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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
- Germ Cell Mutagenicity: Category 2
- Reproductive Toxicity: Category 1B

EU Classification:
- 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.

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
### 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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<tbody>
<tr>
<td>Irinotecan Hydrochloride</td>
<td>100286-90-6</td>
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<td>Mut. Cat.3;R68 Repr. Cat.3;R61 Xn;R22</td>
<td>Acute Tox.4 (H302) Repr.1B (H360D) Muta.2 (H341)</td>
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<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C; R35</td>
<td>Skin Corr. 1A (H314)</td>
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<td>Lactic acid</td>
<td>50-21-5</td>
<td>200-018-0</td>
<td>Xi; R38-41</td>
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<td>Hydrogen chloride</td>
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<td>231-595-7</td>
<td>T; R23 C; R35</td>
<td>STOT SE 3 (H335) Skin Corr. 1A (H314) Press. Gas Acute Tox. 3 (H331)</td>
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<table>
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<th>Ingredient</th>
<th>CAS Number</th>
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<th>EU Classification</th>
<th>GHS Classification</th>
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<tbody>
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<td>Water</td>
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<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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</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 R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of First Aid Measures**
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.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**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

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:**
None

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 Products:**
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

Specific end use(s):
Pharmaceutical drug product

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

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:
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
Austria OEL - MAKs 5 ppm
8 mg/m³
Belgium OEL - TWA 5 ppm
8 mg/m³
Bulgaria OEL - TWA 5 ppm
8.0 mg/m³
Cyprus OEL - TWA 5 ppm
8 mg/m³
Czech Republic OEL - TWA 8 mg/m³
Estonia OEL - TWA 5 ppm
8 mg/m³
Germany - TRGS 900 - TWAs 2 ppm
3 mg/m³
Germany (DFG) - MAK 2 ppm
3.0 mg/m³
Greece OEL - TWA 5 ppm
7 mg/m³
Hungary OEL - TWA 8 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Value</th>
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<tr>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Japan - OELs - Ceilings</td>
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<td></td>
<td>7.5 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
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<td></td>
<td>8 mg/m³</td>
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<td>Slovakia OEL - TWA</td>
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<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Slovenia OEL - TWA</td>
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<tr>
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<td>8 mg/m³</td>
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<td>7.6 mg/m³</td>
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<td>Switzerland OEL - TWAs</td>
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<td></td>
<td>3.0 mg/m³</td>
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<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>


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:

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

Odor: No data available.

Odor Threshold: No data available.

Molecular Formula: Mixture

Molecular Weight: Mixture

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

Water Solubility: No data available
Solubility: Soluble: Water
pH: 3.5
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

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

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.
11. TOXICOLOGICAL INFORMATION

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)

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

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

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

Hydrogen chloride

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

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

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

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: EU EINECS/ELINCS List 200-061-5

Sodium hydroxide
CERCLA/SARA 313 Emission reporting Not Listed
15. REGULATORY INFORMATION

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<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA Hazardous Substances</th>
<th>1000 lb</th>
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<tbody>
<tr>
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<td>California Proposition 65</td>
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<td>Australia (AICS):</td>
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<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
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Water

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<th>Substance</th>
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<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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Lactic acid

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Hydrogen chloride

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<td>Schedule 5</td>
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<tr>
<td>EU EINECS/ELINCS List</td>
<td>231-595-7</td>
<td></td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases and 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
C - Corrosive
Mutagenic: Category 3
Toxic to Reproduction: Category 3
Xi - Irritant
Xn - Harmful
T - Toxic

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 7 - Handling and Storage. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

Revision date: 07-Mar-2015
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