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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 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.

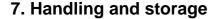
Environmental Must not be released into sewers, drains or wells.

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	
Occupational Exposure Limit (OEL)	0.2 μg/m3	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

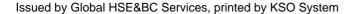
Positive (Chromosome Aberration Study)

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/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 no data available

Bacterial Respiration

Inhibition

Algae Toxicity

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

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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

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 Dr. Marco De Pasquale

Novartis Farma Spa

HSE

L.go Boccioni, 1





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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.