

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** Etoposide Injection, USP  
**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:** January 08, 2009  
**SDS Revision Date:** February 19, 2024

### SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word:

DANGER.

GHS Class:

Flammable Liquid. Category 2.  
 Respiratory sensitisation. category 1.  
 Carcinogenicity. Category 1A.  
 Germ cell mutagenicity. Category 2.  
 Reproductive toxicity. Category 2.  
 Eye Irritation. Category 2.  
 Skin 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.  
 May cause cancer.  
 Suspected of causing genetic defects.  
 Suspected of damaging fertility or the unborn child.  
 Causes serious eye irritation.  
 Causes skin 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/hot surfaces. — 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 occurs: Get medical advice/attention.  
 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:

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure:

Inhalation Ingestion Eye contact Skin Absorption. Injection.

**Potential Health Effects:****Eye:** Contact with eyes may cause irritation.**Skin:** May cause skin irritation.**Inhalation:** May cause irritation of respiratory tract.**Ingestion:** May cause irritation.**Signs/Symptoms:** Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Fever and infection (in patients with neutropenia), nausea, vomiting, transient hypotension (drop in blood pressure), anaphylactic-like reactions (chills, fever, tachycardia, bronchospasm, and dyspnea), back pain, loss of consciousness, rash, reversible alopecia, aftertaste, abdominal pain, constipation, dysphagia and transient cortical blindness have all been reported in association with therapeutic administration of etoposide. Occupational exposure has not been fully investigated.**Aggravation of Pre-Existing Conditions:** Individuals with a previous hypersensitivity to etoposide or any component of the formulation. Pre-existing skin and respiratory conditions.**SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS#	Ingredient Percent	EC Num.
Etoposide	33419-42-0	20 mg/mL	
Ethyl Alcohol	64-17-5	- % Amount: 30.5% by Volume	
Benzyl Alcohol	100-51-6	30 mg/mL	
Citric Acid, Anhydrous	77-92-9	2 mg/mL	
Polyethylene Glycol 300	25322-68-3	650 mg/mL	
Polysorbate 80	9005-65-6	80 mg/mL	

**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:** 55 °F (13 °C)**Flash Point Method:** closed cup.**Auto Ignition Temperature:** Not established.**Lower Flammable/Explosive Limit:** 3.3%**Upper Flammable/Explosive Limit:** 19%**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**

<b>Personal Precautions:</b>	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.
<b>Environmental Precautions:</b>	Avoid runoff into storm sewers, ditches, and waterways.
<b>Methods for containment:</b>	Contain spills with an inert absorbent material such as soil, sand or oil dry.
<b>Methods for cleanup:</b>	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

## SECTION 7 : HANDLING and STORAGE

<b>Handling:</b>	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.
<b>Storage:</b>	Store at controlled room temperature 15 to 30°C (59 to 86°F).
<b>Work Practices:</b>	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
<b>Hygiene Practices:</b>	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

<b>Engineering Controls:</b>	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.
<b>Eye/Face Protection:</b>	Chemical splash goggles. Wear a face shield also when splash hazard exist.
<b>Skin Protection Description:</b>	Protective laboratory coat, apron, or disposable garment recommended.
<b>Hand Protection Description:</b>	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
<b>Respiratory Protection:</b>	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 ( <a href="http://www.cdc.gov/niosh/npptl/topics/respirators/">http://www.cdc.gov/niosh/npptl/topics/respirators/</a> ) for a list of respirator types and approved suppliers.
<b>Other Protective:</b>	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

### EXPOSURE GUIDELINES

#### **Ethyl Alcohol:**

Guideline OSHA: PEL-TWA: 1000 ppm

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid solution.
<b>Color:</b>	Yellow
<b>Boiling Point:</b>	Not established.
<b>Melting Point:</b>	Etoposide - 235.8°C
<b>Solubility:</b>	Etoposide - Sparingly soluble in water and ether. Very soluble in methanol and chloroform.
<b>Vapor Density:</b>	Not established.
<b>Vapor Pressure:</b>	45 mm Hg at 25°C
<b>Percent Volatile:</b>	Not established.
<b>pH:</b>	3.0 - 4.0
<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Etoposide - 588.56
<b>Flash Point:</b>	55 °F (13 °C)
<b>Flash Point Method:</b>	closed cup.
<b>Auto Ignition Temperature:</b>	Not established.

## SECTION 10 : STABILITY and REACTIVITY

<b>Chemical Stability:</b>	Stable under normal temperatures and pressures.
<b>Hazardous Polymerization:</b>	Not reported.
<b>Conditions to Avoid:</b>	Protect from light, heat, and freezing.

SECTION 11 : TOXICOLOGICAL INFORMATION

**Acute Toxicity:** Skin irritation due to accidental exposure may occur.

**Etoposide :**

**Acute Toxicity:** Acute Toxicity:  
LD50 IV Rat: 58 mg/kg  
LD50 IP Rat: 39 mg/kg  
LD50 SC Rat: > 200 mg/kg  
LD50 IV Mouse: 15 mg/kg  
LD50 IP Mouse: 64 mg/kg  
LD50 SC Mouse: 143 mg/kg  
LD50 IV Rabbit: 37 mg/kg  
TDLO IV Human: 2.6 mg/kg  
TDLO IV Child: 183 mg/kg

**Polysorbate 80 :**

**Acute Toxicity:** LD50 IP Rat: 6804 mg/kg  
LD50 IV Rat: 1790 mg/kg

**Etoposide :**

**IARC:** IARC: Group 1: Carcinogenic to humans.

**Acute Effects:** Skin irritation due to accidental exposure may occur.

**Chronic Effects:** Studies in animals have not been performed to evaluate the carcinogenic potential of etoposide. Etoposide is known to produce a variety of chromosomal alterations. Human reproductive studies have not been performed.

**Etoposide :**

**RTECS Number:** KC0190000

**Ingestion:** Oral - Rat LD50: 1784 mg/kg [Behavioral - Somnolence (general depressed activity) Gastrointestinal - Hypermotility, diarrhea Nutritional and Gross Metabolic - Body temperature decrease]  
Oral - Mouse LD50: 215 mg/kg [Details of toxic effects not reported other than lethal dose value]

**Other Toxicological Information:**

Intravenous. - Human TDLo: 2630 ug/kg/10D (intermittent) [Blood - agranulocytosis Blood - aplastic anemia Blood - changes in bone marrow (not otherwise specified)]  
 Intravenous. - Rat LD50: 58 mg/kg [Details of toxic effects not reported other than lethal dose value]  
 Intravenous. - Mouse LD50: 15070 ug/kg [Details of toxic effects not reported other than lethal dose value]  
 Intravenous. - Rabbit LD50: 37 mg/kg [Details of toxic effects not reported other than lethal dose value]  
 Intravenous. - Rat TDLo: 40 mg/kg [Liver - other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - multiple enzyme effects Biochemical - Metabolism (Intermediary) - lipids including transport]  
 Intravenous. - Rat TDLo: 12.5 mg/kg [Blood - changes in other cell count (unspecified)]  
 Intravenous. - Rat TDLo: 50 mg/kg [Blood - changes in bone marrow (not otherwise specified) Blood - changes in spleen]  
 Intravenous. - Rat TDLo: 120 mg/kg [Liver - other changes Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation]  
 Intravenous. - Rat TDLo: 10 mg/kg/2W (intermittent) [Endocrine - changes in thymus weight  
 Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count) Related to Chronic Data - changes in testicular weight]  
 Intravenous. - Rat TDLo: 112 mg/kg/4W (intermittent) [Related to Chronic Data - death]  
 Intravenous. - Mouse TDLo: 60 mg/kg/5D (intermittent) [Tumorigenic - active as anti-cancer agent]  
 Intravenous. - Rat TDLo: 25 mg/kg/2W (intermittent) [Liver - other changes Endocrine - changes in thymus weight Blood - changes in bone marrow (not otherwise specified)]  
 Intravenous. - Rat TDLo: 25 mg/kg/2W (intermittent) [Blood - changes in leukocyte (WBC) count Biochemical - Metabolism (Intermediary) - other]  
 Intravenous. - Mouse Micronucleus test: 25 mg/kg  
 Intravenous. - Rat TDLo: 45 mg/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct]  
 Subcutaneous. - Rat LD50: >200 mg/kg [Details of toxic effects not reported other than lethal dose value]  
 Subcutaneous. - Mouse LD50: 143 mg/kg [Details of toxic effects not reported other than lethal dose value]  
 Intraperitoneal. - Rat LD50: 39 mg/kg [Behavioral - somnolence (general depressed activity)  
 Gastrointestinal - hypermotility, diarrhea]  
 Intraperitoneal. - Mouse LD50: 64 mg/kg [Behavioral - somnolence (general depressed activity)  
 Gastrointestinal - ulceration or bleeding from stomach Skin and Appendages - hair]  
 Intraperitoneal. - Mouse TDLo: 80 mg/kg [Blood - leukemia Tumorigenic - protects against induction of experimental tumors Tumorigenic - active as anti-cancer agent]  
 Intraperitoneal. - Mouse TDLo: 30 mg/kg [Tumorigenic - active as anti-cancer agent]  
 Intraperitoneal. - Rat TDLo: 56 mg/kg/5W (continuous) [Liver - other changes Endocrine - other changes Blood - normocytic anemia]  
 Intraperitoneal. - Rat TDLo: 182 mg/kg/26W (continuous) [Endocrine - other changes Blood - normocytic anemia Related to Chronic Data - death]  
 Intraperitoneal. - Mouse TDLo: 180 mg/kg/9D (intermittent) [Tumorigenic - active as anti-cancer agent]  
 Intraperitoneal. - Mouse TDLo: 750 mg/kg/15D (intermittent) [Tumorigenic - protects against induction of experimental tumors]  
 Intraperitoneal. - Mouse Cytogenetic analysis: 5 mg/kg  
 Intraperitoneal. - Mouse Sister chromatid exchange: 500 ug/kg  
 Intraperitoneal. - Rat Micronucleus test: 5 mg/kg  
 Intraperitoneal. - Rat DNA damage: 50 mg/kg  
 Intraperitoneal. - Rat Unscheduled DNA synthesis: 5 mg/kg  
 Intraperitoneal. - Rat DNA inhibition: 5 mg/kg  
 Intraperitoneal. - Mouse Micronucleus test: 750 ug/kg  
 Intraperitoneal. - Mouse Specific locus test: 75 mg/kg  
 Intraperitoneal. - Mouse DNA damage: 15 mg/kg  
 Intraperitoneal. - Mouse Sperm Morphology: 50 mg/kg  
 Intraperitoneal. - Mouse Mutation in mammalian somatic cells: 5 mg/kg  
 Intraperitoneal. - Rat TDLo: 14 mg/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct]  
 Intraperitoneal. - Mouse TDLo: 2 mg/kg [Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)  
 Reproductive - Effects on Embryo or Fetus - fetal death]  
 Intraperitoneal. - Mouse TDLo: 1 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]  
 Intraperitoneal. - Mouse TDLo: 1 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System]  
 Intraperitoneal. - Mouse TDLo: 1500 ug/kg [Reproductive - Maternal Effects - oogenesis Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]

**Ethyl Alcohol:**

**RTECS Number:** KQ630000

**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/m<sup>3</sup>/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]

**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]

### **Benzyl Alcohol :**

**RTECS Number:** DN3150000

**Skin:** Administration onto the skin - Rabbit LD50: 2000 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Administration onto the skin - Rabbit Standard Draize test.: 100 mg/24H  
Administration onto the skin - Rat LD50: 100 pph/90M [Details of toxic effects not reported other than lethal dose value]

**Inhalation:** Inhalation - Mouse LC50: >500 mg/m3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]  
Inhalation - Rat LC50: >500 mg/m3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]

**Ingestion:** Oral - Rat LD50: 1230 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Excitement Behavioral - Coma]  
Oral - Mouse LD50: 1360 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Oral - Mouse LD50: 1360 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]  
Oral - Rat LD50: 1660 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]  
Oral - Rat LD50: 1.5 mL/kg [Details of toxic effects not reported other than lethal dose value]

**Other Toxicological Information:** Intravenous. - Rat LD50: 53 mg/kg [Lungs, Thorax, or Respiration - dyspnea]  
Intravenous. - Mouse LD50: 324 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Subcutaneous - Rat LDLo: 1700 mg/kg [Sense Organs and Special Senses (Eye) - miosis (pupillary constriction) Behavioral - coma Kidney/Ureter/Bladder - other changes]  
Intraperitoneal. - Rat LD50: 400 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Mouse LD50: 650 mg/kg [Behavioral - altered sleep time (including change in righting reflex) Behavioral - somnolence (general depressed activity) Lungs, Thorax, or Respiration - dyspnea]  
Intraperitoneal. - Rat LDLo: 650 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]  
Intraperitoneal. - Rat TDLo: 514 mg/kg [Behavioral - ataxia]

### **Citric Acid, Anhydrous :**

**RTECS Number:** GE7350000

**Eye:** Eye - Rabbit Standard Draize test.: 750 ug/24H [severe]

**Skin:** Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]

**Ingestion:** Oral - Rat LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value]  
Oral - Mouse LD50: 5040 mg/kg [Lungs, Thorax, or Respiration - Other changes Musculoskeletal - Other changes]  
Oral - Mouse LD50: 7280 mg/kg [Details of toxic effects not reported other than lethal dose value]

**Other Toxicological Information:** Intravenous. - Mouse LD50: 42 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands]  
Intravenous. - Rabbit LD50: 330 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands]  
Subcutaneous - Rat LD50: 5500 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes]  
Subcutaneous - Mouse LD50: 2700 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes]  
Intraperitoneal. - Rat LD50: 290 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Mouse LD50: 903 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Rat LD16: 197 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Rat LD: 382 mg/kg [Details of toxic effects not reported other than lethal dose value]

### **Polyethylene Glycol 300 :**

**RTECS Number:** TQ3630000

**Eye:** Eye - Rabbit Standard Draize test.: 500 mg [mild]  
**Skin:** Administration onto the skin - Rabbit LD50: >20 gm/kg [Details of toxic effects not reported other than lethal dose value]  
**Ingestion:** Oral - Rat LD50: 27500 mg/kg [Kidney/Ureter/Bladder - Other changes]  
Oral - Mouse LD50: 31 gm/kg [Details of toxic effects not reported other than lethal dose value]  
**Other Toxicological Information:** Intravenous. - Rat LD50: 7130 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Rat LD50: 17 gm/kg [Details of toxic effects not reported other than lethal dose value]

**Polysorbate 80 :**

**RTECS Number:** WG2932500  
**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]  
**Other Toxicological Information:** Intravenous. - Rat LD50: 1790 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intravenous. - Mouse LD50: 1790 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Subcutaneous - Rat TDLo: 10 gm/kg/27W (intermittent) [Tumorigenic - equivocal tumorigenic agent by RTECS criteria Tumorigenic - tumors at site of application]  
Intraperitoneal. - Rat LD50: 6804 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Mouse LD50: 7600 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Rat TDLo: 80 uL/kg [Reproductive - Maternal Effects - uterus, cervix, vagina  
Reproductive - Maternal Effects - menstrual cycle changes or disorders Reproductive - Effects on Newborn - physical]

**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 II  
**DOT Exemption:** 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.  
**IATA Shipping Name:** Ethanol Solution.  
**IATA UN Number:** UN 1170  
**IATA Hazard Class:** Class 3  
**IATA Packing Group:** PG II

**SECTION 15 : REGULATORY INFORMATION**

**Etoposide :**

**EINECS Number:** 251-509-1  
**California PROP 65:** Listed: developmental.  
**Canada DSL:** Listed

**Ethyl Alcohol :**

**TSCA Inventory Status:** Listed  
**EINECS Number:** 200-578-6  
**Canada DSL:** Listed  
**Canada IDL:** : 3300 ppm

**Benzyl Alcohol :**

**TSCA Inventory Status:** Listed  
**EINECS Number:** 202-859-9

Canada DSL: Listed  
Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.169(170)

**Citric Acid, Anhydrous :**

TSCA Inventory Status: Listed  
EINECS Number: 201-069-1  
Canada DSL: Listed  
Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.409(80)

**Polyethylene Glycol 300 :**

TSCA Inventory Status: Listed  
EINECS Number: 500-038-2  
Canada DSL: Listed

**Polysorbate 80 :**

TSCA Inventory Status: Listed  
EINECS Number: 500-019-9  
Canada DSL: Listed

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**SECTION 16 : ADDITIONAL INFORMATION**

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**HMIS Ratings:**

HMIS Health Hazard: 3\*  
HMIS Fire Hazard: 3  
HMIS Reactivity: 1  
HMIS Personal Protection: X

SDS Creation Date: January 08, 2009

SDS Revision Date: February 19, 2024

SDS Revision Notes: Overall SDS review - no changes to formulation. Updated the HMIS rating for Health only.

Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

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