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

Product Identifier

Material Name: Docetaxel Injection, USP (Hospira, Inc.)
Trade Name: Not established
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
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
Poisons Information Centre: 13 1126

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
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 CO2, 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric acid, anhydrous</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>Not Listed</td>
<td>**</td>
</tr>
<tr>
<td>Docetaxel anhydrous</td>
<td>114977-28-5</td>
<td>Not Listed</td>
<td>Repr. 1B (H360D)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Muta. 2 (H341)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2A (H319)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lact. (H362)</td>
<td></td>
</tr>
<tr>
<td>Ethyl alcohol (ethanol)</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>Flam. Liq. 2 (H225)</td>
<td>&lt;20</td>
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<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>500-019-9</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>
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
Austria OEL - MAKs 1000 ppm
Belgium OEL - TWA 1000 ppm
Bulgaria OEL - TWA 1000 mg/m³
Czech Republic OEL - TWA 1000 mg/m³
Denmark OEL - TWA 1000 ppm
Estonia OEL - TWA 500 ppm
Finland OEL - TWA 1000 ppm
France OEL - TWA 1000 ppm
Germany - TRGS 900 - TWAs 500 ppm
Germany (DFG) - MAK 500 ppm
Greece OEL - TWA 1000 ppm
Hungary OEL - TWA 1900 mg/m³
Latvia OEL - TWA 1000 mg/m³
Lithuania OEL - TWA 500 ppm
Netherlands OEL - TWA 260 mg/m³
# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material Name: Docetaxel Injection, USP (Hospira, Inc.)</th>
<th>Page 5 of 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date: 25-Mar-2017</td>
<td>Version: 1.0</td>
</tr>
</tbody>
</table>

## 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.)

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Polyethylene glycol
- **Austria OEL - MAKs**: 1000 mg/m³
- **Germany - TRGS 900 - TWAs**: 1000 mg/m³
- **Germany (DFG) - MAK**: 1000 mg/m³ average molecular weight 200-600

Docetaxel anhydrous
- **Pfizer Occupational Exposure Band (OEB)**: OEB 4 (control exposure to the range of 1µg/m³ to <10µg/m³)

---

### OSHA - Final PELS - TWAs:
- 1000 ppm
- 1900 mg/m³

### Poland OEL - TWA:
- 1000 ppm
- 1900 mg/m³

### Portugal OEL - TWA:
- 1000 ppm

### Romania OEL - TWA:
- 1000 ppm
- 1900 mg/m³

### Russia OEL - TWA:
- 1000 ppm
- 1900 mg/m³

### Slovakia OEL - TWA:
- 500 ppm
- 960 mg/m³

### Slovenia OEL - TWA:
- 1000 ppm
- 1900 mg/m³

### Sweden OEL - TWAs:
- 500 ppm
- 1000 mg/m³

### Switzerland OEL - TWAs:
- 500 ppm
- 960 mg/m³
- 1000 mg/m³

### Vietnam OEL - TWAs:
- 1000 mg/m³
### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Solution</td>
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<tr>
<td>Color</td>
<td>Clear, colorless to pale yellow</td>
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<tr>
<td>Odor</td>
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<tr>
<td>Odor Threshold</td>
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<tr>
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<td>Mixture</td>
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<tr>
<td>Solvent Solubility</td>
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<td>Water Solubility</td>
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<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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</tr>
<tr>
<td>Citric acid, anhydrous</td>
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<tr>
<td>Polysorbate 80</td>
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<tr>
<td>Ethyl alcohol (ethanol)</td>
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<tr>
<td>Polyethylene glycol</td>
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<td>Decomposition Temperature (°C)</td>
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<td>Evaporation Rate (Gram/s)</td>
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<tr>
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<tr>
<td>Relative Density</td>
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<td>Viscosity</td>
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<tr>
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<td>Autoignition Temperature (Solid) (°C)</td>
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<td>Flammability (Solids)</td>
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<td>Flash Point (Liquid) (°C)</td>
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<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.)</td>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
<td>3.3 (ethanol)</td>
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### 10. STABILITY AND REACTIVITY

<table>
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<th>Property</th>
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<tbody>
<tr>
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<tr>
<td>Chemical Stability</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
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</tr>
<tr>
<td>Oxidizing Properties</td>
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</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
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</tr>
</tbody>
</table>

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

| General Information                           | The information included in this section describes the potential hazards of the individual ingredients. |
11. TOXICOLOGICAL 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.

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

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

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

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

Polyethylene glycol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

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

Docetaxel anhydrous
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11. TOXICOLOGICAL INFORMATION

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

Docetaxel anhydrous
Reproductive & Fertility  Rat  Intravenous  mg/kg/day  NOEL  Blood forming organs, Male reproductive system
Embryo / Fetal Development  Rat  Intravenous  0.2 mg/kg/day  NOEL  Blood forming organs, Male reproductive system
Embryo / Fetal Development  Dog  Intravenous  0.375 mg/kg/day  LOAEL  Male reproductive system

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:  Carcinogenicity of the mixture has not been determined. Consumption of alcoholic beverages is considered carcinogenic to humans (Group 1) by IARC, though ethanol itself has not been classified by this agency. No other components are listed as carcinogens by IARC, US OSHA or NTP.

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: II

15. REGULATORY INFORMATION

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

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

Ethyl alcohol (ethanol)
CERCLA/SARA 313 Emission reporting: Not Listed
carcinogen 4/29/2011 in alcoholic beverages
developmental toxicity 10/1/1987 in alcoholic beverages

California Proposition 65: Not Listed
15. REGULATORY INFORMATION

| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 200-578-6 |

**Polyethylene glycol**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 2
- EU EINECS/ELINCS List: Not Listed

**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

- 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: New data sheet.

Revision date: 25-Mar-2017


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