



# SAFETY DATA SHEET

Revision date 06-Dec-2021

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Irinotecan Hydrochloride Injection  
**Product Code(s)** IRINOTECAN HYDROCHLORIDE INJECTION  
**Trade Name:** CAMPTOSAR; CAMPTO  
**Item Code** H000400026;H000400738;H000400739;H000403313  
**Chemical Family:** Mixture

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

**Recommended Use** Pharmaceutical product used as Antineoplastic

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

Pfizer Inc  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887  
**E-mail address** pfizer-MSDS@pfizer.com

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification

**Germ cell mutagenicity** Category 2 - (H341)  
**Reproductive toxicity** Category 1B - (H360D)

### 2.2. Label elements

**Signal word** Danger

**Hazard statements** H341 - Suspected of causing genetic defects  
H360D - May damage the unborn child

**Precautionary Statements** P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations

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## 2.3. Other hazards

### Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

### Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Irinotecan Hydrochloride 100286-90-6	2%		Not Listed	Acute Tox.4 (H302) Repr.1B (H360D) Muta.2 (H341)	Not Listed	No data available	No data available
Lactic acid 50-21-5	< 1		200-018-0	Eye Dam. 1 (H318) Skin Irrit. 2 (H315)	Not Listed	No data available	No data available
Sodium hydroxide 1310-73-2	**		215-185-5	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid 7647-01-0	**		231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 ::	No data available	No data available

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					C>=10%		
NonHazardous							
Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water 7732-18-5	*		231-791-2	No data available	Not Listed	No data available	No data available
Sorbitol solution 50-70-4	*		200-061-5	No data available	Not Listed	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

## Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Sorbitol solution 50-70-4	15900	No data available	No data available	No data available	No data available
Irinotecan Hydrochloride 100286-90-6	867	No data available	No data available	No data available	No data available
Lactic acid 50-21-5	3543	2000	7.94	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

## Additional information

+ Substance with a Union workplace exposure limit

\* Proprietary

\*\* to adjust pH

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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

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immediately.

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

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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

**Note to physicians** None.

## **Section 5: FIRE-FIGHTING MEASURES**

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO2, alcohol-resistant foam or water spray.

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

**Specific hazards arising from the chemical** Not flammable.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **Section 6: ACCIDENTAL RELEASE MEASURES**

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

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

#### **Advice on safe handling**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and

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implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

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

**Storage Conditions** Store as directed by product packaging.

## 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical product used as. Antineoplastic.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

Refer to available public information for specific member state Occupational Exposure Limits.

#### **Irinotecan Hydrochloride**

Pfizer OEL TWA-8 Hr: 2 µg/m<sup>3</sup>

#### **Sorbitol solution**

Russia

MAC: 10 mg/m<sup>3</sup>

#### **Sodium hydroxide**

ACGIH OEL (Ceiling)

2 mg/m<sup>3</sup>

ACGIH TLV

Ceiling: 2 mg/m<sup>3</sup>

Austria

2 mg/m<sup>3</sup>

STEL 4 mg/m<sup>3</sup>

Bulgaria

2.0 mg/m<sup>3</sup>

Czech Republic

1 mg/m<sup>3</sup>

Ceiling: 2 mg/m<sup>3</sup>

Denmark

Ceiling: 2 mg/m<sup>3</sup>

Estonia

1 mg/m<sup>3</sup>

STEL: 2 mg/m<sup>3</sup>

Finland

Ceiling: 2 mg/m<sup>3</sup>

France

2 mg/m<sup>3</sup>

Hungary

1 mg/m<sup>3</sup>

STEL: 2 mg/m<sup>3</sup>

Ireland

STEL: 2 mg/m<sup>3</sup>

Ceiling Limit Value

2 mg/m<sup>3</sup>

Latvia

0.5 mg/m<sup>3</sup>

Poland

STEL: 1 mg/m<sup>3</sup>

0.5 mg/m<sup>3</sup>

Romania

1 mg/m<sup>3</sup>

STEL: 3 mg/m<sup>3</sup>

Slovakia

2 mg/m<sup>3</sup>

Spain

STEL: 2 mg/m<sup>3</sup>

Switzerland

2 mg/m<sup>3</sup>

STEL: 2 mg/m<sup>3</sup>

OSHA PEL

2 mg/m<sup>3</sup>

(vacated) Ceiling: 2 mg/m<sup>3</sup>

United Kingdom

STEL: 2 mg/m<sup>3</sup>

#### **+ Hydrochloric Acid**

ACGIH OEL (Ceiling)

2 ppm

ACGIH TLV

Ceiling: 2 ppm

Austria

5 ppm

8 mg/m<sup>3</sup>

STEL 10 ppm

STEL 15 mg/m<sup>3</sup>

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Bulgaria	STEL: 10 ppm STEL: 15.0 mg/m <sup>3</sup> 5 ppm 8.0 mg/m <sup>3</sup>
Czech Republic	8 mg/m <sup>3</sup> Ceiling: 15 mg/m <sup>3</sup>
Denmark	Ceiling: 5 ppm Ceiling: 8 mg/m <sup>3</sup>
Estonia	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
European Union	TWA: 5 ppm TWA: 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Finland	STEL: 5 ppm STEL: 7.6 mg/m <sup>3</sup>
Germany	2 ppm 3.0 mg/m <sup>3</sup> Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m <sup>3</sup>
Germany	2 ppm 3 mg/m <sup>3</sup>
Hungary	8 mg/m <sup>3</sup> STEL: 16 mg/m <sup>3</sup>
Ireland	8 mg/m <sup>3</sup> 5 ppm STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Italy	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Ceiling Limit Value	2 ppm 3.0 mg/m <sup>3</sup>
Latvia	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Netherlands	8 mg/m <sup>3</sup> STEL: 15 mg/m <sup>3</sup>
Poland	STEL: 10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Romania	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Russia	MAC: 5 mg/m <sup>3</sup>
Slovakia	5 ppm 8.0 mg/m <sup>3</sup>
Spain	5 ppm 7.6 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Switzerland	2 ppm 3 mg/m <sup>3</sup> STEL: 4 ppm STEL: 6 mg/m <sup>3</sup>
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm

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OSHA PEL	7 mg/m <sup>3</sup> (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m <sup>3</sup> Ceiling: 5 ppm
United Kingdom	Ceiling: 7 mg/m <sup>3</sup> TWA: 1 ppm TWA: 2 mg/m <sup>3</sup> STEL: 5 ppm STEL: 8 mg/m <sup>3</sup>

**Analytical Method:** Analytical method available for Irinotecan hydrochloride. Contact Pfizer Inc for further information.

## 8.2. Exposure controls

**Engineering controls** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Environmental exposure controls** No information available.

**Personal protective equipment** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Eye/face protection** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

**Hand protection** Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

**Skin and body protection** Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

**Respiratory protection** Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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

<b>Physical state</b>	Aqueous solution
<b>Color</b>	Pale yellow
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture

<u>Property</u>	<u>Values</u>
<b>pH</b>	3.5
<b>Melting point / freezing point</b>	No data available

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<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	Soluble Water
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## **Partition Coefficient: (Method, pH, Endpoint, Value)**

Irinotecan Hydrochloride  
Measured N/A Log P 4.37

## **9.2. Other information**

No information available

### **9.2.1. Information with regard to physical hazard classes**

No information available

### **9.2.2. Other safety characteristics**

No information available

## **Section 10: STABILITY AND REACTIVITY**

### **10.1. Reactivity**

**Reactivity** No data available.

### **10.2. Chemical stability**

**Stability** Stable under normal conditions.

### **Explosion data**

**Sensitivity to Mechanical Impact** No data available.

**Sensitivity to Static Discharge** No data available.

### **10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** No information available.

### **10.4. Conditions to avoid**

**Conditions to avoid** Fine particles (such as dust and mists) may fuel fires/explosions.

### **10.5. Incompatible materials**

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

### **10.6. Hazardous decomposition products**

**Hazardous decomposition products** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**



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## 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

**General Information:** The information included in this section describes the potential hazards of the individual ingredients  
**Short term** May be harmful if swallowed (based on components)  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on gastrointestinal system Animal studies have shown a potential to cause adverse effects on the fetus.  
**Known Clinical Effects:** Effects reported during clinical use included vomiting and diarrhea. Effects on blood and blood-forming organs have also occurred. Serious allergic reactions, including anaphylaxis, have been reported.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### Sorbitol solution

Rat Oral LD50 15,900 mg/kg  
Mouse Oral LD50 17,800 mg/kg

#### Irinotecan Hydrochloride

Rat Oral LD 50 867 mg/kg  
Rat Oral LD 50 1026 mg/kg

#### Lactic acid

Rat Oral LD50 3543 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

#### Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Sorbitol solution	= 15900 mg/kg ( Rat )	-	-
Irinotecan Hydrochloride	= 867 mg/kg ( Rat )	-	-
Lactic acid	= 3543 mg/kg ( Rat )	> 2000 mg/kg ( Rabbit )	> 7.94 mg/L ( Rat ) 4 h
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-
+ Hydrochloric Acid	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### Irritation / Sensitization: (Study Type, Species, Severity)

#### Irinotecan Hydrochloride

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit No effect  
Antigenicity- Passive cutaneous anaphylaxis Mouse Negative

#### Lactic acid

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate Severe

#### Sodium hydroxide

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

#### + Hydrochloric Acid

Skin irritation Severe  
Eye irritation Severe

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Irinotecan Hydrochloride

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4 Week(s) Rat Oral 10 mg/kg/day LOAEL Bone marrow, Gastrointestinal System  
6 Month(s) Rat Intravenous (M) 0.16 / (F) 0.8 mg/kg/day NOAEL Blood, Bone Marrow, Male reproductive system  
4 Week(s) Dog Oral 1 mg/kg/day NOAEL Gastrointestinal system, Bone Marrow  
26 Week(s) Dog Intravenous 0.01 mg/kg/day NOAEL Blood

## **Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Irinotecan Hydrochloride**

Embryo / Fetal Development Rat Intravenous 6 mg/kg/day NOAEL Fetotoxicity  
Embryo / Fetal Development Rabbit Intravenous 6 mg/kg/day NOAEL Fetotoxicity  
Prenatal & Postnatal Development Rat Intravenous 6 mg/kg/day LOAEL Neonatal toxicity  
Embryo / Fetal Development Rat Intravenous 0.24 mg/kg/day NOAEL Teratogenic  
Embryo / Fetal Development Rabbit Intravenous 0.06 mg/kg/day NOAEL Teratogenic

### **Lactic acid**

Reproductive & Fertility Rat Oral 6.25 mg/kg/day NOEL Fertility, Not teratogenic

## **Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

### **Irinotecan Hydrochloride**

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vitro* Cytogenetics Chinese Hamster Ovary (CHO) cells Positive  
*In Vivo* Micronucleus Mouse Positive

### **+ Hydrochloric Acid**

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vivo* Micronucleus Rat Negative

## **Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Irinotecan Hydrochloride**

104 Week(s) Rat Intravenous 2 mg/kg/week NOAEL Not carcinogenic

**Carcinogenicity** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### **+ Hydrochloric Acid**

IARC Group 3 (Not Classifiable)

## **11.2. Information on other hazards**

### **11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** No information available.

### **11.2.2. Other information**

**Other adverse effects** No information available.

## **Section 12: ECOLOGICAL INFORMATION**

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

### **12.1. Toxicity**

**No information available**

### **12.2. Persistence and degradability**

**Persistence and degradability** No information available.

### **12.3. Bioaccumulative potential**

**Bioaccumulation** No information available.

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## Partition Coefficient: (Method, pH, Endpoint, Value)

### Irinotecan Hydrochloride

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## 12.4. Mobility in soil

**Mobility in soil** No information available.

## 12.5. Results of PBT and vPvB assessment

### PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Lactic acid	The substance is not PBT / vPvB
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
+ Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does not apply

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. Other adverse effects

No information available.

## **Section 13: DISPOSAL CONSIDERATIONS**

### 13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## **Section 14: TRANSPORT INFORMATION**

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## **Section 15: REGULATORY INFORMATION**

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %  
California Proposition 65

Not Listed  
Not Listed

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<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present
Sorbitol solution	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-061-5
<b>AICS</b>	Present
Irinotecan Hydrochloride	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
Lactic acid	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-018-0
<b>AICS</b>	Present
Sodium hydroxide	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6
+ Hydrochloric Acid	
<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-595-7
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

### Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid - 7647-01-0	25	250

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## EU - Biocides

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

### Legend:

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

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed. Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled. Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage. Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage. Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation. Reproductive toxicity-Cat.1B; H360D - May damage the unborn child. Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects.

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

**Revision date** 06-Dec-2021

**Prepared By** Pfizer Global Environment, Health, and Safety

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