

SAFETY DATA SHEET

Section 1: Identification	
Material	Colchicine Tablets USP 0.6 mg
Recommended use	Relieves the pain of Gout attacks
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
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.
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.
Section 3: Composition/Information on Ingredients	
Ingredients	Colchicine
CAS	64-86-8
Section 4: First-Aid Measures	
Ingestion:	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.
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.

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.
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.
Section 5: Fire-Fighting Measures	
Fire-Fighting Information	
Suitable Extinguishing Media	Use appropriate medium for the underlying cause of the fire.
Special Exposure Hazards:	Avoid inhalation of combustion products.
Section 6: Accidental Release Measures	
Methods of Cleaning and Collecting:	Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials.
Personal Precautions:	Keep calm.
Environmental Precautions:	Not determined.
Section 7: Handling and Storage	
Handling:	Not determined.
Storage:	Store according to label instructions.
Special Precautions:	Not applicable.
Section 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.
Section 9: Physical and Chemical Properties	
Physical Form	Tablet
Colour	Purple
Description	Colchicine Tablets USP, 0.6 mg are purple, film-coated, capsule-shaped, bevel edged, biconvex tablets, debossed with "H" on one side and scored with "C2" on the other side; where 'C' and '2' are separated by a score line.
	Bottles of 30 Tablets NDC 31722-899-30
	Bottles of 100 Tablets NDC 31722-899-01
Section 10: Stability and Reactivity	
Reactivity	No data available.

Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	No data available
Other decomposition products	No data available.

Section 11: Toxicological Information

Inhalation:	Colchine is extremely toxic by inhalation.
Dermal Irritation:	Colchine is irritating to skin.
Eye Irritation:	Severely irritating and corrosive to eyes.
Sensitization:	Not determined.
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.

Section 12: Ecological Information

Aquatic Toxicity:	Not determined
Biodegradation:	Not determined
Results of PBT and vPvB assessment	Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Section 13: Disposal Considerations

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

Section 14: Transport Information

DOT/ADR:	
Status:	Not Regulated.
ICAO/IATA:	
Status:	Not Regulated.
IMDG:	
Status:	Not Regulated.
TDG (Canada):	
Status:	Not Regulated.

Section 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

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.

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.

Section 16: Other Information

Issue Date : 22-09-2021

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.