromo-12'hydroxy-2'-(1-methylethyl)-5'-(2-methylpropyl)-,(5 α)-,monomethanesulfonate (salt).
Chemical Family	Dopamine receptor agonist
Chemical Formula	C ₃₂ H ₄₀ BrN ₅ O ₅ CH ₄ O ₃ S

SECTION 2: HAZARDOUS INGREDIENTS

CHEMICAL NAME	CAS#	%	OSHA PEL	ACGIH TLV
Bromocriptine Mesylate	22260-51-1	<10	NE	NE
Lactose Anhydrous, NF	63-42-3	>10	NE	NE
Starch, Pregelatinized, NF	9005-25-8	>10	5mg/m ³	10mg/m ³
Povidone	9003-39-8	>10	NE	NE
Magnesium Stearate, NF	557-04-0	<10	NE	NE
Maleic Acid	617-48-1	<10	NE	NE
Colloidal Silicon Dioxide, NF	112945-52-5	<1	6mg/m ³	10mg/m ³

SECTION 3: HAZARDS IDENTIFICATION

Potential Health Effects	The active ingredient is toxic by intravenous route. Harmful by ingestion. May cause nausea, hallucination, headache, convulsion, hypotension, dyspnea, cramps, arterial hypertension.
Pregnancy	Pregnancy category B. Dangerous to breast fed children.

SECTION 4: FIRST AID MEASURES

Skin Exposure	Immediately flush skin with water. Remove contaminated clothing and shoes. Seek medical attention.
Eye Exposure	Flush immediately with copious amounts of water for at least 15 minutes. Obtain emergency medical treatment.
Inhalation	Inhalation exposure is not expected to occur. If exposure occurs, remove to fresh air. If symptoms develop, seek medical attention.
Ingestion	Induce vomiting only in case of awareness, Obtain emergency medical treatment. Limit intestinal adsorption by means of gastric lavage.

SECTION 5: FIRE / EXPLOSION HAZARDS & FIREFIGHTING MEASURES

Flammability of the Product	NA
Auto-ignition Temperature	NA
Flash Points	NA
Flammable Limits (in air by volume, %)	Lower: NA Upper: NA
Fire Extinguishing Equipment	Use extinguishing agent suitable for type of surrounding fire. Water Spray: OK Foam: OK Carbon Dioxide: OK Dry Chemical: OK
Unusual Fire and Explosion Hazards	None
Explosion Hazards in presence of Various substances	NA
Firefighting Procedures	For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by the DOT <i>Emergency Response Guidebook</i> , a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to

fire with water, if it can be done with minimal risk.

SECTION 6: SPILL AND LEAK PROCEDURES

Spills

Collect the product in a suitable container. Dispose in accordance with all Federal, State and local regulations.

SECTION 7: HANDLING AND STORAGE

Work and Hygiene Practices

As with all chemicals, avoid getting this product on you or in you. Do not eat, drink or smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Storage and Handling Practices

Keep out of reach of children. Store at controlled room temperature between 15° – 30° C (59°-86° F)

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls

Use adequate ventilation when handling raw materials

Respiratory Protection

No special requirements under normal conditions of use. In the manufacturing area, use a particulate respirator.

Eye Protection

Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended.

Hand Protection

Gloves are recommended.

Body Protection

No special requirements.

SECTION 9: PHYSICAL / CHEMICAL PROPERTIES

Physical state and appearance

Pink round tablet bisected on one side with the debossed logo 'PAD 0116' on the same side.

Molecular Weight

NA

Boiling Point	NA
Vapor Density (AIR=1)	NA
Vapor Pressure (mm Hg)	NA
Melting/Freezing Point	NA
pH	NA
Water Solubility	Partially soluble
Specific Gravity (Water =1)	NA
Water Reactivity	NA
Volatility	NA
Odor	No odor

SECTION 10: STABILITY AND REACTIVITY

Stability	Stable under labeled storage conditions.
Incompatible Temperature	NA
Incompatible Materials	Oxidizing agents, bases.
Hazardous Polymerization	No
Hazardous Decomposition	When heated to decomposition the material emits very toxic fumes of SO _x , NO _x , and Br

SECTION 11: TOXICOLOGICAL INFORMATION

Oral Rat:	LD50: >2g/kg
Oral Mouse	LD50: 2502 mg/kg
Suspected Cancer Agent	No

SECTION 12: ECOLOGICAL INFORMATION

Environmental Stability	NA
Ecotoxicity	NA
Products of Biodegradation	NA
Special Remarks	NA

SECTION 13: WASTE DISPOSAL

Dispose of material according to local, state, federal and environmental disposal regulations or company operating procedures.

SECTION 14: TRANSPORTATION INFORMATION

DOT classification	Not hazardous
Identification	NA
DOT Label(s) Required	NA

SECTION 15: REGULATORY INFORMATION

US SARA Reporting Requirements	NA
Federal and State Regulations	NA
U.S. TSCA Inventory Status	Bromocriptine Mesylate is a “drug” as defined by the Federal Food, Drug, and Cosmetic Act and is therefore not a chemical substance under TSCA.

SECTION 16: OTHER INFORMATION

DEFINITIONS OF ABBREVIATIONS USED:

ACGIH	American Conference of Governmental Industry Hygienists
CAS	Chemical Abstract Service
IARC	International Agency for Research on Cancer
IDLH	Immediately Dangerous to Life or Health Level
LC₅₀	Medial Lethal Concentration
LD₅₀	Medial Lethal Dose
MSHA	Mine Safety and Health Administration
NA	Not Available
ND	No Data
NE	Not Established
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Limit
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value
TWA	Time Weighted Average

SECTION 17: DISCLAIMER

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