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

Product Identifier

Material Name: Irinotecan Hydrochloride Injection
Trade Name: CAMPTOSAR; CAMPTO
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used as Antineoplastic

Details of the Supplier of the Safety Data Sheet
Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
Germ Cell Mutagenicity: Category 2
Reproductive Toxicity: Category 1B

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
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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irinotecan Hydrochloride</td>
<td>100286-90-6</td>
<td>Not Listed</td>
<td>Acute Tox.4 (H302) Repr.1B (H360D) Muta.2 (H341)</td>
<td>2%</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr.1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>50-21-5</td>
<td>200-018-0</td>
<td>Eye Dam. 1 (H318) Skin Irrit. 2 (H315)</td>
<td>*</td>
</tr>
<tr>
<td>Hydrogen chloride</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>STOT SE 3 (H335) Skin Corr. 1A (H314) Press. Gas Acute Tox. 3 (H331)</td>
<td>**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol crystalline - NF</td>
<td>50-70-4</td>
<td>200-061-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary
** to adjust pH

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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed
SAFETY DATA SHEET

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.

Medical Conditions Aggravated by Exposure: None known

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Not flammable.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for 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 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical product used as Antineoplastic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Irinotecan Hydrochloride

Pfizer OEL TWA-8 Hr: 2 µg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sodium hydroxide

ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK 2 mg/m³
Austria OEL - MAKs 2 mg/m³
Bulgaria OEL - TWA 2.0 mg/m³
Czech Republic OEL - TWA 1 mg/m³
Estonia OEL - TWA 1 mg/m³
France OEL - TWA 2 mg/m³
Greece OEL - TWA 2 mg/m³
Hungary OEL - TWA 2 mg/m³
Japan - OELs - Ceilings 2 mg/m³
Latvia OEL - TWA 0.5 mg/m³
OSHA - Final PELS - TWAs: 2 mg/m³
Poland OEL - TWA 0.5 mg/m³
Slovakia OEL - TWA 2 mg/m³
Slovenia OEL - TWA 2 mg/m³
Sweden OEL - TWAs 1 mg/m³
Switzerland OEL - TWAs 2 mg/m³

Hydrogen chloride

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
Belgium OEL - TWA 5 ppm
Bulgaria OEL - TWA 5 ppm
Cyprus OEL - TWA 5 ppm
Czech Republic OEL - TWA 8 mg/m³
Estonia OEL - TWA 5 ppm
Germany - TRGS 900 - TWAs 2 ppm
Germany (DFG) - MAK 2 ppm
3.0 mg/m³
Greece OEL - TWA 5 ppm
Hungary OEL - TWA 8 mg/m³
Ireland OEL - TWAs 5 ppm
Italy OEL - TWA 5 ppm
Japan - OELs - Ceilings 2 ppm
Latvia OEL - TWA 5 ppm
Lithuania OEL - TWA 5 ppm
8 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Analytical Method:

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

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.

Hands:
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.)

Eyes:
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.)

Skin:
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.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Aqueous solution</th>
<th>Color:</th>
<th>Pale yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| Solvent Solubility:          | No data available                 |                          |                     |
| Water Solubility:            | No data available                 |                          |                     |
| Solubility:                  | Soluble: Water                    |                          |                     |
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>3.5</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Irinotecan Hydrochloride Measured N/A Log P 4.37</td>
</tr>
<tr>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No data available</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td></td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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.

IRINOTECAN HYDROCHLORIDE INJECTION
11. TOXICOLOGICAL INFORMATION

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

Irinotecan Hydrochloride
Rat  Oral  LD50  867 mg/kg
Rat  Oral  LD50  1026mg/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  Sub-tenon injection (eye)  LC50 1H  3,124 ppm
Mouse  Inhalation  LC50 1H  1,108ppm
Mouse  Oral  LD50  900mg/kg

Sorbitol crystalline - NF
Mouse  Oral  LD50  17,800 mg/kg
Rat  Para-periosteal  LD50  7100mg/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))
11. TOXICOLOGICAL INFORMATION

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

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

Hydrogen chloride
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:  No data available

Persistence and Degradability:  No data available

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

Mobility in Soil:  No data available
13. DISPOSAL CONSIDERATIONS

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 waste water 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.

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.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Irinotecan Hydrochloride
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Sorbitol crystalline - NF
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- 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 313 Emission reporting: Not Listed
- CERCLA/SARA Hazardous Substances and their Reportable Quantities: 1000 lb, 454 kg
- California Proposition 65: Not Listed
- 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
15. REGULATORY INFORMATION

**Lactic acid**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-018-0

**Water**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- 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

**Hydrogen chloride**
- CERCLA/SARA 313 Emission reporting: 1.0 %
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - 5000 lb
  - 2270 kg
- CERCLA/SARA - Section 302 Extremely Hazardous TPQs: 500 lb
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs: 5000 lb
- California Proposition 65: Not Listed
- 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: 231-595-7

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in 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
- Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:** 10-Aug-2016

**Prepared by:** Product Stewardship Hazard Communication

Pfizer Global Environment, Health, and Safety Operations
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