



# MATERIAL SAFETY DATA SHEET

Revision date: 29-Mar-2007

Version: 2.0

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## 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**

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

**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

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Etoposide	33419-42-0	251-509-1	7.8
Glycerol	56-81-5	200-289-5	*
Citric acid	77-92-9	201-069-1	*
Iron oxide	1309-37-1	215-168-2	*
Hydrochloric Acid	7647-01-0	231-595-7	###
Titanium dioxide	13463-67-7	236-675-5	*

Ingredient	CAS Number	EU EINECS List	%
Macrogol 400	Not assigned	Not listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Gelatin	9000-70-8	232-554-6	*
Ethylparaben	120-47-8	204-399-4	*
Sorbitol	6706-59-8	Not listed	*
Propylparaben	94-13-3	202-307-7	*
Purified water	7732-18-5	231-791-2	###

**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

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**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

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### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	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.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.
<b>Storage Conditions:</b>	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/m<sup>3</sup>

#### Glycerol

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

#### Iron oxide

OSHA - Final PELs - TWAs: = 10 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 5 mg/m<sup>3</sup> TWA  
Australia TWA = 5 mg/m<sup>3</sup> TWA

#### Hydrochloric Acid

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

#### Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

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

<b>Analytical Method:</b>	Analytical method available for etoposide. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures.
<b>Personal Protective Equipment:</b>	
<b>Hands:</b>	Wear impervious gloves if skin contact is possible.

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**Eyes:** Safety glasses or goggles  
**Skin:** Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.  
**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:** Soft gelatin capsule  
**Color:** No data available.  
**Molecular Formula:** Mixture  
**Molecular Weight:** Mixture

### 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 LD 50 1784 mg/kg  
Rat Intravenous LD 50 58 mg/kg  
Mouse Oral LD 50 215 mg/kg  
Mouse Intravenous LD 50 15.07 mg/kg  
Rabbit Oral LD 50 147 mg/kg

##### **Glycerol**

Rat Oral LD 50 12600 mg/kg

##### **Citric acid**

Rat Oral LD50 3000 mg/kg

##### **Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 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

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### 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 LOEL Male reproductive system

#### Glycerol

28 Day(s) Rat Oral 16800 mg/kg LOEL 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	LOEL	Teratogenic
Embryo / Fetal Development	Rat	Intravenous	0.13 mg/kg/day	LOEL	Developmental toxicity
Embryo / Fetal Development	Mouse	Intravenous	1.2 mg/kg/day	LOEL	Fetotoxicity, Teratogenic
Embryo / Fetal Development	Mouse	Intraperitoneal	1.5 mg/kg/day	LOEL	Fetotoxicity, Teratogenic
Embryo / Fetal Development	Mouse	Intraperitoneal	2 mg/kg	LOEL	Fetotoxicity, Teratogenic

#### Glycerol

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

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

#### Etoposide

<i>In Vitro</i> 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

## 12. ECOLOGICAL INFORMATION

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**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



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### Etoposide

California Proposition 65	Listed: Developmental Toxicity
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	251-509-1

### Glycerol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5

### Citric acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1

### Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

### Iron oxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4 Schedule 5 Schedule 6
EU EINECS List	215-168-2

### Gelatin

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6

### Ethylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-399-4

### Hydrochloric Acid

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 List	231-595-7

### Propylparaben

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-307-7

### Purified water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

### Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

## 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**