

# Irinotecan Hydrochloride Injection

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Irinotecan Hydrochloride Injection  
Other means of identification : 40 mg per 2 mL: single dose vial packaged individually NDC 55150-352-01  
100 mg per 5 mL: single dose vial packaged individually NDC 55150-353-01  
300 mg per 15 mL: single dose vial packaged individually NDC 55150-354-01

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

AuroMedics  
279 Princeton Highstown Road  
East Windsor, NJ 08520

#### 1.4. Emergency telephone number

Emergency number : 1-888-238-7880

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS US classification

Muta. 2 H341  
Repr. 1B H360

Full text of hazard classes and H-statements : see section 16

#### 2.2. Label elements

##### GHS US labeling

Hazard pictograms (GHS US) :



GHS08

Signal word (GHS US) : Danger  
Hazard statements (GHS US) : H341 - Suspected of causing genetic defects  
H360 - May damage fertility or the unborn child  
Precautionary statements (GHS US) : P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P308+P313 - If exposed or concerned: Get medical advice/attention.  
P405 - Store locked up.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

Not applicable

### SECTION 3: Composition/Information on ingredients

#### 3.1. Substances

Not applicable

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### 3.2. Mixtures

Name	Product identifier	%	GHS US classification
Water	(CAS-No.) 7732-18-5	< 95	Not classified
D-Glucitol	(CAS-No.) 50-70-4	< 5	Not classified
Irinotecan hydrochloride	(CAS-No.) 100286-90-6	< 1	Acute Tox. 4 (Oral), H302 Muta. 2, H341 Repr. 1B, H360
Sodium hydroxide	(CAS-No.) 1310-73-2	< 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Hydrochloric acid	(CAS-No.) 7647-01-0	< 1	Skin Corr. 1, H314 Eye Dam. 1, H318
L-Lactic acid	(CAS-No.) 79-33-4	< 1	Skin Irrit. 2, H315 Eye Dam. 1, H318

Full text of hazard classes and H-statements : see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: Remove to fresh air and keep patient at rest. Seek medical attention immediately.
First-aid measures after skin contact	: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
First-aid measures after eye contact	: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after ingestion	: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: None anticipated during normal product use.
Symptoms/injuries after skin contact	: May cause skin irritation.
Symptoms/injuries after eye contact	: May cause eye irritation.
Symptoms/injuries after ingestion	: May be harmful if swallowed.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
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### 5.3. Advice for firefighters

Protection during firefighting	: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
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## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No special measures required.
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#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
Methods for cleaning up	: Absorb spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations.

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### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20° to 25°C (68° to 77°F).

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Water (7732-18-5)		
Not applicable		
D-Glucitol (50-70-4)		
Not applicable		
Irinotecan hydrochloride (100286-90-6)		
Not applicable		
L-Lactic acid (79-33-4)		
Not applicable		
Hydrochloric acid (7647-01-0)		
ACGIH	ACGIH Ceiling (ppm)	2 ppm
OSHA	OSHA PEL (Ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
OSHA	OSHA PEL (Ceiling) [ppm]	5 ppm
IDLH	US IDLH (ppm)	50 ppm
NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
NIOSH	NIOSH REL (Ceiling) [ppm]	5 ppm
Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH Ceiling (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
IDLH	US IDLH (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.  
Hand protection : No protection is ordinarily required under normal conditions of use.  
Eye protection : Wear safety glasses or goggles.  
Skin and body protection : Wear suitable working clothes.  
Respiratory protection : No protection is ordinarily required under normal conditions of use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Liquid  
Appearance : Clear.  
Color : Pale yellow  
Odor : Odorless  
Odor threshold : No data available  
pH : No data available  
Melting point : No data available  
Freezing point : No data available

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Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

Air contact.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

<b>Water (7732-18-5)</b>	
LD50 oral rat	> 90 ml/kg
<b>D-Glucitol (50-70-4)</b>	
LD50 oral rat	15900 mg/kg
<b>Irinotecan hydrochloride (100286-90-6)</b>	
ATE US (oral)	500 mg/kg body weight
<b>L-Lactic acid (79-33-4)</b>	
LD50 oral rat	3730 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
ATE US (oral)	3730 mg/kg body weight
<b>Hydrochloric acid (7647-01-0)</b>	
LD50 oral rat	238 – 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 Inhalation - Rat	1.68 mg/l (Exposure time: 1 h)
ATE US (oral)	238 mg/kg body weight

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Hydrochloric acid (7647-01-0)	
ATE US (vapors)	1.68 mg/l/4h
ATE US (dust, mist)	1.68 mg/l/4h
Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Suspected of causing genetic defects.
Carcinogenicity	: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3 - Not classifiable

Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

L-Lactic acid (79-33-4)	
LC50 fish 1	320 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [semi-static])
EC50 Daphnia 1	240 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	100 – 180 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	180 – 320 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Sodium hydroxide (1310-73-2)	
LC50 fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

L-Lactic acid (79-33-4)	
Partition coefficient n-octanol/water (Log Pow)	-0.62

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

## SECTION 14: Transport information

### Department of Transportation (DOT)

In accordance with DOT

Not applicable

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### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>D-Glucitol (50-70-4)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>L-Lactic acid (79-33-4)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Hydrochloric acid (7647-01-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
<b>Sodium hydroxide (1310-73-2)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb

#### 15.2. US State regulations

<b>Hydrochloric acid (7647-01-0)</b>
U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
<b>Sodium hydroxide (1310-73-2)</b>
U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

### SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Muta. 2	Germ cell mutagenicity Category 2
Repr. 1B	Reproductive toxicity Category 1B
Skin Corr. 1	Skin corrosion/irritation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H341	Suspected of causing genetic defects
H360	May damage fertility or the unborn child

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*