

Issuing Date 10-Jan-2013

Revision Date 10-Jan-2013

Revision Number 0

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**GHS product identifier****Product Name** Irinotecan Hydrochloride Injection**Other means of identification****Synonyms** None**Recommended use of the chemical and restrictions on use****Recommended Use** Cancer Treatment. This material is intended for IV injection under the supervision of physicians.**Uses advised against** No information available**Supplier's details****Supplier Address**
West-Ward Pharmaceuticals
Eatontown, NJ 07724**Manufacturer Address**
Thymoorgan Pharmazie GMBH
Schiffgraben 23
Vienenburg 38690
Germany
TEL: + 49 (0) 5324 7701 84; + (351) 21 960 84 10**Emergency telephone number****Emergency Telephone Number** + 49 (0) 5324 7701 84
+ (351) 21 960 84 10**2. HAZARDS IDENTIFICATION****Classification**

This chemical is considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200)

Germ Cell Mutagenicity	Category 1B
Carcinogenicity	Category 2
Reproductive Toxicity	Category 1B Effects on or via lactation

GHS Label elements, including precautionary statements**Emergency Overview****Signal Word** Danger

Hazard Statements

- May cause genetic defects
- Suspected of causing cancer
- May damage fertility or the unborn child
- May cause harm to breast-fed children
- Effects on or via lactation

**Appearance** Colorless-slightly yellow**Physical State** Liquid.**Odor** No information available**Precautionary Statements****Prevention**

- Obtain special instructions before use
- Do not handle until all safety precautions have been read and understood
- Use personal protective equipment as required
- Do not breathe dust/fume/gas/mist/vapors/spray
- Avoid contact during pregnancy/while nursing
- Wash face, hands and any exposed skin thoroughly after handling
- Do not eat, drink or smoke when using this product

General Advice

- IF exposed or concerned: Get medical attention/advice

Storage

- Store locked up

Disposal

- Dispose of contents/container to an approved waste disposal plant

Hazard Not Otherwise Classified (HNOC)

Not applicable

Other information

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %	Trade secret
Purified Water, USP	7732-18-5	QS	*
Sorbitol	50-70-4	45 mg/mL	*
Irinotecan hydrochloride	100286-90-6	20 mg/mL	*
Lactic acid	50-21-5	0.9 mg/mL	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES**Description of necessary first-aid measures****Eye Contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention immediately if symptoms occur.

Skin Contact	Wash off immediately with soap and plenty of water. Get medical attention if irritation persists.
Inhalation	If symptoms develop move victim to fresh air. Get medical attention
Ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Drink plenty of water. Call a physician or Poison Control Center immediately.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects No information available.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media None

Specific Hazards Arising from the Chemical

None known

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Ensure adequate ventilation.

Environmental Precautions

Environmental Precautions See Section 12 for additional Ecological Information

Methods and materials for containment and cleaning up

Methods for Containment Stop leak if you can do it without risk

Methods for Cleaning Up Soak up with inert absorbent material. Sweep up and shovel into suitable containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wear personal protective equipment. Precautions should be taken during the following activities: 1) withdrawal of needles from the drug vials, 2) drug transfers using syringes and needles or filter straws, 3) expulsion of air from drug filled syringes.

Conditions for safe storage, including any incompatibilities

Storage	Keep in properly labeled containers. Store in original container. Protect from light. Keep at temperatures between 15 °C and 30 °C.
Incompatible Products	Water-reactive materials

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Control parameters**

Exposure Guidelines	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
----------------------------	---

Appropriate engineering controls

Engineering Measures	Showers Eyewash stations Ventilation systems
-----------------------------	--

Individual protection measures, such as personal protective equipment

Eye/Face Protection	No special protective equipment required.
Skin and Body Protection	Nitrile rubber. Rubber gloves. Latex gloves Check gloves for leaks.
Respiratory Protection	No special protective equipment required.

Hygiene Measures	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Follow standard procedures for handling pharmaceutical materials and recommendations on the package insert.
-------------------------	---

9. PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

Physical State	Liquid	Appearance	Colorless-slightly yellow
Odor	No information available	Odor Threshold	No information available

Property	Values	Remarks/ - Method
pH	6.7 - 7.3	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Relative Density	No data available	None known
Specific Gravity	No data available.	None known
Water Solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known

Flammable Properties	Not flammable
-----------------------------	---------------

Explosive Properties	No data available
-----------------------------	-------------------

Oxidizing Properties No data available

Other information

VOC Content (%) No data available

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

None known based on information supplied.

Incompatible materials

Water-reactive materials

Hazardous decomposition products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	May cause irritation of respiratory tract.
Eye Contact	Contact with eyes may cause irritation.
Skin Contact	May cause irritation.
Ingestion	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Component Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Purified Water, USP	> 90 mL/kg (Rat)	-	-
Sorbitol	15900 mg/kg (Rat)	-	-
Irinotecan hydrochloride	900 mg/kg (rat)	-	-
Lactic acid	= 3543 mg/kg (Rat)	> 2 g/kg (Rabbit)	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization No information available.

Mutagenic Effects Irinotecan hydrochloride was clastogenic in the in vitro chromosomal aberration test in Chinese ovary cells and in vivo micronucleus test in mice but negative in in vitro Ames bacterial mutagenicity test.

Carcinogenicity Contains no ingredient listed as a carcinogen.

Reproductive Toxicity	All captothecins should be considered to possess reproductive/developmental toxicity potential. Irinotecans was embryolethal and teratogenic to rats and rabbits.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration Hazard	No information available.

Numerical measures of toxicity • - Product

The following values are calculated based on chapter 3.1 of the GHS document:

LD50 Oral 23348 mg/kg; Acute toxicity estimate

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Persistence and Degradability The product can be degraded by abiotic (e.g. chemical or photolytic) processes.

Bioaccumulation Not likely to bioaccumulate.

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging Dispose of in accordance with federal, state, and local regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

MEX Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Exempt
DSL	Exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

NFPA	Health Hazard 0	Flammability 0	Instability 0	Physical and Chemical Hazards - Personal Protection X
HMIS	Health Hazard 0*	Flammability 0	Physical Hazard 0	

*Indicates a chronic health hazard.

Prepared By	Product Stewardship 23 British American Blvd. Latham, NY 12110 1-800-572-6501
Issuing Date	10-Jan-2013
Revision Date	10-Jan-2013
Revision Note	Initial Release.

General Disclaimer

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet