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HYCAMTIN VIAL 4MG 1 733419 (MARS)



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

Product name HYCAMTIN 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 Water spray or fog, foam, dry chemical powder, CO2, dry sand

Media

**Unsuitable** No restrictions

**Extinguishing Media** 

Dangerous Combustion carbon oxides, nitrogen oxides, hydrogen chloride

**Products** 

**Protective equipment** Wear self-contained breathing apparatus and fire protective suite.

for firefighters

# 6. Accidental release measures

**Personal precautions** Avoid contact with skin, eyes and clothing.

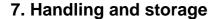
**Environmental** Must not be released into sewers, drains or wells.

precautions

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discharge properly.



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/m3

#### 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

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# 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)

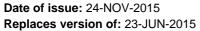
in vitroCell: Cultured peripheral human lymphocytes

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

**Chronic Effects** 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.

**Reproduction Toxicity** 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

**Biological Elimination** Data of Topotecan hydrochloride

Degradation: 0 % (aerobic: )

Duration: 28 days

Fish acute toxicity Data of Topotecan hydrochloride

> EC50: 45.7 mg/l NOEC: 25 mg/l

Species: fathead minnow (pimephales promelas)





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Exp. time: 96 hours

Aquatic invertebrate

acute toxicity

Data of Topotecan hydrochloride

EC50: 61.8 mg/l

Species: daphnia magna (water flea)

Exp. time: 48 hours

Algae Toxicity
Bacterial Respiration

Inhibition

unknown unknown

Ecotoxicity Summary

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

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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	Ш	6.1	5 kg	
ICAO/IATA-DGR:	6.1	3249	Ш	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

14. Transport information

Section

#### 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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McKesson