

# Topotecan Hydrochloride

sc-204919



The Power to Question

## Material Safety Data Sheet

Hazard Alert Code  
Key:

EXTREME

HIGH

MODERATE

LOW

## Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

### PRODUCT NAME

Topotecan Hydrochloride

### STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

### NFPA



### SUPPLIER

Santa Cruz Biotechnology, Inc.  
2145 Delaware Avenue  
Santa Cruz, California 95060  
800.457.3801 or 831.457.3800

### EMERGENCY

ChemWatch

Within the US & Canada: 877-715-9305

Outside the US & Canada: +800 2436 2255

(1-800-CHEMCALL) or call +613 9573 3112

### SYNONYMS

C23-H23-N3-O5.HCl, "(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", "9-[(dimethylamino)methyl]-10-hydroxy-(20S)-camptothecin HCl", "hycamptamine hydrochloride", "Hycamtin hydrochloride", "Nogitecan hydrochloride", "NSC-609669, SKF-1048644, "DNA topoisomerase inhibitor", "antineoplastic/ cytotoxic"

## Section 2 - HAZARDS IDENTIFICATION

### CHEMWATCH HAZARD RATINGS

|               | Min | Max                 |
|---------------|-----|---------------------|
| Flammability: | 1   |                     |
| Toxicity:     | 2   |                     |
| Body Contact: | 2   | Min/Nil=0<br>Low=1  |
| Reactivity:   | 1   | Moderate=2          |
| Chronic:      | 3   | High=3<br>Extreme=4 |

### CANADIAN WHMIS SYMBOLS



## EMERGENCY OVERVIEW

### RISK

May cause heritable genetic damage.  
May cause harm to the unborn child.  
Irritating to eyes, respiratory system and skin.  
Cumulative effects may result following exposure\*.  
Possible cancer-causing agent\*.  
Inhalation and/or ingestion may produce health damage\*.  
\* (limited evidence).

## POTENTIAL HEALTH EFFECTS

### ACUTE HEALTH EFFECTS

#### SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- The killing action of antineoplastic drugs used for cancer chemotherapy is not selective for cancerous cells alone but affect all dividing cells.

Acute side effects include loss of appetite, nausea and vomiting, allergic reaction (skin rash, itch, redness, low blood pressure, unwellness and anaphylactic shock) and local irritation.

#### EYE

- Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals. Prolonged eye contact may cause inflammation characterised by a temporary redness of the conjunctiva (similar to windburn).

#### SKIN

- This material can cause inflammation of the skin on contact in some persons.
- The material may accentuate any pre-existing dermatitis condition.
- Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

#### INHALED

- The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
- Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
- Side effects of topoisomerase I and II inhibitors (used to treat cancer) include early diarrhoea with runny nose, increased production of saliva, watery eyes, sweating, flushing and abdominal cramps. Late diarrhoea may also occur, up to 11 days after treatment.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

- Clinical signs of quinoline intoxication include lethargy, respiratory distress and prostration leading to coma.

## CHRONIC HEALTH EFFECTS

- Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.

There is ample evidence that this material can be regarded as being able to cause cancer in humans based on experiments and other information.

Based on experiments and other information, there is ample evidence to presume that exposure to this material can cause genetic defects that can be inherited.

Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.

Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

Anti-cancer drugs used for chemotherapy can depress the bone marrow with reduction in the number of white blood cells and platelets and bleeding. Susceptibility to infections and bleeding is increased, which can be life-threatening. Digestive system effects may include inflammation of the mouth cavity, mouth ulcers, oesophagus inflammation, abdominal pain and bleeds, diarrhoea, bowel ulcers and perforation. Reversible hair loss can result and wound healing may be delayed. Long-term effects on the gonads may cause periods to stop and inhibit sperm production. Most anti-cancer drugs can potentially cause mutations and birth defects, and coupled with the effects of the suppression of the immune system, may also cause cancer.

Quinoline is a metabolite of this material and in mammals has been shown to cause cancers of the liver and blood vessels. Adequate data in humans is not available.

Topoisomerase inhibitors represent a subgroup of plant alkaloids. The earliest drugs in this class were inhibitors of topoisomerase II, however topoisomerase I inhibitors such as topotecan is available. DNA topoisomerase II inhibitors are among the most efficacious drugs for the treatment of cancer. Despite their widespread use, the use of topoisomerase II inhibitors is limited by its severe adverse effects to normal tissues, including cardiotoxicity. In addition to problems associated with toxicity, sensitivity of cancer cells to topoisomerase II inhibitors is also, like many other cancer therapeutics susceptible to resistance.

### Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

| NAME                    | CAS RN      | %   |
|-------------------------|-------------|-----|
| topotecan hydrochloride | 119413-54-6 | >98 |

### Section 4 - FIRST AID MEASURES

#### SWALLOWED

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.

#### EYE

If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

#### SKIN

If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

#### INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.

#### NOTES TO PHYSICIAN

- Treat symptomatically.

For employees potentially exposed to antineoplastic and/ or cytotoxic agents on a regular basis, a preplacement physical examination and history (noting risk factors) is recommended. Periodic follow-up examinations should also be undertaken and should be overseen by a physician familiar with the toxic effects of the substance and full details of the nature of work undertaken by the employee.

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### Section 5 - FIRE FIGHTING MEASURES

|                             |                |
|-----------------------------|----------------|
| Vapour Pressure (mmHG):     | Not Applicable |
| Upper Explosive Limit (%):  | Not Available  |
| Specific Gravity (water=1): | Not Available  |
| Lower Explosive Limit (%):  | Not Available  |

#### EXTINGUISHING MEDIA

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).

#### FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.

- Prevent, by any means available, spillage from entering drains or water course.
- Use fire fighting procedures suitable for surrounding area.

When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 800 metres in all directions.

#### **GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS**

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds.; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
- In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC)
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), hydrogen chloride, phosgene, nitrogen oxides (NO<sub>x</sub>), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

#### **FIRE INCOMPATIBILITY**

- Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

## **Section 6 - ACCIDENTAL RELEASE MEASURES**

### **MINOR SPILLS**

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.

It is recommended that areas handling final finished product have cytotoxic spill kits available.

Spill kits should include:

- impermeable body covering,
- shoe covers,
- latex and utility latex gloves,
- goggles,

To avoid accidental exposure due to waste handling of cytotoxics:

- Place waste residue in a segregated sealed plastic container.
- Used syringes, needles and sharps should not be crushed, clipped, recapped, but placed directly into an approved sharps container.
- Dispose of any cleanup materials and waste residue according to all applicable laws and regulations e.g. secure chemical landfill disposal.

All personnel likely to be involved in an antineoplastic (cytotoxic) spill must receive practical training in:

- the correct procedures for handling cytotoxic drugs or waste in order to prevent and minimise the risk of spills
- the location of the spill kit in the area
- the arrangements for medical treatment of any affected personnel
- the procedure for containment of the spill, and decontamination of personnel and the environment, including the different procedures for major and **MINOR SPILLS**

Surfaces should be decontaminated so that potential exposures do not exceed exposure standards. The pH of collected wash water should be adjusted using base, such as sodium hydroxide, to a pH greater than 8; commercial bleach (approximately 5% hypochlorite) should be added to the waste water. Microgram levels of surface contamination can be visualised using ultraviolet light.

### **MAJOR SPILLS**

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by all means available, spillage from entering drains or water courses.

## **Section 7 - HANDLING AND STORAGE**

### **PROCEDURE FOR HANDLING**

The National Institute of Health (USA) recommends that the preparation of injectable antineoplastic drugs should be performed in a Class II laminar flow biological safety cabinet and that personnel preparing drugs of this class should wear appropriate personal protective gear. Emphasise controls on containment.

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

### RECOMMENDED STORAGE METHODS

- Glass container is suitable for laboratory quantities
- Lined metal can, lined metal pail/ can.
- Plastic pail.
- Polyliner drum.
- Packing as recommended by manufacturer.

For low viscosity materials

- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.

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### STORAGE REQUIREMENTS

Antineoplastics (cytotoxics):

- should be clearly identifiable to all personnel involved in their handling
- should be stored in impervious break-resistant containers
- should be stored in separate, clearly marked storage areas to minimise the risk of breakage, and to limit contamination in the event of leakage.

Spill kits should be available in storage areas.

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.

## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE CONTROLS

The following materials had no OELs on our records

- topotecan hydrochloride: CAS:119413-54-6

### PERSONAL PROTECTION



### RESPIRATOR

- Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

### EYE

- Chemical protective goggles with full seal
- Shielded mask (gas-type)
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

### HANDS/FEET

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- frequency and duration of contact,
- chemical resistance of glove material,

- glove thickness and
- dexterity
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers. [AS/NZS 2210]

#### OTHER

- Employees working with confirmed human carcinogens should be provided with, and be required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), shoe covers and gloves prior to entering the regulated area. [AS/NZS ISO 6529:2006 or national equivalent]
- Employees engaged in handling operations involving carcinogens should be provided with, and required to wear and use half-face filter-type respirators with filters for dusts, mists and fumes, or air purifying canisters or cartridges. A respirator affording higher levels of protection may be substituted. [AS/NZS 1715 or national equivalent]
- Emergency deluge showers and eyewash fountains, supplied with potable water, should be located near, within sight of, and on the same level with locations where direct exposure is likely.
- Prior to each exit from an area containing confirmed human carcinogens, employees should be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers must be identified with suitable labels. For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood.
- Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
- When handling antineoplastic materials, it is recommended that a disposal work-uniform (such as Tyvek or closed front surgical-type gown with knit cuffs) is worn.
- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

#### ENGINEERING CONTROLS

■ Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.

For potent pharmacological agents:

Powders

To prevent contamination and overexposure, no open handling of powder should be allowed.

- Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.
- In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.
- Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
- An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).

## Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

### PHYSICAL PROPERTIES

Mixes with water.

|                         |                      |                           |                |
|-------------------------|----------------------|---------------------------|----------------|
| State                   | Divided Solid        | Molecular Weight          | 457.9          |
| Melting Range (°F)      | 415- 424(decomposes) | Viscosity                 | Not Applicable |
| Boiling Range (°F)      | Not Available        | Solubility in water (g/L) | Miscible       |
| Flash Point (°F)        | Not Available        | pH (1% solution)          | 3              |
| Decomposition Temp (°F) | >392                 | pH (as supplied)          | Not Applicable |
| Autoignition Temp (°F)  | Not Available        | Vapour Pressure (mmHG)    | Not Applicable |

|                           |                |                                 |                |
|---------------------------|----------------|---------------------------------|----------------|
| Upper Explosive Limit (%) | Not Available  | Specific Gravity (water=1)      | Not Available  |
| Lower Explosive Limit (%) | Not Available  | Relative Vapour Density (air=1) | Not Applicable |
| Volatile Component (%vol) | Not Applicable | Evaporation Rate                | Not Applicable |

## APPEARANCE

Crystalline, odourless powder; mixes with water (up to 1 mg/ml).

Flammability

Physical State

Odour

Miscibility  
with water

- Solid

Crystalline

Miscible

## Section 10 - CHEMICAL STABILITY

### CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

### STORAGE INCOMPATIBILITY

- Avoid reaction with oxidising agents

For incompatible materials - refer to Section 7 - Handling and Storage.

## Section 11 - TOXICOLOGICAL INFORMATION

topotecan hydrochloride

### TOXICITY AND IRRITATION

■ Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound.

Studies done on animals showed that quinoline and its metabolites are almost completely excreted via the urine but caused fatty liver and bile duct proliferation in some cases. There is no evidence to suggest that quinoline causes cancer in humans, but it is reported to cause liver cancer in rats and skin cancer in mice. As such, it is predicted to be a cancer causing agent. It is equally said to cause no toxic effect on human and animal gene but some of its metabolites may cause abnormal gene alterations (4-methyl isomer and 2-methyl isomer).

Camptothecin (CPT) is a cytotoxic (cellkilling) quinoline which causes genetic damage, and its properties are significantly affected by structural alterations in the molecule.

No significant acute toxicological data identified in literature search.

## Section 12 - ECOLOGICAL INFORMATION

This material and its container must be disposed of as hazardous waste.

### Ecotoxicity

| Ingredient              | Persistence:<br>Water/Soil | Persistence: Air  | Bioaccumulation | Mobility |
|-------------------------|----------------------------|-------------------|-----------------|----------|
| topotecan hydrochloride | No Data Available          | No Data Available |                 |          |

## Section 13 - DISPOSAL CONSIDERATIONS

### Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life

considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted.

- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Antineoplastic (cytotoxic) wastes must be packed directly, ready for incineration, into colour-coded, secure, labelled, leak-proof containers sufficiently robust to withstand handling without breaking, bursting or leaking.
- Containers of special design are available for particular needs (such as disposal of sharps) and should be used.
- Once filled and closed, such containers must never be re-opened.
- Immediate containers must bear a nationally accepted symbol or device depicting cytotoxic substances and be labelled with the words: CYTOTOXIC WASTE - INCINERATE in a style of lettering approved by the national/ state authority.
- Where policies and procedures permit the merging of cytotoxic wastes with medical waste in an outer container used for medical waste, cytotoxic waste must first be placed in identifiable colour-coded/ labelled cytotoxic containers prior to merging.
- Management procedures must ensure that merged medical and cytotoxic waste is subjected to the incineration requirements appropriate for the total destruction of the cytotoxic waste.

**WASTE STORAGE OF CYTOTOXIC WASTES** For the storage of cytotoxic waste, segregated or merged with medical waste, provide:

- special storage areas with adequate lighting.
- waste security and restriction of access to authorised persons.
- storage areas designed to facilitate easy routine cleaning and maintenance to hygienic standards, or post-spill decontamination.
- storage of cytotoxic waste in standard, identifying bins or other appropriate containers.

#### COLLECTION OF CYTOTOXIC WASTES

- Procedures for the collection of cytotoxic wastes, which are compatible with existing operational needs, and which protect workers, other people and the environment, must be developed.
- Waste must be removed from the site by contractors whose workers have been instructed in the protective methods to be used against the hazards involved, and who comply with the safe work practices established by internal and/or national/ state policies. Contractors must instruct, train and direct their personnel in the safe and legal handling of cytotoxic wastes. Contractor's personnel should observe the operating procedures of the waste-generator.
- Transport of cytotoxic wastes, through the community, must comply with the appropriate national/ state codes.

#### DESTRUCTION OF CYTOTOXIC WASTES

- Destruction of cytotoxic wastes should be carried out in multi-chambered incinerators, licenced for this purpose, operating at 1100 deg. C. or more, with a residence time of at least 1 second.
- Operators must be trained in handling procedures and hazards involved with handling the waste.
- Waste which arrives at the incinerator inappropriately packaged should NOT be returned to the waste generator. An authorised representative of the waste generator must attend the incinerator site to rectify the situation.

## Section 14 - TRANSPORTATION INFORMATION

### DOT:

|                                               |        |                                                   |          |
|-----------------------------------------------|--------|---------------------------------------------------|----------|
| Symbols:                                      | None   | Hazard class or Division:                         | 6.1      |
| Identification Numbers:                       | UN3249 | PG:                                               | III      |
| Label Codes:                                  | 6.1    | Special provisions:                               | T1, TP33 |
| Packaging: Exceptions:                        | 153    | Packaging: Non-bulk:                              | 213      |
| Packaging: Exceptions:                        | 153    | Quantity limitations:<br>Passenger aircraft/rail: | 5 kg     |
| Quantity Limitations: Cargo<br>aircraft only: | 5 kg   | Vessel stowage: Location:                         | C        |
| Vessel stowage: Other:                        | 40     |                                                   |          |

Hazardous materials descriptions and proper shipping names:  
Medicine, solid, toxic, n.o.s.

### Air Transport IATA:

|                       |      |                    |        |
|-----------------------|------|--------------------|--------|
| ICAO/IATA Class:      | 6.1  | ICAO/IATA Subrisk: | None   |
| UN/ID Number:         | 3249 | Packing Group:     | III    |
| Special provisions:   | A3   |                    |        |
| Cargo Only            |      |                    |        |
| Packing Instructions: | 677  | Maximum Qty/Pack:  | 200 kg |

|                                         |      |                                         |        |
|-----------------------------------------|------|-----------------------------------------|--------|
| Passenger and Cargo                     |      | Passenger and Cargo                     |        |
| Packing Instructions:                   | 670  | Maximum Qty/Pack:                       | 100 kg |
| Passenger and Cargo<br>Limited Quantity |      | Passenger and Cargo<br>Limited Quantity |        |
| Packing Instructions:                   | Y645 | Maximum Qty/Pack:                       | 5 kg   |

Shipping name: MEDICINE, SOLID, TOXIC, N.O.S. (contains topotecan hydrochloride)

#### Maritime Transport IMDG:

|                     |         |                     |         |
|---------------------|---------|---------------------|---------|
| IMDG Class:         | 6.1     | IMDG Subrisk:       | None    |
| UN Number:          | 3249    | Packing Group:      | III     |
| EMS Number:         | F-A,S-A | Special provisions: | 221 223 |
| Limited Quantities: | 5 kg    |                     |         |

Shipping name: MEDICINE, SOLID, TOXIC, N.O.S. (contains topotecan hydrochloride)

### Section 15 - REGULATORY INFORMATION



#### topotecan hydrochloride (CAS: 119413-54-6) is found on the following regulatory lists;

"Canada List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient 'Hotlist')", "Canada Substances in Products Regulated Under the Food and Drugs Act (F&DA) That Were In Commerce between January 1, 1987 and September 13, 2001 (English)", "US - Massachusetts Drinking Water - Secondary Contaminants Maximum Contaminant Levels (MCLs)", "US - Utah Secondary Drinking Water Standards - Inorganic Contaminants", "US NIOSH New FDA Drugs and Warnings Fitting NIOSH Criteria for Hazardous Drugs 2006 (Draft)", "US NIOSH Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings - Appendix A: Sample list of drugs that should be handled as hazardous", "WHO Guidelines for Drinking-water Quality - Chemicals for which guideline values have not been established"

### Section 16 - OTHER INFORMATION

#### LIMITED EVIDENCE

- Inhalation and/or ingestion may produce health damage\*.
- Cumulative effects may result following exposure\*.
- Possible cancer-causing agent\*.

\* (limited evidence).

■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

[www.chemwatch.net/references](http://www.chemwatch.net/references).

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

■ For detailed advice on Personal Protective Equipment, refer to the following U.S. Regulations and Standards:

OSHA Standards - 29 CFR:

1910.132 - Personal Protective Equipment - General requirements

1910.133 - Eye and face protection

1910.134 - Respiratory Protection

1910.136 - Occupational foot protection

1910.138 - Hand Protection

Eye and face protection - ANSI Z87.1

Foot protection - ANSI Z41

Respirators must be NIOSH approved.

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Issue Date: Oct-25-2010

Print Date: Apr-14-2012