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:
Poisons Information Centre: 13 1126

Material Name: Docetaxel Injection

Trade Name: Not applicable
Chemical Family: Not determined
Intended Use: Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to pale yellow solution
Signal Word: DANGER

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

Additional Hazard Information:
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.

EU Indication of danger:
Toxic to reproduction: Category 1
Mutagenic: Category 3
Irritant

EU Hazard Symbols:

EU Risk Phrases:
R10 - Flammable.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.
R64 - May cause harm to breastfed babies.

2. HAZARDS IDENTIFICATION

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	%
Ethyl alcohol (ethanol)	64-17-5	200-578-6	F; R11	<40
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	**
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Docetaxel anhydrous	114977-28-5	Not Listed	Repr.Cat.1;R61 Mut.Cat.3;R68 R64 Xi;R36	1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU 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.

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. 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.

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 spill with absorbent material. Clean spill area thoroughly.

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

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: 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.

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.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
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

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)

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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
pH:	4-7		

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)

Docetaxel anhydrous
Rat Oral LD50 > 2000 mg/kg
Mouse IV LD50 138 mg/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
Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

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

Edetate disodium
Rat Oral LD50 2000-2200 mg/kg

11. TOXICOLOGICAL INFORMATION

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)

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)
OSHA: Listed

12. ECOLOGICAL INFORMATION

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

Mobility, Persistence and Degradability: Not readily biodegradable (0% in 28 days)

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.

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

EU Symbol: T
EU Indication of danger: Toxic to reproduction: Category 1
Mutagenic: Category 3
Irritant

EU Risk Phrases:
R10 - Flammable.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.
R64 - May cause harm to breastfed babies.

15. REGULATORY INFORMATION

EU Safety Phrases:

S22 - Do not breathe dust.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
Flammable liquid and vapor.
Suspected of causing genetic defects.
May damage the unborn child.
May cause harm to breastfed babies.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
Class D, Division 2, Subdivision B
(Bad file name or number)

Polysorbate 80

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

Edetate disodium

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

Ethyl alcohol (ethanol)

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

Citric acid, anhydrous

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

Propylene glycol

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

15. REGULATORY INFORMATION

Docetaxel anhydrous

California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.
R36 - Irritating to eyes.
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.
R68 - Possible risks of irreversible effects.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 11 - Toxicology Information.

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