	Sagent Pharmaceuticals, Inc.				
	Topotecan Hydrochloride for Injection			Material Safety Data Sheet (MSDS)	
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Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Topotecan Hydrochloride for Injection
Product Code: 25021-206
Common/Trade Name: Topotecan HCl
Chemical Name: (S)-10-[(dimethylamino)methyl]-4-ethyl-4,9-dihydroxy-1H-pyrano[3',4':6,7] indolizino [1,2-b]quinoline-3,14-(4H,12H)-dione monohydrochloride
Chemical Family: Anti-tumor
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vials

Section 2 - Composition / Information on Ingredients

Ingredient	mg/vial	CAS No.
Topotecan Hydrochloride	4.34	119413-54-6
Mannitol	48	69-65-8
Tartaric Acid	20	526-83-0


Section 3 - Hazards Identification

Primary Physical and Health Hazards: CAUTION: Potent pharmaceutical agent. May cause cancer. May produce adverse effects on the development of human offspring.

Routes of Entry: Inhalation, ingestion, skin and eye contact.

Signs & Symptoms of Exposure: Possible effects of overexposure in the workplace include: nausea; vomiting; diarrhea; bone marrow toxicity.

Chemical Listed as Carcinogen: NTP: No IARC: No OSHA: No

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Medical Conditions Generally Aggravated by Exposure:


Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells.

Section 4 - First Aid Measures

- Eye Exposure:** Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.
- Skin Exposure:** Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
- Ingestion:** Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
- Injection:** See patient package insert in shipping carton for complete information.
- Inhalation:** Physical form suggests that risk of inhalation exposure is negligible. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
- Notes to Physician:** Medical treatment in cases of overexposure should be treated as an overdose of cytotoxic agent. There are no known antidotes.

Section 5 - Fire Fighting Measures

- Flash Point:** Not established
- Auto-ignition Temperature:** Not established
- Flammable Limits in Air:** Lower %: Not established
Upper %: Not established
- Flammable Limits:** Not established
- Extinguishing Media:** Water is recommended for fires involving packaging.

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Special Fire Fighting Procedures:

For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

Unusual Fire/Explosion Hazards:


Not expected for the product, although the packaging is combustible.

Section 6 - Accidental Release Measures

- Spill:** For all spills, isolate the spill area, restrict access. Post the area for a carcinogen and immediately implement emergency procedures for cleanup and control of occupational carcinogens. Wear protective clothing and equipment consistent with the degree of hazard.
- Release to Air:** Do not allow this material to enter surface drainage systems, sewers and poorly ventilated areas.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

- General Handling:** Keep locked up. Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk. Evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.
- Waste Disposal Method:** Waste must be disposed of in accordance with federal, state and local environmental control regulations.
- Storage Conditions:** Protect from light and store at controlled room temperature Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Retain in carton until time of use. Follow instructions provided in packaging.

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Section 8 - Exposure Controls / Personal Protection

Respiratory Protection: Respirator proactive equipment is not required for normal handling of this material.

Eye Protection: Wear appropriate safety glasses with side shields if eye contact is possible.

Ventilation: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.


Skin Protection: Wear appropriate clothing to avoid skin contact. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must take into account any solvents and other hazards present. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Care must be exercised if no data are available and further guidance should be sought from your local safety department.

Other Protective Equipment: Not established

Additional Exposure Precautions: Not established

Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Topotecan Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

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Section 9 - Physical and Chemical Properties


Physical State:	Lyophilized powder	Specific Gravity:	Not available
Appearance and Odor:	Light yellow to greenish	Evaporation Rate:	Not available
Boiling Point:	Not available	Melting Point:	213° to 218°C
Vapor Pressure:	Not available	Solubility in Water:	Soluble
Vapor Density:	Not available	pH:	2.5 to 3.5
		Molecular Weight:	457.9

Section 10 - Stability and Reactivity

Stability:	Stable
Incompatibility (Materials to avoid):	None for normal handling of this product..
Hazardous Decomposition:	Avoid these products: carbon oxides (Co, CO2), nitrogen oxides (NO, NO2)
Hazardous Polymerization:	Will not occur
Conditions to Avoid:	Hygroscopic; keep container tightly closed.

Section 11 - Toxicological Information

Oral Toxicity:	Toxicity might occur following ingestion.
Acute Toxicity:	No studies have been conducted.
Organ Effect:	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells.
Genetic Toxicity:	Known or probable human mutagen.
Other Adverse Effects:	Overexposure in the work place might have the following effects: reduced white blood cell count; nausea; diarrhea; vomiting; fatigue

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Section 12 - Ecological Information

No information is available about the potential of this product to produce adverse environmental effects. This material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.

Section 13 - Disposal Considerations

Waste Disposal: Recommended method of disposal is incineration. Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: ORM-D

ICAO/IATA: Class/Division 9

IMO: Class/Division 6.1

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations


TSCA - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 - *Not on this list*

OSHA Substance Specific - Hazardous


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Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)