

Product Name: ABT-888 Capsules, 10 mg & 50 mg
Issued: Jan-23-2007



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories
Global Pharmaceutical Research and Development
Abbott Park Rd.
Abbott Park, IL 60064

Emergency Telephone: 1 (800) 424-9300 CHEMTREC (USA)
1 (703) 527 3887 CHEMTREC (INTERNATIONAL)

Product Name: ABT-888 Capsules, 10 mg & 50 mg

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Magnesium Stearate 557-04-0	proprietary	Not Listed	10 mg/m ³ total dust	Not Applicable	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	proprietary	Not Listed	10 mg/m ³ total dust	Not Applicable	Not Applicable	None
A-861695 L-02-3268	proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None

Notes: OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.
Abbott EEL: Abbott Laboratories Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.
C: Ceiling Limit.

3. HAZARDS IDENTIFICATION

Emergency Overview:
Capsule.
Odor: Not determined.
No data are available to evaluate the health risk of this material.

Routes of Exposure:
Oral: Unlikely Clinical Route
Dermal: Unlikely
Inhalation: Unlikely

Hazard Information:
Ingestion Rating: Not determined.
Skin Absorption Rating: Not determined.
Inhalation Rating: Not determined.
Corrosiveness Rating: Not determined.
Skin Contact Rating: Not determined.
Skin Sensitization Rating: Not determined.
Eye Contact Rating: Not determined.

Product Name: ABT-888 Capsules, 10 mg & 50 mg
Target Organs: Hematopoietic System , Nervous System.

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Magnesium Stearate	proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	proprietary	Not Listed	Not Listed	Not Listed	Not Listed
A-861695	proprietary	Not Listed	Not Listed	Not Listed	Not Listed

NFPA Rating: Not determined.

Signs and Symptoms: No signs and symptoms from occupational exposure are known. Analogy suggests the following: gastrointestinal upset, seizures, ataxia, blood disorders.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any preexisting ailments in the following organs: female reproductive system, central nervous system, DNA, or hematopoietic system. gastrointestinal system, Pregnancy.

4. FIRST AID MEASURES

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability:

Flammability Class: Active Ingredient : Combustible.

Lower Explosive Limit: Not determined.

Autoignition Temp. (°C): Not determined.

Fire-Fighting Information:

Suitable Extinguishing Media: Use appropriate medium for the underlying cause of the fire.

Special Exposure Hazards: Avoid inhalation of combustion products.

Explosivity: Fine dust clouds may form explosive mixtures with air.

6. ACCIDENTAL RELEASE MEASURES

Product Name:	ABT-888 Capsules, 10 mg & 50 mg
Methods of Cleaning and Collecting:	Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.
Personal Precautions:	Use personal protective equipment identified in Section 8.
Environmental Precautions:	Not determined.

7. HANDLING AND STORAGE

Handling:	Minimize dust generation. Use appropriate personal protective equipment. Avoid breathing dust and contact with the skin or eyes. Do not consume food, drink or smoke while handling this material.
Storage:	Store according to label instructions.
Special Precautions:	Not applicable.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls:	Use in a well ventilated area.
Respiratory Protection:	None known.
Eyes:	Wear eye protection appropriate to handling activities.
Gloves:	Impervious gloves.
Other PPE Data:	Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Capsule.
Odor:	Odor: Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point:	Not determined.
Vapor Pressure (mm Hg)	Not determined.
Bulk Density at 20°C:	Not determined.
Solubility:	Sparingly soluble in: acetone, acetonitrile, methylene chloride. Slightly soluble in: ethanol. Soluble in: methanol. for active ingredient.
Specific Gravity:	Not determined.
pH:	Not determined.
Viscosity (centipoise):	Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable at normal temperature and pressures.
Self-Heating Tendency:	Not determined.
Materials to Avoid:	Strong oxidizers. for active ingredient
Hazardous Decomposition Products:	Not determined.
Hazardous Polymerization:	Not known to occur.
Conditions to Avoid:	Not determined.

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11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: Not determined. No effect anticipated from intact clinical product. Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Cellulose Microcrystalline	proprietary	LD50 >	5000	mg/kg	Rats

Acute Toxicity - Dermal: Not determined. No effect anticipated from intact clinical product. Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Cellulose Microcrystalline	proprietary	LD50 >	2000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Not determined. No effect anticipated from intact clinical product. Data for component (s) given below.

Ingredients	Percent	Test	Value	Units	Species
Magnesium Stearate	proprietary	LC 50 >	2000	mg/m ³ , 1 hour	Rats
Cellulose Microcrystalline	proprietary	LC 50 >	5800	mg/m ³ , 4 hour	Rats

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Target Organ Effects: Not determined. None expected from normal clinical use of this product. Active Ingredient : In animal testing, target organs include: central nervous system, blood.

A-861695: In repeat-dose studies with the dihydrochloride salt, seizures and ataxia occurred in dogs at 30 mg/kg/day; emesis, decreased body weight and food consumption and decreased thymus weight noted at 15 mg/kg/day. In rats, seizures reported following 300 mg/kg ip; no toxicologically relevant changes detected in rats following oral doses of 75 mg/kg/day. Decreased reticulocyte counts noted in dogs and rats.

Reproductive Effects: Not determined. None expected from normal clinical use of this product. Active Ingredient : Considered to be a probable reproductive hazard based on available information.

By analogy: For A-620223, a screening Segment II study was conducted in pregnant rats (dosages 0, 60, 180 and 360 mg base/kg/day). Maternal toxicity (decreased body weight and food consumption) and severe embryotoxicity (100% early resorptions) were noted. An additional screening study with 0, 0.02, 0.2 and 2.0 mg/kg/day had no effect; NOEL for maternal and fetal toxicity = 2.0 mg/kg/day.

Carcinogenicity: Not determined.

Mutagenicity: Not determined. Active Ingredient : Negative for clastogenicity in the in vitro V79 Chinese hamster lung cell assay. Negative for mutagenicity in the screening Ames Assay.

Ingredients	Percent	Ames Test:	Mouse Lymphoma Assay	Micronucleus Assay	Chromosomal Abbr. Assay
Magnesium Stearate	proprietary	Negative	No Data.	No Data.	No Data.

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Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined.

Biodegradation: Not determined.

General Notes: Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: All waste must be packaged, labeled, transported and disposed of in conformance with applicable local, state, and federal laws and regulations and in accordance with good engineering practices.

14. TRANSPORT INFORMATION

DOT/ADR:

Status: Pharmaceutical/Therapeutic Candidate. Contact local dangerous goods coordinator.

ICAO/IATA:

Status: Pharmaceutical/Therapeutic Candidate. Contact local dangerous goods coordinator.

IMDG:

Status: Pharmaceutical/Therapeutic Candidate. Contact local dangerous goods coordinator.

TDG (Canada):

Status: Pharmaceutical/ Therapeutic Candidate. Contact local dangerous goods coordinator.

15. REGULATORY INFORMATION

SARA 313 Information

Product Name: ABT-888 Capsules, 10 mg & 50 mg

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Magnesium Stearate	proprietary	No	Not Applicable	Not applicable
Cellulose Microcrystalline	proprietary	No	Not Applicable	Not applicable
A-861695	proprietary	No	Not Applicable	Not applicable

SARA 311/312 Hazard Categories:

Immediate Health: Not Applicable (Clinical use)
Delayed Health: Not Applicable (Clinical use)
Fire: Not Applicable
Sudden Pressure: Not Applicable
Reactivity: Not determined.
TSCA Inventory Status: Not determined.
CERCLA Status: Not determined.
RCRA Status: Not determined.
Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

EC HAZARD CLASSIFICATION:

Category of Danger: Not determined.
Indication of danger: Not a hazardous substance according to the guidelines.
GHS Classification: Exempt

CANADIAN REGULATIONS:

Canadian Inventory: Not applicable.
Canadian NDSL: Not applicable.
WHMIS Hazard Class: Not determined.

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

16. OTHER INFORMATION

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Disclaimer:

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