

# Safety Data Sheet for Drug product



Date of issue: 24-NOV-2015

Replaces version of: 23-JUN-2015

HYCANTIN VIAL 4MG 1 733419 (MARS)

## 1. Identification of the substance/preparation and of the company

Product name	HYCANTIN VIAL 4MG 1
Generic Name	Topotecan hydrochloride
Usage	Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)
Company name	Novartis Pharmaceuticals Corporation One Health Plaza East Hanover, NJ 07936-1080, USA +1 862 778 7777, email: sds.support@novartis.com
Emergency phone number	CHEMTEL (USA/Canada) 1(800)255-3924 (365/24/7)

## 2. Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

## 3. Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:	CAS Number
Topotecan hydrochloride	10 %	119413-54-6

Remaining components are inert ingredients.

For TLV values of declared components, see Section 8, Exposure controls / Personal

## 4. First aid measures

Eye Contact	Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
Skin Contact	Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Inhalation	Remove the victim from danger zone, avoid further exposure.
Ingestion	If swallowed, seek medical advice immediately and show this container or label.
Notes to Physician	General measures to eliminate the substance and to reduce absorption.

## 5. Fire fighting measures

Suitable Extinguishing Media	Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media	No restrictions
Dangerous Combustion Products	carbon oxides, nitrogen oxides, hydrogen chloride
Protective equipment for firefighters	Wear self-contained breathing apparatus and fire protective suite.

## 6. Accidental release measures

Personal precautions	Avoid contact with skin, eyes and clothing.
Environmental precautions	Must not be released into sewers, drains or wells.
Methods for cleaning	Transfer large quantities into a container. Clean up the rest with absorbent material and

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discharge properly.

## 7. Handling and storage

No special handling requirements for normal use of this material.

Store in a dry and cool place and observe special instructions from supplier.

## 8. Exposure controls / Personal protection

### Occupational Exposure Limit (OEL)

no data available

### TLV values of declared components

Contains:

Topotecan hydrochloride

List type	Value Unit
Exposure limit of supplier	0.03 µg/m <sup>3</sup>

### Personal protection for open handling

Health care personnel



Safety glasses (EN166) Disposable fine dust protection mask (EN149); Double disposable gloves (EN374) Disposable dust-proof lab coat

## 9. Physical and chemical properties

**Formulation** lyophilized powder

**Flash Point** no data available

## 10. Stability and reactivity

Under the normal conditions of use, the product is stable.

## 11. Toxicological information

**Acute Toxicity** Data of Topotecan hydrochloride  
LD50: 5 - 50 mg/kg  
Route: oral  
Species: rat

**Irritation, Corrosion** unknown

**Sensitisation** Values of Topotecan hydrochloride  
Sensitization cannot be excluded.  
unknown

**Mutagenicity** Data of Topotecan hydrochloride  
Negative (AMES-Test (reverse mutation assay))  
in vitro  
Method: AMES test  
Data of Topotecan hydrochloride  
Positive (Chromosome Aberration Study)  
in vitroCell: Cultured peripheral human lymphocytes  
Data of Topotecan hydrochloride  
Positive (Micronucleus Test)  
in vivo, Species: mouse  
Data of Topotecan hydrochloride  
Positive (Mouse Lymphoma Mutagenicity Assay in vitro)  
in vitroCell: Lymphoma cells L5178Y of the mouse

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	Data of Topotecan hydrochloride Positive (Sister Chromatid Exchange) Cell: V79 cells (embryonic lung fibroblasts) of the Chinese hamster
<b>Chronic Effects</b>	Values of Topotecan hydrochloride The substance causes concern for man owing to possible carcinogenic effects, but in respect of which the available information is not adequate for making a satisfactory assessment.
<b>Reproduction Toxicity</b>	Data of Topotecan hydrochloride (Embryo-Fetal Development) LOAEL: 4 mg/m2 NOAEL: 1.25 mg/m2 Route: intravenous Species: rabbit for maternal toxicity  Data of Topotecan hydrochloride (Embryo-Fetal Development) LOAEL: 1.25 mg/m2 NOAEL: 0.125 mg/m2 Route: intravenous Species: rabbit  Data of Topotecan hydrochloride (Embryo-Fetal Development) LOAEL: 0.59 mg/m2 NOAEL: 0.059 mg/m2 Route: intravenous Species: rat for maternal toxicity  Data of Topotecan hydrochloride (Embryo-Fetal Development) LOAEL: 0.59 mg/m2 NOAEL: 0.059 mg/m2 Route: intravenous Species: rat  Data of Topotecan hydrochloride (Effect on fertility.) LOAEL: 1.36 mg/m2 NOAEL: 0.136 mg/m2 Species: rat, Sex: female  Data of Topotecan hydrochloride (Effect on fertility.) LOAEL: 1.36 mg/m2 NOAEL: 0.136 mg/m2 Species: rat, Sex: female for maternal toxicity  Data of Topotecan hydrochloride (Effect on fertility.) NOAEL: 0.68 mg/m2 Route: intravenous Species: rat, Sex: male

## 12. Ecological information

<b>Biological Elimination</b>	Data of Topotecan hydrochloride Degradation: 0 % (aerobic: ) Duration: 28 days
<b>Fish acute toxicity</b>	Data of Topotecan hydrochloride EC50: 45.7 mg/l NOEC: 25 mg/l Species: fathead minnow (pimephales promelas)

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<b>Aquatic invertebrate acute toxicity</b>	Exp. time: 96 hours
	Data of Topotecan hydrochloride
	EC50: 61.8 mg/l
	Species: daphnia magna (water flea)
<b>Algae Toxicity</b>	Exp. time: 48 hours
	unknown
<b>Bacterial Respiration Inhibition</b>	unknown
<b>Ecotoxicity Summary</b>	Data of Topotecan hydrochloride
	Avoid release to the environment.
	Data of Topotecan hydrochloride
	Bioaccumulation in water organisms is not likely based on the n-octanol/water partition coefficient (log Pow < 3.0).

## 13. Disposal considerations

**Disposal Requirements** Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.

## 14. Transport information



Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	Not restricted	0			N.A.
IMDG-Code:	6.1	3249	III	6.1	5 kg
ICAO/IATA-DGR:	6.1	3249	III	6.1	

**ICAO/IATA-DGR:** classified

**Proper shipping name:** Medicine, solid, toxic, n.o.s.

## 15. Regulatory information

**Classifications of components:**

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
Topotecan hydrochloride	10 %	119413-54-6	 	D	H300, H340, H351, H361fd, H370, H372, H402, H412

Remaining components are inert ingredients.

## 16. Other information

**Changes since the previous version in Section** 14. Transport information

**Abbreviations used**

H300: Fatal if swallowed.

H340: May cause genetic defects.

H351: Suspected of causing cancer.

H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.

H370: Causes damage to organs.

H372: Causes damage to organs through prolonged or repeated exposure.

H402: Harmful to aquatic life.(in EU not leading to classification as hazardous)

H412: Harmful to aquatic life with long lasting effects.

**Recipient** Tiffany Burton

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