

Product Name:
Issued:

Meridia Capsules
Sep-11-2007



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories
Pharmaceutical Products Group
100 Abbott Park Road
Abbott Park, IL 60064

Customer Service Telephone: 1-800-255-5162 (US and Canada only)

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada) or Access Code + (703) 527-3887

Product Name: Meridia Capsules

Synonyms: Reductil
Adecid
Ectiva
Raductil

List Number: 2456, 2457, 2458 , K445 , N136 , N137

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Lactose 63-42-3.	Proprietary	15 mg/m ³ total dust, 5 mg/m ³ respirable dust	10 mg/m ³ total dust, 3 mg/m ³ respirable dust	Not Applicable.	Not Applicable.	None.
Cellulose Microcrystalline 9004-34-6.	Proprietary	15 mg/m ³ TWA 5 mg/m ³ TWA	10 mg/m ³ total dust	Not Applicable.	Not Applicable.	None.
Sibutramine Hydrochloride Monohydrate 125494-59-9.	Proprietary	Not Listed.	Not Listed.	Not Applicable.	20 mcg/m ³ in 8-hr TWA	None.
Magnesium Stearate 557-04-0.	Proprietary	Not Listed	10 mg/m ³ total dust	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.

Abbott : Hazardous per OSHA criteria

3. HAZARDS IDENTIFICATION

Emergency Overview:

White to off-white powder in a capsule.
Odorless.
No data are available to evaluate the health risk of this material.

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3. HAZARDS IDENTIFICATION

Routes of Exposure:

Oral: Clinical Route
Dermal: Not determined.
Inhalation: Not determined.

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.
Target Organs: Respiratory System, Cardiovascular System , Nervous System.

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Lactose.	Proprietary	Not Listed.	Not Listed.	Not Listed.	Not Listed.
Cellulose Microcrystalline.	Proprietary	Not Listed.	Not Listed.	Not Listed.	Not Listed.
Sibutramine Hydrochloride Monohydrate.	Proprietary	Not Listed.	Not Listed.	Not Listed.	Not Listed.
Magnesium Stearate.	Proprietary	Not Listed.	Not Listed.	Not Listed.	Not Listed.

NFPA Rating: Not determined.

Signs and Symptoms: None known from occupational exposure. Clinical data suggests the following: headaches, fast heart rate, increased blood pressure, rash, drowsiness, dizziness, diarrhea, nasal discharge, constipation.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Medical conditions exacerbated due to exposure to the following organs: cardiovascular system, gastrointestinal system, respiratory system. Concurrent use of medications.

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.

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5. FIRE FIGHTING MEASURES

Flammability:

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.

6. ACCIDENTAL RELEASE MEASURES

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: Not determined.

Storage: Store according to label instructions.

Special Precautions: Not applicable.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.

Respiratory Protection: Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

Gloves: Not needed during typical product use conditions. Wear impervious gloves when handling the bulk formulation.

Other PPE Data: Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White to off-white powder in a capsule.

Odor: Odorless.

Boiling Pt. @ 760 mm Hg (°C): Not determined.

Melting/Freezing Point: Not determined.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Vapor Pressure (mm Hg) Not determined.
Bulk Density at 20°C: Not determined.
Solubility: Not determined.
Specific Gravity: Not determined.
pH: Not determined.
Viscosity (centipoise): Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Not determined.
Self-Heating Tendency: Not determined.
Materials to Avoid: Not determined.
Hazardous Decomposition Products: Not determined.
Hazardous Polymerization: Not determined.
Conditions to Avoid: Not determined.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Lactose.	Proprietary	LD50 >	5000	mg/kg	Mice Rats
Cellulose Microcrystalline.	Proprietary	LD50 >	5000	mg/kg	Rats

Acute Toxicity - Dermal: Data for component (s) given below.

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

Acute Toxicity - Inhalation: Data for component (s) given below.

Ingredients	Percent	Test	Value	Units	Species
Cellulose Microcrystalline.	Proprietary	LC 50 >	5800	mg/m ³ , 4 hour	Rats
Sibutramine Hydrochloride Monohydrate.	Proprietary	LC 50 =	63	mg/m ³ , 4 hour	Rats
Magnesium Stearate.	Proprietary	LC 50 >	2000	mg/m ³ , 1 hour	Rats

Other Toxicology Data: Data for component (s) given below:

Ingredients	Percent	Test Type	Value	Units	Species	Comments
Sibutramine Hydrochloride Monohydrate.	Proprietary	LD Lo (po) = LD Lo (ip) =	100 - 200 75	mg/kg	Rats Mice Rats	None.

Corrosivity: Not determined.
Dermal Irritation: Not determined.
Eye Irritation: Not determined.

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Sensitization: Not determined.

Target Organ Effects: Data for component (s) given below.

Ingredients	Percent	Target Organs:	Species	Dosage	Units	Route	Duration
Sibutramine Hydrochloride Monohydrate.	Proprietary	Liver Central Nervous System	Rats Mice Dogs Monkeys	>=1 >=10	mg/kg	Oral	Variable exposure periods

Reproductive Effects: Data for component (s) given below.

Ingredients	Percent	Reproductive Effects	Species	Dosage	Units	Route	Duration
Sibutramine Hydrochloride Monohydrate.	Proprietary	Reduced fertility in females, Maternal Toxicity, Fetal Abnormalities.	Rats Rabbits	>= 1 >12	mg/kg	Oral	Variable Treatment Regimens

Carcinogenicity: Not determined.

Mutagenicity: Data for component (s) given below.

Ingredients	Percent	Ames Test:	Mouse Lymphoma Assay	Micronucleus Assay	Chromosomal Abbr. Assay
Sibutramine Hydrochloride Monohydrate.	Proprietary	Negative	No Data.	Negative	Negative
Magnesium Stearate.	Proprietary	Negative	No Data.	No Data.	No Data.

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: Data for component (s) given below.

Ingredients	Percent	EC50 (mg/l)	Species	Duration
Sibutramine Hydrochloride Monohydrate.	Proprietary	1.8	Daphnia magna	48 Hours

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: Incineration recommended in approved incinerator according to federal, state, and local regulations. This material is not a RCRA hazardous waste. This material is DEA regulated.

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14. TRANSPORT INFORMATION

DOT/ADR:
Status: Not Regulated.

ICAO/IATA:
Status: Not Regulated.

IMDG:
Status: Not Regulated.

TDG (Canada):
Status: Not determined.

15. REGULATORY INFORMATION

SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Lactose.	Proprietary	No.	Not Applicable.	Not applicable.
Cellulose Microcrystalline.	Proprietary	No.	Not Applicable.	Not applicable.
Sibutramine Hydrochloride Monohydrate.	Proprietary	No.	Not Applicable.	Not applicable.
Magnesium Stearate.	Proprietary	No.	Not Applicable.	Not applicable.

SARA 311/312 Hazard Categories:

Immediate Health: No
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

TSCA Inventory Status: Exempt.

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: Exempt.
Indication of danger: Exempt.
GHS Classification: Not determined.

CANADIAN REGULATIONS:

Canadian Inventory: Not determined.

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Canadian NDSL: Not determined.
WHMIS Hazard Class: Exempt

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

Document Authored By: Global Occupational Toxicology (D-05TX)

Supersedes the MSDS dated: Aug-31-2007

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