SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Irinotecan Hydrochloride Injection (Hospira, Inc.)

Product Code(s) PZ03118
Trade Name: Not applicable
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

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

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

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

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

OSHA Classification

Hazards not otherwise classified (HNOC)
Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200
Not applicable

2.2. Label elements

Signal word Danger
Hazard statements H341 - Suspected of causing genetic defects
H360D - May damage the unborn child

Precautionary Statements - EU (§28, 1272/2008) 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 advice/attention
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

2.3. Other hazards

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

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

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 (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Irinotecan Hydrochloride (CAS #: 100286-90-6)	2%		Not Listed	Acute Tox.4 (H302) Repr.1B (H360D) Muta.2 (H341)	Not classified	No data available	No data available
Lactic acid (CAS #: 50-21-5)	<1.0		200-018-0	Eye Dam. 1 (H318)	Not classified	No data available	No data available

				Skin Irrit. 2 (H315)			
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	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 (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Sorbitol solution (CAS #: 50-70-4)	*		200-061-5	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	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

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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

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.

Explosion data
Sensitivity to mechanical impact No information available.
Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions 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 dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and 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/m³

Sorbitol solution

Russia	MAC: 10 mg/m³

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m³
ACGIH TLV	Ceiling: 2 mg/m³
Austria	TWA-TMW: 2 mg/m³; inhalable fraction STEL-KZGW: 4 mg/m³ (8 X 5 min); inhalable fraction
Bulgaria	TWA: 2.0 mg/m³; alkaline aerosols
Czech Republic	1 mg/m³

	Ceiling: 2 mg/m³
Denmark	Ceiling: 2 mg/m³;
Estonia	TWA: 1 mg/m³;
	STEL: 2 mg/m³;
Finland	Ceiling: 2 mg/m³;
France	2 mg/m³
Hungary	TWA-AK: 1 mg/m³;
	STEL-CK: 2 mg/m³;
Ireland	STEL: 2 mg/m³;
Ceiling Limit Value	2 mg/m³
Latvia	TWA: 0.5 mg/m³;
Poland	TWA-NDS: 0.5 mg/m³;
	STEL-NDSCh: 1 mg/m³;
Romania	TWA: 1 mg/m³;
	STEL: 3 mg/m³;
Slovakia	TWA: 2 mg/m³;
Spain	STEL (VLA-EC): 2 mg/m³;
Switzerland	TWA-MAK: 2 mg/m³; inhalable dust
	STEL-KZGW: 2 mg/m³; inhalable dust
OSHA PEL	TWA: 2 mg/m³
	(vacated) Ceiling: 2 mg/m³
United Kingdom	STEL: 2 mg/m³;
+ Hydrochloric Acid	
ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	TWA-TMW: 5 ppm;
	TWA-TMW: 8 mg/m³;
	STEL-KZGW: 10 ppm (8 X 5 min);
	STEL-KZGW: 15 mg/m³ (8 X 5 min);
Bulgaria	TWA: 5 ppm;
	TWA: 8.0 mg/m³;
	STEL: 10 ppm;
	STEL: 15.0 mg/m³;
Czech Republic	8 mg/m³
	Ceiling: 15 mg/m³
Denmark	STEL: 5 ppm;
	STEL: 8 mg/m³;
Estonia	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
European Union	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Finland	STEL: 5 ppm;
	STEL: 7.6 mg/m³;
Germany DFG	TWA-MAK: 2 ppm; I(2);
	TWA-MAK: 3.0 mg/m³; I(2);
	Peak: 4 ppm;
	Peak: 6 mg/m³;
Germany TRGS	TWA-AGW; 2 ppm (exposure factor 2);
	TWA-AGW; 3 mg/m³ (exposure factor 2);
Hungary	TWA-AK: 8 mg/m³;
	TWA-AK: 5 ppm;
	STEL-CK: 165 mg/m³;
	STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m³;

	TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m³;
Italy MDLPS	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Ceiling Limit Value	2 ppm 3.0 mg/m³
Latvia	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Netherlands	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Poland	TWA-NDS: 5 mg/m³; STEL-NDSCh: 10 mg/m³;
Romania	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Russia	MAC: 5 mg/m³
Slovakia	TWA: 5 ppm; TWA: 8.0 mg/m³; Ceiling: 15 mg/m³;
Spain	TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m³; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m³;
Switzerland	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m³; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m³;
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m³
OSHA PEL	Ceiling: 5 ppm Ceiling: 7 mg/m³ (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m³
United Kingdom	TWA: 1 ppm; gas and aerosol mist TWA: 2 mg/m³; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m³; gas and aerosol mist

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.

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.).

Thermal hazards No information available.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	aqueous solution
Physical state	Liquid
Color	Pale yellow
Odor	No information available.
Odor threshold	No information available

Property	**Values**
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	3.5
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	Soluble Water
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available

Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)
Irinotecan Hydrochloride
Measured N/A Log P 4.37

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

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 information available.

10.2. Chemical stability

Stability	Stable under normal conditions.
Explosion data	
Sensitivity to mechanical impact	No information available.
Sensitivity to static discharge	No information 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

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	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.

Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Classification is based on mixture calculation methods based on component data.
Germ cell mutagenicity	Classification is based on mixture calculation methods based on component data.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

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 (M) Oral LD 50 867 mg/kg
Rat (F) Oral LD 50 1026 mg/kg
Mouse (M) Oral LD50 1045 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Lactic acid

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

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

+ Hydrochloric Acid

Skin irritation Severe
Eye irritation Severe

Lactic acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate Severe

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

Irinotecan Hydrochloride

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

11.2. Information on other hazards
11.2.1. Endocrine disrupting properties
Endocrine disrupting properties Based on available data, the classification criteria are not met.

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

Partition Coefficient: (Method, pH, Endpoint, Value)
Irinotecan Hydrochloride
Measured N/A Log P 4.37

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
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply
Lactic acid	Not PBT/vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.
PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products
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.

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

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 %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

Sorbitol solution

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-061-5
AICS	Present

Irinotecan Hydrochloride

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

Lactic acid

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-018-0
AICS	Present

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

+ Hydrochloric Acid

CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable
Storage of Hazardous Material Not applicable
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable
Major Accidents Ordinance SR 814.012 Not applicable

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	75	-
+ Hydrochloric Acid 7647-01-0	75	-

Persistent Organic Pollutants

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

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Lactic acid 50-21-5	Simplified procedure - Category 1
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15
H302 - Harmful if swallowed H331 - Toxic if inhaled H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage H315 - Causes skin irritation H335 - May cause respiratory irritation

Data Sources:	Publicly available toxicity information. Pfizer proprietary drug development information.
Reason for revision	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 11 - Toxicology Information.
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Prepared By	Pfizer Global Environment, Health, and Safety

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