



MATERIAL SAFETY DATA SHEET

Revision date: 03-Apr-2013

Version: 1.0

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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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Ifosfamide Injection

Trade Name:	Not applicable
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Sterile Solution
Signal Word: DANGER

Statement of Hazard: Toxic if swallowed.
May cause cancer.
May damage fertility or the unborn child.
May cause genetic defects.

Additional Hazard Information:
Known Clinical Effects: Adverse effects associated with therapeutic use include bone marrow suppression, loss of hair, nausea, vomiting, skin and acute mucous membrane irritation, effects on blood forming organs, neutropenia, effects on central nervous system. Clinical use of this drug has caused impairment of male fertility.

EU Classification
EU Indication of danger: Toxic
Toxic to reproduction: Category 1
Carcinogenic: Category 2
Mutagenic: Category 2

EU Hazard Symbols:



EU Risk Phrases:

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2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC):

R25 - Toxic if swallowed.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
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	%
Ifosfamide	3778-73-2	223-237-3	T;R25 Repr.Cat.1;R60-61 Carc. Cat.2;R45 Mut. Cat.2;R46	5

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium Phosphate Monobasic, Monohydrate	10049-21-5	Not Listed	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Water for Injection	7732-18-5	231-791-2	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.

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Hazardous Combustion Products: Carbon dioxide, carbon monoxide, and oxides of nitrogen phosphorous

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.

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 spill with absorbent material. 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: Restrict access to work area. Designate a change area to facilitate 'good manufacturing' decontamination practices. Ground and bond all bulk transfer equipment. No open handling permitted. All operations should be fully enclosed. Avoid inhalation and contact with skin, eye, 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

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. All operations should be fully enclosed. No air recirculation permitted.

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: Wear impervious, disposable gloves as minimum protection (double recommended).

Eyes: Wear safety glasses as minimum protection.

Skin: Wear impervious disposable protective clothing when handling this compound.

Respiratory protection: Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	No data available.
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.
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Acute Toxicity: (Species, Route, End Point, Dose)

Sodium phosphate, dibasic

Rat Oral LD 50 17 g/kg

Ifosfamide

Rat Oral LD50 143 mg/kg

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

Sodium phosphate, dibasic

Eye Irritation	Rabbit	Mild
Skin Irritation	Rabbit	Mild

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

Ifosfamide

Prenatal & Postnatal Development	Rat	Intravenous	2.5 mg/kg/day	LOAEL	Teratogenic, Embryotoxicity
Prenatal & Postnatal Development	Rabbit	Intravenous	5 mg/kg/day	LOAEL	Embryotoxicity, Fetal mortality, Teratogenic
Embryo / Fetal Development	Mouse	Intravenous	20 mg/kg/day	LOAEL	Teratogenic

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

Ifosfamide

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Positive
<i>In Vivo</i> Mammalian Cell Mutagenicity	Mouse	Positive
<i>In Vivo</i> Dominant Lethal Assay	Mouse	Positive
<i>In Vivo</i> Sex-Linked Recessive Lethal Test	<i>Drosophila</i>	Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ifosfamide

52 Week(s) Rat Intraperitoneal 6 mg/kg LOAEL Malignant tumors

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11. TOXICOLOGICAL INFORMATION

Carcinogen Status: See below

Ifosfamide
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

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.

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic
Toxic to reproduction: Category 1
Carcinogenic: Category 2
Mutagenic: Category 2

EU Risk Phrases:
R25 - Toxic if swallowed.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

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15. REGULATORY INFORMATION

OSHA Label:

DANGER

Toxic if swallowed.

May cause cancer.

May damage fertility or the unborn child.

May cause genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:

D1b toxic materials

D2a very toxic materials



Ifosfamide

California Proposition 65

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

developmental toxicity initial date 7/1/90

Schedule 4

223-237-3

Sodium Phosphate Monobasic, Monohydrate

Australia (AICS):

Present

Sodium phosphate, dibasic

CERCLA/SARA Hazardous Substances
and their Reportable Quantities:

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS/ELINCS List

5000 lb

2270 kg

Present

Present

231-448-7

Water for Injection

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the
obligations of Register:

EU EINECS/ELINCS List

Present

Present

Present

231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

R25 - Toxic if swallowed.

R45 - May cause cancer.

R46 - May cause heritable genetic damage.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

Data Sources:

Pfizer proprietary drug development information. Publicly available toxicity information.

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Prepared by:

Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet