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

Material Name: Etoposide Soft Gelatin Capsules
Trade Name: Lastet; Citodox
Chemical Family: Mixture
Intended Use: Pharmaceutical active used for Antineoplastic

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etoposide</td>
<td>33419-42-0</td>
<td>251-509-1</td>
<td>7.8</td>
</tr>
<tr>
<td>Glycerol</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>*</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>*</td>
</tr>
<tr>
<td>Iron oxide</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>*</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>###</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>*</td>
</tr>
<tr>
<td>Macrogol 400</td>
<td>Not assigned</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>*</td>
</tr>
<tr>
<td>Ethylparaben</td>
<td>120-47-8</td>
<td>204-399-4</td>
<td>*</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>6706-59-8</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>*</td>
</tr>
<tr>
<td>Purified water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>###</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: Capsules
Signal Word: WARNING
Statement of Hazard: May be harmful if swallowed.  
May cause adverse effects on blood forming organs. 
May cause harm to the unborn child. 
Mutagen 
Possible carcinogen

Additional Hazard Information:

Short Term: May cause eye and skin irritation; Harmful if swallowed (based on components).

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. 

Known Clinical Effects: Bone marrow suppression is the most serious adverse effect seen during clinical use. 
Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

EU Indication of danger: Carcinogenic: Category 2 
Toxic to Reproduction: Category 2 
Mutagenic Category 2 

EU Hazard Symbols: 

EU Risk Phrases:
R45 - May cause cancer. 
R46 - May cause heritable genetic damage. 
R61 - May cause harm to the unborn child.

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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

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 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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Etoposide
Pfizer OEL TWA-8 Hr: 0.7 ug/m³

Glycerol
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA)
Australia TWA = 10 mg/m³ TWA

Iron oxide
OSHA - Final PELS - TWAs: = 10 mg/m³ TWA

ACGIH Threshold Limit Value (TWA)
Australia TWA = 5 mg/m³ TWA

Hydrochloric Acid
ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling
Australia PEAK = 5 ppm Peak
= 7.5 mg/m³ Peak

Titanium dioxide
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:
Hands: Wear impervious gloves if skin contact is possible.
Material Name: Etoposide Soft Gelatin Capsules
Revision date: 29-Mar-2007
Version: 2.0

8. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Soft gelatin capsule</th>
<th>Color:</th>
<th>No data available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

**Etoposide**
- Rat Oral LD50 1784 mg/kg
- Rat Intravenous LD50 58 mg/kg
- Mouse Oral LD50 215 mg/kg
- Mouse Intravenous LD50 15.07 mg/kg
- Rabbit Oral LD50 147 mg/kg

**Glycerol**
- Rat Oral LD50 12600 mg/kg

**Citric acid**
- Rat Oral LD50 3000 mg/kg

**Titanium dioxide**
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD50 50 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)

**Glycerol**
- Skin Irritation Rabbit Mild
- Eye Irritation Rabbit Mild

**Citric acid**
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Mild
Hydrochloric Acid
Skin Irritation  Severe
Eye Irritation  Severe

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

Etoposide
3 Month(s)  Rat  Intravenous  0.5 mg/kg/day  LOAEL  Male reproductive system

Glycerol
28 Day(s)  Rat  Oral  16800 mg/kg  LOAEL  Endocrine system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Etoposide
Embryo / Fetal Development  Mouse  Intraperitoneal  0.5 mg/kg/day  LOAEL  Teratogenic
Embryo / Fetal Development  Rat  Intravenous  0.13 mg/kg/day  LOAEL  Developmental toxicity
Embryo / Fetal Development  Mouse  Intravenous  1.2 mg/kg/day  LOAEL  Fetotoxicity, Teratogenic
Embryo / Fetal Development  Mouse  Intraperitoneal  1.5 mg/kg/day  LOAEL  Fetotoxicity, Teratogenic
Embryo / Fetal Development  Mouse  Intraperitoneal  2 mg/kg  LOAEL  Fetotoxicity, Teratogenic

Glycerol
Reproductive & Fertility-Males  Rat  Oral  100 mg/kg  LOEL  Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Etoposide
In Vitro Chromosome Aberration  Mouse  Positive
Sister Chromatid Exchange  Chinese Hamster Ovary (CHO) cells  Positive
Mammalian Cell Mutagenicity  Chinese Hamster Ovary (CHO) cells  Positive
Direct DNA Interaction  Positive
Chromosome Aberration  Human Lymphocytes  Positive

Carcinogen Status:  See below

Etoposide
IARC:  Group 2A - Probably Carcinogenic to Humans
OSHA:  Present

Titanium dioxide
IARC:  Group 2B
OSHA:  Present

Iron oxide
IARC:  Group 3

Hydrochloric Acid
IARC:  Group 3
Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Carcinogenic: Category 2
Toxic to Reproduction: Category 2
Mutagenic Category 2

EU Risk Phrases:
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.

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
May be harmful if swallowed.
May cause adverse effects on blood forming organs.
May cause harm to the unborn child.
Mutagen
Possible carcinogen

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
Etoposide
  California Proposition 65
  Australia (AICS):
  Standard for the Uniform Scheduling
  for Drugs and Poisons:
  EU EINECS List

Glycerol
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  EU EINECS List

Citric acid
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  EU EINECS List

Hydroxypropyl cellulose
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):

Iron oxide
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  Standard for the Uniform Scheduling
  for Drugs and Poisons:
  EU EINECS List

Gelatin
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  EU EINECS List

Ethylparaben
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  EU EINECS List

Hydrochloric Acid
  CERCLA/SARA 313 Emission reporting
  CERCLA/SARA Hazardous Substances
  and their Reportable Quantities:
  CERCLA/SARA - Section 302 Extremely Hazardous
  Substances EPCRA RQs
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  Standard for the Uniform Scheduling
  for Drugs and Poisons:
  EU EINECS List

Propylparaben
MATERIAL SAFETY DATA SHEET

Material Name: Etoposide Soft Gelatin Capsules
Revision date: 29-Mar-2007

16. OTHER INFORMATION

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Hazard Identification. Updated Section 15 - Regulatory Information.

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

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End of Safety Data Sheet