MATERIAL SAFETY DATA SHEET

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

Pfizer Global Manufacturing
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Emergency telephone number:
1-212-573-2222
Hours of Operation - 24 Hours
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

Trade Name:	Not applicable
Compound Number:	PNU-00101440E
Synonyms:	CPT-11
Chemical Family:	Not determined
Intended Use:	Pharmaceutical active

2. HAZARDS IDENTIFICATION

Appearance: Light yellow crystalline powder
Signal Word: WARNING

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

Additional Hazard Information:

Short Term: Minimal eye irritant in experimental animals . 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
Harmful
Mutagenic Category 3

EU Hazard Symbols:

EU Risk Phrases:

R22 - Harmful if swallowed.
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	100

Additional Information: 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: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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: Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Irinotecan Hydrochloride
Pfizer OEL TWA-8 Hr: 2 µg/m^3

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Equipment:

Hands: Wear impervious gloves as minimum protection.
Eyes: Wear safety glasses as minimum protection.
Skin: Wear impervious protective clothing when handling this compound.
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:	Crystalline powder	**Color:**	Light yellow
Molecular Formula:	C33H38N4O6 * HCl * 3H2O	**Molecular Weight:**	677.19

Solubility: Slightly Soluble: Water
pH: 3.5-4.5
Partition Coefficient (Calculated; pH 7.4 - Log D): 1.54

Partition Coefficient (Measured - Log Pow/Log Kow): 4.37

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.
Conditions to Avoid: Fine particles (such as mists) may fuel fires/explosions.
Incompatible Materials: No data available

Decomposition Temperature (°C): 256.5

11. TOXICOLOGICAL INFORMATION

1.3

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

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

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

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

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

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: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Partition Coefficient (Calculated; pH 7.4 - Log D):	1.54
Partition Coefficient (Measured - Log Pow/Log Kow):	4.37

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
Harmful
Mutagenic Category 3

EU Risk Phrases:

R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

EU Safety Phrases:

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

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

Canada - WHMIS: Classifications

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

Data Sources:	Pfizer proprietary drug development information.
Reasons for Revision:	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information.
Prepared by:	Corporate Occupational Toxicology & Hazard Assessment

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