



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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

Pfizer Inc
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Sandwich, Kent
CT13 9NJ
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Estradurine* (Polyestradiol Phosphate, Mepivavaine Hydrochloride, Nicotinamide) Powder for Solution for Injection

Trade Name: Estradurine*
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of prostate cancer

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Polyestradiol Phosphate	28014-46-2	Not listed	80 mg####
Sodium hydroxide	1310-73-2	215-185-5	*
Mepivacaine Hydrochloride	1722-62-9	217-023-9	5 mg####

Ingredient	CAS Number	EU EINECS List	%
Water for Injection	7732-18-5	231-791-2	2 mL####
Niacinamide	98-92-0	202-713-4	40 mg####
Sodium phosphate, dibasic	7558-79-4	231-448-7	*

Additional Information: * Proprietary
per vial/cartridge/ampule
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Lyophilised powder / Liquid in glass ampules or vials
Signal Word: DANGER

Statement of Hazard: May cause cancer.
May damage fertility or the unborn child.

Additional Hazard Information:
Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.

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Long Term: Repeated or prolonged exposure may cause effects similar to those seen in clinical use. Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged breasts and milk secretion. Loss of libido, breast tenderness, and changes in sex hormone levels have also occurred. Occupational exposure in females has resulted in menstrual irregularities (breakthrough bleeding, menstrual flow changes, spotting and amenorrhea).

Known Clinical Effects: 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. Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache. There have been rare reports of changes to heart rate, atrioventricular block, premature ventricular beats, blood count changes, skin rashes, and hypersensitivity reactions.

EU Indication of danger: Carcinogenic: Category 1
Toxic to reproduction: Category 1

EU Hazard Symbols:



EU Risk Phrases:

R45 - May cause cancer.
R60 - May impair fertility.
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 contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

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.

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

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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:** Avoid contact with eyes, skin and clothing. Avoid breathing dust. Wash thoroughly after handling. Keep away from heat, sparks, and flame.
- Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sodium hydroxide

- OSHA - Final PELS - TWAs:** 2 mg/m³
ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
Australia PEAK = 2 mg/m³ Peak
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Polyestradiol Phosphate

- Pfizer Occupational Exposure Band (OEB):** OEB4 (control exposure to the range of >1ug/m³ to <10ug/m³)

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.
Eyes: Not required for the normal use of this product. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES:

- | | | | |
|---------------------------|--------------------|--------------------------|--------------------|
| Physical State: | Lyophilized powder | Color: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |

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10. STABILITY AND REACTIVITY

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)

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Polyestradiol Phosphate

Rat Subcutaneous LD 50 5800 mg/kg
Mouse Subcutaneous LD 50 6100 mg/kg

Mepivacaine Hydrochloride

Mouse Intraperitoneal LD 50 117 mg/kg
Mouse Subcutaneous LD 50 260 mg/kg
Rat Oral LD 50 > 5000 mg/kg
Rat Intravenous LD 50 30 mg/kg

Niacinamide

Rat Oral LD50 3500 mg/kg
Mouse Oral LD50 2500 mg/kg
Rat Subcutaneous LD50 1680 g/kg
Mouse IP LD50 2050 mg/kg
Rabbit Dermal LD 50 >2000 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 hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Sodium phosphate, dibasic

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Carcinogen Status: See below

Polyestradiol Phosphate

IARC: Group 1
NTP: Listed

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OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been 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 1
Toxic to reproduction: Category 1

EU Risk Phrases:
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
May cause cancer.
May damage fertility or the unborn child.

Canada - WHMIS: Classifications

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WHMIS hazard class:

Class D, Division 2, Subdivision A



Water for Injection

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

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	215-185-5

Niacinamide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-713-4

Sodium phosphate, dibasic

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-448-7

Mepivacaine Hydrochloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	217-023-9

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet