MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Irinotecan Hydrochloride Injection

Trade Name: CAMPTOSAR; CAMPTO
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Clear, pale yellow sterile solution
Signal Word: WARNING

Statement of Hazard: Suspected of damaging the unborn child.
Possible mutagen

Additional Hazard Information:
Short Term: Not an eye irritant (based on components) . May cause skin irritation to cut or abraded skin. Active ingredient is not a skin irritant ; May be harmful if swallowed. (based on animal data) .
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.

EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic Category 3

EU Hazard Symbols:

EU Risk Phrases:
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Irinotecan Hydrochloride	100286-90-6	Not listed	Mut. Cat.3;R68 Repr. Cat.3;R61 Xn;R22	2%
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Lactic acid	50-21-5	200-018-0	Not Listed	*
Hydrogen chloride	7647-01-0	231-595-7	C;R35 T;R23	**

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sorbitol crystalline - NF	50-70-4	200-061-5	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General 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.

Storage Conditions: Store as directed by product packaging. Protect from light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Irinotecan Hydrochloride

Pfizer OEL TWA-8 Hr:	2 µg/m^3

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	= 2 mg/m^3 Ceiling
Australia PEAK	= 2 mg/m^3 Peak
Austria OEL - MAKs	= 2 mg/m^3 MAK
Belgium OEL - TWA	= 2 mg/m^3 TWA
Bulgaria OEL - TWA	= 2.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 1 mg/m^3 TWA
Finland OEL - TWA	= 2 mg/m^3 TWA
France OEL - TWA	= 2 mg/m^3 VME
Greece OEL - TWA	= 2 mg/m^3 TWA
Hungary OEL - TWA	= 2 mg/m^3 TWA
Latvia OEL - TWA	= 0.5 mg/m^3 TWA
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	= 0.5 mg/m^3 NDS
Slovakia OEL - TWA	= 2 mg/m^3 TWA
Slovenia OEL - TWA	= 2 mg/m^3 TWA
Sweden OEL - TWAs	= 1 mg/m^3 LLV

Hydrogen chloride

ACGIH Ceiling Threshold Limit:	= 2 ppm Ceiling
Australia PEAK	= 5 ppm Peak
	= 7.5 mg/m^3 Peak

Austria OEL - MAKs	= 5 ppm MAK = 8 mg/m^3 MAK
Belgium OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Bulgaria OEL - TWA	= 8.0 mg/m^3 TWA
Cyprus OEL - TWA	= 5.0 ppm TWA = 8.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 8 mg/m^3 TWA
Estonia OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Germany - TRGS 900 - TWAs	= 2 ppm TWA = 3 mg/m^3 TWA
Greece OEL - TWA	= 5 ppm TWA = 7 mg/m^3 TWA
Hungary OEL - TWA	= 8 mg/m^3 TWA
Ireland OEL - TWAs	= 5 ppm TWA = 7 mg/m^3 TWA
Italy OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Latvia OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Lithuania OEL - TWA	= 5 ppm IPRV = 8 mg/m^3 IPRV
Luxembourg OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Malta OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Netherlands OEL - TWA	= 5 ppm MAC = 8 mg/m^3 MAC
Poland OEL - TWA	= 5 mg/m^3 NDS
Romania OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Slovakia OEL - TWA	= 5 ppm TWA = 8.0 mg/m^3 TWA
Slovenia OEL - TWA	= 5 ppm TWA anhydrous = 8 mg/m^3 TWA anhydrous
Spain OEL - TWA	= 5 ppm VLA-ED = 7.6 mg/m^3 VLA-ED

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

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:

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. Wash hands and arms thoroughly after handling this material.

Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Aqueous solution	**Color:**	Pale yellow
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solubility: Soluble: Water
pH: 3.5

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Exposure to light
Incompatible Materials: Bases

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

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

Hydrogen chloride
Rat Inhalation LC50 1H 3,124 ppm
Mouse Inhalation LC50 1H 1,108 ppm
Mouse Oral LD50 900 mg/kg

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

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 0.016 mg/kg/day NOAEL Blood, Bone Marrow, Male reproductive system
4 Week(s) Dog Oral 1 mg/kg/day NOAEL Bone Marrow, Gastrointestinal system
26 Week(s) Dog Intravenous 0.01 mg/kg/day NOAEL Blood

Reproduction & Developmental Toxicity: (Study Type, 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

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

Irinotecan Hydrochloride
104 Week(s) Rat Intravenous 2 mg/kg/week NOAEL Not carcinogenic
Carcinogenicity Comments Animals in this study were dosed for 91 days, and they were observed for 91 weeks.

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Hydrogen chloride
IARC: Group 3

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic Category 3

EU Risk Phrases:

R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

EU Safety Phrases:

S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Suspected of damaging the unborn child.
Possible mutagen

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
Class D, Division 2, Subdivision B

Sorbitol crystalline - NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-061-5

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Lactic acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-018-0

Hydrogen chloride

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 5000 lb EPCRA RQ gas only
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R23 - Toxic by inhalation.
R35 - Causes severe burns.
R61 - May cause harm to the unborn child.
R68 - Possible risks of irreversible effects.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet