

Safety Data Sheet





Bristol-Myers Squibb Company

1. IDENTIFICATION											
<i>Product Information</i>											
Product name	VePesid for Injection, 20 mg/mL										
Version	1.1, 18.10.2012										
Jurisdiction	This Safety Data Sheet was prepared in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for the United States of America (USA) (CFR 1910.1200), European Union (EU) (EC 1272/2008) and United Nations (UN). The following countries utilize the UN GHS classification process: Mexico, Brazil, China, New Zealand, Canada, Japan, Korea and Australia.										
Synonyms	Etoposide for injection; VP-16-213; BMY 26600										
Intended Uses	This material is a finished drug product for patient use. It is used in the treatment of cancer.										
<i>Company/Undertaking Identification</i>											
Address	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;"><u>USA</u></td> <td style="width: 33%;"><u>Ireland</u></td> </tr> <tr> <td>Bristol-Myers Squibb Company</td> <td>Bristol-Myers Squibb Company</td> </tr> <tr> <td>P.O. Box 191</td> <td>Swords Laboratories, Watery Lane</td> </tr> <tr> <td>New Brunswick, New Jersey 08903</td> <td>Swords, Ireland</td> </tr> <tr> <td>United States of America</td> <td>MG-GBS-MSDS-Request@bms.com</td> </tr> </table>	<u>USA</u>	<u>Ireland</u>	Bristol-Myers Squibb Company	Bristol-Myers Squibb Company	P.O. Box 191	Swords Laboratories, Watery Lane	New Brunswick, New Jersey 08903	Swords, Ireland	United States of America	MG-GBS-MSDS-Request@bms.com
<u>USA</u>	<u>Ireland</u>										
Bristol-Myers Squibb Company	Bristol-Myers Squibb Company										
P.O. Box 191	Swords Laboratories, Watery Lane										
New Brunswick, New Jersey 08903	Swords, Ireland										
United States of America	MG-GBS-MSDS-Request@bms.com										
Emergency Phone Number	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">USA (also Canada, Puerto Rico and the Virgin Island): 1-800-424-9300</td> <td style="width: 33%;"><u>Ireland</u>: 353-1813-9456</td> </tr> <tr> <td colspan="2" style="text-align: center;">Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.</td> </tr> </table>	USA (also Canada, Puerto Rico and the Virgin Island): 1-800-424-9300	<u>Ireland</u> : 353-1813-9456	Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.							
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Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.											

2. HAZARDS IDENTIFICATION	
Classification and Labelling Common to All Jurisdictions	
Classification	Flammable Liquid - Category 2 Germ Cell Mutagenicity - Category 1B Carcinogenicity - Category 1A Toxic To Reproduction - Reproductive Toxicity - Category 1A Toxic To Reproduction - Developmental Toxicity - Category 1A Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 1
Symbol	
Signal Word	Danger
Hazard Statements	Highly flammable liquid and vapour May cause genetic defects. May cause cancer. May damage fertility May damage the unborn child Causes damage to organs (bone marrow, gastrointestinal tract, central nervous system, peripheral nervous system, liver, heart, cardiovascular system, female reproductive

2. HAZARDS IDENTIFICATION

	organs, male reproductive organs, lymphatic system) through prolonged or repeated exposure.
Precautionary Statements	Obtain special instructions before use. Keep away from heat, sparks and open flame - No smoking. Store container tightly closed in well-ventilated place. Do not breathe dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Use personal protective equipment as required.
Classification and Labelling for Specific Jurisdictions	
USA	
Classification	Serious Eye Damage/Eye Irritation - Category 2B Specific Target Organ Systemic Toxicity (Single Exposure) - Category 3
Symbol	
Hazard Statements	Causes eye irritation. May cause respiratory irritation, May cause drowsiness or dizziness. .
EU	
Classification	No additional classifications
UN	
Classification	Skin Corrosion/Irritation - Category 3 Serious Eye Damage/Eye Irritation - Category 2B Specific Target Organ Systemic Toxicity (Single Exposure) - Category 3
Symbol	
Hazard Statements	Causes mild skin irritation. Causes eye irritation. May cause respiratory irritation, May cause drowsiness or dizziness. .

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	Concentration	CAS-No.	EU only		
			EINECS/ELINCS/ Number	Symbol(s)/ R-phrase(s)	H-code(s)
<i>Hazardous components</i> Etoposide	2 %	33419-42-0	251-509-1	T: R22, R45, R46, R48, R60,	H302 H340 H350

				R61	H360F H360D H372
Benzyl Alcohol	< 5 %	100-51-6	202-859-9	Xn: R20/22	H302 H332 H335
Ethyl Alcohol	< 25 %	64-17-5	200-578-6	F: R11	H225
<i>Other ingredients</i>					
Non-Hazardous Ingredients	< 75 %	Not available	--	--	--
See section 16 for Symbol, R-phrase and H-code text.					

4. FIRST AID MEASURES

Eye contact	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. Discard contaminated clothing or wash before re-use.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. If exposed or concerned: Get medical attention/advice.
Ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical attention/advice.
Notes to Physician	Medical conditions aggravated include: disorders affecting target organs. This product has been reported to interact with the following medications: cytotoxic and cytostatic medicines, cyclosporine. Refer to Section 11. May cause harm to unborn child.
Medical Surveillance	A pre-placement physical examination and history for employees with potential exposure to this compound is recommended. Baseline testing would include: a complete blood count with differential, a blood test for liver function, EKG, lung function test. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. This exam should be overseen by a physician thoroughly knowledgeable about both the toxicity of this compound and the extent of work place exposure. It is recommended that the content be similar to the pre-placement exam. Employees who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Flammable
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Not available Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides (COx)
Other information	Decontaminate protective clothing and equipment before reuse.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
Cleanup Methods	Eliminate sources of ignition and ventilate area. Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up. This material is rapidly deactivated by bleach solution (sodium hypochlorite 5.25%) which may be used to decontaminate the spill area. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials. Use non-sparking tools and equipment.

7. HANDLING AND STORAGE

Handling Precautions	Highly potent material. Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. When handling larger quantities, such as in a manufacturing setting, ensure worker exposure is below the recommended exposure limit. Forms explosive concentrations over a wide range. Sensitive to static charge. Containers should be bonded and grounded for transfer to avoid spark. Prevent release to drains and waterways. Ground/Bond container and receiving equipment. Use explosion proof electrical / ventilating / lighting / equipment. Use only non-sparking tools.
Container Requirements	Store in the original primary packaging as provided. Containers of this material may be hazardous when empty since they retain product residues (liquid/vapors).
Storage Conditions	Store at room temperature in the original container. Protect against light. Keep away from heat, sparks and flames. Do not store near incompatible substances. Storage in a facility or cabinet designed for storage of flammable/combustible materials is recommended.
Specific use(s)	Refer to Section 1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)	Company Guideline	ACGIH	Germany OEL	UK MEL
Etoposide	0.14 µg/m ³	--	--	--
Benzyl Alcohol		--	--	--
Ethyl Alcohol		1,000 ppm STEL	500 ppm TWA 960 mg/m ³ TWA 1,000 ppm Peak 1,920 mg/m ³ Peak 500 ppm MAK 960 mg/m ³ MAK	1,000 ppm TWA 1,920 mg/m ³ TWA

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PEG 300	--	1,000 mg/m3 TWA 8,000 mg/m3 Peak average molecular weight 200-600 1,000 mg/m3 MAK average molecular weight 200-600	--
Benzyl Alcohol	Occupational Exposure Limits have been established by: - Czech Republic - Poland		
Ethyl Alcohol	Occupational Exposure Limits have been established by: - Austria - Belgium - Switzerland - Czech Republic - Denmark - Estonia - Spain - Finland - France - Greece - Hungary - Ireland - The Netherlands - Norway - Poland - Portugal - Sweden		
PEG 300	Occupational Exposure Limits have been established by: - Austria - Switzerland - The Netherlands		
Recommended Industrial Hygiene Monitoring Methods	Contact the Bristol-Myers Squibb AIHA accredited Industrial Hygiene Laboratory at 732-227-6338. See Section 4 "Notes to Physician" for information on medical surveillance.		
EXPOSURE CONTROLS / PERSONAL PROTECTION FOR MATERIAL AS SUPPLIED			
<p><u>VePesid for Injection, 20 mg/mL</u> 4 -- Material is assigned to Exposure Control Band 4 (range 1 - <10 µg/m3).</p>			
Engineering Controls and Ventilation	<p>Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. When handling quantities up to 30 milligrams, a standard laboratory with general laboratory dilution ventilation (e.g. 6-12 air changes per hour) is appropriate. When handling 30 milligrams to 1 kilogram, work in either a standard laboratory or designated laboratory using a fume hood, biological safety cabinet (Class II, Type A2 with thimble connection, B1 or B2), or approved vented enclosure. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment facility using appropriate containment technology. A laminar flow/powder containment booth or appropriate isolation technology should be considered for handling more than 1 kilogram of active compound. HEPA filtered exhaust preferred. When handling solutions with low energy operations (pipette transfers, pouring, low velocity stirring, fraction collection, etc.) use protective shielding to limit the spread of splash or splatter. For manufacturing and pilot plant operations, barrier/containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) with use of double or split butterfly valves, hybrid unidirectional airflow/local exhaust ventilation solutions (e.g. powder containment booth) should be used. Glove bags, isolator/glove box systems are optional.</p>		

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection	Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges (EN 140/EN 136) when exposures are up to 10 times the exposure control guideline. Wear a loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) (EN 12941) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters (EN 136) when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR (EN 12942) when exposures are 50-100 times the exposure control guideline. Wear a hood-shroud HEPA PAPR (EN 12941) or full facepiece supplied air respirator (EN 139) operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline.
Eye protection	Safety glasses with side-shields are recommended (EN 166). Face shields or chemical safety goggles (EN 166) may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.
Hand protection	Wear gloves at all times when handling containers, including when unpacking, inspecting or transporting within a facility. Impervious nitrile, rubber and latex gloves are recommended. Double gloving for all manufacturing personnel potentially in direct contact with the compound should be considered. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.
Skin and body protection	Wear a non-disposable laboratory coat (EN340) when handling quantities up to 30 milligrams. When handling >30 milligrams to 1 kilogram, wear a non-disposable lab coat, disposable lab coat (EN340), or disposable coverall of low permeability (EN 1149-1). When handling > 1 kilogram, wear a disposable coverall of low permeability (EN 1149-1) and disposable shoe covers.
Hygiene	Wash hands and face before breaks and immediately after handling the product.
Environmental exposure controls	Prevent release to drains and waterways.

9. PHYSICAL AND CHEMICAL PROPERTIES*General Information**Appearance*

Physical State	liquid
Color	clear to yellow
Form	solution

Odour

Odour	Not available
Odor Threshold	Not available

pH	3 - 4
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Other information

Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable

9. PHYSICAL AND CHEMICAL PROPERTIES

Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	sparingly soluble
Specific Gravity/ Relative density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available

Thermal/Stability properties

Autoignition temperature	Not available
Boiling Point	78 °C, -, for ethanol component
Thermal decomposition	Not available
Explosive Limits, LEL	3.3 % (V)
Explosive limits, UEL	19. % (V)
Explosiveness	Non-explosive based on chemical structure.
Flammability	Not available
Flash point	21.1 °C
Melting Point	Not available
Oxidizing Potential	Non-oxidizer based on chemical structure.

Vapor Properties

Vapor Density	Not available
Vapor Pressure	The ethyl alcohol component is volatile.
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY*Stability*

Chemical Stability	Stable under normal conditions.
Conditions to avoid	Not available
Materials to avoid	oxidizers alkali metals, nitric acid, hydrogen peroxide, sodium peroxide
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx)
Hazardous reactions	Vapours may form explosive mixture with air.

11. TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact
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11. TOXICOLOGICAL INFORMATION

Eye Irritation	<p><u>Benzyl Alcohol</u> Irritating to eyes.</p> <p><u>Ethyl Alcohol</u> Moderate eye irritant but not classifiable. Irritating to eyes.</p>
Skin Irritation	<p><u>Etoposide Phosphate</u> Mildly and/or transiently irritating to skin.</p> <p><u>Benzyl Alcohol</u> Mildly irritating to skin</p> <p><u>Ethyl Alcohol</u> Mildly irritating to skin</p>
Respiratory Irritation	<p><u>Benzyl Alcohol</u> Irritating to respiratory tract.</p> <p><u>Ethyl Alcohol</u> Irritating to respiratory tract.</p>
Sensitization	<p><u>Etoposide Phosphate</u> Not a dermal sensitizer in an experimental study</p> <p><u>Benzyl Alcohol</u> Several studies were conducted. The results were negative and positive. Only rare mild cutaneous sensitization reactions have been observed in adults.</p> <p><u>Ethyl Alcohol</u> Not a dermal sensitizer</p>

11. TOXICOLOGICAL INFORMATIONAcute Toxicity
Study**Acute Oral**Etoposide

LD50 (rat): 1,784 mg/kg

LD50 (rat): 1,784 mg/kg

LD50 (rat): 1,784 mg/kg

LD50 (rat): 1,784 mg/kg

Etoposide Phosphate

LD50 (mouse, males and females): 3,800 mg/kg High exposure effects include: abnormal posture, abnormal gait, hypoactivity, labored respiration, dehydration, fecal changes.

Benzyl Alcohol

LD50 (rat): 1,230 mg/kg

LD50 (mouse): 1,360 mg/kg

LD50 (rabbit): 1,040 mg/kg

LD50 (guinea pig): 2,500 mg/kg

Ethyl Alcohol

LD50 (rat): 7,060 mg/kg

Acute DermalBenzyl Alcohol

LD50 (rabbit): 2,000 mg/kg

Acute inhalation toxicityBenzyl Alcohol

LC50 (rat): 8.8 mg/l/4 H

Ethyl Alcohol

LC50 (rat): 20000 ppm/10 H

LC50 (mouse): 39 mg/m³/4 H**Acute toxicity (other routes of administration)**Etoposide Phosphate

Maximum nonlethal dose (rat, males and females, intravenous): 31 mg/kg

LD50 (mouse, males and females, intravenous): 147 mg/kg

LD50 (mouse, males, Intraperitoneal): 89 mg/kg

11. TOXICOLOGICAL INFORMATIONRepeated Dose
ToxicityEtoposide

1 - 3 months intravenous (daily) Study with recovery period (2 months) (males and females): LOAEL = 0.15 mg/kg; Low dose effects include: decreased body weight, decreased food consumption, changes in clinical chemistry parameters, decreased white blood cell count, changes in red blood cell parameters, injection site reactions, mortality. Low dose microscopic effects include: lymphatic system, spleen, bone marrow, peripheral nervous system, male reproductive organs, gastrointestinal tract, lungs, mammary gland, skeletal muscles. Effects still present after recovery include: testes, axonal degeneration. No mortality occurred.

Etoposide Phosphate

1 months intravenous (daily) Study with recovery period (1 months) (males and females): LOAEL = 0.15 mg/kg; Low dose effects include: decreased body weight, decreased food consumption, changes in clinical chemistry parameters, changes in white blood cell parameters, changes in red blood cell parameters, injection site reactions, mortality. Low dose microscopic effects include: lymphatic system, spleen, bone marrow, peripheral nervous system, male reproductive organs, gastrointestinal tract, lungs, mammary gland, heart, skin.

5 D Oral (daily) mouse, rat, dog Study with recovery period (30 - 60 days) (males and females): LOAEL = 3.44 mg/kg; Low dose effects include: abnormal posture, dehydration, drooping eyelids, loose stools, hypoactivity, breathing difficulties, decreased body weight, decreased food consumption, tremors, decrease in body temperature, weakness, collapse, vomiting, changes in clinical pathology parameters, decreased organ weights included:, thymus, testes, mortality. Low dose microscopic effects include: bone marrow, thymus, gastrointestinal tract, spleen, lymph nodes, mammary gland, testes. Effects still present after recovery include: testes.

20 D Intraperitoneal (5/week) mouse, rat Study with recovery period (28 - 31 D) (males): LOAEL = 2 mg/kg; Low dose effects include: decreased body weight, decreased organ weights included:, testes, mortality. Low dose microscopic effects include: small intestine, liver, salivary gland, spleen, thymus, bone marrow, testes.

Benzyl Alcohol

16 D - 24 months Oral (daily) rat, mouse Study (males and females): LOAEL = 200 mg/kg; High dose effects include: irregular respiration, lethargy, abnormal gait, decreased weight gain, mortality. High dose microscopic effects include: kidney, brain, muscle, thymus.

Ethyl Alcohol**Assessment Repeat Dose Toxicity**

Several studies were conducted. See Section 11 Target Organs and Symptoms for a description of effects.

11. TOXICOLOGICAL INFORMATION

Genetic Toxicity

Etoposide

In vitro

Ames reverse-mutation assay -- positive
Mutagenicity (micronucleus test) -- positive
Chromosome aberrations assay -- positive

in vivo

Intraperitoneal, Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) (mouse) -- positive
Intraperitoneal, mammalian germ cell cytogenetics assay (spermatogonia) (rat) -- positive

Mutagenicity Assessment

This material was positive in a battery of in vivo and in vitro genotoxicity assays.

Benzyl Alcohol

Mutagenicity Assessment

The weight of evidence demonstrates that this material is not genotoxic.

Ethyl Alcohol

Mutagenicity Assessment

Several studies were conducted. This material was positive and negative in both in vitro and animal studies. This compound is considered to have low risk for induction of genetic toxicity in controlled occupational settings.

Carcinogenicity

Etoposide

Carcinogenicity Assessment

The carcinogenic potential has not been studied. Compounds with similar mechanisms of action and mutagenic potential were reported to be carcinogenic. Some secondary cancers developed in persons with other cancers who were treated with this drug, either alone or in combination with other anticancer drugs. It is not known whether these were a result of the treatment with this drug, with one of the other drugs, or a result of progression of the underlying disease. See Human Experience. This material is probably carcinogenic to humans.

Benzyl Alcohol

2 Years Oral (5/week) rat Study : Tumor NOAEL = 400 mg/kg (males and females). No treatment-related tumors were observed.

2 Years Oral (5/week) mouse Study : Tumor NOAEL = 200 mg/kg (males and females). No treatment-related tumors were observed.

Carcinogenicity Assessment

This material did not show carcinogenic potential in animal studies.

Ethyl Alcohol

Carcinogenicity Assessment

IARC Group 1 There is sufficient evidence of the carcinogenicity of alcoholic beverages in humans.

Carcinogenicity	ACGIH	IARC	NTP
Etoposide	--	2A	--
Etoposide Phosphate	--	1	--
Benzyl Alcohol	--	--	--

11. TOXICOLOGICAL INFORMATION

Ethyl Alcohol	A3	1	Listed
Reproductive Toxicity	<p><u>Etoposide</u> Assessment Reproductive Toxicity Animal studies indicate that reproductive effects can occur. See "Human Experience".</p> <p><u>Ethyl Alcohol</u> Assessment Reproductive Toxicity Animal studies indicate that reproductive effects can occur. (only at high doses) Adverse reproductive effects are not expected in controlled occupational settings.</p>		
Developmental Toxicity	<p><u>Etoposide</u> Developmental Toxicity Assessment This material has been shown to cross the placenta. Birth defects were observed in animal studies. This compound and/or its metabolites may be excreted into the milk. See "Human Experience".</p> <p><u>Benzyl Alcohol</u> Developmental Toxicity Assessment Limited data are available.</p> <p><u>Ethyl Alcohol</u> Developmental Toxicity Assessment Fetal malformations were observed after very high doses in animal studies. Drinking ethanol during pregnancy is associated with fetal alcohol syndrome. This material has been shown to cross the placenta. This compound and/or its metabolites may be excreted into the milk.</p>		

11. TOXICOLOGICAL INFORMATION

Human experience	<p>Experiences with Human Exposure</p> <p><u>Etoposide</u> General effects therapeutic use low exposure - acute effects include: nausea, vomiting, diarrhoea, loss of appetite, abdominal pain, chest pain, heart attack, congestive heart failure, hair loss, rash, nail changes, menstrual irregularities, asthma, breathing difficulties, difficulty swallowing, bruising, confusion, skin effects, eye effects, fatigue, headache, vision changes, tingling, numbness, pain, lowered blood pressure, decreased red blood cell count, decreased white blood cell count, anaphylaxis. low exposure - long term exposure effects include: colitis, acute leukemia, changes in blood clotting parameters, cardiac irregularities, inflammation of gastrointestinal tract, liver toxicity, peripheral neuropathies, ovarian changes, sperm abnormalities.</p> <p><u>Benzyl Alcohol</u> See also symptoms below.</p> <p><u>Ethyl Alcohol</u> General effects Oral low exposure - acute effects include: sedation, increase in heart rate, uncoordination, speech difficulty, decreased concentration. low exposure - long term exposure effects include: liver toxicity, cardiac disorders, gastrointestinal tract toxicity. severe exposure - acute effects include: respiratory depression, hypotension, hypothermia, coma. Inhalation worker exposure low exposure - acute effects include: redness and swelling of eyes, tearing, nasal inflammation, headache, numbness, breathing difficulties, drowsiness, fatigue.</p>
Target Organs	<p><u>Etoposide</u> bone marrow, gastrointestinal tract, peripheral nervous system, lymphatic system, cardiovascular system, female reproductive organs, male reproductive organs</p> <p><u>Etoposide Phosphate</u> bone marrow, gastrointestinal tract, peripheral nervous system, lymphatic system, cardiovascular system, female reproductive organs, male reproductive organs</p> <p><u>Benzyl Alcohol</u> central nervous system</p> <p><u>Ethyl Alcohol</u> central nervous system, liver, heart, gastrointestinal tract</p>
Symptoms	<p><u>Etoposide</u> See "Human Experience".</p> <p><u>Benzyl Alcohol</u> nausea, vomiting, diarrhoea, CNS depression, dizziness, headache, vision changes, rash, redness and swelling of skin, vertigo, delirium</p> <p><u>Ethyl Alcohol</u> See "Human Experience".</p>

11. TOXICOLOGICAL INFORMATION

Pharmacokinetics/ Toxicokinetics	<u>Etoposide</u> Absorption: Not available Distribution: Not available Metabolism: Not available Elimination: Half-life = 0.6 - 10.8 Hour(s) (Human).
Other Toxicity Information	Not available
Other Information:	This MSDS may contain toxicological and/or pharmacological information derived from either the specified product or from a compound(s) with similar structure and/or pharmacological class.

12. ECOLOGICAL INFORMATION**Ecotoxicity effects****Acute Toxicity to Fish**Benzyl Alcohol

LC50 (Pimephales promelas, 96 H) : 460 mg/l.

LC50 (Lepomis macrochirus, 96 H) : 10 mg/l.

Ethyl Alcohol

LC50 (Oncorhynchus mykiss (rainbow trout), 96 H) : 12.0 ml/L - 16.0 ml/L.

LC50 (Pimephales promelas, 96 H) : > 100 mg/l.

LC50 (Pimephales promelas, 96 H) : 13,400 - 15,100 mg/l.

Acute Toxicity to Aquatic InvertebratesBenzyl Alcohol

EC50 (water flea, 48 H) : 23 mg/l.

Ethyl Alcohol

LC50 (20 - 25°C, 48 H) : 11,853 - 13,248 mg/l.

LC50 (20 - 25°C, 48 H) : 9,268 - 14,221 mg/l.

EC50 (20 - 25°C, 24 H) : 10,800 mg/l.

EC50 (20 - 25°C, 48 H) : 2 mg/l.

Toxicity to aquatic plantsBenzyl Alcohol

EC50 (Anabaena variabilis, 3 H) : 35 mg/l

Ethyl Alcohol

EC50 (Chlorella pyrenoidosa, Algae growth rate, 48 H) : 9,310 mg/l

Toxicity to microorganismsBenzyl Alcohol

EC50 (Photobacterium phosphoreum, 30 Minute) : 71.4 mg/l

Ethyl Alcohol

EC50 (Photobacterium phosphoreum, 5 Minute) : 35,470 mg/l

EC50 (Photobacterium phosphoreum, 30 Minute) : 34,634 mg/l

Mobility Not available**Persistence and degradability****Biodegradation**Benzyl Alcohol

Ready biodegradation (30 D) : > 90 % ; Readily biodegradable - rapidly biodegrades in the environment

Ethyl Alcohol

Ready biodegradation (5 D) : 37 - 86 % Readily biodegradable.

PBT and vPvB Assessment: Not available

13. DISPOSAL CONSIDERATIONS

Advice On Disposal And Packaging	Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.
Other information	Disposal by incineration is recommended.

14. TRANSPORT INFORMATION

IMDG	
UN/ID No.	UN1170
Proper shipping name	Ethanol Solution
Class	3
Packing group	III
Labelling	3
EmS	F-ES-D
ICAO/IATA-DGR	
UN/ID No.	UN1170
Proper shipping name	Ethanol Solution
Class	3
Packaging group	III
Labelling	3
ADR	
UN/ID No.	UN1170
Proper shipping name	Ethanol Solution
Class	3
Packaging group	III
Labelling	3
RID	
UN/ID No.	UN1170
Proper shipping name	Ethanol Solution
Class	3
Packaging group	III
Labelling	3
US DOT	
UN/ID No.	UN1170
Proper shipping name	Ethanol Solution
Class	3
Packing group	III
Labelling	3

15. REGULATORY INFORMATION**United States of America**

313 Toxic Release Inventory. Listed
Chemicals/Compounds
No components listed on the SARA 313 inventory.

TSCA Inventory Not listed. Food, drug and cosmetic products are exempt from TSCA.

EU Directive 1999/45/ECBULK MATERIAL

15. REGULATORY INFORMATION

Symbol(s)	F: Highly flammable T: Toxic
R-phrases(s)	R11: Highly flammable. R45: May cause cancer. R46: May cause heritable genetic damage. R48: Danger of serious damage to health by prolonged exposure. R60: May impair fertility. R61: May cause harm to the unborn child.
S-phrases(s)	S23: Do not breathe gas/fumes/vapour/spray. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible). S53: Avoid exposure - obtain special instructions before use. S60: This material and its container must be disposed of as hazardous waste.

DRUG PRODUCT

Classification	Medicinal products are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC.
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Regulatory
Authorizations and
Restrictions:

Not available

16. OTHER INFORMATION

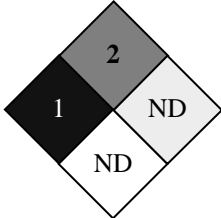
Text of Symbol(s), R-phrases(s) and H-code(s) mentioned in Section 3

F	Highly flammable
H225	Highly flammable liquid and vapour
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H340	May cause genetic defects.
H350	May cause cancer.
H360D	May damage the unborn child
H360F	May damage fertility
H372	Causes damage to organs through prolonged or repeated exposure.
R11	Highly flammable.
R20/22	Harmful by inhalation and if swallowed.
R22	Harmful if swallowed.
R45	May cause cancer.
R46	May cause heritable genetic damage.
R48	Danger of serious damage to health by prolonged exposure.
R60	May impair fertility.
R61	May cause harm to the unborn child.
T	Toxic
Xn	Harmful

Recommended Restrictions for Use:

Not available

SDS preparation information

Prepared by	Research and Development Environment, Health and Safety 1-732-227-7380		
Prepared on	18.10.2012 DD/MM/YYYY		
This Safety Data Sheet has been revised. This data sheet contains changes from the previous version in section(s): 1, 4, and 16.			
<i>Other information</i>			
HMIS	Health		2*
	Flammability		2
	Reactivity		Not Determined (ND)
	Personal protective equipment		See Section 8.
NFPA	Health	1	
	Fire	2	
	Reactivity	ND	
	Special	ND	

Country- Specific Emergency
Phone Numbers

CHEMTREC In-Country Dial Numbers	Local # Provided in Country	Toll Free in Country*	Greeting Language
CHEMTREC South Africa*		0-800-983-611	English
CHEMTREC Argentina (Buenos Aires)	+(54)-1159839431		Latin American Spanish
CHEMTREC Brazil (Rio De Janeiro)	+(55)-2139581449		Portuguese
CHEMTREC Chile (Santiago)	+(56)-25814934		Latin American Spanish
CHEMTREC Colombia *		01800-710-2151	Latin American Spanish
CHEMTREC Mexico*		01-800-681-9531	Latin American Spanish
CHEMTREC Peru (Lima)	+(51)-17071295		Latin American Spanish
CHEMTREC China*	4001-204937		Mandarin
CHEMTREC Hong Kong (Hong Kong)*		800-968-793	Cantonese
CHEMTREC India *		000-800-100-7141	Hindi
CHEMTREC Indonesia *		001-803-017-9114	Indonesian
CHEMTREC Japan (Tokyo)	+(81)-345209637		Japanese
CHEMTREC Malaysia *		1-800-815-308	Malay
CHEMTREC Philippines *		1-800-1-116-1020	Tagalog
CHEMTREC Singapore*		800-101-2201	Mandarin
CHEMTREC Singapore	+(65)-31581349		Mandarin
CHEMTREC South Korea*		00-308-13-2549	Korean
CHEMTREC Taiwan*		00801-14-8954	Mandarin
CHEMTREC Thailand *		001-800-13-203-9987	Thai
CHEMTREC Vietnam (Ho Chi Minh City)	+(84)-838012436		Vietnamese
CHEMTREC Australia (Sydney)	+(61)-290372994		English
CHEMTREC Belgium (Brussels)	+(32)-28083237		French and Flemish
CHEMTREC Czech Republic (Prague)	+(420)-228880039		Czech
CHEMTREC France	+(33)-975181407		French
CHEMTREC Germany *		0800-181-7059	German
CHEMTREC Hungary (Budapest)	+(36)-18088425		Hungarian
CHEMTREC Italy *		800-789-767	Italian
CHEMTREC Italy (Milan)	+(39)-0245557031		Italian
CHEMTREC Netherlands	+(31)-858880596		Dutch
CHEMTREC Poland (Warsaw)	+(48)-223988029		Polish
CHEMTREC Spain*		900-868538	European Spanish
CHEMTREC Sweden (Stockholm)	+(46)-852503403		Swedish
CHEMTREC Switzerland (Zurich)	+(41)-435016715		German
CHEMTREC UK (London)	+(44)-870-8200418		English
CHEMTREC Bahrain (Bahrain)	+(973)-16199372		Arabic
CHEMTREC Israel (Tel Aviv)	+(972)-37630639		Hebrew

*Phone numbers for countries marked with an asterisk must be dialed within the country

The information contained in this SDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information, and we assume no liability from its use.