



# SAFETY DATA SHEET

Revision date: 17-Apr-2018

Version: 5.3

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## 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

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
Emergency telephone number:  
Poisons Information Centre: 13 1126

**Emergency telephone number:**

**CHEMTREC (24 hours): 1-800-424-9300**

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

## 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

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**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<sub>2</sub>, extinguishing powder, foam, or water for extinction



**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	%
Propylene glycol	57-55-6	200-338-0	Not Listed	*
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
Ethyl alcohol (ethanol)	64-17-5	200-578-6	Flam. Liq. 2 (H225)	<40

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Edetate disodium	139-33-3	205-358-3	Not Listed	*
Polysorbate 80	9005-65-6	500-019-9	Not Listed	*

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**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 CO<sub>2</sub>, 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 firefighting 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

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<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup 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

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Propylene glycol

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

#### Ethyl alcohol (ethanol)

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm 1880 mg/m <sup>3</sup>
Austria OEL - MAKs	1000 ppm 1900 mg/m <sup>3</sup>
Belgium OEL - TWA	1000 ppm 1907 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1000 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1000 mg/m <sup>3</sup>
Denmark OEL - TWA	1000 ppm 1900 mg/m <sup>3</sup>
Estonia OEL - TWA	500 ppm 1000 mg/m <sup>3</sup>
Finland OEL - TWA	1000 ppm 1900 mg/m <sup>3</sup>
France OEL - TWA	1000 ppm 1900 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Germany - TRGS 900 - TWAs</b>	500 ppm 960 mg/m <sup>3</sup>
<b>Germany (DFG) - MAK</b>	500 ppm 960 mg/m <sup>3</sup>
<b>Greece OEL - TWA</b>	1000 ppm 1900 mg/m <sup>3</sup>
<b>Hungary OEL - TWA</b>	1900 mg/m <sup>3</sup>
<b>Latvia OEL - TWA</b>	1000 mg/m <sup>3</sup>
<b>Lithuania OEL - TWA</b>	500 ppm 1000 mg/m <sup>3</sup>
<b>Netherlands OEL - TWA</b>	260 mg/m <sup>3</sup>
<b>OSHA - Final PELs - TWAs:</b>	1000 ppm 1900 mg/m <sup>3</sup>
<b>Poland OEL - TWA</b>	1900 mg/m <sup>3</sup>
<b>Portugal OEL - TWA</b>	1000 ppm
<b>Romania OEL - TWA</b>	1000 ppm 1900 mg/m <sup>3</sup>
<b>Russia OEL - TWA</b>	1000 mg/m <sup>3</sup>
<b>Slovakia OEL - TWA</b>	500 ppm 960 mg/m <sup>3</sup>
<b>Slovenia OEL - TWA</b>	1000 ppm 1900 mg/m <sup>3</sup>
<b>Sweden OEL - TWAs</b>	500 ppm 1000 mg/m <sup>3</sup>
<b>Switzerland OEL -TWAs</b>	500 ppm 960 mg/m <sup>3</sup>
<b>Vietnam OEL - TWAs</b>	1000 mg/m <sup>3</sup>

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.

#### Docetaxel anhydrous

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

#### 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.)

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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

<b>Physical State:</b>	Solution	<b>Color:</b>	Clear, colorless to pale yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	4-7		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Docetaxel anhydrous</b>			
No data available			
<b>Citric acid, anhydrous</b>			
No data available			
<b>Polysorbate 80</b>			
No data available			
<b>Propylene glycol</b>			
No data available			
<b>Ethyl alcohol (ethanol)</b>			
No data available			
<b>Edetate disodium</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		

#### Flammability:

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

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers

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### 10. STABILITY AND REACTIVITY

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.

#### 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

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### 11. TOXICOLOGICAL INFORMATION

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 LOEL Male reproductive system

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

##### Docetaxel anhydrous

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



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### 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  
**Ethyl alcohol (ethanol)** Not Ready

**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

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### 15. REGULATORY INFORMATION

#### 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

#### 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

#### 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

#### Ethyl alcohol (ethanol)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 4/29/2011 in alcoholic beverages developmental toxicity 10/1/1987 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

#### 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	500-019-9

### 16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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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 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

**Revision date:** 17-Apr-2018  
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**