

Safety Data Sheet for Drug Products (EU)



Date of issue: 18-SEP-2018

Replaces version of: 13-DEC-2017

HYCAM LYVI 4MG GLW (X5) IT 733552 (MARS)

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

Product name	HYCAM LYVI 4MG GLW (X5) IT
Generic Name	Topotecan hydrochloride
Usage	Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)
Company name	Novartis Pharma AG 4002 Basel Switzerland Tel: +41 61 324 11 11, email: sds.support@novartis.com
Emergency phone number	CHEMTEL (International) +1 813 676 1670 (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	
Occupational Exposure Limit (OEL)	0.2	µg/m ³	HHA Database

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 not applicable

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 no data available

Sensitisation Values of Topotecan hydrochloride
Sensitization cannot be excluded.

no data available

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/m ² NOAEL: 1.25 mg/m ² Route: intravenous Species: rabbit for maternal toxicity Data of Topotecan hydrochloride (Embryo-Fetal Development) LOAEL: 1.25 mg/m ² NOAEL: 0.125 mg/m ² Route: intravenous Species: rabbit Data of Topotecan hydrochloride (Embryo-Fetal Development) LOAEL: 0.59 mg/m ² NOAEL: 0.059 mg/m ² Route: intravenous Species: rat for maternal toxicity Data of Topotecan hydrochloride (Embryo-Fetal Development) LOAEL: 0.59 mg/m ² NOAEL: 0.059 mg/m ² Route: intravenous Species: rat Data of Topotecan hydrochloride (Effect on fertility.) LOAEL: 1.36 mg/m ² NOAEL: 0.136 mg/m ² Species: rat, Sex: female Data of Topotecan hydrochloride (Effect on fertility.) LOAEL: 1.36 mg/m ² NOAEL: 0.136 mg/m ² Species: rat, Sex: female for maternal toxicity Data of Topotecan hydrochloride (Effect on fertility.) NOAEL: 0.68 mg/m ² 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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Aquatic invertebrate acute toxicity	Exp. time: 96 hours Data of Topotecan hydrochloride EC50: 61.8 mg/l Species: daphnia magna (water flea) Exp. time: 48 hours
Algae Toxicity	no data available
Bacterial Respiration Inhibition	no data available
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 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

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.

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ITALIA

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.