SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Paclitaxel Injection, USP - 6 mg/ml**
Product Use/Restriction:	Antineoplastic.
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	March 19, 2009
SDS Revision Date:	June 01, 2015
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Flammable Liquid. Category 2.
Respiratory sensitisation. Category 1.
Germ cell mutagenicity. Category 2.
Reproductive toxicity. Category 2.
Eye Irritation. Category 2.
Skin Sensitization. Category 1.
Specific Target Organ Toxicity - STOT, Single Exposure SE. Category 3 (CNS).
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
Highly flammable liquid and vapor.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of causing genetic defects.
Suspected of damaging fertility or the unborn child.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Keep away from heat/sparks/open flames/hotsurfaces. — No smoking.
Keep container tightly closed.
Ground/Bond container and receiving equipment.
Use explosion-proof electrical/ventilating/lighting equipment.
Use only non-sparking tools.
Take precautionary measures against static discharge.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF exposed or concerned: Get medical advice/attention.
Call a POISON CENTER or doctor/physician if you feel unwell.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
In case of fire: Use dry chemical, carbon dioxide to extinguish small fires. Use water for large fires.
Store in a well-ventilated place. Keep container tightly closed.
Store in a well-ventilated place. Keep cool.
Store locked up.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: Flammable. Contains pharmacologically active material with anti-cancer properties. Excessive exposure may cause adverse effects on rapidly dividing cells (e.g., blood cells, reproductive organs, developing embryo), CNS effects, and liver effects. Direct contact may cause irritation.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects: Paclitaxel may cause adverse effects to rapidly dividing cells (e.g., blood cells, reproductive organs, developing embryo, skin cells).
Ethanol may cause CNS depression, liver effects, and birth defects.

	Cremophor EL may cause sensitization reactions.
Eye:	Contact with eyes may cause irritation.
Skin:	May cause skin irritation.
Inhalation:	May cause irritation of respiratory tract.
Ingestion:	May cause irritation.
Carcinogenicity:	None of the constituents are listed by U.S. OSHA, NTP, or IARC as a carcinogen.
Target Organs:	Blood cells, reproductive organs, developing embryo, liver, nervous system, cardiovascular system.
Aggravation of Pre-Existing Conditions:	Pre-existing skin and respiratory conditions.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Paclitaxel	33069-62-4	6 mg/mL	
Cremophor EL	61791-12-6	527 mg/mL	
Ethyl Alcohol	64-17-5	49.7% by Volume	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flammable Properties:	Flammable.
Flash Point:	75 °F (24 °C)
Flash Point Method:	Not reported.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Remove all sources of ignition. Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. Provide ventilation. Collect spill with a non-sparking tool. Place into a suitable container for disposal. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Retain in carton until time of use.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Ethyl Alcohol :

Guideline ACGIH:	TLV-TWA: 1000 ppm
Guideline OSHA:	PEL-TWA: 1000 ppm
Guideline NIOSH:	REL-TWA: 1000 ppm

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.
Boiling Point:	74-80 °C
Melting Point:	Not established.
Specific Gravity:	<1
Solubility:	Insoluble in water.
Vapor Density:	Not established.
Vapor Pressure:	5.3kPa @ 20 °C
Percent Volatile:	Not established.
pH:	Not established.
Molecular Formula:	Mixture
Molecular Weight:	Mixture
Flash Point:	75 °F (24 °C)
Flash Point Method:	Not reported.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from light, heat, and freezing.
Incompatible Materials:	Avoid contact with strong oxidizing agents.
Special Decomposition Products:	Thermal decomposition or burning may produce noxious products including carbon monoxide, carbon dioxide, and nitrogen oxides.

SECTION 11 : TOXICOLOGICAL INFORMATION

Paclitaxel :

RTECS Number:	DA8340750
Carcinogenicity:	No studies identified.
Mutagenicity:	Mixed results reported.
Reproductive Toxicity:	Fertility impairment effects reported in rats given 1 mg/kg/day intravenously.
Teratogenicity:	Fetotoxic effects but not birth defects reported in rats and rabbits given around 1 mg/kg/day intravenously.
Neurological Effects:	Neurological effects reported in rats given daily injections that corresponded to about 6 mg/kg/week.
Other Toxicological Information:	Intravenous. - Rat LDLo: 85 mg/kg [Lungs, Thorax, or Respiration - other changes Blood - changes in bone marrow (not otherwise specified)] Intravenous. - Mouse LD50: 12 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression] Intravenous. - Mouse LD50: 7.53 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat LDLo: 30 mg/kg [Brain and Coverings - other degenerative changes] Intravenous. - Rat TDLo: 9 mg/kg [Brain and Coverings - other degenerative changes] Intravenous. - Mouse LD99: 24 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 15 mg/kg [Vascular - other changes Lungs, Thorax, or Respiration - acute pulmonary edema] Intravenous. - Human TDLo: 4.5 mg/kg [Blood - leukopenia] Intravenous. - Rat TDLo: 10 mg/kg [Gastrointestinal - hypermotility, diarrhea Biochemical - Metabolism (Intermediary) - other proteins] Intravenous. - Human TDLo: 2.21 mg/kg [Cardiac - arrhythmias (including changes in conduction) Cardiac - other changes Blood - changes in other cell count (unspecified)] Intravenous. - Rat TDLo: 4 mg/kg [Tumorigenic - protects against induction of experimental tumors] Intravenous. - Mouse TDLo: 115 mg/kg [Peripheral Nerve and Sensation - structural change in nerve or sheath Sense Organs and Special Senses (Olfaction) - effect, not otherwise specified] Intravenous. - Rat TDLo: 42500 ug/kg/5D (intermittent) [Spinal Cord - demyelination Spinal Cord - other degenerative changes] Intravenous. - Rat TDLo: 89100 ug/kg/26W (intermittent) [Endocrine - other changes Blood - changes in bone marrow (not otherwise specified) Blood - changes in erythrocyte (RBC) count] Intravenous. - Rat TDLo: 60 mg/kg/4W (intermittent) [Blood - changes in leukocyte (WBC) count Related to Chronic Data - changes in testicular weight Related to Chronic Data - changes in uterine weight] Intravenous. - Mouse TDLo: 180 mg/kg/3D (intermittent) [Peripheral Nerve and Sensation - structural change in nerve or sheath Behavioral - changes in motor activity (specific assay)] Intravenous. - Mouse TDLo: 30 mg/kg/5D (intermittent) [Related to Chronic Data - death] Intravenous. - Human TDLo: 27 mg/kg/15W (intermittent) [Lungs, Thorax, or Respiration - tumors Tumorigenic - active as anti-cancer agent] Intravenous. - Mouse TDLo: 100 mg/kg/15D (intermittent) [Tumorigenic - active as anti-cancer agent] Intravenous. - Human TDLo: 15.4 mg/kg/9W (intermittent) [Blood - granulocytopenia Musculoskeletal - joints Skin and Appendages - hair] Intravenous. - Human TDLo: 226 mg/kg/5Y (intermittent) [Immunological Including Allergic - hypersensitivity delayed] Intravenous. - Mouse TDLo: 0.9 mg/kg/9D (intermittent) [Tumorigenic - active as anti-cancer agent] Intravenous. - Mouse TDLo: 162 mg/kg/8D (intermittent) [Vascular - other changes Tumorigenic - active as anti-cancer agent] Intravenous. - Mouse TDLo: 180 mg/kg/9D (intermittent) [Tumorigenic - active as anti-cancer agent Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intravenous. - Mouse TDLo: 180 mg/kg/9D (intermittent) [Tumorigenic - active as anti-cancer agent Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intravenous. - Human TDLo: 7.5 mg/kg/3W (intermittent) [Gastrointestinal - hypermotility, diarrhea Gastrointestinal - nausea or vomiting Blood - normocytic anemia] Intravenous. - Human TDLo: 7.5 mg/kg/3W (intermittent) [Blood - thrombocytopenia Blood - changes in other cell count (unspecified) Skin and Appendages - hair] Intravenous. - Human TDLo: 7.5 mg/kg/3W (intermittent) [Nutritional and Gross Metabolic - body temperature increase] Intravenous. - Mouse TDLo: 162 mg/kg/12D (intermittent) [Vascular - structural changes in vessels Tumorigenic - active as anti-cancer agent] Intravenous. - Human TDLo: 27 mg/kg/84D (intermittent) [Blood - granulocytopenia Blood - changes in erythrocyte (RBC) count Tumorigenic - active as anti-cancer agent] Intravenous. - Human TDLo: 7 mg/kg/21D (intermittent) [Blood - granulocytopenia] Intravenous. - Human TDLo: 280 mg/kg/21D (intermittent) [Blood - granulocytopenia Blood - leukopenia Blood - thrombocytopenia] Intravenous. - Human TDLo: 13.5 mg/kg/6W (intermittent) [Peripheral Nerve and Sensation - sensory change involving peripheral nerve Blood - changes in bone marrow (not otherwise specified)] Intravenous. - Mouse TDLo: 90 mg/kg/2W (intermittent) [Tumorigenic - protects against induction of experimental tumors] Intravenous. - Mouse TDLo: 48 mg/kg/4W (intermittent) [Tumorigenic - active as anti-cancer agent] Intravenous. - Mouse TDLo: 40 mg/kg/3D (intermittent) [Peripheral Nerve and Sensation - flaccid paralysis without anesthesia (usually neuromuscular blockage)] Intravenous. - Mouse TDLo: 150 mg/kg/16D (intermittent) [Tumorigenic - active as anti-cancer agent] Intravenous. - Mouse TDLo: 300 mg/kg/34D (intermittent) [Tumorigenic - active as anti-cancer agent] Intravenous. - Mouse Micronucleus test: 6 mg/kg/6D Intravenous. - Rat TDLo: 84 mg/kg [Reproductive - Maternal Effects - other effects Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea) Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord)] Intravenous. - Rat TDLo: 6600 ug/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Effects on Newborn - delayed effects] Intravenous. - Rat TDLo: 26 mg/kg [Reproductive - Effects on Newborn - growth statistics (e.g.%, reduced weight gain) Reproductive - Effects on Newborn - behavioral Reproductive - Effects on Newborn - physical] Subcutaneous - Mouse TDLo: 80 mg/kg/8D (intermittent) [Vascular - other changes] Subcutaneous - Mouse TDLo: 80 mg/kg/8D (intermittent) [Vascular - structural changes in vessels Tumorigenic - active as anti-cancer agent] Subcutaneous - Mouse Micronucleus test: 20 mg/kg Intraperitoneal. - Rat LD50: 32530 ug/kg [Behavioral - somnolence (general depressed activity) Lungs, Thorax, or Respiration - dyspnea Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Mouse LD50: 128 mg/kg [Skin and Appendages - hair Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Mouse TDLo: 7.5 mg/kg [Reproductive - Maternal Effects - oogenesis] Intraperitoneal. - Mouse TDLo: 20 mg/kg [Tumorigenic - active as anti-cancer agent] Intraperitoneal. - Rat TDLo: 10 mg/kg [Peripheral Nerve and Sensation - structural change in nerve or sheath] Intraperitoneal. - Mouse TDLo: 29 mg/kg [Blood - changes in bone marrow (not otherwise specified)] Intraperitoneal. - Rat TDLo: 10 mg/kg [Spinal Cord - other degenerative changes] Intraperitoneal. - Rat TDLo: 15 mg/kg/11D (intermittent) [Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Rat TDLo: 20 mg/kg/5D (intermittent) [Gastrointestinal - other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - other Enzymes] Intraperitoneal. - Rat TDLo: 18 mg/kg/3W (intermittent) [Blood - pigmented or nucleated red blood

cells Blood - changes in erythrocyte (RBC) count Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intraperitoneal. - Mouse TDLo: 65 mg/kg/15D (intermittent) [Skin and Appendages - tumors Tumorigenic - protects against induction of experimental tumors]
Intraperitoneal. - Mouse TDLo: 80 mg/kg/4D (intermittent) [Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse TDLo: 75 mg/kg/9D (intermittent) [Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Rat TDLo: 25 mg/kg/10D (intermittent) [Peripheral Nerve and Sensation - recording from afferent nerve Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intraperitoneal. - Mouse TDLo: 31.25 mg/kg/5D (intermittent) [Tumorigenic - protects against induction of experimental tumors]
Intraperitoneal. - Rat TDLo: 132 mg/kg/4W (intermittent) [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - multiple enzyme effects]
Intraperitoneal. - Rat TDLo: 112.5 mg/kg/9W (intermittent) [Peripheral Nerve and Sensation - sensory change involving peripheral nerve Peripheral Nerve and Sensation - structural change in nerve or sheath]
Intraperitoneal. - Mouse TDLo: 140 mg/kg/23D (intermittent) [Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse TDLo: 100 mg/kg/15D (intermittent) [Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse TDLo: 100 mg/kg/8D (intermittent) [Tumorigenic - active as anti-cancer agent]

Cremophor EL :

RTECS Number: GO5661000

Eye: Eye - Rabbit Standard Draize test.: 150 mg [mild]

Ingestion: Oral - Rat LD50: 34500 uL/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 25 gm/kg [Details of toxic effects not reported other than lethal dose value]

Carcinogenicity: No studies identified.

Mutagenicity: No studies identified.

Reproductive Toxicity: No studies identified.

Teratogenicity: Negative.

Other Toxicological Information: Intravenous. - Mouse LD50: 6500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat TDLo: 0.322 mL/kg/7D (intermittent) [Liver - other changes Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol) Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - transaminases]

Chronic Effects: Soft feces after an oral dose up to 5.3 mL/kg/day, 5 days/week for 4 weeks.

Ethyl Alcohol :

RTECS Number: KQ6300000

Eye: Eye - Rabbit Rinsed with water.: 100 mg/4S

Skin: Administration onto the skin - Rabbit LDLo: 20 gm/kg [Details of toxic effects not reported other than lethal dose value]
Administration onto the skin - Rabbit Open irritation test: 400 mg
Administration onto the skin - Rabbit Standard Draize test.: 20 mg/24H

Inhalation: Inhalation - Rat LC50: 20000 ppm/10H [Details of toxic effects not reported other than lethal dose value]
Inhalation - Mouse LC50: 39 gm/m3/4H [Details of toxic effects not reported other than lethal dose value]

Ingestion: Oral - Rat LD50: 7060 mg/kg [Lungs, Thorax, or Respiration - Other changes]
Oral - Mouse LD50: 3450 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Rat LD50: 7 gm/kg [Details of toxic effects not reported other than lethal dose value]

Carcinogenicity: Studies considered equivocal.

Mutagenicity: Mixed results reported.

Reproductive Toxicity: No studies identified.

Teratogenicity: Birth defects reported after oral ingestion.

Other Toxicological Information: Intravenous. - Human TDLo: 1.6 gm/kg/6H [Biochemical - Metabolism (Intermediary) - other]
Intravenous. - Mouse TDLo: 3 gm/kg [Behavioral - sleep]
Intravenous. - Mouse TDLo: 3 gm/kg [Behavioral - sleep Behavioral - tolerance]
Intravenous. - Rat LD50: 1440 mg/kg [Lungs, Thorax, or Respiration - dyspnea]
Intravenous. - Rabbit LD50: 2374 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rat TDLo: 0.5 gm/kg [Brain and Coverings - recordings from specific areas of CNS]
Intravenous. - Human TDLo: 0.89 mL/kg [Vascular - regional or general arteriolar constriction Vascular - measurement of regional blood flow]
Intravenous. - Mouse LD50: 1973 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rat TDLo: 4 gm/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord) Reproductive - Effects on Embryo or Fetus - other effects to embryo Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intravenous. - Rat TDLo: 3 gm/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
Intravenous. - Rat TDLo: 4 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intravenous. - Rabbit TDLo: 15 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - other effects to embryo]
Subcutaneous - Mouse LD50: 8285 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rabbit LDLo: 20 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse TDLo: 5 gm/kg [Liver - hepatitis (hepatocellular necrosis), zonal]
Intraperitoneal. - Rat TDLo: 3000 mg/kg [Nutritional and Gross Metabolic - body temperature decrease]
Intraperitoneal. - Rat TDLo: 3500 mg/kg [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - dehydrogenases]
Intraperitoneal. - Rat TDLo: 1000 mg/kg [Brain and Coverings - other degenerative changes Liver - other changes Biochemical - Metabolism (Intermediary) - lipids including transport]
Intraperitoneal. - Rat TDLo: 0.25 gm/kg [Behavioral - alteration of operant conditioning]
Intraperitoneal. - Rat TDLo: 0.5 gm/kg [Behavioral - changes in motor activity (specific assay) Behavioral - alteration of operant conditioning]
Intraperitoneal. - Mouse TDLo: 1.5 mg/kg [Behavioral - antianxiety]
Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - alteration of operant conditioning Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Mouse TDLo: 2.5 gm/kg [Behavioral - somnolence (general depressed activity) Behavioral - alteration of operant conditioning Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Mouse TDLo: 4 gm/kg [Behavioral - somnolence (general depressed activity)]
Intraperitoneal. - Mouse TDLo: 2 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - alteration of classical conditioning]
Intraperitoneal. - Mouse TDLo: 1 gm/kg [Behavioral - antianxiety Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Mouse TDLo: 1000 mg/kg [Liver - other changes]
Intraperitoneal. - Mouse TDLo: 0.25 gm/kg [Behavioral - analgesia]
Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Rat TDLo: 1000 mg/kg [Behavioral - food intake (animal)]
Intraperitoneal. - Rat LD50: 3600 ug/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 528 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rabbit LD50: 963 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Guinea pig LD50: 3414 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse TDLo: 4.2 gm/kg [Nutritional and Gross Metabolic - body temperature decrease]
Intraperitoneal. - Rat TDLo: 2.45 gm/kg [Behavioral - altered sleep time (including change in righting reflex)]
Intraperitoneal. - Rat TDLo: 0.5 gm/kg [Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Mouse TDLo: 1.75 gm/kg [Behavioral - ataxia]
Intraperitoneal. - Mouse TDLo: 0.5 gm/kg [Behavioral - changes in motor activity (specific assay)]
Intraperitoneal. - Rat TDLo: 3000 mg/kg [Behavioral - sleep]
Intraperitoneal. - Rat TDLo: 2 gm/kg [Brain and Coverings - other degenerative changes Endocrine - differential effect of sex or castration on observed toxicity Biochemical - Metabolism (Intermediary) - other]
Intraperitoneal. - Rat TDLo: 1 gm/kg [Sense Organs and Special Senses (Taste) - change in function]
Intraperitoneal. - Mouse TDLo: 4.25 gm/kg [Behavioral - sleep]
Intraperitoneal. - Rat TDLo: 2.4 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Neurotransmitters or modulators (putative) - dopamine at other sites]
Intraperitoneal. - Mouse TDLo: 2 mg/kg [Brain and Coverings - recordings from specific areas of CNS]
Intraperitoneal. - Rat TDLo: 1.5 gm/kg [Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]
Intraperitoneal. - Rat TDLo: 1.25 mg/kg [Behavioral - changes in motor activity (specific assay)]
Intraperitoneal. - Mouse LDLo: 4000 mg/kg [Behavioral - alteration of classical conditioning Nutritional and Gross Metabolic - body temperature decrease]
Intraperitoneal. - Rat TDLo: 2700 mg/kg [Behavioral - ataxia]
Intraperitoneal. - Rat TDLo: 500 mg/kg [Behavioral - analgesia]
Intraperitoneal. - Rat TDLo: 2000 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Metabolism (Intermediary) - other]
Intraperitoneal. - Mouse TDLo: 4 gm/kg [Behavioral - withdrawal]
Intraperitoneal. - Mouse TDLo: 2.0 gm/kg [Behavioral - ataxia Nutritional and Gross Metabolic - body temperature decrease]
Intraperitoneal. - Rat TDLo: 2 gm/kg [Brain and Coverings - other degenerative changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - phosphokinase]
Intraperitoneal. - Rat TDLo: 1000 mg/kg [Behavioral - muscle weakness]
Intraperitoneal. - Rat TDLo: 2000 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - ataxia Behavioral - alteration of operant conditioning]
Intraperitoneal. - Rat TDLo: 500 mg/kg [Behavioral - alteration of classical conditioning]
Intraperitoneal. - Rat TDLo: 3000 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Metabolism (Intermediary) - amino acids (including renal excretion)]
Intraperitoneal. - Mouse TDLo: 1.5 gm/kg [Behavioral - changes in motor activity (specific assay) Behavioral - antianxiety]
Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - ataxia Behavioral - alteration of classical conditioning]
Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - alteration of classical conditioning]
Intraperitoneal. - Mouse TDLo: 3.5 gm/kg [Behavioral - altered sleep time (including change in righting reflex)]
Intraperitoneal. - Mouse TDLo: 0.3 mg/kg [Behavioral - alteration of operant conditioning]
Intraperitoneal. - Mouse TDLo: 1.2 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - antianxiety Behavioral - alteration of operant conditioning]
Intraperitoneal. - Mouse TDLo: 1.8 mg/kg [Behavioral - alteration of classical conditioning Behavioral - antianxiety Behavioral - alteration of operant conditioning]
Intraperitoneal. - Mouse TDLo: 4 gm/kg/8D (intermittent) [Behavioral - alteration of classical conditioning Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Rat TDLo: 4.8 mg/kg/4D (intermittent) [Behavioral - changes in motor activity (specific assay)]
Intraperitoneal. - Mouse TDLo: 12 mg/kg/3D (intermittent) [Behavioral - alteration of classical conditioning]
Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - changes in psychophysiological tests Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - tolerance Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Rat TDLo: 3 gm/kg/3D (intermittent) [Behavioral - alteration of classical conditioning]
Intraperitoneal. - Mouse TDLo: 37.8 mg/kg/21D (intermittent) [Behavioral - changes in motor activity (specific assay) Behavioral - tolerance Behavioral - alteration of classical conditioning]
Intraperitoneal. - Mouse TDLo: 12.6 mg/kg/21D (intermittent) [Behavioral - tolerance]
Intraperitoneal. - Rat Mutation test systems not otherwise specified: 250 gm/kg/16D (continuous)
Intraperitoneal. - Mouse Micronucleus test: 1240 mg/kg/2D
Intraperitoneal. - Rat TDLo: 15 gm/kg [Reproductive - Effects on Newborn - behavioral Reproductive - Effects on Newborn - physical]
Intraperitoneal. - Rat TDLo: 2240 mg/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord)]
Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 3600 mg/kg [Reproductive - Effects on Newborn - behavioral]
Intraperitoneal. - Mouse TDLo: 5800 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Mouse TDLo: 5800 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
Intraperitoneal. - Mouse TDLo: 5622 ug/kg [Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Mouse TDLo: 4 mg/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
Intraperitoneal. - Mouse TDLo: 4300 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]

Intraperitoneal. - Mouse TDLo: 2.9 gm/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
Intraperitoneal. - Rat TDLo: 11.25 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intraperitoneal. - Mouse TDLo: 15 mg/kg [Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - other effects to embryo Reproductive - Specific Developmental Abnormalities - eye/ear]
Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intraperitoneal. - Mouse TDLo: 5.8 gm/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - eye/ear]

Chronic Effects: CNS depression and liver effects.

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Ethanol Solution

DOT UN Number: UN 1170

DOT Hazard Class: Class 3 Flammable

DOT Packing Group: PG III

DOT Exemption: Historically, this product has been covered under DOT Special Permit 9275 (DOT-SP 9275): No DOT Shipping Name required for shipments within the U.S. Must follow all DOT-SP 9275 requirements. As of 04/17/2014, the USDOT-PHMSA adopted Special Permit DOT-SP 9275 into the Hazardous Materials Regulations (HMR). There will be no need to apply for renewals of DOT-SP 9275 for containers (vials) of 8 fluid ounces and below. DEPARTMENT OF TRANSPORTATION Pipeline and Hazardous Materials Safety Administration 49 CFR Parts 107, 171, 172, 173, 175 and 178 [Docket No. PHMSA–2011–0158 (HM –233C)] RIN 2137–AE82 Hazardous Materials: Adoption of Certain Special Permits and Competent Authorities Into Regulations AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT. ACTION: Final rule. DOT–SP 9275—Authorization for the transportation in commerce of certain limited quantities of liquids and solids containing ethyl alcohol and exempt these shipments from the provisions of the HMR. PHMSA is modifying this adoption to limit containers using this exception to 8 fluid ounces and eliminating the need for marking the words ''contains ethyl alcohol on the package.'' Packages shipping between 8 fluid ounces and 1 gallon under this section are required to place the words ''contains ethyl alcohol'' on the package.

IATA Shipping Name: Ethanol Solution.

IATA UN Number: UN 1170

IATA Hazard Class: Class 3

IATA Packing Group: PG III

SECTION 15 : REGULATORY INFORMATION

Paclitaxel :

TSCA Inventory Status: Listed

Canada DSL: Listed

Cremophor EL :

TSCA Inventory Status: Listed

Canada DSL: Listed

Ethyl Alcohol :

TSCA Inventory Status: Listed

EINECS Number: 200-578-6

Canada DSL: Listed

Canada IDL: : 3300 ppm

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	2
HMIS Fire Hazard:	3
HMIS Reactivity:	1
HMIS Personal Protection:	X

SDS Creation Date:	March 19, 2009
SDS Revision Date:	June 01, 2015
MSDS Revision Notes:	Revision due to change to Section 14 - Transportation, due to the USDOT-PHMSA adopting Special Permit DOT-SP 9275 into the Hazardous Materials Regulations (HMR), effective as of April 17, 2014. There will be no need to apply for renewals of DOT-SP 9275 for containers (vials) of 8 fluid ounces and below.
SDS Format:	

Disclaimer:

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