



300 Northfield Road
 Bedford, OH 44146
 Telephone: (800) 562-4797
 -Or- (440) 232-3320

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Topotecan Hydrochloride for Injection, USP (4 mg /vial)
Synonyms: 9-[(Dimethylamino) methyl]-10-hydroxy-(20S)-camptothecin, HCl
Chemical formula: C₂₃H₂₃N₃O₅ HCl

Manufactured by Cipla Ltd., Verna-Salcette for Bedford Laboratories
Emergency Telephone Number: Chemtrec: 1(800)424-9300
Telephone Number for Info.: (440) 232-3320 or (800) 562-4797
Medical Emergency: Professional Services (800) 521-5169
Date Revised: December 1, 2010

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Topotecan HCl	5.5%	119413-54-6	NONE	NONE	27 ng/m ³
Mannitol (Pyrogen free),USP	66.7%	69-65-8	NONE	NONE	NONE
Tartaric Acid, USP	27.8%	87-69-4	NONE	NONE	NONE

Topotecan Hydrochloride is a sterile parenteral injectable anticancer drug presented as a powder. It must be reconstituted with Sterile Water for Injection prior to administration.

Section III - HEALTH HAZARD DATA

Routes of Exposure: Skin, Inhalation, Ingestion, and Eye contact.
Health Hazard (Acute & Chronic): Potent pharmaceutical agent. Probable human carcinogen, teratogen, and genotoxin. Potential for loss of hair. Respiratory tract, eye, and skin irritant.

Carcinogenicity: NTP Not listed **IARC Monographs:** Not listed

OSHA Regulated: NO

Signs & Symptoms of Exposure: May cause reduced white blood cell count, nausea, diarrhea, vomiting and fatigue.

Medical Conditions Generally Aggravated by Exposure: May adversely affect bone marrow and formation of blood cells.

BVL Hazard Category: 5

BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):

1 = Low Toxicity

2= Moderate Toxicity

3A/3B = Potent or Toxic

4 = Highly Potent or Toxic

5 = Extremely Potent or Toxic

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes.

Skin Exposure: Remove contaminated clothing and flush exposed area with large amount of water. Obtain medical attention if skin reaction occurs.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Obtain medical attention.

Inhalation: If difficulty breathing, administer oxygen. Get medical attention immediately. If necessary, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not Applicable **LEL:** Not Applicable **UEL:** Not Applicable

Flammable Limits: Not Applicable

Extinguishing Media: Use water or a multi-purpose ABC extinguisher.

Special Fire Fighting Procedures: Fire fighters must wear self-contained breathing. Product is not expected to present a fire hazard.

Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wet Topotecan with water to prevent dusting and absorb with proper absorbents. Prevent contact with sewers and waterways.

Release to Air: If dust is generated, reduce exposures by ventilating and prevent the generation of dust. Wear respiratory protection.

Release to Water: Refer to local water authority; drain disposal is not recommended. Refer to local, state, and federal guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above.

Wear all necessary protective equipment including gloves, protective clothing, safety glasses, and air-purifying respirator with HEPA (P100) cartridges.

Large spills require the use of SCBA.

Waste Disposal Method: Topotecan HCl is not a RCRA listed hazardous waste.

Precautions to be taken in handling and storing: Store at 20°- 25°C.

Other Precautions: None

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Ventilation: Use with adequate ventilation such as in an isolator or biological safety cabinet.

Respiratory Protection: Under normal use, respirators are not required. If dust generation is possible, an air-purifying respirator with HEPA (P100) cartridges may be required. For spill emergencies, PAPR or SCBA may be required.

Protective Gloves: Use powder-free, labeled and tested for use with chemotherapy drugs, made of latex, nitrile, or neoprene.

Eye Protection: Safety glasses. Goggles, face shield, or other full-face protection if potential for splash or squirt hazard exists.

Other Protective Clothing or Equipment: Disposable gown or lab coat made of fabric that has low-permeability to the agents in use, with closed-front and cuffs, intended for single use. Additional body protection should be used based upon the task being performed (e.g., sleeves, apron, gauntlets, and disposable suits).

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking when handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State:	Solid	Specific Gravity:	Not applicable
Appearance:	Light yellow to greenish powder	Melting Point:	213 – 218 °C
Boiling Point:	Not Applicable	Evaporation Rate:	Not Applicable
Vapor Pressure:	Not Applicable	Solubility in Water:	Soluble in water
Vapor Density:	Not Applicable	pH:	Aqueous solution = 3.0

Section X - STABILITY AND REACTIVITY DATA

Stability: Unopened vial is stable until package date, stored at 20-25 °C. Protect from light in original package. Contents should be used immediately after reconstitution – stable for 24 hours after reconstitution.

Incompatibility (Materials to Avoid): Strong oxidizers.

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include Potentially hazardous byproducts of nitrogen oxides, carbon monoxide and carbon dioxide.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Avoid contact with light.

Section XI - TOXICOLOGICAL INFORMATION

For active ingredient Topotecan HCl: RTECS # UQ0491400

TDLo intraperitoneal, mouse = 5.4 mg/kg/3D intermittent

Toxic effects: Blood – changes in bone marrow.

TDLo intravenous, mouse = 7.5 mg/kg/3D intermittent

Toxic effects: tumorigenic – protects against induction of experimental tumors.

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Topotecan HCl. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of via incineration at an approved/permitted waste disposal facility according to federal, state, and local guidelines.

Section XIV - TRANSPORTATION INFORMATION

UN Number: UN3249
Proper Shipping Name: Medicine, Solid, Toxic N.O.S. (Topotecan HCl for Injection)
Class: 6.1 Toxic
Packing Group: PG III

Section XV - REGULATORY INFORMATION

SARA 313 listed: Not Listed
CERCLA listed: Not Listed
RCRA listed: Not Listed

Section XVI - OTHER DATA

Topotecan is considered a Hazardous Drug as described in the [NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings](#). Employees who prepare or administer hazardous drugs or who work in areas where these drugs are used should follow specific handling guidelines in order to prevent exposure to these agents in the air or on work surfaces, clothing, or equipment. The NIOSH Alert can be found at: <http://www.cdc.gov/niosh/docs/2004-165/>

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