



MATERIAL SAFETY DATA SHEET

Revision date: 27-Jul-2011

Version: 3.0

Page 1 of 8

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

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Material Name: Estramustine Phosphate Sodium Capsules

Trade Name:	EMCYT; ESTRACYT
Chemical Family:	Nitrogen Mustard
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: White Capsules
Signal Word: DANGER

Statement of Hazard: Suspected of causing cancer.
May damage the unborn child.
Suspected of damaging fertility.

Additional Hazard Information:
Long Term:

Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system. Clinical use of estrogens has resulted in breast changes (enlargement, tenderness, and secretion), along with effects on the genitourinary (changes in vaginal bleeding), and GI systems. Effects on the skin, eyes, and CNS have also been reported.

Known Clinical Effects:

EU Indication of danger:

Toxic to reproduction, Category 2
Carcinogenic: Category 3



EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect
R61 - May cause harm to the unborn child.
R62 - Possible risk of impaired fertility.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification
(NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Estramustine Phosphate Sodium Capsules
Revision date: 27-Jul-2011

Page 2 of 8
Version: 3.0

2. HAZARDS IDENTIFICATION

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	%
Estramustine Phosphate Sodium	52205-73-9	257-735-7	Repr.Cat.2;R61 Repr.Cat. 3;R62 Cat.3;R40	140mg***
Silicon dioxide, colloidal NF	7631-86-9	231-545-4 418-260-2	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Hard gelatin capsules	MIXTURE	Not Listed	Not Listed	*

Additional Information: 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.

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: Fine particles (such as dust and mists) may fuel fires/explosions.

MATERIAL SAFETY DATA SHEET

Material Name: Estramustine Phosphate Sodium Capsules
Revision date: 27-Jul-2011

Page 3 of 8
Version: 3.0

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:	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Estramustine Phosphate Sodium	
Pfizer OEL TWA-8 Hr:	2 µg/m ³
Silicon dioxide, colloidal NF	
Australia TWA	2 mg/m ³
Austria OEL - MAKs	4 mg/m ³
Czech Republic OEL - TWA	0.1 mg/m ³
	4.0 mg/m ³
Estonia OEL - TWA	2 mg/m ³
Germany - TRGS 900 - TWAs	4 mg/m ³
Germany (DFG) - MAK	4 mg/m ³ inhalable fraction
Ireland OEL - TWAs	6 mg/m ³
	2.4 mg/m ³
Latvia OEL - TWA	1 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m ³
Slovenia OEL - TWA	4 mg/m ³
Talc (non-asbestiform)	
ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	2.5 mg/m ³
Austria OEL - MAKs	2 mg/m ³

MATERIAL SAFETY DATA SHEET

Material Name: Estramustine Phosphate Sodium Capsules
Revision date: 27-Jul-2011

Page 4 of 8
Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Belgium OEL - TWA	2 mg/m ³
Bulgaria OEL - TWA	1.0 fiber/cm ³
	6.0 mg/m ³
	3.0 mg/m ³
Czech Republic OEL - TWA	2.0 mg/m ³
	10 mg/m ³
Denmark OEL - TWA	0.3 fiber/cm ³
Finland OEL - TWA	0.5 fiber/cm ³
	5 mg/m ³
Greece OEL - TWA	10 mg/m ³
	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	0.8 mg/m ³
Lithuania OEL - TWA	2 mg/m ³
	1 mg/m ³
Netherlands OEL - TWA	0.25 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m ³
	1.0 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Romania OEL - TWA	2 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
	10 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Spain OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	2 mg/m ³
	1 mg/m ³
Magnesium stearate	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Sodium lauryl sulfate	
Pfizer OEL TWA-8 Hr:	0.3 mg/m ³
Analytical Method:	Analytical method available. 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).
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.

MATERIAL SAFETY DATA SHEET

Material Name: Estramustine Phosphate Sodium Capsules
Revision date: 27-Jul-2011

Page 5 of 8
Version: 3.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Capsule	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

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)

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Estramustine Phosphate Sodium

Rat Oral LD50 > 2000 mg/kg
Rat Para-periosteal LD50 225 mg/kg
Rat Intraperitoneal LD50 337-550 mg/kg
Mouse Oral LD50 > 2000 mg/kg
Mouse Intravenous LD50 440 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)

Sodium lauryl sulfate

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild Moderate
Skin Sensitization - GPMT Guinea Pig Negative
Skin Sensitization - LLNA Mouse Negative

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

Estramustine Phosphate Sodium

4 Week(s) Rat Intraperitoneal 40 mg/kg/day LOAEL Male reproductive system, Female reproductive system

MATERIAL SAFETY DATA SHEET

Material Name: Estramustine Phosphate Sodium Capsules
Revision date: 27-Jul-2011

Page 6 of 8
Version: 3.0

11. TOXICOLOGICAL INFORMATION

4 Week(s)	Rat	Oral	100 mg/kg/day	LOAEL	Male reproductive system, Female reproductive system
6 Week(s)	Rat	Oral	30 mg/kg/day	LOAEL	Male reproductive system, Female reproductive system
8 Week(s)	Dog	Intravenous	0.1 mg/kg/day	LOAEL	
6 Month(s)	Non-human Primate	Oral	30 mg/kg/day	LOAEL	Male reproductive system, Female reproductive system

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

Estramustine Phosphate Sodium

Embryo / Fetal Development Rat Oral 2 mg/kg/day LOAEL Fetotoxicity

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

Sodium lauryl sulfate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Estramustine Phosphate Sodium

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vitro Micronucleus Mouse Bone Marrow Negative

Carcinogen Status: See below

Silicon dioxide, colloidal NF

IARC: Group 3 (Not Classifiable)

Talc (non-asbestiform)

IARC: Group 3 (Not Classifiable)

Estramustine Phosphate Sodium

IARC: Estrogen use in post-menopausal women - Group 1
Nitrogen Mustard - Group 2A

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)

Sodium lauryl sulfate

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 3.6 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.

MATERIAL SAFETY DATA SHEET

Material Name: Estramustine Phosphate Sodium Capsules
Revision date: 27-Jul-2011

Page 7 of 8
Version: 3.0

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

EU Symbol: T
EU Indication of danger: Toxic to reproduction, Category 2
Carcinogenic: Category 3

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect
R61 - May cause harm to the unborn child.
R62 - Possible risk of impaired fertility.

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:
DANGER
Suspected of causing cancer.
May damage the unborn child.
Suspected of damaging fertility.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials



Estramustine Phosphate Sodium
EU EINECS/ELINCS List 257-735-7

Silicon dioxide, colloidal NF
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 231-545-4
418-260-2

MATERIAL SAFETY DATA SHEET

Material Name: Estramustine Phosphate Sodium Capsules
Revision date: 27-Jul-2011

Page 8 of 8
Version: 3.0

15. REGULATORY INFORMATION

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	205-788-1

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R40 - Limited evidence of a carcinogenic effect

R61 - May cause harm to the unborn child.

R62 - Possible risk of impaired fertility.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory 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