



A Pfizer Company

SAFETY DATA SHEET

Revision date: 02-Aug-2016

Version: 1.1

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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

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

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

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 + 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

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**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 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	%
Paclitaxel	33069-62-4	Not Listed	Repr. 1B (H360FD) Mut. 2 (H341)	0.6
Ethyl alcohol (ethanol)	64-17-5	200-578-6	Flam. Liq. 2 (H225)	40-50
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Castor oil, ethoxylated	61791-12-6	Not Listed	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.

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

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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: 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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 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
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

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)

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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

Physical State:	Solution	Color:	Clear
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):	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

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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

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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 NOEL 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 NOEL Fetotoxicity, Maternal toxicity, Paternal toxicity
Embryo / Fetal Development Rat Intravenous 0.3 mg/kg/day NOEL Developmental toxicity
Embryo / Fetal Development Rabbit Intravenous 1 mg/kg/day NOEL Fetotoxicity, Maternal Toxicity
Prenatal & Postnatal Development Rat Intravenous 0.3 mg/kg/day NOEL 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

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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

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15. REGULATORY INFORMATION

Paclitaxel

CERCLA/SARA 313 Emission reporting California Proposition 65	Not Listed developmental toxicity 8/26/1997 female reproductive toxicity 8/26/97
Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS/ELINCS List	Schedule 4 Not Listed

Ethyl alcohol (ethanol)

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

Citric acid, anhydrous

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

Castor oil, ethoxylated

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

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