



MATERIAL SAFETY DATA SHEET

Revision date: 07-May-2012

Version: 4.0

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

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Material Name: Etoposide Solution for Injection - 20 mg/ml

Trade Name:	Toposar; Citodox; Lastet
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to slightly yellow solution
Signal Word: WARNING

Statement of Hazard: Flammable liquid and vapor.
May cause harm to the unborn child.
May cause genetic defects.
Suspected of causing cancer.

Additional Hazard Information:
Short Term: May cause eye and skin irritation; May be harmful if swallowed. (based on components)
Exposure to high concentrations may cause irritation, headache, drowsiness, and symptoms of alcohol intoxication.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system and the developing fetus. This product contains ethanol which can cause liver changes, central nervous system effects, and birth defects in the developing fetus Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and, if ingested during pregnancy, congenital malformations.

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:

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2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC):

R10 - Flammable.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.
Hazardous Substance. 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	EU Classification	%
Etoposide	33419-42-0	251-509-1	Xn;R22 Carc.Cat.2;R45 Mut.Cat.2;R46 Repr.Cat.2;R61	2
Ethanol	64-17-5	200-578-6	F;R11	30.5
Citric acid	77-92-9	201-069-1	Xi; R36	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Polyoxyethylene (20) sorbitan monooleate	9005-65-6	Not Listed	Not Listed	*

Additional Information:

* Proprietary
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.

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5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon dioxide, carbon monoxide

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

Fire / Explosion Hazards: Flammable liquid.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

Measures for Cleaning / Collecting: Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

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: 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. Wash hands and any exposed skin after removal of PPE. 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.

Storage Conditions: Store as directed by product packaging.

Storage Temperature: Store at 25°C (77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Etoposide

Pfizer OEL TWA-8 Hr: 0.7 µg/m³

Polyethylene glycol

Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ inhalable fraction
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³

Ethanol

ACGIH Threshold Limit Value (STEL) 1000 ppm

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	1000 ppm 1880 mg/m ³
Austria OEL - MAKs	1000 ppm 1900 mg/m ³
Belgium OEL - TWA	1000 ppm 1907 mg/m ³
Bulgaria OEL - TWA	1000.0 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³
Denmark OEL - TWA	1000 ppm 1900 mg/m ³
Estonia OEL - TWA	500 ppm 1000 mg/m ³
Finland OEL - TWA	1000 ppm 1900 mg/m ³
France OEL - TWA	1000 ppm 1900 mg/m ³
Germany - TRGS 900 - TWAs	500 ppm 960 mg/m ³
Germany (DFG) - MAK	500 ppm 960 mg/m ³
Greece OEL - TWA	1000 ppm 1900 mg/m ³
Hungary OEL - TWA	1900 mg/m ³
Ireland OEL - TWAs	1000 ppm 1900 mg/m ³
Latvia OEL - TWA	1000 mg/m ³
Lithuania OEL - TWA	500 ppm 1000 mg/m ³
Netherlands OEL - TWA	260 mg/m ³
OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m ³
Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm 1900 mg/m ³
Slovakia OEL - TWA	500 ppm 960 mg/m ³
Slovenia OEL - TWA	1000 ppm 1900 mg/m ³
Spain OEL - TWA	1000 ppm 1910 mg/m ³
Sweden OEL - TWAs	500 ppm 1000 mg/m ³

Analytical Method:

Analytical method available for etoposide. Contact Pfizer Inc for further information.

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

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:	Solution	Color:	Clear, colorless to pale yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	Slightly Soluble: Water		
pH:	3-4		
Boiling Point (°C):	78		
Flash Point (Liquid) (°C):	21		

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: None known Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electrostatic discharge).

Incompatible Materials: None known

11. TOXICOLOGICAL INFORMATION

General Information: 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	Para-periosteal	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

Ethanol

Mouse	Oral	LD50	3,450 g/m ³
Rat	Oral	LD50	7,060 mg/kg
Mouse	Inhalation	LC50 4h	39 g/m ³
Rat	Inhalation	LC50 10h	20,000 ppm

Citric acid

Rat	Oral	LD50	3000 mg/kg
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11. TOXICOLOGICAL INFORMATION

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

Ethanol

Eye Irritation Rabbit Severe

Polyethylene glycol

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

Citric acid

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

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

1 Month(s) Rat Intravenous 0.15 mg/kg/day LOAEL Blood forming organs, Bone Marrow, Gastrointestinal system, Male reproductive system, Peripheral nervous 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

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

Etoposide

In Vitro Chromosome Aberration Mouse Positive

In Vitro Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive

In Vitro Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Positive

In Vivo Micronucleus Rat Bone Marrow Positive

In Vitro Chromosome Aberration Human Lymphocytes Positive

Carcinogen Status: See below

Etoposide

IARC: Group 1 (Carcinogenic to Humans)

OSHA: Listed

Ethanol

IARC: Group 1 (Carcinogenic to Humans)

OSHA: Listed

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12. ECOLOGICAL INFORMATION

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

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Etoposide

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 12,900 mg/L
Pimephales promelas (Fathead Minnow) LC50 96 Hours 14,200 mg/L
Daphnia Magna (Water Flea) EC50 48 Hours > 61.8 mg/L

Ethanol

Fingerling Trout NPDES LC50 24 Hours 11,200 mg/L
Oncorhynchus mykiss (Rainbow Trout) NPDES LC50 96 Hours 12,900 mg/L
Pimephales promelas (Fathead Minnow) NPDES LC50 96 Hours 14,200 mg/L

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.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 1170
UN proper shipping name: Ethanol solution
Transport hazard class(es): 3
Packing group: II
Flash point: 21C

15. REGULATORY INFORMATION

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

EU Risk Phrases:
R10 - Flammable.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.

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15. REGULATORY INFORMATION

EU Safety Phrases:

S23 - Do not breathe fumes/vapour/spray.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

WARNING

Flammable liquid and vapor.
May cause harm to the unborn child.
May cause genetic defects.
Suspected of causing cancer.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class B, Division 2

Class D, Division 2, Subdivision A



Etoposide

California Proposition 65	developmental toxicity initial date 7/1/90
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	251-509-1

Polyethylene glycol

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

Polyoxyethylene (20) sorbitan monooleate

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

Ethanol

California Proposition 65	developmental toxicity initial date 10/1/87
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

Citric acid

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

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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R10 - Flammable.
R36 - Irritating to eyes.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.
R22 - Harmful if swallowed.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information. Updated Section 2 - Hazard Identification. Updated Section 14 - Transport Information.

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