SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

PART I *What is the material and what do I need to know in an emergency?*

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE

IDENTIFICATION of the SUBSTANCE or PREPARATION:

TRADE NAME:	**PACLITAXEL INJECTION**
CHEMICAL NAME: Active Ingredient:	5β,20-Epoxy-1,2α,4,7β,10β,13α-hexahydroxytax-11-en-9-one 4,10-diacetate 2-benzoate 13-ester with (2R,3S)-N-benzoyl-3-phenylisoserine
CHEMICAL CLASS: Active Ingredients:	Taxane
THERAPEUTIC CLASS:	Antineoplastic/Cytotoxic Agent
HOW SUPPLIED:	30 mg (5 mL), 100 mg (16.7 mL), 150 mg (25 mL), and 300 mg (50 mL) multidose vials
RELEVANT USE of the SUBSTANCE:	Human Pharmaceutical
USES ADVISED AGAINST:	Other than Relevant Use

COMPANY/UNDERTAKING IDENTIFICATION:

U.S. SUPPLIER/MANUFACTURER'S NAME:	**TEVA**
ADDRESS:	1090 Horsham Road North Wales, PA 19454
BUSINESS PHONE:	215-591-3000 [08:00 AM --> 05:00 PM]
EUROPEAN. SUPPLIER/MANUFACTURER'S NAME:	**Teva Pharmachemie**
ADDRESS:	Swensweg 5 2031 GA Haarlem, The Netherlands
BUSINESS PHONE:	+31 23 5147 147 [08:00 AM --> 05:00 PM]
EMERGENCY PHONE:	United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs] International: 01-703-527-3887 (Chemtrec) [24-hours]
EMAIL:	bernadette.pogozelski@tevapharm.com
DATE OF PREPARATION:	October 10, 2012
DATE OF REVISION:	New

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The product is also classified per all applicable EU Directives through EC 1907: 2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW: Product Description: This product is a clear, colorless to slightly yellow viscous solution. **Health Hazards:** WARNING! THIS PRODUCT CONTAINS A CYTOTOXIC AGENT. EXPOSURE BY ALL ROUTES OF EXPOSURE MUST BE AVOIDED. May be harmful if ingested, inhaled or in skin contact. In the workplace, exposure via inhalation and skin contact may cause irritation. Inhalation of vapors or accidental ingestion may cause adverse central nervous system effects, due Denatured Alcohol content. Eye contact can cause irritation and mechanical irritation. In therapeutic use, this material may induce blood disorders and/or aggravate pre-existing blood, cardiovascular and gastrointestinal disorders. Allergic reaction, including anaphylaxis, may occur and be severe; no information is available that workplace exposure can cause reactions. May harm cause to the fetus, based on animal information. Limited evidence of mutagenic effects and adverse effects on fertility for both genders, based on animal data. These effects may be possible as a result of workplace exposure. Refer to Section 11 (Toxicological Information) for additional information on adverse effects. **Flammability Hazards:** This product is flammable and can ignite if exposed to high temperature, an ignition source or direct flame. When involved in a fire, this product may ignite and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** This product may cause harm to animals and aquatic organisms if accidentally released to the environment. **Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/v	LABEL ELEMENTS EU Classification (67/548/EEC) GHS and EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
ACTIVE INGREDIENT				
Paclitaxel 5β,20-Epoxy-1,2α,4,7β,10β,13α-hexahydroxytax-11-en-9-one 4,10-diacetate 2-benzoate 13-ester with (2R,3S)-N-benzoyl-3-phenylisoserine	33069-62-4	Not Listed	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Germ Cell Mutagenic Cat. 3, Reproductive Toxicity Cat. 2, Harmful, Irritant Risk Phrase Codes: R33, R36/37/38, R68, R61 Hazard Symbols: T GHS and EU 1272/2008 Classification: Germ Cell Mutagenic Cat. 2, Reproductive Toxicity Cat. 1B, STOT RE Cat. 2, Skin Irritation Cat. 2, Eye Irritation Cat. 2B, STOT (Inhalation-Respiratory Irritation) SE Cat. 3 Hazard Codes: H341, H360Df, H373, H315 + H320, H335 Hazard Symbol/Pictogram: GHS07, GHS08
EXCIPIENTS				
Castor Oil, Ethoxylated	61791-12-6	NLP# 500-151-7	Proprietary	EU 67/548 Hazard Classification: GHS and EU 1272/2008 Hazard Classification:
Citric Acid	77-92-9	201-069-1	Proprietary	EU 67/548 CLASSIFICATION: Not Applicable GHS AND EU 1272/2008 Classification: Not Applicable
Dehydrated Alcohol	64-17-5	200-578-6	Proprietary	EU 67/548 Classification: Highly Flammable Risk Phrases: R11 Symbols: F GHS & EU 1272/2008 Classification: Flammable Liquid Cat. 2 Hazard Statement Codes: H225 Hazard Symbols/Pictograms: GHS02

See Section 16 for full classification information of this product.

PART II *What should I do if a hazardous situation occurs?*

4. FIRST-AID MEASURES

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

SKIN EXPOSURE: If skin contact with this material occurs, flush affected area with water. Minimum flushing is for 20 minutes. The contaminated individual must seek immediate medical attention if any adverse effects occur after flushing.

EYE EXPOSURE: If this material enters the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect occurs or continues after flushing.

INHALATION: If aerosols of this material are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur.

INGESTION: If this material is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, give victim up to three glasses of water. Do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain emergency medical attention.

INJECTION: If this product is accidentally injected, flush injection site with water. Seek medical attention. Refer to Section 11.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing hypersensitivity to Paclitaxel, hepatic and renal insufficiency, bone marrow or blood disorders, pre-existing heart disease may be aggravated by exposure to this material. Workplace exposure may also aggravate these conditions.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. Allergic reaction, including anaphylaxis, may occur and be severe. In event of severe hypersensitivity reactions, corticosteroids (such as dexamethasone), diphenhydramine and H2 antagonists (such as cimetidine or ranitidine) can be administered.

5. FIRE-FIGHTING MEASURES

FLASH POINT: 14-16°C (57.2-60.8°F)

AUTOIGNITION TEMPERATURE: Not available for product. For Dehydrated Alcohol: 363°C (685°F)

FLAMMABLE LIMITS (in air by volume, %): Not available for product.

	LEL	UEL
For Dehydrated Alcohol:	3.3%	19.0%

FIRE EXTINGUISHING MEDIA: Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product.

5. FIRE-FIGHTING MEASURES (Continued)

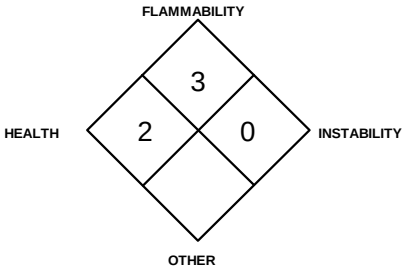
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE: This product is combustible and can ignite if exposed to direct flame or high temperature. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides). Vapors can accumulate in confined spaces resulting in a toxicity and flammability hazard. Vapor may be slightly heavier than air and can travel a considerable distance to a source of ignition and flash back to a leak or open container.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: May be sensitive.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Evacuate area and fight fire from a safe distance. Approach fire from upwind to avoid hazardous vapors and toxic decomposition products. In the event of fire, cool containers of this material with water to prevent failure. For small releases, if it is not possible to stop the leak, and it does not endanger personnel, let the fire burn itself out. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water and rinsed before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: An accidental release can result in a fire. Eliminate any possible sources of ignition, and provide maximum explosion-proof ventilation. Use only non-sparking tools and equipment during the response. Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows and a small scoop to collect glass fragments (if applicable). Absorbents should be incinerable. Finally, the kit should contain two large waste-disposal bags. Avoid generating aerosols from this product.

PROTECTIVE EQUIPMENT:

Small Spills/Spills in Hoods: Personnel wearing nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection should immediately clean spills of less than 5 mL.

Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves, protective clothing (i.e., Tyvek coveralls), and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Cleanup of Small Spills: The spilled product should be gently covered with absorbent pads. Clean spill with pad and dispose of properly. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Spills in Hoods: Decontamination of all interior hood surfaces may be required after the above procedures have been followed. If the HEPA filter of a hood is contaminated, label the unit "Do not use-contaminated" and have trained personnel wearing appropriate protective equipment change and dispose of the filter properly as soon as possible.

Large Spills: Restrict access to the spill areas. For spills of amounts larger than 5 mL, limit spread by gently covering with absorbent sheets, or spill-control pads or pillows. Be sure not to generate aerosols. The dispersion of aerosols into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

All Spills: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered material and report spill per regulatory requirements.

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and STORAGE

NOTE: Consistent with the OSHA Bloodborne Pathogen regulation (29 CFR 1910.1030), observe Universal Precautions while using this product. Place used or product-contaminated hypodermic needles and syringes in a rigid "Sharps" container. Do not recap or clip used or product-contaminated hypodermic needles. Dispose of materials in accordance with regulations.

PRECAUTIONS FOR SAFE HANDLING: THIS PRODUCT CONTAINS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.

7. HANDLING and STORAGE (Continued)

PRECAUTIONS FOR SAFE HANDLING (continued): All employees who handle this product should be thoroughly trained to handle it safely. Special attention must be paid in avoiding releasing aerosols of this product in areas in which this material is handled or used. As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat or drink while handling this material. After handling this material, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection). Areas in which this product is used should be wiped down, so that this product does not accumulate. Particular care in working with this product must be practiced during manufacture of this product, in pharmacies and other preparation areas, and during patient administration. Operations of high risk associated with the use of this product include:

- Filling, packaging and handling of vials
- Withdrawal of needles from drug vials;
- Drug transfers using syringes and needles or filter straws;
- Opening ampoules; and
- Expulsion of air from drug-filled syringes.

DO NOT CLIP OR CRUSH NEEDLE WITH WHICH THIS PRODUCT WAS IN CONTACT. Preparation and administration of this product should meet the following provisions:

- Work should be performed in a designated area for working with hazardous drugs;
- Containment devices, such as a Biological Safety Cabinet, should be used; contaminated waste must be properly handled; and
- Work areas must be regularly decontaminated.

Good hygiene practices must be in place for workers handling this material, including change facilities and a work place clothing program. Workers whose clothing may have become contaminated should change into uncontaminated clothing before leaving the work premises. Contaminated protective clothing should be segregated in such a manner so that there is no direct personal contact by personnel who handle, dispose, or clean the clothing. Contaminated clothing is required to be disposed of properly or remain in the work place for cleaning. No contaminated clothing should be taken from the employee's place of work.

CONDITIONS FOR SAFE STORAGE: Containers of this material must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20° to 25°C (68° to 77°F). Protect from light. Store away from incompatible materials (see Section 10, Stability and Reactivity). Material should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Containers should be separated from oxidizing materials by a minimum distance of 20 ft. or by a barrier of non-combustible material at least 5 ft. high having a fire-resistance rating of at least 0.5 hours. Storage areas should be made of fire resistant materials. Post warning and “NO SMOKING” signs in storage and use areas, as appropriate. Refer to NFPA 30, *Flammable and Combustible Liquids Code*, for additional information on storage. Have appropriate extinguishing equipment in the storage area (such as sprinkler systems or portable fire extinguishers). Inspect all incoming containers before storage to ensure containers are properly labeled and not damaged. Empty containers may contain residual product; therefore, empty containers should be handled with care.

SPECIFIC END USE(S): This material is a human pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean up of equipment. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

VENTILATION AND ENGINEERING CONTROLS: General: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Prevent accumulation of product on work surfaces by routinely cleaning areas appropriately.

WORKPLACE EXPOSURE LIMITS/CONTROL PARAMETERS:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA ppm	STEL ppm	TWA ppm	STEL ppm	TWA ppm	STEL ppm	IDLH ppm	ppm
Paclitaxel	33069-62-4	THIS IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.							
Castor Oil	61791-12-6	NE	NE	NE	NE	NE	NE	NE	NE
Citric Acid	77-92-0	NE	NE	NE	NE	NE	NE	NE	NE
Dehydrated Alcohol	64-17-5	NE	1000	1000	NE	1000	NE	3300 (based on 10% of LEL)	DFG MAKs: TWA = 500 PEAK = 2•MAK 15 min average value, 1-hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C DFG MAK Mutagenic Category 5

NE = Not Established

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently, the following exposure limits are in force for components of this product. Exposure limits change or are added and should be checked periodically.

CITRIC ACID:
Russia: STEL = 1 mg/m^3, JUN 2003

DEHYDRATED ALCOHOL:
Australia: TWA = 1000 ppm (1880 mg/m^3), JUL 2008
AUSTRIA: MAK-TMW = 1000 ppm (1900 mg/m^3); KZW = 2000 ppm (3800 mg/m^3), 2007
Belgium: TWA = 1000 ppm (1907 mg/m^3), MAR 2002
Denmark: TWA = 1000 ppm (1900 mg/m^3), MAY 2011
Finland: TWA = 1000 ppm (1900 mg/m^3), STEL = 1300 ppm (2500 mg/m^3), NOV2011
France: VME = 1000 ppm (1900 mg/m^3), VLE = 5000 ppm (9500), FE B2006
Germany: MAK = 960 mg/m^3 (500 mL/m^3), 2005
Hungary: TWA = 1900 mg/m^3, STEL = 7600 mg/m^3, SEP 2000
Iceland: TWA = 1000 ppm (1900 mg/m^3), NOV 2011
Korea: TWA = 1000 ppm (1900 mg/m^3), 2006
Mexico: TWA = 1000 ppm (1900 mg/m^3), 2004

DEHYDRATED ALCOHOL (continued):
The Netherlands: MAC-TGG = 1000 mg/m^3, 2003
New Zealand: TWA = 1000 ppm (1880 mg/m^3), JAN 2002
Norway: TWA = 500 ppm (950 mg/m^3), JAN 1999
Peru: TWA = 1000 ppm (1884 mg/m^3), JUL2005
The Philippines: TWA = 1000 ppm (1900 mg/m^3), JAN 1993
Poland: MAC(TWA) = 1000 mg/m^3, MAC(STEL) = 3000 mg/m^3, JAN 1999
Russia: TWA = 1000 mg/m^3, STEL = 2000 mg/m^3, JUN 2003
Sweden: TWA = 500 ppm (1000 mg/m^3); STEL = 1000 ppm (1900 mg/m^3), JUN 2005
Switzerland: MAK-W =500 ppm (960 mg/m^3), KZG-W = 1000 ppm (1920 mg/m^3), DEC 2006
Thailand: TWA = 1000 ppm (1900 mg/m^3), JAN 1993
Turkey: TWA = 1000 ppm (1900 mg/m^3), JAN 1993
United Kingdom: TWA = 1000 ppm (1920 mg/m^3), OCT 2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

PROTECTIVE EQUIPMENT: *The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including* U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132)*, equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

RESPIRATORY PROTECTION: Maintain airborne contaminant concentrations below exposure limits listed above. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998). The following are NIOSH respiratory protective equipment guidelines for the Dehydrated Alcohol component and are presented to assist in selection of protective respiratory equipment, if needed.

ETHYL ALCOHOL

CONCENTRATION	RESPIRATORY PROTECTION
Up to 3300 ppm:	Any Supplied-Air Respirator (SAR), or any Self-Contained Breathing Apparatus (SCBA) with a full facepiece.
Emergency or Planned Entry into Unknown Concentrations or IDLH Conditions:	Any SCBA that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode, or any SAR that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary SCBA operated in pressure-demand or other positive-pressure mode.
Escape:	Any appropriate escape-type, SCBA.

EYE PROTECTION: Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.

HAND PROTECTION: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.

SKIN PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.

SPECIAL NOTE: Any contaminated protective clothing or gloves should be changed immediately and disposed of properly. Hands and wrists should be washed immediately after removing contaminated gloves.

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the drug product.

PHYSICAL FORM: Slightly viscous liquid
COLOR: Pale yellow.
ODOR: Alcohol-like.
ODOR THRESHOLD: Not applicable.
MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.
pH: Not available.
FLASH POINT: 14-16°C (57.2-60.8°F)

HOW TO DETECT THIS SUBSTANCE (identification/warning properties): The appearance and odor may be a distinguishing characteristic of this product in event of accidental release.

The following information is for the active ingredient.

FORM: Crystalline solid.
COLOR: Pale yellow.
MOLECULAR FORMULA: $C_{47}H_{51}NO_{14}$
MOLECULAR WEIGHT: 853.9
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
MELTING POINT: 213-216°C (415-420.8°F)
SPECIFIC GRAVITY: 1.399 g/cm^3
BOILING POINT @ 760 mmHg: 957.1°C (1754.8°F) [predict.]
FLASH POINT: 532.6°C (990.7°F) [predict.]
VAPOR PRESSURE @ 25°C: 0 mmHg [predict.]
pH: Not applicable to solid.
SOLUBILITY IN WATER: Insoluble.
OTHER SOLUBILITIES: Soluble in methanol and methylene chloride.
COEFFICIENT OF OIL/WATER DISTRIBUTION (PARTITION COEFFICIENT): Log P: 3.95 (predict.)

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Normally stable. Protect from light.
DECOMPOSITION PRODUCTS: *Combustion:* Products of thermal decomposition may include carbon and nitrogen oxides.
Hydrolysis: None known.

10. STABILITY and REACTIVITY (Continued)

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Strong acids and bases. Due the high level of Denatured Alcohol this product may also have incompatibilities to hydrogen peroxide, perchloric acid, metal perchlorates, mercuric nitrate, silver nitrate, silver and nitric acid, or silver oxide and aqueous ammonia, alkali metals, bromine pentafluoride or bromides, sodium hydrazide, zirconium tetrachloride, phosphorus (iii) oxide, potassium tert-butoxide, acids, acid anhydrides, or acid chlorides, calcium oxide or cesium oxide, platinum black catalyst, bromine and phosphorus or iodine and phosphorus.

SPECIAL NOTE ON INCOMPATIBILITY: Contact of this material and solutions made with it with plasticized polyvinyl chloride (PVC) equipment or devices used to prepare solutions for infusion is not recommended. In order to minimize patient exposure to the plasticizer DEHP [di-(2-ethylhexyl)phthalate], which may be leached from PVC infusion bags or sets, diluted Paclitaxel injection solutions should preferably be stored in bottles (glass, polypropylene) or plastic bags (polypropylene, polyolefin) and administered through polyethylene-lined administration sets.

POSSIBILITY OF HAZARDOUS REACTION/POLYMERIZATION: None known.

CONDITIONS TO AVOID: Exposure to or contact with extreme temperatures, incompatible chemicals.

PART IV *Is there any other useful information about this material?*

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: This product contains a cytotoxic and anti-neoplastic agent that may cause significant health effects from workplace exposure. The main route of occupational exposure to this product is via inhalation of aerosols and skin or eye contact. The anticipated symptoms of exposure, by route of exposure are described further in this section.

INHALATION: Inhalation of aerosols may irritate the mucous membranes and upper respiratory tract. May be harmful by inhalation, especially if exposure is chronic. Upon inhalation, dyspnea, chest pain, burning eyes, sore throat, and nausea have been reported. Chronic, low-level inhalation exposure may cause lightheadedness, dizziness, nausea, headache. Although unlikely to occur, due to the high level of Denatured Alcohol, inhalation of high vapor concentration will cause adverse central nervous system effects.

CONTACT WITH SKIN or EYES: May be harmful by skin contact. Tingling, burning, and redness have been reported following skin contact. Symptoms of eye contact can cause redness, pain, and watering, as well as mechanical irritation.

SKIN ABSORPTION: Caution in handling this material must be exercised due to potential harmful effect by skin contact.

INGESTION: Ingestion of this material is not anticipated to be a significant route of occupational exposure. Ingestion of this material (i.e., through poor hygiene practices) may be harmful; no specific information is available.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	3
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	See Section 8		See Section 8

For Routine Industrial Use and Handling Applications

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate
3 = Serious 4 = Severe * = Chronic hazard

INJECTION: Accidental injection of this product, by a contaminated needle or via laceration or puncture wound from a contaminated object may cause pain and irritation. Accidental injection may cause leakage of the drug into surrounding tissues and cause tissue damage. In addition effects described under 'Other Potential Health Effects' may occur.

OTHER POTENTIAL HEALTH EFFECTS: The most common adverse effects from therapeutic use have been low red blood cell count (anemia) feeling weak or tired hair loss, numbness, tingling, or burning in your hands or feet (neuropathy), joint and muscle pain, nausea and vomiting, hypersensitivity reaction - trouble breathing; sudden swelling of your face, lips, tongue, throat, or trouble swallowing; hives (raised bumps) or rash, diarrhea, mouth or lip sores (mucositis), infections, swelling of your hands, face, or feet, bleeding events, irritation and reaction at the injection site, low blood pressure (hypotension). Other adverse effects have been allergic reactions, including anaphylaxis. Body systems adversely affected during therapeutic use are provided below. The actual risk in the workplace is not known. More details are also given in the Teva Active Ingredient SDS for Paclitaxel. For more detailed information on possible adverse effects associated with product administration to patients, consult the Prescribing Information Sheet for this product.

- Bone Marrow
- Cardiovascular System
- Dermatologic
- Ears:
- Eyes
- Gastrointestinal System
- Blood System
- Hepatic and System
- Injection Site Reactions
- Neurological System
- Respiratory System
- Reproductive Toxicity System

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: This product may be harmful by ingestion and inhalation or skin contact. May cause irritation by inhalation and skin or eye contact.

Chronic: Dermatitis (inflammation and redness of the skin) may occur after chronic, low-level skin contact. May cause adverse effects on blood forming system. No other chronic effects have been reported from workplace exposure. Chronic exposure may also lead to symptoms described under 'Other Potential Health Effects'.

11. TOXICOLOGICAL INFORMATION (Continued)

TARGET ORGANS: It is anticipated that for Occupational Exposure the target organs are: Acute: Skin, eyes, respiratory system. Chronic: Skin and blood forming system. In therapeutic use this product may have an impact on the body systems listed under 'Other Potential Health Effects'.

TOXICITY DATA: The following toxicity data are currently available for active ingredient of this product. Data are available for the excipient ingredient, but are not presented in this SDS. Contact Teva for more information.

PACLITAXEL:

TDLo (Oral-Human) 2.3 mg/kg: Gastrointestinal: hypermotility, diarrhea; Gastrointestinal: nausea or vomiting

LDLo (Intravenous-Human-Woman) 4995 mg/kg/3 hours-continuous: Cardiac: cardiomyopathy including infarction; Blood: leukopenia, thrombocytopenia

LDLo (Intravenous-Human-Man) 5.14 mg/kg: Immunological Including Allergic: anaphylaxis

LDLo (Intravenous-Human-Man) 5.14 mg/kg: Cardiac: arrhythmias (including changes in conduction); Lungs, Thorax, or Respiration: respiratory obstruction; Immunological Including Allergic: anaphylaxis

TDLo (Intravenous-Human-Man) 9.26 mg/kg/8 weeks-intermittent: Blood: granulocytopenia; Skin and Appendages: dermatitis, allergic (after systemic exposure); Immunological Including Allergic: hypersensitivity delayed

TDLo (Intravenous-Human-Man) 7.7 mg/kg/15 days-intermittent: Blood: leukopenia; Musculoskeletal: other changes; Skin and Appendages: dermatitis, other (after systemic exposure

TDLo (Intravenous-Human-Man) 3.09 mg/kg/15 days-intermittent: Behavioral: anorexia (human); Blood: leukopenia, aplastic anemia

TDLo (Intravenous-Human) 4.5 mg/kg: Blood: leukopenia

TDLo (Intravenous-Human) 2.3 mg/kg: Lungs, Thorax, or Respiration: dyspnea; Skin and Appendages: dermatitis, allergic (after systemic exposure); Immunological Including Allergic: increase in cellular immune response

TDLo (Intravenous-Human) 2.21 mg/kg: Cardiac: arrhythmias (including changes in conduction), other changes; Blood: changes in other cell count (unspecified

TDLo (Intravenous-Human) 27 mg/kg/15 weeks-intermittent: Lungs, Thorax, or Respiration: tumors; Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Human) 27 mg/kg/15 weeks-intermittent: Lungs, Thorax, or Respiration: tumors; Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Human) 15.4 mg/kg/9 weeks-intermittent: Blood: granulocytopenia; Musculoskeletal: joints; Skin and Appendages: hair

TDLo (Intravenous-Human) 226 mg/kg/5 years-intermittent: Immunological Including Allergic: hypersensitivity delayed

TDLo (Intravenous-Human) 7.5 mg/kg/3 weeks-intermittent: Nutritional and Gross Metabolic - body temperature increase

TDLo (Intravenous-Human) 27 mg/kg/84 days-intermittent: Blood: granulocytopenia, changes in erythrocyte (RBC) count; Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Human) 7.5 mg/kg/3 weeks-intermittent: Blood: thrombocytopenia, changes in other cell count (unspecified); Skin and Appendages: hair

TDLo (Intravenous-Human-Woman) 17 mg/kg/12 weeks-intermittent: Skin and Appendages: dermatitis, other (after systemic exposure

TDLo (Intravenous-Human) 7 mg/kg/21 days-intermittent: Blood: granulocytopenia

TDLo (Intravenous-Human) 280 mg/kg/21 days-intermittent: Blood: granulocytopenia, leukopenia, thrombocytopenia

TDLo (Intravenous-Human) 13.5 mg/kg/6 weeks-intermittent: Peripheral Nerve and Sensation: sensory change involving peripheral nerve; Blood: changes in bone marrow (not otherwise specified

TDLo (Intravenous-Human) 7.5 mg/kg/3 weeks-intermittent: Gastrointestinal: hypermotility, diarrhea, nausea or vomiting; Blood: normocytic anemia

TDLo (Intravenous-Human) 13.3 mg/kg/6 weeks-intermittent: Peripheral Nerve and Sensation: sensory change involving peripheral nerve; Blood: thrombocytopenia, changes in other cell count (unspecified

TDLo (Intravenous-Human) 5.9 mg/kg/25 days-intermittent: Behavioral: somnolence (general depressed activity), normocytic anemia, changes in other cell count (unspecified

TDLo (Intravenous-Human) 44.23 mg/kg/36 weeks-intermittent: Immunological Including Allergic: uncharacterized

TDLo (Intravenous-Human) 2.96571428571429 mg/kg/15 days-intermittent: Gastrointestinal: nausea or vomiting; Blood: leukopenia, changes in leukocyte (WBC) count

TDLo (Intravenous-Human) 4.44857142857143 mg/kg/15 days-intermittent: Behavioral: somnolence (general depressed activity), anorexia (human

TDLo (Intravenous-Human) 5.19 mg/kg/15 days-intermittent: Liver: liver function tests impaired; Skin and Appendages: dermatitis, other (after systemic exposure); Nutritional and Gross Metabolic: changes in potassium

TDLo (Intravenous-Human) 4.04 mg/kg/15 days-intermittent: Gastrointestinal: hypermotility, diarrhea; Liver: liver function tests impaired; Skin and Appendages: hair

TDLo (Intravenous-Human-Woman) 6.43 mg/kg: Peripheral Nerve and Sensation: paresthesis; Behavioral: muscle weakness

TDLo (Intravenous-Human-Woman) 3.47 mg/kg: Blood: changes in other cell count (unspecified)

TDLo (Intravenous-Human-Woman) 1.54 mg/kg: Lungs, Thorax, or Respiration: bronchiolar constriction; Immunological Including Allergic: other immediate (humoral): urticaria, allergic rhinitis, serum sickness; Nutritional and Gross Metabolic: body temperature decrease

TDLo (Intravenous-Human-Woman) 3.47 mg/kg: Behavioral: convulsions or effect on seizure threshold; Vascular: BP lowering not characterized in autonomic section; Lungs, Thorax, or Respiration: bronchiolar constriction

TDLo (Intravenous-Human-Woman) 3.47 mg/kg: Immunological Including Allergic: anaphylaxis

TDLo (Intravenous-Human-Woman) 4.5 mg/kg: Peripheral Nerve and Sensation: sensory change involving peripheral nerve; Cardiac: other changes; Gastrointestinal: nausea or vomiting

TDLo (Intravenous-Human-Woman) 4.5 mg/kg: Blood: thrombocytopenia, changes in other cell count (unspecified); Skin and Appendages: hair

TDLo (Intravenous-Human-Woman) 4.96 mg/kg: Peripheral Nerve and Sensation: paresthesis

TDLo (Intravenous-Human-Woman) 34 mg/kg/126 days-intermittent: Immunological Including Allergic: increase in cellular immune response; Immunological Including Allergic: increased immune response; Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Human-Woman) 93.3 mg/kg/48 weeks-intermittent: Blood: aplastic anemia; Musculoskeletal: other changes; Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Human-Woman) 240 mg/kg/28 days-intermittent: Peripheral Nerve and Sensation: sensory change involving peripheral nerve; Behavioral: somnolence (general depressed activity); Vascular: BP elevation not characterized in autonomic section

TDLo (Intravenous-Human-Woman) 240 mg/kg/28 days-intermittent: Gastrointestinal: nausea or vomiting; Blood: normocytic anemia, changes in cell count (unspecified)

TDLo (Intravenous-Human-Woman) 240 mg/kg/28 days-intermittent: Skin and Appendages: hair, nails; Immunological Including Allergic: hypersensitivity delayed

TDLo (Intravenous-Human-Woman) 240 mg/kg/28 days-intermittent: Musculoskeletal: other changes

TDLo (Intravenous-Human-Woman) 6 mg/kg/3 weeks-intermittent: Behavioral: somnolence (general depressed activity); Blood: changes in cell count (unspecified), changes in leukocyte (WBC) count

TDLo (Intravenous-Human-Woman) 6 mg/kg/3 weeks-intermittent: Skin and Appendages: dermatitis, other (after systemic exposure); Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Human-Woman) 8.5 mg/kg/21 days-intermittent: Blood: normocytic anemia, changes in other cell count (unspecified; Skin and Appendages: hair

TDLo (Intravenous-Human-Woman) 25.5 mg/kg/126 days-intermittent: Peripheral Nerve and Sensation: sensory change involving peripheral nerve; Blood: granulocytopenia; Skin and Appendages: hair

TDLo (Intravenous-Human-Woman) 17 mg/kg/12 weeks-intermittent: Blood: granulocytopenia; Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Human-Woman) 23.39 mg/kg/12 weeks-intermittent: Peripheral Nerve and Sensation: sensory change involving peripheral nerve; Blood: granulocytopenia; Skin and Appendages: nails

TDLo (Intravenous-Human-Woman) 23.59 mg/kg/12 weeks-intermittent: Gastrointestinal: nausea or vomiting; Blood: changes in other cell count (unspecified); Skin and Appendages: nails

TDLo (Intravenous-Human-Woman) 14.88 mg/kg/43 days-intermittent: Peripheral Nerve and Sensation - structural change in nerve or sheath

TDLo (Unreported-Human-Man) 30.9 mg/kg/12 weeks-intermittent: Skin and Appendages: dermatitis, other (after systemic exposure); Skin and Appendages: hair; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation

TDLo (Unreported-Human-Woman) 8.5 mg/kg/42 days-intermittent: Lungs, Thorax, or Respiration: cough, dyspnea; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation

TDLo (Unreported-Human) 17 mg/kg/12 weeks-intermittent: Skin and Appendages: dermatitis, other (after systemic exposure)

TDLo (Unreported-Human-Woman) 6.8 mg/kg/3 weeks-intermittent: Blood: hemorrhage

LD_{50} (Intraperitoneal-Rat) 32,530 µg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea; Nutritional and Gross Metabolic: weight loss or decreased weight gain

LD_{50} (Intraperitoneal-Mouse) 128 mg/kg: Skin and Appendages: hair; Nutritional and Gross Metabolic: weight loss or decreased weight gain

LD_{50} (Intravenous -Mouse) 7.53 mg/kg

LD_{50} (Intravenous-Mouse) 12 mg/kg: Behavioral: somnolence (general depressed activity), ataxia; Lungs, Thorax, or Respiration: respiratory depression

LD_{99} (Intravenous-Mouse) 24 mg/kg

LDLo (Intravenous-Rat) 85 mg/kg: Lungs, Thorax, or Respiration: other changes; Blood: changes in bone marrow (not otherwise specified

LDLo (Intravenous-Mammal-Dog) 15 mg/kg: Behavioral: somnolence (general depressed activity), ataxia; Lungs, Thorax, or Respiration: respiratory stimulation

LDLo (Intravenous-Rat) 30 mg/kg: Brain and Coverings: other degenerative changes

TDLo (Oral-Mouse) 120 mg/kg/3 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Oral-Mouse) 420 mg/kg/14 days-intermittent: Tumorigenic: protects against induction of experimental tumors

TDLo (Intravenous-Rat) 9 mg/kg: Brain and Coverings: other degenerative changes

TDLo (Intravenous-Rat) 15 mg/kg: Vascular: other changes; Lungs, Thorax, or Respiration: acute pulmonary edema

TDLo (Intravenous-Rat) 10 mg/kg: Gastrointestinal: hypermotility, diarrhea; Biochemical: Metabolism (Intermediary): other proteins

TDLo (Intravenous-Rat) 4 mg/kg: Tumorigenic: protects against induction of experimental tumors

TDLo (Intravenous-Rat) 42500 µg/kg/5 days-intermittent: Spinal Cord: demyelination, other degenerative changes

TDLo (Intravenous-Rat) 89100 µg/kg/26 weeks-intermittent: Endocrine: other changes; Blood: changes in bone marrow (not otherwise specified); Blood: changes in erythrocyte (RBC) count

TDLo (Intravenous-Rat) 60 mg/kg/4 weeks-intermittent: Blood: changes in leukocyte (WBC) count; Related to Chronic Data: changes in testicular weight, changes in uterine weight

TDLo (Intravenous-Rat) 84 mg/kg: male 9 week(s) pre-mating female 2 week(s) pre-mating 1-7 day(s) after conception: Reproductive: Maternal Effects: other effects; Fertility: pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea); Effects on Embryo or Fetus: extra-embryonic structures (e.g., placenta, umbilical cord

TDLo (Intravenous-Rat) 6600 µg/kg: female 7-17 day(s) after conception: Reproductive: Specific Developmental Abnormalities: musculoskeletal system, Effects on Newborn: delayed effects

TDLo (Intravenous-Rat) 26 mg/kg: female 17-21 day(s) after conception lactating female 21 day(s) post-birth: Reproductive: Effects on Newborn: growth statistics (e.g.%, reduced weight gain, behavioral, physical

TDLo (Intravenous-Rat) 115 mg/kg: Peripheral Nerve and Sensation: structural change in nerve or sheath; Sense Organs and Special Senses (Olfaction): effect, not otherwise specified

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (continued):

PACLITAXEL (continued):

TDLo (Intravenous-Mouse) 60 mg/kg: Tumorigenic: active as anti-cancer agent; Biochemical: Metabolism (Intermediary): other

TDLo (Intravenous-Mouse) 60 mg/kg: Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Mouse) 180 mg/kg/3 days-intermittent: Peripheral Nerve and Sensation: structural change in nerve or sheath; Behavioral: changes in motor activity (specific assay)

TDLo (Intravenous-Mouse) 30 mg/kg/5 days-intermittent: Related to Chronic Data: death

TDLo (Intravenous-Mouse) 100 mg/kg/15 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Mouse) 0.9 mg/kg/9 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Mouse) 162 mg/kg/8 days-intermittent: Vascular: other changes; Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Mouse) 180 mg/kg/9 days-intermittent: Tumorigenic: active as anti-cancer agent; Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intravenous-Mouse) 162 mg/kg/12 days-intermittent: Vascular: structural changes in vessels; Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Mouse) 90 mg/kg/2 weeks-intermittent: Tumorigenic: protects against induction of experimental tumors

TDLo (Intravenous-Mouse) 48 mg/kg/4 weeks-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Mouse) 40 mg/kg/3 days-intermittent: Peripheral Nerve and Sensation: flaccid paralysis without anesthesia (usually neuromuscular blockage)

TDLo (Intravenous-Mouse) 150 mg/kg/16 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Mouse) 300 mg/kg/34 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Mouse) 150 mg/kg/4 days-intermittent: Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intravenous-Mouse) 50 mg/kg/10 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Mouse) 80 mg/kg/13 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intravenous-Mouse) 50 mg/kg/13 days-intermittent: Tumorigenic: protects against induction of experimental tumors

TDLo (Intravenous-Mouse) 100 mg/kg/5 days-intermittent: Tumorigenic: protects against induction of experimental tumors

TDLo (Intravenous-Mouse) 150 mg/kg/9 days-intermittent: Tumorigenic: protects against induction of experimental tumors

TDLo (Intravenous-Mouse) 40 mg/kg/8 days-intermittent: Tumorigenic: protects against induction of experimental tumors

TDLo (Intravenous-Mouse) 180 mg/kg/1 weeks-intermittent: Peripheral Nerve and Sensation: recording from afferent nerve; Peripheral Nerve and Sensation: structural change in nerve or sheath; Behavioral: ataxia

TDLo (Intravenous-Mouse) 12.5 mg/kg/8 days-intermittent: Nutritional and Gross Metabolic: weight loss or decreased weight gain; Tumorigenic: protects against induction of experimental tumors

TDLo (Intravenous-Mouse) 60 mg/kg/28 days-intermittent: Tumorigenic: protects against induction of experimental tumors

TDLo (Intravenous-Mammal-Dog) 15 mg/kg/5 weeks-intermittent: Blood: agranulocytosis

TDLo (Intravenous-Mammal-Dog) 39 mg/kg/26 weeks-intermittent: Blood: agranulocytosis

TDLo (Intraperitoneal-Rat) 10 mg/kg: Peripheral Nerve and Sensation: structural change in nerve or sheath

TDLo (Intraperitoneal-Rat) 10 mg/kg: Spinal Cord: other degenerative changes

PACLITAXEL (continued):

TDLo (Intraperitoneal-Rat) 15 mg/kg/11 days-intermittent: Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intraperitoneal-Rat) 20 mg/kg/5 days-intermittent: Gastrointestinal: other changes; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other Enzymes

TDLo (Intraperitoneal-Rat) 18 mg/kg/3 weeks-intermittent: Blood: pigmented or nucleated red blood cells, changes in erythrocyte (RBC) count; Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intraperitoneal-Rat) 25 mg/kg/10 days-intermittent: Peripheral Nerve and Sensation: recording from afferent nerve; Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intraperitoneal-Rat) 132 mg/kg/4 weeks-intermittent: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects

TDLo (Intraperitoneal-Rat) 112.5 mg/kg/9 weeks-intermittent: Peripheral Nerve and Sensation: sensory change involving peripheral nerve, structural change in nerve or sheath

TDLo (Intraperitoneal-Rat) 20 mg/kg/2 weeks-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intraperitoneal-Rat) 108 mg/kg/9 weeks-intermittent: Peripheral Nerve and Sensation: sensory change involving peripheral nerve

TDLo (Intraperitoneal-Mouse) 7.5 mg/kg: Reproductive: Maternal Effects: oogenesis

TDLo (Intraperitoneal-Mouse) 20 mg/kg: Tumorigenic: active as anti-cancer agent

TDLo (Intraperitoneal-Mouse) 29 mg/kg: Blood: changes in bone marrow (not otherwise specified)

TDLo (Intraperitoneal-Mouse) 5 mg/kg: Spinal Cord: other degenerative changes

TDLo (Intraperitoneal-Mouse) 5 mg/kg: Vascular: measurement of regional blood flow

TDLo (Intraperitoneal-Mouse) 65 mg/kg/15 days-intermittent: Skin and Appendages: tumors; Tumorigenic: protects against induction of experimental tumors

TDLo (Intraperitoneal-Mouse) 80 mg/kg/4 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intraperitoneal-Mouse) 150 µg/kg/15 days-intermittent: Tumorigenic: protects against induction of experimental tumors

TDLo (Intraperitoneal-Mouse) 100 mg/kg/15 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intraperitoneal-Mouse) 100 mg/kg/8 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intraperitoneal-Mouse) 140 mg/kg/23 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intraperitoneal-Mouse) 40.2 mg/kg/12 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intraperitoneal-Mouse) 60 mg/kg/3 weeks-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intraperitoneal-Mouse) 45 mg/kg/9 days-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intraperitoneal-Mouse) 16 mg/kg/2 weeks-intermittent: Tumorigenic: active as anti-cancer agent

TDLo (Intraperitoneal-Mouse) 100 mg/kg/5 days-intermittent: Nutritional and Gross Metabolic: weight loss or decreased weight gain; Tumorigenic: protects against induction of experimental tumors

TDLo (Intraperitoneal-Mouse) 12.5 mg/kg/5 days-intermittent: Tumorigenic: protects against induction of experimental tumors

TDLo (Intraperitoneal-Mouse) 75 mg/kg/19 days-continuous: Tumorigenic: protects against induction of experimental tumors

TDLo (Intraperitoneal-Mouse) 40 mg/kg/2 weeks-intermittent: Tumorigenic: protects against induction of experimental tumors

TDLo (Intraperitoneal-Mouse) 60 mg/kg/3 weeks-continuous: Tumorigenic: protects against induction of experimental tumors

PACLITAXEL (continued):

TDLo (Subcutaneous-Mouse) 80 mg/kg/8 days-intermittent: Vascular: other changes

TDLo (Subcutaneous-Mouse) 80 mg/kg/8 days-intermittent: Vascular: structural changes in vessels; Tumorigenic: active as anti-cancer agent

TDLo (Unreported-Mouse) 180 mg/kg/2 days-intermittent: Peripheral Nerve and Sensation: structural change in nerve or sheath

TDLo (Chicken-Neurons) 117 nmol/L/48 hours: In Vitro Toxicity Studies: cell membrane integrity: cytoplasmic enzymes leakage (lactate dehydrogenase, ATP enzymes etc

DNA damage (Human Lymphocyte) 0.02 mg/L/48 hours

Morphological transformation (Human Liver) 0.5 µmol/L/24 hours

Micronucleus test (Human Lymphocyte) 5 nmol/L/48H

Micronucleus test (Human Lymphocyte) 15 nmol/L/52 hours

Micronucleus test (Human Cells-Not Otherwise Specified) 3.13 µg/L/24 hours

Micronucleus test (Human Cells-Not Otherwise Specified) 0.625 mg/L/3 hours

DNA damage (Human Lymphocyte) 10 µmol/L/4 hours

DNA repair (Human Lymphocyte) 10 µmol/L/4 hours

DNA damage (Human Cells - not otherwise specified) 1 µmol/L/48 hours

DNA damage (Human Liver) 1 µmol/L/48 hours

Cytogenetic analysis (Human Lymphocyte) 0.003 mg/L/24 hours

Specific locus test (Human Cells-Not Otherwise Specified) 0.02 mg/L

Specific locus test (Human Cells-Not Otherwise Specified) 0.06 mg/L

Specific locus test (Human Cells-Not Otherwise Specified) 0.125 mg/L/3 hours

Specific locus test (Human Cells-Not Otherwise Specified) 0.0313 mg/L/48 hours

Specific locus test (Human Cells-Not Otherwise Specified) 0.012 mg/L/16 hours

Specific locus test (Human Cells-Not Otherwise Specified) 0.069 mg/L/16 hours

Micronucleus test (Human Cells-Not Otherwise Specified) 3.16 µmol/L/3 hours

Micronucleus test (Subcutaneous-Mouse) 20 mg/kg

DNA damage (Rodent - Mouse Cells-Not Otherwise Specified) 1 mg/L/24 hours

DNA damage (Intraperitoneal-Rat) 1 mg/kg

Cytogenetic analysis (Hamster Lung) 80 µg/L

Cytogenetic analysis (Oral- Primate-Monkey) 7.5 mg/kg

Cytogenetic analysis (Oral-Insect-Drosophila Melanogaster) 0.01 mmol/L/6 hours

Cytogenetic analysis (Intravenous-Mouse) 1 mg/kg

Cytogenetic analysis (Intravenous-Primate-Monkey) 6 mg/kg/96 hours-continuous

Sex chromosome loss and Non-Disjunction (Mouse Lymphocyte) 0.75 mg/L/4 hours

Gene conversion and mitotic recombination (Oral-Insect-Drosophila Melanogaster) 0.01 mmol/L/6 hours

Specific locus test (Mouse Ascites Tumor) 10 µg/L/24 hours

Mutation in mammalian somatic cells (Mouse Cells-Not Otherwise Specified) 2.4 mg/L/4 hours

Micronucleus test (Mouse Cells-Not Otherwise Specified) 1 nmol/L/48 hours

Micronucleus test (Hamster Ovary) 0.07 µmol/L/24 hours

Micronucleus test (Intravenous-Mouse) 6 mg/kg/6 days

Micronucleus test (Mouse Cells-Not Otherwise Specified) 12.5 mg/L/4 hours

Micronucleus test (Mouse Cells-Not Otherwise Specified) 0.12 µmol/L

Micronucleus test (Mouse Cells-Not Otherwise Specified) 0.427 mg/L/24 hours

Micronucleus test (Intraperitoneal-Rat) 0.5 mg/kg

Micronucleus test (Hamster Ovary) 1 µmol/L/3 hours

Micronucleus test (Hamster Lung) 100 µg/L/24 hours

CARCINOGENIC POTENTIAL OF COMPONENTS: The carcinogenic potential of Paclitaxel has not been studied. The excipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

DEHYDRATED ALCOHOL: ACGIH TLV-A3 (Animal Carcinogen with Unknown Relevance to Humans); MAK-5 (Substances with Carcinogenic and Genotoxic Effects, the potency of which is considered to be so low that, provided the MAK and BAT values are observed, no significant contribution to human cancer risk is to be expected.)

The remaining components are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

IRRITANCY OF PRODUCT: May cause respiratory, skin or eye irritation.

SENSITIZATION TO THE PRODUCT: Anaphylaxis and severe hypersensitivity reactions characterized by dyspnea and hypotension requiring treatment, angioedema, and generalized urticaria have occurred. Fatal reactions have occurred in patients despite premedication with corticosteroids.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION: This product is rated Pregnancy Risk Category D (There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks). There are no adequate and well-controlled studies in pregnant women.

Mutagenicity: Paclitaxel has been shown to be clastogenic in vitro (chromosome aberrations in human lymphocytes) and in vivo (micronucleus test in mice). Paclitaxel was not mutagenic in the Ames test or the CHO/HGPRT gene mutation assay.

Embryotoxicity/Teratogenicity: Administration of Paclitaxel during the period of organogenesis to rabbits at doses of 3 mg/kg/day (about 0.2 the daily maximum recommended human dose on a mg/m^2 basis) caused embryo- and fetotoxicity, as indicated by intrauterine mortality, increased resorptions, and increased fetal deaths. Maternal toxicity was also observed at this dose. No teratogenic effects were observed at 1 mg/kg/day (about 1/15 the daily maximum recommended human dose on a mg/m^2 basis); teratogenic potential could not be assessed at higher doses due to extensive fetal mortality.

Reproductive Toxicity: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from the drug, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother. Administration of Paclitaxel prior to and during mating produced impairment of fertility in male and female rats at doses equal to or greater than 1 mg/kg/day (about 0.04 the daily maximum recommended human dose on a mg/m^2 basis). At this dose, Paclitaxel caused reduced fertility and reproductive indices, and increased embryo- and fetotoxicity

BIOLOGICAL EXPOSURE INDICES: Currently, there are no Biological Exposure Indices (BEIs) determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY IN SOIL: This product has not been tested for mobility in soil. The following information is available for the Dehydrated Alcohol component.

DEHYDRATED ALCOHOL: Using a structure estimation method based on molecular connectivity indices, the Koc can be estimated to be 1. According to a classification scheme, this estimated Koc value suggests that this compound is expected to have very high mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that some biodegradation will occur to this product; however, no specific information is known. The following information is available for the Dehydrated Alcohol component.

DEHYDRATED ALCOHOL: If released to the atmosphere, an extrapolated vapor pressure of 59.3 mm Hg at 25°C indicates that this compound will exist solely in the vapor phase. Vapor phase material is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 5 days. If released to soil, this compound is expected to have very high mobility based upon an estimated Koc of 1. Volatilization from moist soil surfaces is expected to be an important fate process based upon a Henry's Law constant of 5X10-6 atm-cu m/mole. This material may also volatilize from dry soils based upon it vapor pressure. Biodegradation is expected to occur rapidly in the environment based on numerous screening tests using different types of inocula and incubation periods. This compound was degraded with half-lives on the order of a few days using microcosms constructed with a low organic sandy soil and groundwater, indicating it is unlikely to be persistent in the environment. If released into water, this material is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 3 and 39 days, respectively. Hydrolysis and photolysis in sunlit surface waters are not expected since this compound lacks functional groups that are susceptible to hydrolysis or photolysis under environmental conditions.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential. The following information is available for the Dehydrated Alcohol component.

DEHYDRATED ALCOHOL: An estimated BCF of 3 was calculated, using a log Kow of -0.31 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

ECOTOXICITY: This product may be harmful or fatal to contaminated plant and animal-life (especially if large quantities are released). This product has not been tested for aquatic toxicity. This product may be harmful or fatal to contaminated aquatic plant and animal life. The following data are available for the Dehydrated Alcohol and Citric Acid components.

CITRIC ACID:

EC_0 (*Pseudomonas putida* bacteria) 16 hours = > 10,000 mg/L
EC_0 (*Microcystis aeruginosa* algae) 8 days - 80 mg/L
EC_0 (*Scenedesmus quadricauda* green algae) 7 days = 640 mg/L
EC_0 (*Entosiphon sulcatum* protozoa) 72 hours = 485 mg/L
EC_0 (*Uronema parduczi* Chatton-Lwoff protozoa) = 622 mg/L
LC_{50} (*Carcinus maenas* Green or European shore crab) 48 hour = 160 mg/L; renewal /formulated product LD_0 (*Daphnia magna* giant water flea) = 80 mg/L, long-time exposure in soft water
LD_0 (goldfish) 625 mg/L, long-time exposure in hard water
LD_{100} (*Daphnia magna* giant water flea) = 120 mg/l long-time exposure in soft water
LD_{100} (goldfish) 894 mg/L, long-time exposure in hard water
Toxic (*Daphnia* water flea) = 100 mg/L
Toxic (goldfish) 4 hours = 894 ppm fresh water
Period of survival at pH 4.0 (goldfish) 48 hours = 894 mg/L
Period of survival at pH 4.5 (goldfish) = 625 mg/L
TLm (shore crab) 48 hours = 160 ppm salt water

DEHYDRATED ALCOHOL:

EC_{50} (*Chlorella pyrenoidosa* Green algae; growth inhibition) 48 hours = 9310 mg/L; static
EC_{50} (*Pimephales promelas* fathead minnows) 96 hours = 12.9 g/L; age 30 days old, water hardness 47.3 mg/L (CaCO3), temp 24.3°C, pH 7.60, dissolved oxygen 6.8 mg/L, alkalinity 43.7 mg/L (CaCO3); tank vol: 6.3 L; additions: 3.81 vol/day /Flow-through bioassay
LC_{50} (*Salmo gairdnerii* Rainbow trout) 96 hours = 13,000 mg/Lat 12°C (95% Confidence limit 12000-16000 mg/L), wt 0.8 g /Static bioassay
LC_{50} (*Poecilia reticulata* Guppy) 24 hours = 12,500 mg/L/Conditions of bioassay not specified in source examined
LC_{50} (*Artemia franchiscana* Brine shrimp) 96 hours = 7.00 mg/L; static
LC_{50} (*Leuciscus idus melanotus* Golden orfe) 48 hours = 8140 mg/L; static
LC_{50} (*Danio rerio* Zebrafish) 24 hours = >100 mg/L; static
LC_{50} (*Daphnia magna* Water flea) 48 hours = 9268-14221 mg/L; static, 24°C
LC_{50} (*Gammarus fasciatus* Scud) 96 hours = >100 mg/L; static
LC_{50} (*Oryzias latipes* Medaka) 48 hours = 1350 mg/L; static

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

OTHER ADVERSE EFFECTS: The components of this product are not listed as having ozone depletion potential.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority

13. DISPOSAL CONSIDERATIONS (Continued)

WASTE TREATMENT/DISPOSAL METHODS (continued): . All protective clothing, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures and/or regulated medical waste requirements.

It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters. Reusable equipment should be cleaned with soap and water and thoroughly rinsed.

DISPOSAL CONTAINERS: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

U.S. EPA WASTE NUMBER: Not applicable.

EUROPEAN EWC WASTE CODE: Wastes from natal care, diagnosis, treatment, or prevention of disease in humans: cytotoxic and cytostatic medicines, 18-01-08

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

UN IDENTIFICATION NUMBER: UN 1993
PROPER SHIPPING NAME: Flammable liquids, n.o.s. (Ethyl Alcohol)
HAZARD CLASS NUMBER and DESCRIPTION: 3 (Flammable)
PACKING GROUP: PG II
DOT LABEL(S) REQUIRED: Class 3 (Flammable)
NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (2012): 128
MARINE POLLUTANT: The components of this product are not classified by the DOT as Marine Pollutants (as defined by 49 CFR 172.101, Appendix B).

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product meets the criteria as Dangerous Goods, per regulations of Transport Canada.

UN IDENTIFICATION NUMBER: UN 1993
PROPER SHIPPING NAME: Flammable liquid, n.o.s. (Ethyl Alcohol)
HAZARD CLASS NUMBER and DESCRIPTION: 3 (Flammable)
PACKING GROUP: PG II
HAZARD SHIPPING LABEL(S) REQUIRED: Class 3 (Flammable)
SPECIAL PROVISIONS: 16
EXPLOSIVE LIMIT & LIMITED QUANTITY INDEX: 1
ERAP INDEX: None
PASSENGER CARRYING SHIP INDEX: None
PASSENGER CARRYING ROAD OR RAIL VEHICLE INDEX: 5

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product meets the criteria as Dangerous Goods, per rules of IATA.

UN IDENTIFICATION NUMBER: UN 1993
PROPER SHIPPING NAME/DESCRIPTION Flammable liquid, n.o.s. (Ethyl Alcohol)
HAZARD CLASS or DIVISION: 3 (Flammable)
HAZARD LABEL(S) REQUIRED: Class 3 (Flammable)
PACKING GROUP: II
EXCEPTED QUANTITIES: E2
PASSENGER and CARGO AIRCRAFT PACKING INSTRUCTION: 353
PASSENGER and CARGO AIRCRAFT MAXIMUM NET QUANTITY PER PKG: 5 L
PASSENGER and CARGO AIRCRAFT LIMITED QUANTITY PACKING INSTRUCTION: Y341
PASSENGER and CARGO AIRCRAFT LIMITED QUANTITY MAXIMUM NET QUANTITY PER PKG: 1 L
CARGO AIRCRAFT ONLY PACKING INSTRUCTION: 364
CARGO AIRCRAFT ONLY MAXIMUM NET QUANTITY PER PKG: 60 L
SPECIAL PROVISIONS: A3
ERG CODE: 3H

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is classified as Dangerous Goods by the International Maritime Organization.

UN No.: 1993
PROPER SHIPPING NAME: Flammable liquid, n.o.s. (Ethyl Alcohol)
HAZARD CLASS NUMBER: 3
PACKING GROUP: II
SPECIAL PROVISIONS: 274

14. TRANSPORTATION INFORMATION (Continued)

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION (continued):

LIMITED QUANTITIES:	1 L
EXCEPTED QUANTITIES:	E2
PACKING:	Instructions: P001, Provisions: None
IBCs:	Instructions: IBC02, Provisions: None
TANKS:	Instructions: T7, Provisions: TP8, TP28
EmS:	F-E, S-E
STOWAGE CATEGORY:	Category B.

MARINE POLLUTANT: The components of this product do not meet the criteria of a Marine Pollutant under UN criteria.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product meets the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

UN NO.:	1993
NAME and DESCRIPTION:	Flammable liquid, n.o.s. (Ethyl Alcohol)
CLASS:	3
CLASSIFICATION CODE:	F1
PACKING GROUP:	II
LABELS:	3
SPECIAL PROVISIONS:	274, 601, 640D
LIMITED QUANTITIES:	LQ4
EXCEPTED QUANTITIES:	E2
PACKING INSTRUCTIONS:	Instructions: P001, IBC02, R001
SPECIAL PACKING PROVISIONS:	None
MIXED PACKING PROVISIONS:	MP19
PORTABLE TANKS AND BULK CONTAINERS:	Instructions: T7, Provisions: TP8, TP28
HAZARD IDENTIFICATION No.:	33

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: See the information under the individual jurisdiction listings for IBC information. See the information under the individual jurisdiction listings for IBC information.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and no component is specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for this material. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. SARA HAZARD CATEGORIES (SECTION 311/312, 40 CFR 370-21): ACUTE: Yes; CHRONIC: Yes; FIRE: Yes; REACTIVE: No; SUDDEN RELEASE: No

U.S. CERCLA REPORTABLE QUANTITY (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration (FDA) standards; this product is not subject to requirements under TSCA.

OTHER U.S. FEDERAL REGULATIONS: This product is regulated under FDA regulations.

STATE REGULATIONS: Regulated Medical Waste.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The Dehydrated Alcohol component is on the California Proposition 65 lists; however, this listing does applies only to Dehydrated Alcohol consumed as an alcoholic beverage and does not apply to workplace exposure.

ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL/NDSL STATUS: This product is regulated by the Therapeutic Products Programme (TPP) of Health Canada; it is exempt from the requirements of CEPA.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITY SUBSTANCES LISTS: Components are not on the CEPA substances lists.

OTHER CANADIAN REGULATIONS: Requirements under the Canadian Heath Canada, Laboratory Biosafety Guidelines may be applicable.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

ADDITIONAL EUROPEAN REGULATIONS:

SAFETY, HEALTH, AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE PRODUCT: Formulated, finished medicinal products for human use, are subject to Directive 2001/83/EC and subsequent amendments to the directive.

CHEMICAL SAFETY ASSESSMENT: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Z129.1, Provided to Summarize Occupational Hazard Information): **DANGER!** FLAMMABLE LIQUID AND VAPOR. STRONG CYTOTOXIC AGENT. ALL EXPOSURE MUST BE MINIMIZED. MAY BE HARMFUL IF INHALED INGESTED, OR IN CONTACT WITH SKIN. MAY CAUSE RESPIRATORY SYSTEM, EYE, AND SKIN IRRITATION. MAY CAUSE HYPERSENSITIVITY AND ALLERGIC RESPONSE, INCLUDING ANAPHYLAXIS. CHRONIC EXPOSURE MAY CAUSE DAMAGE TO ORGANS. MAY CAUSE HARM TO FETUS DURING PREGNANCY. MAY CAUSE MUTAGENIC EFFECTS, BASED ON ANIMAL DATA. SUSPECTED OF LIMITED ADVERSE EFFECTS TO FERTILITY. MAY CAUSE ADVERSE EFFECTS ON BLOOD FORMING SYSTEM. Do not taste or swallow. Avoid contact with skin, eyes, and clothing. Keep container closed. Use gloves, safety glasses, and appropriate respiratory and body protection. **FIRST-AID:** If exposed, seek immediate medical attention. If swallowed, do not induce vomiting. If alert, give victim up to three glasses of water. Never give anything by mouth to an unconscious person. In case of contact, immediately flush skin with copious amounts of warm water for 20 minutes. Remove contaminated clothing and shoes. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. **IN CASE OF FIRE:** Use water fog, dry chemical or CO_2, or alcohol foam. **IN CASE OF SPILL:** Refer to Safety Data Sheet for complete spill response procedures. Spill response should be performed by persons properly trained to do so. Decontaminate area with bleach and detergent solution and triple rinse area. Place spill debris in a suitable container. Refer to SDS for additional information.

SPECIAL HANDLING AND DISPOSAL REQUIRED

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

67/548/EEC EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION FOR COMPONENTS:

FULL TEXT GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008:

PACLITAXEL: This is a self-classification.

Classification: Germ Cell Mutagenic Category 2, Reproductive Toxicity Category 1B, Specific Target Organ Toxicity Repeated Exposure Category 2, Skin Irritation Category 2, Eye Irritation Category 2B, Specific Target Organ Toxicity (Inhalation-Respiratory Irritation) Single Exposure Category 3

Hazard Statement Codes: H360Df: May damage the unborn child. Suspected of damaging fertility. H341: Suspected of causing genetic effects. H373: May cause damage to organs through prolonged or repeated exposure.H315 + H320: Causes skin and eye irritation. H335: May cause respiratory irritation.

DEHYDRATED ALCOHOL: The following is a Published Classification.

Classification: Flammable Liquid Category 2

Hazard Statements: H225: Highly flammable liquid and vapour.

ALL OTHER COMPONENTS:

An official classification for these substances has not been published in the CLP 1272: 2008 and is not applicable for self-classification.

FULL TEXT EU 67/548/EEC:

PACLITAXEL: This is a self-classification.

Classification: Germ Cell Mutagen Category 3, Reproductive Toxicity Category 2, Harmful/Irritant

Risk Phrases: R33: Danger of cumulative effects. R36/37/38: Irritating to eyes, respiratory system and skin. R68: Possible risk of irreversible effects. R61: May cause harm to the unborn child.

DEHYDRATED ALCOHOL: The following is a Published Classification.

Classification: Highly Flammable

Risk Phrases: R11: Highly Flammable

ALL OTHER COMPONENTS:

An official classification for these substances has not been published in Commission Directives 93/72/EEC, 94/69 EC, 96/54/EC or subsequent directives and is not applicable for self-classification.

REVISION DETAILS: New

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721-1961 • (800) 441-3365

DATE OF PRINTING: October 12, 2012

REVISION HISTORY: New

DEFINITIONS OF TERMS

For information on medical terms used in this SDS consult an on-line database such as Medline Plus: http://www.nlm.nih.gov/medlineplus/druginformation.html. A large number of abbreviations and acronyms appear on a SDS. Some of these, which are commonly used, include the following:

CAS #: This is the Chemical Abstract Service Number that uniquely identifies each constituent.

EXPOSURE LIMITS IN AIR:

CEILING LEVEL: The concentration that shall not be exceeded during any part of the working exposure.

ACGIH - American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

Ceiling Level (C). Skin absorption effects must also be considered.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens which have been shown to increase the mutant frequency in the progeny of exposed humans. **2:** Germ cell mutagens which have been shown to increase the mutant frequency in the progeny of exposed mammals. **3A:** Substances which have been shown to induce genetic damage in germ cells of human of animals, or which produce mutagenic effects in somatic cells of mammals *in vivo* and have been shown to reach the germ cells in an active form. **3B:** Substances which are suspected of being germ cell mutagens because of their genotoxic effects in mammalian somatic cell *in vivo*; in exceptional cases, substances for which there are no *in vivo* data, but which are clearly mutagenic *in vitro* and structurally related to known in vivo mutagens. **4:** Not applicable (Category 4 carcinogenic substances are those with non-genotoxic mechanisms of action. By definition, germ cell mutagens are genotoxic. Therefore, a Category 4 for germ cell mutagens cannot apply. At some time in the future, it is conceivable that a Category 4 could be established for genotoxic substances with primary targets other than DNA [e.g. purely aneugenic substances] if research results make this seem sensible.) **5:** Germ cell mutagens, the potency of which is considered to be so low that, provided the MAK value is observed, their contribution to genetic risk for humans is expected not to be significant.

DFG MAK Pregnancy Risk Group Classification: Group A: A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed. **Group B:** Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. **Group C:** There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. **Group D:** Classification in one of the groups A-C is not yet possible because, although the data available may indicate a trend, they are not sufficient for final evaluation.

IDLH-Immediately Dangerous to Life and Health: This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury.

LOQ: Limit of Quantitation.

MAK: Federal Republic of Germany Maximum Concentration Values in the workplace.

NE: Not Established. When no exposure guidelines are established, an entry of NE is made for reference.

NIC: Notice of Intended Change.

NIOSH CEILING: The exposure that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.

NIOSH RELs: NIOSH's Recommended Exposure Limits.

PEL-Permissible Exposure Limit: OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL," is placed next to the PEL that was vacated by Court Order.

SKIN: Used when a there is a danger of cutaneous absorption.

STEL-Short Term Exposure Limit: Short Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

TLV-Threshold Limit Value: An airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour.

TWA-Time Weighted Average: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

HEALTH HAZARD: 0 (Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation*: Essentially non-irritating. PII or Draize = "0". *Eye Irritation*: Essentially non-irritating, or minimal effects which clear in < 24 hours [e.g. mechanical irritation]. Draize = "0". *Oral Toxicity LD_{50} Rat*: < 5000 mg/kg. *Dermal Toxicity LD_{50}Rat or Rabbit*: < 2000 mg/kg. *Inhalation Toxicity 4-hrs LC_{50} Rat*: < 20 mg/L.); **1** (Slight Hazard: Minor reversible Injury may occur; slightly or mildly irritating. *Skin Irritation*: Slightly or mildly irritating. *Eye Irritation*: Slightly or mildly irritating. *Oral Toxicity LD_{50} Rat*: > 500-5000 mg/kg. *Dermal Toxicity LD_{50}Rat or Rabbit*: > 1000-2000 mg/kg. *Inhalation Toxicity LC_{50}* 4-hrs *Rat*: > 2-20 mg/L); **2** (Moderate Hazard: Temporary or transitory injury may occur. *Skin Irritation*: Moderately irritating; primary irritant; sensitizer. PII or Draize > 0, < 5. *Eye Irritation*: Moderately to severely irritating and/or corrosive; reversible corneal opacity; corneal involvement or irritation clearing in 8-21 days. Draize > 0, ≤ 25. *Oral Toxicity LD_{50} Rat*: > 50-500 mg/kg. *Dermal Toxicity LD_{50}Rat or Rabbit*: > 200-1000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.5-2 mg/L.); **3** (Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation*: Severely irritating and/or corrosive; may destroy dermal tissue, cause skin burns, dermal necrosis. PII or Draize > 5-8 with destruction of tissue. *Eye Irritation*: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity LD_{50} Rat*: > 1-50 mg/kg. *Dermal Toxicity LD_{50}Rat or Rabbit*: > 20-200 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.05-0.5 mg/L.); **4** (Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure. *Skin Irritation*: Not appropriate. Do not rate as a "4", based on skin irritation alone. *Eye Irritation*: Not appropriate. Do not rate as a "4", based on eye irritation alone. *Oral Toxicity LD_{50} Rat*: ≤ 1 mg/kg. *Dermal Toxicity LD_{50}Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: ≤ 0.05 mg/L).

FLAMMABILITY HAZARD: 0 (Minimal Hazard-Materials that will not burn in air when exposure to a temperature of 815.5°C [1500°F] for a period of 5 minutes.); **1** (Slight Hazard-Materials that must be pre-heated before ignition can occur. Material require considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur, Including: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C [200°F] (e.g. OSHA Class IIIB, or; Most ordinary combustible materials [e.g. wood, paper, etc.];

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): 2 (Moderate Hazard-Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres in air, Including: Liquids having a flash-point at or above 37.8°C [100°F]; Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp; Solids and semisolids that readily give off flammable vapors.); **3** (Serious Hazard- Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions, including: Liquids having a flash point below 22.8°C [73°F] and having a boiling point at or above 38°C [100°F] and below 37.8°C [100°F] [e.g. OSHA Class IB and IC]; Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air [e.g., dusts of combustible solids, mists or droplets of flammable liquids]; Materials that burn extremely rapidly, usually by reason of self-contained oxygen [e.g. dry nitrocellulose and many organic peroxides]); **4** (Severe Hazard-Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and which will burn readily, including: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C [73°F] and a boiling point below 37.8°C [100°F] [e.g. OSHA Class IA; Material that ignite spontaneously when exposed to air at a temperature of 54.4°C [130°F] or below [e.g. pyrophoric]).

PHYSICAL HAZARD: 0 (*Water Reactivity*: Materials that do not react with water. *Organic Peroxides*: Materials that are normally stable, even under fire conditions and will not react with water. *Explosives*: Substances that are Non-Explosive. Unstable *Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No "0" rating allowed. *Unstable Reactives*: Substances that will not polymerize, decompose, condense or self-react.); **1** (*Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy. *Explosives*: Division 1.5 and 1.6 substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases*: Pressure below OSHA definition. *Pyrophorics*: No Rating. *Oxidizers*: Packaging Group III; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives*: Substances that may decompose, condense or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosive hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors.); **2** *Water Reactivity*: Materials that may react violently with water. *Organic Peroxides*: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives*: Division 1.4 – Explosive substances where the explosive effect are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. *Compressed Gases*: Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group II Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature); **3** (*Water Reactivity*: Materials that may form explosive reactions with water. *Organic Peroxides*: Materials that are capable of detonation or explosive reaction, but require a strong initiating source, or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives*: Division 1.2 – Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases*: Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group I Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3.:2 potassium bromate/cellulose mixture. Liquids: Any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives*: Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a moderate potential to cause significant heat generation or explosion.); **4** (*Water Reactivity*: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides*: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives*: Division 1.1 and 1.2-explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability "4". *Oxidizers*: No "4" rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a high potential to cause significant heat generation or explosion.).

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: **0** Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD_{50} for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. **1** Materials that, under emergency conditions, can cause significant irritation. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD_{50} for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **2** Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC_{50} for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm.

DEFINITIONS OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD (continued): **2 (continued):** Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers. Materials whose LD_{50} for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD_{50} for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **3** (materials that, under emergency conditions, can cause serious or permanent injury): Gases and vapors whose LC_{50} for acute inhalation toxicity is greater than 1,000 ppm but less than or equal to 3,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials whose LD_{50} for acute dermal toxicity is greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials whose LD_{50} for acute oral toxicity is greater than 5 mg/kg but less than or equal to 50 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials that are respiratory irritants. Cryogenic gases that cause frostbite and irreversible tissue damage. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials that are corrosive to the skin. **4** (materials that, under emergency conditions, can be lethal): Gases and vapors whose LC_{50} for acute inhalation toxicity less than or equal to 1,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD_{50} for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD_{50} for acute oral toxicity is less than or equal to 5 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 1000 ppm.

FLAMMABILITY HAZARD: **0** Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand: Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D. Liquids, solids and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendation on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85 percent by weight. Liquids that have no fire point when tested by ASTM D 92 Standard Test Method for Flash and Fire Points by Cleveland Open Cup, up to a boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed up flash point of the solvent. Most ordinary combustible materials. **2** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air: Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures in air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **3** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that, on account of their physical form or environmental conditions, can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with a representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **4** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily: Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air, Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD: **0** Materials that in themselves are normally stable, even under fire conditions: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. **1** Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. **2** Materials that readily undergo violent chemical change at elevated temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100W/mL. **3** Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures.

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the **N**ational **F**ire **P**rotection **A**ssociation (**NFPA**). Flash Point - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. Autoignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD_{50}** - Lethal Dose (solids and liquids) which kills 50% of the exposed animals; **LC_{50}** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m^3** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, and **LDo**, or **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** The sources are: **IARC** - the International Agency for Research on Cancer; **NTP** - the National Toxicology Program, **RTECS** - the Registry of Toxic Effects of Chemical Substances, **OSHA** and **CAL/OSHA**. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** **BEI** - ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REPRODUCTIVE TOXICITY INFORMATION:

A mutagen is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An embryotoxin is a chemical which causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical which causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance which interferes in any way with the reproductive process.

ECOLOGICAL INFORMATION:

EC is the effect concentration in water. **BCF** = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. **TL_m** = median threshold limit; Coefficient of Oil/Water Distribution is represented by **log K_{ow}** or **log K_{oc}** and is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S. and CANADA:

ACGIH: American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. **O**ccupational **S**afety and **H**ealth **A**dministration (**OSHA**). **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively. Superfund Amendments and Reauthorization Act **(SARA)**; the Canadian Domestic/Non-Domestic Substances List **(DSL/NDSL)**; the U.S. Toxic Substance Control Act **(TSCA)**; Marine Pollutant status according to the **DOT**; the Comprehensive Environmental Response, Compensation, and Liability Act **(CERCLA or Superfund)**; and various state regulations. This section also includes information on the precautionary warnings which appear on the material's package label. **OSHA** - U.S. Occupational Safety and Health Administration.

EUROPEAN and INTERNATIONAL:

The DFG: This is the Federal Republic of Germany's Occupation Health Agency, similar to the U.S. OSHA. **EU** is the European Community (formerly known as the **EEC,** European Economic Community). **EINECS:** This is the European Inventory of Now-Existing Chemical Substances. The **ARD** is the European Agreement Concerning the International Carriage of Dangerous Goods by Road and the **RID** are the International Regulations Concerning the Carriage of Dangerous Goods by Rail. **AICS** is the Australian Inventory of Chemical Substances.