

Product Name: COLCHICINE 0.6 mg TABLETS
Issued: Mar-16-2007



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories
Pharmaceutical Products Division
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

Customer Service Telephone: 1 - 800 - 441 - 4987 (PPD Technical Information)

Emergency Telephone: CHEMTREC (USA): 1 - 800 - 424 - 9300

Product Name: COLCHICINE 0.6 mg TABLETS

Synonyms: Colchicine Tablets, USP 0.6mg

List Number: 3781

National Drug Code Number: 0074-3781-01

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Colchicine 64-86-8	proprietary	Not Listed	Not Listed	Not Applicable	0.2 mcg/m ³	Skin
Sucrose 57-50-1	proprietary	15 mg/m ³ TWA (total dust); 5 mg/m ³ TWA (respirable fraction)	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate	Not Applicable	Not Applicable	None
Talc, Nonasbestos Containing 14807-96-6	proprietary	see Table Z-3	2 mg/m ³ , respirable 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:

Yellow convex tablet.

Odorless.

Potent drug: clinical dose less than 10 mg per day. Highly toxic by ingestion. Highly toxic by inhalation. Eye irritant.

Routes of Exposure:

Oral: Yes

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Dermal: Unlikely
Inhalation: Yes

Hazard Information:

Ingestion Rating: Highly Toxic
Skin Absorption Rating: Not determined.
Inhalation Rating: Highly Toxic
Corrosiveness Rating: Not determined.
Skin Contact Rating: Irritant
Skin Sensitization Rating: Not determined.
Eye Contact Rating: Irritant
Target Organs: Nervous System, Eyes, Skin , Digestive System , Bone Marrow , Kidney, Respiratory System.

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Colchicine	proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Sucrose	proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Talc, Nonasbestos Containing	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: nausea, diarrhea, abdominal pain, burning sensation, vascular damage, muscle weakness, respiratory depression, variable central nervous system effects, hematuria, death. Exposure may result in the following: bone marrow depression, cardiac changes, peripheral neuropathy, hair loss, skin discoloration, altered testicular function. Direct contact may cause: skin irritation, eye irritation.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any preexisting ailments in the following organs: kidney, liver, central nervous system, cardiovascular system, or hematopoietic system. respiratory system, gastrointestinal system, skin, eyes. Hypersensitivity to the material and/or similar materials.

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 irritation or toxicity occur seek medical attention. Provide symptomatic/supportive care as necessary. Monitor respiratory function. Measure and monitor vital signs to prevent shock.

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Ingestion: Remove from source of exposure. Seek immediate medical attention. If swallowed dilute with 1-2 glasses of milk or water and then induce vomiting. If patient is alert, induce vomiting and give activated charcoal. Atropine and morphine may be helpful to treat abdominal pain and artificial respiratory with oxygen may combat respiratory distress. Provide symptomatic/supportive care as necessary.

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: Keep calm. 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: Use in a well ventilated area.

Respiratory Protection: An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Safety glasses or goggles.

Gloves: Impervious gloves.

Other PPE Data: Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Yellow convex tablet.
Odor: Odorless.

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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: 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
Sucrose	proprietary	LD50 >	29,700	mg/kg	Rats

Notes to Toxicologist: Fatal dose for colchicine in adults is reported to be as low as 7-20 mg.

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

Notes to Toxicologist: Colchicine is absorbed through skin.

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

Notes to Toxicologist: Colchicine is extremely toxic by inhalation.

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

Ingredients	Percent	Test Type	Value	Units	Species	Comments
Colchicine	proprietary	LD Lo (po) =	0.125- 50	mg/kg	Dogs Cats Rabbits Guinea Pigs	Toxic

Corrosivity: Not determined.

Dermal Irritation: Reported to produce skin irritation in humans.

Notes to Toxicologist: Colchicine is irritating to skin.

Eye Irritation: Severely irritating and corrosive to eyes.

Notes to Toxicologist: Colchicine is severely irritating to eyes and can be cause cornea damage.

Sensitization: Not determined.

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Target Organ Effects: In clinical use target organ effects include: kidneys, gastrointestinal tract, central nervous system, hematopoietic system, eyes, skin, respiratory system. Clinical dose is less than (<) 10 mg/day.

Clinically, colchicine may produce damage to the kidneys, gastrointestinal tract, and the nervous, vascular and hematopoietic systems.

Reproductive Effects: In animals adverse reproductive effects include: reduced sperm count, reduced fertility in males.

Colchicine arrests cell division in animals, adversely affects spermatogenesis in humans causing impairment of fertility and has been shown to be teratogenic in mice at dosages of 1.25 and 1.5 mg/kg and in hamsters at a dosage of 10 mg/kg.

Carcinogenicity: Not determined.

Mutagenicity: Not determined.

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: Disposal should be made in accordance with federal, state and local regulations. This material is not a RCRA hazardous waste.

14. TRANSPORT INFORMATION

DOT/ADR:
Status: Not Regulated.

ICAO/IATA:
Status: Not Regulated.

IMDG:
Status: Not Regulated.

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TDG (Canada):
Status: Not Regulated.

15. REGULATORY INFORMATION

SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Colchicine	proprietary	No	Not Applicable	Not applicable
Sucrose	proprietary	No	Not Applicable	Not applicable
Talc, Nonasbestos Containing	proprietary	No	Not Applicable	Not applicable

SARA 311/312 Hazard Categories:

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

TSCA Inventory Status: Exempt.

CERCLA Status: Not regulated.

RCRA Status: Not a hazardous waste.

Proposition 65 Status: Listed.

Ingredients	Percent	Proposition 65 Listed Materials
Colchicine	proprietary	Developmental, Male : October 1,1992

EC HAZARD CLASSIFICATION:

Category of Danger: Exempt.
Indication of danger: Exempt.
GHS Classification: Exempt

CANADIAN REGULATIONS:

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

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Notes:

1. SARA = Superfund Ammendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insectacide, 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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