



MATERIAL SAFETY DATA SHEET

Revision date: 07-May-2012

Version: 1.2

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

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Material Name: Paclitaxel Injection

Trade Name:	Not applicable
Chemical Family:	Taxane
Intended Use:	Pharmaceutical product; Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Clear solution
Signal Word: DANGER

Statement of Hazard: Highly flammable liquid and vapor.
Suspected of causing genetic defects.
May damage fertility or the unborn child.

Additional Hazard Information:
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, inflammation of the mouth (stomatitis)

EU Indication of danger: Flammable
Toxic to Reproduction: Category 2
Mutagenic: Category 3

EU Hazard Symbols:



EU Risk Phrases:
R11 - Highly flammable.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.
R64 - May cause harm to breastfed babies.
Dangerous Goods. Hazardous Substance.

Australian Hazard Classification (NOHSC):

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2. HAZARDS IDENTIFICATION

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	%
Paclitaxel	33069-62-4	Not Listed	Repr. Cat.2;R60-61Cat.3;R68	0.6
Ethyl alcohol (ethanol)	64-17-5	200-578-6	F;R11	<50
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU 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.

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.

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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
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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Ireland OEL - TWAs	1000 ppm
	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

Paclitaxel

Pfizer Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of >1ug/m³ to <10ug/m³)

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.

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

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Boiling Point (°C):

78

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9. PHYSICAL AND CHEMICAL PROPERTIES

Flammability:

Flash Point (Liquid) (°C): 14.87

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)

Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

Paclitaxel

Rat IP LD50 32.5 mg/kg

Mouse IP LD50 128 mg/kg

Mouse Intravenous LD50 12 mg/kg

Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg

Rat Oral LD50 7060 mg/kg

Rat Inhalation LC50 10h 20,000 ppm

Castor oil, ethoxylated

Rat Oral LC50 > 20 g/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)

Citric acid, anhydrous

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

Castor oil, ethoxylated

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

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

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

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11. TOXICOLOGICAL INFORMATION

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

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> HGPRT Forward Gene Mutation Assay	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Chromosome Aberration	Not specified	Positive
<i>In Vivo</i> 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)
OSHA:	Listed

12. ECOLOGICAL INFORMATION

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

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ethyl alcohol (ethanol)

Oncorhynchus mykiss (Rainbow Trout) LC50/96h 12,900-15,300 mg/L

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

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15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Flammable
Toxic to Reproduction: Category 2
Mutagenic: Category 3

EU Risk Phrases:
R11 - Highly flammable.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.
R64 - May cause harm to breastfed babies.

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
Highly flammable liquid and vapor.
Suspected of causing genetic defects.
May damage fertility or the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
Class D, Division 2, Subdivision B



Paclitaxel

California Proposition 65

developmental toxicity initial date 8/26/97
female reproductive toxicity 8/26/97
male reproductive toxicity initial date 8/26/97
Schedule 4

**Standard for the Uniform Scheduling
for Drugs and Poisons:**

Ethyl alcohol (ethanol)

California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS/ELINCS List

developmental toxicity initial date 10/1/87
Present
Present
200-578-6

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15. REGULATORY INFORMATION

Citric acid, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

Castor oil, ethoxylated

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

R68 - Possible risks of irreversible effects.

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

Reasons for Revision: Updated Section 9 - Physical and Chemical Properties. Updated Section 14 - Transport Information.

Prepared by: Product Stewardship Hazard Communication
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