SAFETY DATA SHEET

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

Product Identifier

Material Name: Bendamustine for Injection (Hospira, Inc.)

Trade Name: Not established
Chemical Family: Cytotoxic and Antineoplastic

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product for the treatment of cancer

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 3
Germ Cell Mutagenicity: Category 2
Reproductive Toxicity: Category 2
Carcinogenicity: Category 2

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger
Hazard Statements:
H301 - Toxic if swallowed
H341 - Suspected of causing genetic defects
H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.
H351 - Suspected of causing cancer
May form combustible dust concentrations in air

Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+ P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P330 - Rinse mouth
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Bendamustine hydrochloride monohydrate	1374784-02-7	Not Listed	Acute Tox.3 (H301) Muta.2(H341) Repr.2(H361fd) Carc.2(H351)	5-10

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling

7. HANDLING AND STORAGE

Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eyes, 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product Antineoplastic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Bendamustine hydrochloride monohydrate

Pfizer Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of 1ug/m^3 to <10ug/m^3)

Exposure Controls

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.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Lyophilized powder	**Color:**	White to off-white
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Bendamustine hydrochloride monohydrate
No data available
Mannitol
No data available
Water for Injection
No data available
Bendamustine
No data available
Bendamustine hydrochloride
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
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
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: fever, nausea, vomiting, fatigue, malaise, weakness, dry mouth, sleepiness (somnolence), cough, constipation, headache, immunosuppression, low platelet count, and inflammation of the mouth (stomatitis).

Acute Toxicity: (Species, Route, End Point, Dose)

Mannitol
Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Bendamustine hydrochloride
Rat Oral LD 50 200 - 300 mg/kg

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

Bendamustine hydrochloride
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Positive
In Vivo Micronucleus Rat Bone Marrow Positive
In Vitro Sister Chromatid Exchange Not specified Positive

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

Bendamustine hydrochloride
4 Day(s) Mouse Intraperitoneal 12.5 mg/kg/day LOAEL Tumors
4 Day(s) Mouse Oral 62.5 mg/kg/day LOAEL Tumors, Lungs

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Bendamustine hydrochloride monohydrate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Mannitol	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8
Water for Injection	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Reproductive toxicity-Cat.2; H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer

Data Sources:	Publicly available toxicity information. Commercial vendor MSDS.
Reasons for Revision:	Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 7 - Handling and Storage.
Revision date:	07-Nov-2016
	Product Stewardship Hazard Communication
Prepared by:	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

SAFETY DATA SHEET

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

Product Identifier

Material Name: Docetaxel Injection

Trade Name: Docetaxel; Pfizer Docetaxel
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Antineoplastic

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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:
Poisons Information Centre: 13 1126

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 2
Reproductive Toxicity: Category 1B
Effects on or via lactation
Flammable liquids- Category 2

Label Elements

Signal Word: Danger
Hazard Statements:
H225 - Highly flammable liquid and vapor
H319 - Causes serious eye irritation
H341 - Suspected of causing genetic defects
H360D - May damage the unborn child
H362 - May cause harm to breast-fed children

Precautionary Statements:

P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed
P240 - Ground/Bond container and receiving equipment
P241 - Use explosion-proof electrical/ventilating/lighting/equipment
P242 - Use only non-sparking tools
P243 - Take precautionary measures against static discharge
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P403 + P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
P370 + P378 - In case of fire: Use CO_2, extinguishing powder, foam, or water for extinction

Other Hazards
No data available

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Ethyl alcohol (ethanol)	64-17-5	200-578-6	Flam. Liq. 2 (H225)	<40
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	**
Docetaxel anhydrous	114977-28-5	Not Listed	Repr. 1B (H360D) Muta. 2 (H341) Eye Irrit. 2A (H319) Lact. (H362)	1
Propylene glycol	57-55-6	200-338-0	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Edetate disodium	139-33-3	205-358-3	Not Listed	*

Additional Information:

* Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.
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

Precautions for Safe Handling

Flammable liquid and vapor- keep away from ignition sources and clean up spills promptly. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin, and clothing. Use appropriate personal protective equipment. Wash thoroughly after 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:	Store as directed by product packaging.
Specific end use(s):	Pharmaceutical product used as Antineoplastic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Ethyl alcohol (ethanol)

ACGIH Threshold Limit Value (STEL)	1000 ppm
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
Latvia OEL - TWA	1000 mg/m^3
Lithuania OEL - TWA	500 ppm 1000 mg/m^3
Netherlands OEL - TWA	260 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Russia OEL - TWA	1000 mg/m^3
Slovakia OEL - TWA	500 ppm 960 mg/m^3
Slovenia OEL - TWA	1000 ppm 1900 mg/m^3
Sweden OEL - TWAs	500 ppm 1000 mg/m^3
Switzerland OEL -TWAs	500 ppm 960 mg/m^3
Vietnam OEL - TWAs	1000 mg/m^3

Propylene glycol

Australia TWA	150 ppm 474 mg/m^3 10 mg/m^3
Ireland OEL - TWAs	150 ppm 470 mg/m^3 10 mg/m^3
Latvia OEL - TWA	7 mg/m^3
Lithuania OEL - TWA	7 mg/m^3

Docetaxel anhydrous

Pfizer Occupational Exposure Band (OEB):	OEB 4 (control exposure to the range of 1ug/m^3 to <10ug/m^3)

Exposure Controls

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.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	**Color:**	Clear, colorless to pale yellow
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture
Solvent Solubility:	No data available		

9. PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility: No data available
pH: 4-7
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Docetaxel anhydrous
No data available
Citric acid, anhydrous
No data available
Polysorbate 80
No data available
Propylene glycol
No data available
Ethyl alcohol (ethanol)
No data available
Edetate disodium
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	24
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions

Oxidizing Properties:	No data available
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
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
Short Term:	May cause eye irritation (based on components) .
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on central nervous system, gastrointestinal system, blood and blood forming organs, and testes.
Known Clinical Effects:	Common adverse effects include blood cell changes, nervous system/brain toxicity (neurotoxicity). Serious allergic reactions, including anaphylaxis, have been reported.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

Docetaxel anhydrous
Rat Oral LD50 > 2000 mg/kg
Mouse IV LD50 138mg/kg

Citric acid, anhydrous
Rat Oral LD50 3000 mg/kg

Polysorbate 80
Rat Intravenous LD 50 1790 mg/kg
Mouse Oral LD 50 25 g/kg

Propylene glycol
Rat Oral LD 50 22,000 mg/kg
Mouse Oral LD 50 24,900mg/kg
Rabbit Dermal LD 50 20,800mg/kg

Ethyl alcohol (ethanol)
Mouse Oral LD50 3450 mg/kg
Rat Oral LD50 7060mg/kg
Rat Inhalation LC50 10h 20,000ppm

Edetate disodium
Rat Oral LD50 2000-2200 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)

Docetaxel anhydrous
Eye Irritation Rabbit Irritant
Skin Irritation Rabbit Non-irritating
Skin Sensitization Negative

Citric acid, anhydrous
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Ethyl alcohol (ethanol)
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

11. TOXICOLOGICAL INFORMATION

Docetaxel anhydrous
28-31 Day(s) Rat Intravenous mg/m2/day NOEL Blood forming organs, Male reproductive system
6 Month(s) Rat Intravenous 0.2 mg/kg/day NOEL Blood forming organs, Male reproductive system
6 Month(s) Dog Intravenous 0.375 mg/kg/day LOAEL Male reproductive system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Docetaxel anhydrous
Reproductive & Fertility Rat Intravenous mg/kg/day LOAEL Paternal toxicity
Embryo / Fetal Development Rat Intravenous 0.3 mg/kg/day LOAEL Maternal Toxicity, Embryotoxicity, Fetotoxicity, Not Teratogenic
Embryo / Fetal Development Rabbit Intravenous 0.03 mg/kg/day LOAEL Embryotoxicity, Fetotoxicity, Maternal Toxicity, Not Teratogenic

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

Docetaxel anhydrous
In Vitro Bacterial Mutagenicity (Ames) ***Salmonella* , *E. coli*** Negative
In Vivo Micronucleus Mouse Positive
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Ethyl alcohol (ethanol)
IARC: Group 1 (Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

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

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

Docetaxel anhydrous
Daphnia magna (Water Flea) LC50 48 Hours > 3.3 mg/L

Ethyl alcohol (ethanol)
Oncorhynchus mykiss (Rainbow Trout) LC50/96h 12,900-15,300 mg/L
Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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:	III
Flash Point (°C):	24
Flash Point (°C):	24

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Polysorbate 80

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Ethyl alcohol (ethanol)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 4/29/11 in alcoholic beverages developmental toxicity initial date 10/1/87 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

15. REGULATORY INFORMATION

Citric acid, anhydrous

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

Docetaxel anhydrous

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

Propylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

Edetate disodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-358-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

Data Sources:	Publicly available toxicity information. Safety data sheets for individual ingredients.
Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 7 - Handling and Storage. Updated Section 2 - Hazard Identification.
Revision date:	01-Mar-2016
	Product Stewardship Hazard Communication
Prepared by:	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

SAFETY DATA SHEET

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

Product Identifier

Material Name: Doxorubicin Hydrochloride Powder for Injection

Trade Name:	Adriamycin, Adriblastina; Adriblastine; Adriblastin; Farmiblastina; Adriablastina; Adriacin; Pfizer Doxorubicin
Synonyms:	Doxorubicin RDF Injection
Chemical Family:	Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as Antineoplastic

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 1B
Reproductive Toxicity: Category 1B
Carcinogenicity: Category 1B

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word:	Danger
Hazard Statements:	H340 - May cause genetic defects H350 - May cause cancer H360FD - May damage fertility. May damage the unborn child. May form combustible dust concentrations in air
Precautionary Statements:	P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P281 - Use personal protective equipment as required P308 + P313 - IF exposed or concerned: Get medical attention/advice P405 - Store locked up P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Doxorubicin Hydrochloride	25316-40-9	246-818-3	Muta.1B (H340) Carc.1B (H350) Repr.1B (H360FD)	16.4

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Methylparaben	99-76-3	202-785-7	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.
Medical Conditions Aggravated by Exposure:	None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:	None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO_2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.
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

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:	Store as directed by product packaging.
Specific end use(s):	Pharmaceutical drug product; Antineoplastic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Doxorubicin Hydrochloride
Pfizer OEL TWA-8 Hr: 0.5 µg/m³

Exposure Controls

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.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Lyophilized powder	**Color:**	Red-orange
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Doxorubicin Hydrochloride
No data available
Lactose
No data available
Methylparaben
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
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
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on testes, the developing fetus.
Known Clinical Effects:	Bone marrow suppression is the most serious adverse effect seen during clinical use. Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Acute Toxicity: (Species, Route, End Point, Dose)

Doxorubicin Hydrochloride
Mouse Oral LD 50 698 mg/kg
Mouse Para-periosteal LD 50 1.2 mg/kg
Rat Intravenous LD 50 12.5 mg/kg
Rat Intraperitoneal LD 50 16 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.

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

Doxorubicin Hydrochloride
Reproductive & Fertility-Females Rat Intraperitoneal 0.05 mg/kg/day LOAEL Fertility
Reproductive & Fertility-Males Rat Intraperitoneal 0.1 mg/kg/day LOAEL Fertility
Embryo / Fetal Development Rat Intraperitoneal 0.8 mg/kg/day LOAEL Teratogenic, Embryotoxicity
Embryo / Fetal Development Rabbit Intraperitoneal 0.4 mg/kg/day LOAEL Embryotoxicity

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

Doxorubicin Hydrochloride
Bacterial Mutagenicity (Ames) ***Salmonella* , *E. coli*** Positive

11. TOXICOLOGICAL INFORMATION

In Vivo Micronucleus Mouse Positive
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive
In Vitro Sister Chromatid Exchange Human Lymphocytes Positive
Dominant Lethal Assay Mouse Positive

Carcinogen Status: See below

Doxorubicin Hydrochloride
IARC: 2A
NTP: Reasonably Anticipated To Be A Human Carcinogen

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.
Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects
Carcinogenicity-Cat.1B; H350 - May cause cancer

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information.
Reasons for Revision:	Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.
Revision date:	21-Jun-2017
Prepared by:	Product

MATERIAL SAFETY DATA SHEET

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: 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:

T

EU Risk Phrases:

2. HAZARDS IDENTIFICATION

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

Australian Hazard Classification (NOHSC): 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.

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/m^3

Polyethylene glycol

Austria OEL - MAKs	1000 mg/m^3
Germany - TRGS 900 - TWAs	1000 mg/m^3
Germany (DFG) - MAK	1000 mg/m^3 inhalable fraction
Slovakia OEL - TWA	1000 mg/m^3
Slovenia OEL - TWA	1000 mg/m^3

Ethanol

ACGIH Threshold Limit Value (STEL)	1000 ppm

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).

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

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

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.

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

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

MATERIAL SAFETY DATA SHEET

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: Fluorouracil Injection

Trade Name:	Fluoroblastin; Fluroblastin; Adrucil
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance:	Colorless solution
Signal Word:	DANGER
Statement of Hazard:	May damage fertility or the unborn child. May cause genetic defects.
Additional Hazard Information:	
Short Term:	May be absorbed through the skin and cause systemic effects. Active ingredient may be harmful if swallowed.
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs.
Known Clinical Effects:	Adverse effects associated with therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation. Effects on blood and blood-forming organs have also occurred.
EU Indication of danger:	Toxic to reproduction, Category 2 Mutagenic: Category 2

EU Hazard Symbols:

T

EU Risk Phrases:

R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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	%
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Fluorouracil	51-21-8	200-085-6	Muta. Cat 2;R46 Repr. Cat.2;R60-61 Xn;R22	5

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:
* Proprietary
** to adjust pH
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: Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

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

Fire / Explosion Hazards: Not flammable.

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 the spill if it is safe to do so. Soak up with inert absorbent material and dispose of as hazardous waste.

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. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). It is recommended that all operations be fully enclosed and no air recirculated. 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.

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m^3
Australia PEAK	2 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Bulgaria OEL - TWA	2.0 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
France OEL - TWA	2 mg/m^3
Greece OEL - TWA	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Fluorouracil

Pfizer Occupational Exposure Band (OEB): OEB 5 (control exposure to <1ug/m^3)

Analytical Method: Analytical method available for Fluorouracil. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. It is recommended that all operations be fully enclosed and no air recirculated.

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, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Safety glasses or goggles

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	**Color:**	Colorless
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)

Fluorouracil
Rat Oral LD 50 230 mg/kg
Rat Para-periosteal LD 50 245 mg/kg
Mouse Oral LD 50 115 mg/kg
Mouse Intravenous LD 50 81 mg/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

11. TOXICOLOGICAL INFORMATION

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

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

Fluorouracil
5 Week(s) Dog Oral 175 mg/kg LOAEL Bone marrow

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

Fluorouracil
Embryo / Fetal Development Mouse Intraperitoneal 10 - 40 mg/kg/day LOAEL Teratogenic
Embryo / Fetal Development Rat Intraperitoneal 12 - 37 mg/kg LOAEL Teratogenic
Embryo / Fetal Development Hamster Intraperitoneal 3 - 9 mg/kg LOAEL Teratogenic, Fetotoxicity
Embryo / Fetal Development Monkey Intramuscular 40 mg/kg NOAEL Not Teratogenic
Reproductive & Fertility-Males Mouse Intraperitoneal 25 - 50 mg/kg LOAEL Fertility

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

Fluorouracil
In Vivo Chromosome Aberration Rat Spermatogonia Positive
Sister Chromatid Exchange Human Lymphocytes Positive
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive
In Vivo Micronucleus Mouse Positive

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Fluorouracil
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 Indication of danger: Toxic to reproduction, Category 2
Mutagenic: Category 2

EU Risk Phrases:

R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
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/ELINCS List	215-185-5

Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

15. REGULATORY INFORMATION

Fluorouracil

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA - Section 302 Extremely Hazardous	500 lb
TPQs	10000 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	developmental toxicity initial date 1/1/89
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-085-6

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. 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

MATERIAL SAFETY DATA SHEET

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: Oxaliplatin Powder for Injection

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

2. HAZARDS IDENTIFICATION

Appearance: White lyophilised cake
Signal Word: DANGER

Statement of Hazard:
May damage the unborn child.
May cause genetic defects.

Additional Hazard Information:

Short Term: Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on testes and the developing fetus. May cause effects on blood and blood forming organs

Known Clinical Effects: Adverse effects most commonly reported in clinical use include vomiting nausea diarrhea bone marrow suppression decreased red blood cell count (anemia) decreased white blood cells (leukopenia) decrease in platelets and red/white blood cells (pancytopenia) nervous system/brain toxicity (neurotoxicity) and skin and acute mucous membrane irritation

EU Classification

EU Indication of danger:
Toxic to Reproduction: Category 2
Mutagenic: Category 2

EU Hazard Symbols:

T

EU Risk Phrases:

R61 - May cause harm to the unborn child.
R46 - May cause heritable genetic damage.

2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-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	%
Oxaliplatin	61825-94-3	Not Listed	Repr. Cat.2,R61; Muta. Cat.2,R46	10

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Lactose NF, monohydrate	64044-51-5	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.

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.

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. Avoid breathing dust. 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.

Oxaliplatin

Pfizer Occupational Exposure Band (OEB):	OEB 4 (control exposure to the range of 1ug/m^3 to <10ug/m^3)
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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	lyophilised cake	**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 active ingredient

Acute Toxicity: (Species, Route, End Point, Dose)

Oxaliplatin
Rat Oral LD50 > 100 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)

Oxaliplatin
Eye Irritation (*In vitro* , BCOP) Irritant
Skin Irritation (*In vitro* , RhE) Negative

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

Oxaliplatin
Fertility and Embryonic Development Rat No route specified 1 mg/kg/day NOAEL Fetotoxicity

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

Oxaliplatin
Bacterial Mutagenicity (Ames) ***Salmonella*** Negative
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Positive
In Vitro Chromosome Aberration Human Lymphocytes Positive
In Vivo Micronucleus Mouse Bone Marrow Positive

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. 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 to Reproduction: Category 2
Mutagenic: Category 2

EU Risk Phrases:

R61 - May cause harm to the unborn child.
R46 - May cause heritable genetic damage.

EU Safety Phrases:

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

OSHA Label:
DANGER
May damage the unborn child.
May cause genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B

15. REGULATORY INFORMATION

Lactose NF, monohydrate
Australia (AICS): Present

Oxaliplatin
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.
Data Sources: Publicly available toxicity 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

1. PRODUCT AND COMPANY INFORMATION

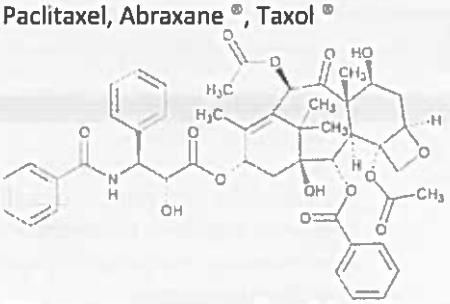
Distributed By: WG Critical Care, LLC.
120 Route 17 North
Suite 115
Paramus, NJ 07652 USA

Product Name: **Paclitaxel for Injection, USP**

Product Code:
30mg/5ml Vial: 44567-504-01
100mg/16.7ml Vial: 44567-505-01
300mg/50ml Vial: 44567-506-01

Common / Trade Name: Paclitaxel, Abraxane ®, Taxol ®

Structure:



Chemical Name: (1) Benzenepropanoic acid, β-(benzoylamino)-α-hydroxy-, 6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,11-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1*H*-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, [2a*R*-[2aα,4β,4aβ,6β,9α(α*R**,β*S**),11α,12α,12aα,12bα]]-;

(2) (2a*R*,4*S*,4a*S*,6*R*,9*S*,11*S*,12*S*,12a*R*,12b*S*)-1,2a,3,4,4a,6,9,10,11,12,12a,12b-Dodecahydro-4,6,9,11,12,12b-hexahydroxy-4a,8,13,13-tetramethyl-7,11-methano-5*H*-cyclodeca[3,4]benz[1,2-*b*]oxet-5-one 6,12b-diacetate, 12-benzoate, 9-ester with (2*R*,3*S*)-*N*-benzoyl-3-phenylisoserine

Molecular Formula: $C_{47}H_{51}NO_{14}$

UNII Code: *UNII-P88XT4IS4D*

CAS Number: *33069-62-4*

Chemical Family: Antineoplastic

Product Use: Pharmaceutical

Product Type: Prescription Drug

Container Information: Vials

1. PRODUCT AND COMPANY INFORMATION (continued)

General Phone Number:	+1-847-549-3200
Customer Service Phone Number:	+1-888-493-0861
Emergency Phone Number:	+1-866-562-4708 (Prosar)

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Weight %	CAS No.
Paclitaxel		33069-62-4

3. HAZARDS INDENTIFICATION

PRIMARY PHYSICAL AND HEALTH HAZARDS:	Possible irritation of eyes and skin as well as redness and local swelling after injection. Paclitaxel is a potent Cytotoxic drug and potential carcinogen.
ROUTES OF ENTRY:	Inhalation, skin and eye contact, and ingestion of large quantities would not be expected to occur.
SIGNS & SYMPTOMS OF EXPOSURE:	Repeated exposure to paclitaxel in sufficient dose may affect the bone marrow, the peripheral nervous system, GI tract and/or the reproductive system
CHEMICAL LISTED AS CARCINOGEN:	**NTP:** NO **IARC:** NO **OSHA:** NO

4. FIRST AID MEASURES

EYE EXPOSURE:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.
SKIN EXPOSURE:	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If exposed or concerned: Get medical attention/advice
INGESTION:	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical attention/advice.
INHALATION:	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. If exposed or concerned: Get medical attention/advice.
NOTE TO PHYSICIAN:	Medical conditions aggravated include: asthma, bone marrow suppression, cardiac irregularities. This product has been reported to interact with the following medications: cisplatin, other chemotherapy drugs, radiation treatment to the lung.

5. FIRE FIGHTING MEASURES	
FLASH POINT:	Not established
AUTO-IGNITION TEMPERATURE:	Not established
FLAMMABLE LIMITS IN AIR:	Lower %:Not established Upper %: Not established
FLAMMABLE LIMITS:	The product contains ethanol that is a flammable product. However, flashpoint test has been complete on this product and the product is considered as non-explosion hazard.
EXTINGUISHING MEDIA:	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
UNUSUAL FIRE / EXPLOSION HAZARDS:	Dehydrated alcohol is flammable. Keep this product away from ignition sources such as sparks and open flames.

6. ACCIDENTAL RELEASE MEASURE	
SPILL:	Since Paclitaxel Injection is a flammable solution, remove all sources of ignition. Absorb solution with activated charcoal or absorbent pads.
RELEASE TO AIR:	If aerosolized, reduce exposures by ventilation area. Clean up spill immediately to prevent evaporation.
RELEASE TO WATER:	Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

7. HANDLING AND STORAGE	
GENERAL HANDLING:	Paclitaxel is a cytotoxic agent. All work practices must be designed to reduce human exposure to the lowest level. Employees must be trained to properly use the product. Ensure vials are properly labeled. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling this product. Wash hands thoroughly after handling. Particular care in working with this product must be practices in pharmacies and other preparation areas, and during patient administration.
STORAGE CONDITIONS:	Store at 20°C to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] **Protect from light.** Retain in carton until time of use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION:	Not normally required for routine, medical administration of this product.
EYE PROTECTION:	Approved eye protection (e.g., safety glasses with side shields) to safeguard against potential eye contact, irritation or injury is recommended.
VENTILATION	Use with adequate ventilation.
SKIN PROTECTION:	A full body gown which is closed at the front and has long sleeves is recommended.
OTHER PROTECTIVE EQUIPMENT:	Not established.
ADDITIONAL EXPOSURE PRECAUTIONS:	Avoid contact with skin, eyes and clothing. Wash hands following use before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Liquid	**SPECIFIC GRAVITY:**	0.926
APPEARANCE AND ODOR:	Clear colorless to slightly yellow viscous solution	**EVAPORATION RATE:**	Not available
BOILING POINT:	173°F (78°C)	**MELTING POINT:**	Not applicable
VAPOR PRESSURE:	5.8 Pa @20°C	**SOLUBILITY IN WATER:**	Soluble in water
VAPOR DENSITY:	1.6 (anhydrous ethanol)	**pH:**	3.5

10. STABILITY AND REACTIVITY

STABILITY:	Product is stable under normal conditions of storage and handling.
INCOMPATIBILITY : (MATERIALS TO AVOID)	Paclitaxel Injection should not be stored with oxidizers, acids, and bases. Keep away from heat and ignition sources.
HAZARDOUS POLYMERIZATION:	Will not occur.
HAZARDOUS DECOMPISITION:	Carbon oxides, nitrogen oxides and possibly other compounds with carcinogenic potential.
CONDITIONS TO AVOID:	Avoid exposure to heat, oxidizers or open flame.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

COMPONENT	TYPE	ROUTE	SPECIES	DOSAGE
Paclitaxel	LD_{50}	Intravenous	Mouse	12 mg/kg
Paclitaxel	LD_{50}	Intraperitoneal	Mouse	128 mg/kg

12. ECOLOGICAL INFORMATION

No applicable ecological information found.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Used vials and other items that have come into contact with the product must be treated as Hazardous Waste. The waste must be disposed of by a licensed waste contractor preferably by incineration.

14. TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:
DOT: Not Regulated
ICAO / IATA: Not Regulated
IMO: Not Regulated

15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

US Regulations
TSCA – No
CERCLA-No
SARA 302 – No
SARA 313 – No
OSHA Substance Specific - No

16. OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PUROPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

MATERIAL SAFETY DATA SHEET

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: Cyclophosphamide Powder for Injection

Trade Name:	SYKLOFOSFAMID, CYCLOBLASTIN, CYCLOPHOSPHAMIDE, CYCLOPHOSPHAMID, CYCLOSTIN, NEOSAR
Chemical Family:	Alkylating Agent
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: White crystalline powder
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:
Long Term: The use of this drug during pregnancy has resulted in birth defects. 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.

Known Clinical Effects: Effects on blood and blood-forming organs have also occurred.

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

EU Hazard Symbols:
T

EU Risk Phrases:

2. HAZARDS IDENTIFICATION

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.

Australian Hazard Classification (NOHSC): 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	%
Cyclophosphamide	50-18-0	200-015-4	T;R25 Repr.Cat.1;R60-61 Carc. Cat.1;R45 Mut. Cat.1;R46	100

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: 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 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:	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 at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Crystalline powder	**Color:**	White
Molecular Formula:	C7 H15 Cl2 N2 O2 P	**Molecular Weight:**	261.09
Water solubility:	4%		

9. PHYSICAL AND CHEMICAL PROPERTIES

Melting/Freezing Point (°C): 41

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

Acute Toxicity: (Species, Route, End Point, Dose)

Cyclophosphamide
Rat Oral LD 50 160 mg/kg
Rat Para-periosteal LD 50 148 mg/kg
Mouse Oral LD 50 137 mg/kg
Mouse Intravenous LD 50 140 mg/kg

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

Cyclophosphamide
Embryo / Fetal Development Rat Intraperitoneal 10 mg/kg LOAEL Teratogenic
Embryo / Fetal Development Rat Intraperitoneal 30 mg/kg LOAEL Fetotoxicity
Embryo / Fetal Development Mouse Intravenous 10 mg/kg LOAEL Teratogenic
Embryo / Fetal Development Mouse Intraperitoneal 5 mg/kg LOAEL Fetotoxicity, Fertility

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

Cyclophosphamide
In Vivo Micronucleus Rodent Positive
In Vivo Chromosome Aberration Rodent Positive
In Vivo Sister Chromatid Exchange Rodent Positive
In Vitro Chromosome Aberration Human Lymphocytes Positive
Dominant Lethal Assay Drosophila Positive

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

Cyclophosphamide
2 Year(s) Rat Intravenous Benign tumors, Malignant tumors
2 Year(s) Rat Intraperitoneal Benign tumors, Malignant tumors, Female reproductive system
2 Year(s) Mouse Intraperitoneal Benign tumors, Malignant tumors

Carcinogen Status: See below

Cyclophosphamide
IARC: Group 1 (Carcinogenic to Humans)
NTP: Known Human Carcinogen
OSHA: Listed

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.

Cyclophosphamide
RCRA - U Series Wastes Listed

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 2811
UN proper shipping name: Toxic solid, organic, n.o.s. (cyclophosphamide)
Transport hazard class(es): 6.1
Packing group: III

15. REGULATORY INFORMATION

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

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.

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

Cyclophosphamide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	10 lb 4.54 kg
California Proposition 65	carcinogen initial date 2/27/87 developmental toxicity initial date 1/1/89 female reproductive toxicity 1/1/89 male reproductive toxicity initial date 1/1/89
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-015-4

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.

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients.

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

MATERIAL SAFETY DATA SHEET

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

Pfizer Global Manufacturing
Pfizer Inc
235 East 42nd Street
New York, NY 10017

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
Contact E-Mail: pfizer-MSDS@pfizer.com

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

Material Name: Epirubicin Hydrochloride Powder for Injection

Trade Name:	Ellence, Farmorubicin
Synonyms:	Pharmorubicin Rapid Dissolution
Chemical Family:	Anthracycline
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance:	Red freeze-dried powder
Signal Word:	WARNING
Statement of Hazard:	Harmful if swallowed. Suspected of causing cancer. Suspected of damaging fertility or the unborn child. Suspected of causing genetic defects.
Additional Hazard Information:	
Short Term:	Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on testes the developing fetus.
Known Clinical Effects:	Adverse effects most commonly reported in clinical use include local irritation, nausea, vomiting, inflammation of the mouth (stomatitis), facial flushing, conjunctivitis of the eye, tearing (lachrymation), loss of hair, and discoloration of skin. Effects on blood and blood-forming organs have also occurred.
EU Indication of danger:	Harmful Toxic to reproduction, Category 2 Carcinogenic: Category 2 Mutagenic: Category 2

EU Hazard Symbols:

T

2. HAZARDS IDENTIFICATION

EU Risk Phrases:

R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R22 - Harmful if swallowed.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-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	Classification	%
Epirubicin Hydrochloride	56390-09-1	260-145-2	Xn;R22 Repr.Cat.2;R60-61 Muta.Cat.2;R46 Carc.Cat.2;R45	0.2

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Methylparaben	99-76-3	202-785-7	Not Listed	*
Lactose Monohydrate	64044-51-5	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:	May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.
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 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:	Restrict access to work area. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

Epirubicin Hydrochloride
Pfizer OEL TWA-8 Hr: 0.6 µg/m^3

Analytical Method:	Analytical method available for epirubicin. 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. It is recommended that all operations be fully enclosed and no air recirculated.
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, disposable gloves (double suggested) 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 disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:	Freeze-dried powder	**Color:**	Red
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

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)

Epirubicin Hydrochloride
Rat Oral LD 50 1350 mg/kg
Rat Intravenous LD50 17mg/kg
Mouse Oral LD50 > 2000mg/kg
Mouse Intravenous LD50 3150mg/kg

Lactose Monohydrate
Rat Oral LD 50 29700 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.

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

Epirubicin Hydrochloride
6 Week(s) Rabbit Intravenous 1 mg/kg/day LOAEL Heart, Kidney
6 Week(s) Dog Intravenous 0.4 mg/kg/day LOAEL Kidney

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

Epirubicin Hydrochloride
Reproductive & Fertility Rat Oral 0.3 mg/kg/day LOAEL Fertility
Reproductive & Fertility Rat Oral 0.1 mg/kg/day NOAEL Fertility
Embryo / Fetal Development Rat Intravenous 0.8 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rat Intravenous 2 mg/kg/day LOAEL Teratogenic, Fetotoxicity
Embryo / Fetal Development Rat Intravenous 0.2 mg/kg/day NOAEL Teratogenic, Fetotoxicity

11. TOXICOLOGICAL INFORMATION

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

Epirubicin Hydrochloride
Bacterial Mutagenicity (Ames) Positive
Mammalian Cell Mutagenicity HGPRT Positive
Chromosome Aberration Human Lymphocytes Positive
Chromosome Aberration Mouse Lymphoma Positive

Lactose Monohydrate
In Vitro Bacterial Mutagenicity (Ames) Negative

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

Epirubicin Hydrochloride
1 Year(s) Rat Intravenous 3.6 mg/kg LOAEL Tumors, Female reproductive system
18 Month(s) Rat Intravenous 0.5 mg/kg LOAEL Tumors

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

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. 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

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

14. TRANSPORT INFORMATION

15. REGULATORY INFORMATION

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

EU Risk Phrases:

R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R22 - Harmful if swallowed.

EU Safety Phrases:

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

OSHA Label:
WARNING
Harmful if swallowed.
Suspected of causing cancer.
Suspected of damaging fertility or the unborn child.
Suspected of causing genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials

Epirubicin Hydrochloride
EU EINECS/ELINCS List 260-145-2

Methylparaben
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-785-7

Lactose Monohydrate
Australia (AICS): Present

15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful 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:	Publicly available toxicity information. Pfizer proprietary drug development information.
Reasons for Revision:	Updated Section 2 - Hazard Identification. 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 13 - Disposal Considerations. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

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