SAFETY DATA SHEET

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

Product Identifier

Material Name: Paclitaxel Injection, USP (Hospira Inc.)
Trade Name: Taxol®
Chemical Family: Taxane

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product 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

Emergency telephone number:
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
- Flammable liquids- Category 2

Label Elements

Signal Word: Danger
Hazard Statements:
- H225 - Highly flammable liquid and vapor
- H360FD - May damage fertility. May damage the unborn child.
- H341 - Suspected of causing genetic defects

Precautionary Statements:
- P201 - Obtain special instructions before use
- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P233 - Keep container tightly closed
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P303 + P361 + P335 - 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
SAFETY DATA SHEET

Other Hazards
Note: No data available
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 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

<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>Paclitaxel</td>
<td>33069-62-4</td>
<td>Not Listed</td>
<td>Repr. 1B (H360FD)</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mut. 2 (H341)</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>40-50</td>
</tr>
<tr>
<td>Citric acid, anhydrous</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>Not Listed</td>
<td>**</td>
</tr>
</tbody>
</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>Castor oil, ethoxylated</td>
<td>61791-12-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>

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.

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: None known
Aggravated by Exposure: None

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: Flammable liquid and vapor. Fine particles (such as 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 Antineoplastic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Paclitaxel

Pfizer Occupational Exposure Band (OEB):

OEB 4 (control exposure to the range of 1ug/m³ to <10ug/m³)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 (e.g. Nitrile, etc.) are 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 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 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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Solution</th>
<th>Color:</th>
<th>Clear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available</td>
<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): 78

Partition Coefficient: (Method, pH, Endpoint, Value)
Citric acid, anhydrous
No data available
Paclitaxel
Predicted 7.4  Log D  3.95
Castor oil, ethoxylated
No data available
Ethyl alcohol (ethanol)
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): 14.87
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: As a precautionary measure, keep away from heat sources and electrostatic discharge. Fine particles (such as 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 blood and blood forming organs.
Known Clinical Effects: Adverse effects associated with therapeutic use include decrease in blood pressure (hypotension), neutropenia, dizziness, nausea, vomiting, loss of hair, infection, blood cell changes, flushing, skin rash, and inflammation of the mouth (stomatitis).

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

Citric acid, anhydrous
- Rat  Oral  LD50  3000 mg/kg

Paclitaxel
- Rat  IP  LD50  32.5 mg/kg
- Mouse  IP  LD50  128mg/kg
- Mouse  Intravenous  LD50  12mg/kg

Castor oil, ethoxylated
- Rat  Oral  LC50  > 20g/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)

Citric acid, anhydrous
- Eye Irritation  Rabbit  Severe
- Skin Irritation  Rabbit  Mild
11. TOXICOLOGICAL INFORMATION

Castor oil, ethoxylated
Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Non-irritating

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

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

Paclitaxel
6 Month(s)  Rat  Intravenous  1 mg/kg/day  NOAEL  Blood forming organs, Bone marrow, Thymus, Spleen

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

Paclitaxel
Fertility and Embryonic Development  Rat  Intravenous  1 mg/kg/day  NOAEL  Fetotoxicity, Maternal toxicity, Paternal toxicity
Embryo / Fetal Development  Rat  Intravenous  0.3 mg/kg/day  NOAEL  Developmental toxicity
Embryo / Fetal Development  Rabbit  Intravenous  1 mg/kg/day  NOAEL  Fetotoxicity, Maternal Toxicity
Prenatal & Postnatal Development  Rat  Intravenous  0.3 mg/kg/day  NOAEL  Neonatal toxicity, Maternal Toxicity

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

Paclitaxel
In Vitro Bacterial Mutagenicity (Ames)  Salmonella , E. coli  Negative
In Vitro HGPRT Forward Gene Mutation Assay  Chinese Hamster Ovary (CHO) cells  Negative
In Vitro Chromosome Aberration  Not specified  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.

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)

Paclitaxel
Daphnia magna (Water Flea)  N/A  EC50  N/A  > 0.74 ppm

Ethyl alcohol (ethanol)
Oncorhynchus mykiss (Rainbow Trout)  LC50/96h  12,900-15,300 mg/L
Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Paclitaxel
Activated sludge N/A EC50 > 1000 ppm

Persistence and Degradability: No data available

Bio-accumulative Potential: Partition Coefficient: (Method, pH, Endpoint, Value)
Paclitaxel
Predicted 7.4 Log D 3.95

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

Flash Point (°C): 14.87

IMDG
Flash Point (°C): 14.87

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture
15. REGULATORY INFORMATION

Paclitaxel
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: development toxicity 8/26/1997; female reproductive toxicity 8/26/97
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-578-6

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

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

Castor oil, ethoxylated
- 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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
- Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor
- Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.
- Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects

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

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients, Updated Section 8 - Exposure Controls / Personal Protection, Updated Section 4 - First Aid Measures.

Revision date: 02-Aug-2016


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