Safety Data Sheet

Bristol-Myers Squibb Company

1. PRODUCT AND COMPANY IDENTIFICATION

Product Information	
Product name	Vumon for Injection
Version	3.1, 13.09.2013
Jurisdiction	This Safety Data Sheet was prepared for the European Union (EU).
Active substance	Teniposide
Synonyms	Teniposide Injection; BMY 26604; VM-26
Intended Uses	This material is a finished drug product for patient use. It is used to treat certain neoplastic diseases.
Registration Number:	Not available
Company/Undertaking Identification	
Address	**Bristol-Myers Squibb Company** Swords Laboratories, Watery Lane Swords Ireland 353-1813-9456
E-mail:	MG-GBS-MSDS-Request@bms.com
Emergency Phone Number	In the EU, call 353-1813-9456.

2. HAZARDS IDENTIFICATION

Emergency Overview

EU Globally Harmonized System (GHS)

Classification
Flammable Liquid - Category 2
Germ Cell Mutagenicity - Category 1B
Carcinogenicity - Category 1
Toxic To Reproduction - Male Reproductive Toxicity - Category 1A
Toxic To Reproduction - Female 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 or the unborn child (male reproductive toxicity, female reproductive toxicity, Developmental Toxicity) .
Causes damage to organs (bone marrow, spleen, lymph nodes, liver, gastrointestinal tract, skin, cardiovascular system, testes, central nervous system, ovary, heart) through prolonged or repeated exposure.

2. HAZARDS IDENTIFICATION

Precautionary Statements	Do not breathe dust/fume/gas/mist/vapours/spray. Ground/Bond container and receiving equipment. Use explosion proof electrical / ventilating / lighting / equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/clothing and eye/face protection.
Regulatory Status	Substance is classified as dangerous according to Directives 1999/45/EC and 67/548/EEC.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	Concentration	CAS-No.	EINECS/ELINCS/ Number	Symbol(s)	R-phrase(s)
Hazardous components					
Teniposide	1.0 %	29767-20-2	249-831-2	T	R25, R45, R46, R48, R60, R61
Benzyl Alcohol	< 5 %	100-51-6	202-859-9	Xn	R20/22
N,N-dimethylacetamide	< 10 %	127-19-5	204-826-4	T	R61
Ethyl Alcohol	< 50 %	64-17-5	200-578-6	F	R11
Other ingredients					
Non-Hazardous Ingredients	< 55 %	Trade Secret	--	--	--

See section 16 for R-Phrase 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	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. If exposed or concerned: Get medical attention/advice.
Ingestion	Do NOT induce vomiting. If exposed or concerned: Get medical attention/advice.
Notes to Physician	This product may cause: bone marrow suppression, infection, liver disorders, hypotension, congestive heart failure, CNS depression, neurological disorder, peripheral neuropathies, kidney disorders, changes in metabolism, decreased white blood cell count, decreased red blood cell count, decreased platelets, increased blood urea nitrogen. This product has been reported to interact with the following medications: cyclosporine. Refer to Section 11. May cause harm to unborn child. Pregnant or nursing women should avoid exposure.
Medical Surveillance	The need for a pre-placement physical examination and history for employees with potential exposure to this compound is to be evaluated by a physician that is thoroughly knowledgeable about both the toxicity of this compound and the extent of work place exposure. Baseline testing would include: a complete blood count with differential, a blood test for kidney function, a blood test for liver function. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. 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.
Other information	Precautionary risk management may be different from the exposure categories in the annex.

5. FIRE-FIGHTING MEASURES	
Flammable Properties	Highly flammable liquid and vapour
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Toxic Eye irritant Respiratory Irritant Developmental Toxicity Mutagen Carcinogen Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides (COx), sulphur oxides (SOx)
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. Spill prevention procedures and a spill response procedure should be implemented. 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. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

7. HANDLING AND STORAGE	
Handling Precautions	Highly flammable. Highly potent material. Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat, sparks and open flame - No smoking. Ground/Bond container and receiving equipment. Prevent release to drains and waterways.
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 2 - 8°C. For transportation purposes to all markets outside of the United States, the product has to be shipped according to the registered storage condition (< 25°C). Protect against light. Keep away from heat, sparks and flames. Storage in a facility or cabinet designed for storage of flammable/combustible materials is recommended. Do not store near incompatible substances.
Specific use(s)	Refer to Section 1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION
COMPONENT EXPOSURE LIMIT(S)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION				
Exposure limit(s)	Company Guideline	ACGIH	Germany OEL	UK MEL
Teniposide	0.04 µg/m3	--	--	--
Ethyl Alcohol	--	1,000 ppm STEL	500 ppm TWA 960 mg/m3 TWA 1,000 ppm Peak 1,920 mg/m3 Peak 500 ppm MAK 960 mg/m3 MAK	1,000 ppm TWA 1,920 mg/m3 TWA
N,N-dimethylacetamide	--	10 ppm TWA	10 ppm TWA 36 mg/m3 TWA 20 ppm Peak 72 mg/m3 Peak 10 ppm MAK 36 mg/m3 MAK	20 ppm STEL 72 mg/m3 STEL 10 ppm TWA 36 mg/m3 TWA
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			
N,N-dimethylacetamide	Occupational Exposure Limits have been established by: - Austria - Belgium - Switzerland - Denmark - Spain - Finland - France - Greece - Hungary - Ireland - The Netherlands - Norway - Poland - Portugal - Sweden			
Exposure Control Band	Teniposide ***5sc*** -- The established company exposure guideline falls within Exposure Control Band 5, Special Case (range < 0.1 µg/m3).			
Bristol-Myers Squibb Exposure Guidelines Summary	Teniposide Materials require particular care and handling. Adherence to this guideline should protect employees from experiencing the therapeutic and/or adverse effects of this drug.			
Recommended Industrial Hygiene Monitoring Methods	A specific exposure sampling method is not available. Contact the Bristol-Myers Squibb AIHA accredited Industrial Hygiene Laboratory at 732-227-6338.			
EXPOSURE CONTROLS / PERSONAL PROTECTION FOR MATERIAL AS SUPPLIED				
This mixture contains material(s) with the exposure limit(s) noted above. The mixture as supplied should be controlled during handling to limit total airborne exposure to the limit noted below or less.				
Exposure Control Band - For Operations Using Material as Supplied	Vumon for Injection ***5sc*** -- Material is assigned to Exposure Control Band 5, Special Case (range < 0.1 µg/m3).			
Engineering Controls and Ventilation	When handling quantities from 0-5 grams work in a designated laboratory or containment facility using a fume hood, biological safety cabinet (Class II, Type B1, or B2) ; glove box; and, approved vented enclosure. HEPA filtered exhaust with Bag-In/Bag-Out capacity preferred for hoods, BSCs and glove boxes. Quantities exceeding 100 grams should be handled in a containment facility using appropriate containment isolation technology.			

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 double gloves (EN 420, EN 374). Wear gloves at all times when handling containers, including when unpacking, inspecting or transporting within a facility. Disposable chemotherapy gloves made from nitrile, neoprene, polyurethane and natural latex have been shown to have low permeability to many chemotherapy agents. Persons who are allergic to natural rubber latex should select gloves made from one of the other materials. Check gloves frequently to ensure that there are no small cuts or holes. Change gloves frequently, and remove immediately after overt contamination. Use care when removing and disposing of gloves in order to minimize exposure. If material is handled in solution, the solvent should also be considered when selecting protective clothing material.
Skin and body protection	When handling quantities from 0-10 grams wear disposable labcoat or coverall of low permeability (EN 1149-1); disposable wrist gauntlets/sleeves unless working in glove box. For quantities over 10 grams and manufacturing operations, wear disposable coverall of low permeability (EN 1149-1) disposable shoe covers ; disposable wrist gauntlets/sleeves unless working in glove box. . For manufacturing operations, gloves and booties should be taped to protective clothing to prevent gaps in PPE and air supplied full-body suits (EN 1073) may be required as associated with advanced respiratory protection.
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 , colourless
Form	solution
Odour	
Odour	Not available
Odor Threshold	Not available

9. PHYSICAL AND CHEMICAL PROPERTIES

pH	5
Other information	
Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
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	Not available
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), for ethanol component
Explosive limits, UEL	19.0 %(V), for ethanol component
Explosiveness	Not available
Flammability	Flammable Liquid
Flash point	12.7 °C(closed cup), for ethanol component
Melting Point	Not available
Oxidizing Potential	Not available
Vapor Properties	
Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY

Stability

Chemical Stability	Stable under normal conditions.
Conditions to avoid	Heat, flames and sparks.
Materials to avoid	strong oxidizing agents acids and bases
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx), sulphur oxides (SOx)
Hazardous reactions	Vapours may form explosive mixture with air.

11. TOXICOLOGICAL INFORMATION	
Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact
Eye Irritation	Benzyl Alcohol Irritating to eyes. N,N-dimethylacetamide Mildly irritating to eyes. Ethyl Alcohol Irritating to eyes.
Skin Irritation	Benzyl Alcohol Mildly irritating to skin N,N-dimethylacetamide Mildly irritating to skin Ethyl Alcohol Mildly irritating to skin
Respiratory Irritation	Benzyl Alcohol Irritating to respiratory tract. N,N-dimethylacetamide Mildly irritating to respiratory tract. Ethyl Alcohol Irritating to respiratory tract.
Sensitization	Teniposide A computerized structure-toxicity analysis of this chemical class predicted this material to be a dermal sensitizer. See "Human Experience". Benzyl Alcohol Several studies were conducted. The results were negative and positive. Only rare mild cutaneous sensitization reactions have been observed in adults. N,N-dimethylacetamide Not a dermal sensitizer in an experimental study Ethyl Alcohol Not a dermal sensitizer

11. TOXICOLOGICAL INFORMATION

Acute Toxicity Study

Acute Oral

Teniposide
LD50 (dog, males and females): > 300 mg/kg

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

N,N-dimethylacetamide
LD50 (mouse): 4,620 mg/kg
LD50 (rat): 3,000 - 6,000 mg/kg

Ethyl Alcohol
LD50 (rat): 7,060 mg/kg

Acute Dermal

Benzyl Alcohol
LD50 (rabbit): 2,000 mg/kg

N,N-dimethylacetamide
LD50 (rat): 7,500 mg/kg
LD50 (mouse): 9,600 mg/kg
LD50 (rabbit): 2,100 - 3,600 mg/kg
LD50 (guinea pig): < 940 mg/kg

Acute inhalation toxicity

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

N,N-dimethylacetamide
LC50 (rat): 2.2 mg/l/4 H

Ethyl Alcohol
LC50 (rat): 20,000 ppm/10 H

Acute toxicity (other routes of administration)

Teniposide
LD50 (rat, males and females, intravenous): 11.3 mg/kg
LD50 (mouse, males and females, intravenous): 16 mg/kg
LD50 (mouse, males and females, subcutaneous): 24 mg/kg
LD50 (rabbit, males and females, intravenous): 7 mg/kg
LD50 (dog, males and females, intravenous): 10 mg/kg

11. TOXICOLOGICAL INFORMATION

Repeated Dose Toxicity	Teniposide 4 weeks - 6 months parenteral (3-6/week) rat, dog, monkey study with recovery period (4 weeks - 2 months): LOAEL = 0.4 mg/kg (males and females). Low dose effects include: decreased food consumption, diarrhoea, decreased weight gain, lethargy, hair loss, changes in red blood cell parameters, changes in white blood cell parameters, inflammation of gastrointestinal tract, convulsions, mortality. Low dose microscopic effects include: bone marrow, spleen, lymph nodes, liver, gastrointestinal tract, testes, ovary. Benzyl Alcohol 16 D - 24 months oral (daily) rat, mouse study : LOAEL = 200 mg/kg (males and females). High dose effects include: irregular respiration, lethargy, abnormal gait, decreased weight gain, mortality. High dose microscopic effects include: kidney, brain, muscle, thymus. N,N-dimethylacetamide 24 months drinking water (daily) rat study : LOAEL = 100 mg/kg (males and females). Low dose effects include: decreased weight gain, increased organ weights included:, liver, adrenal glands. High dose effects include: increased organ weights included:, kidney. High dose microscopic effects include: spleen. 24 months Inhalation (5/week) exposure time = 6 H rat, mouse study : NOAEL = 25 PPM (males and females). Low dose effects include: changes in clinical chemistry parameters, Increased serum cholestrol, Increased serum glucose, liver effects, eye effects, increased organ weights included:, liver. High dose effects include: decreased weight gain, increased organ weights included:, kidney. High dose microscopic effects include: kidney. Ethyl Alcohol **Assessment Repeat Dose Toxicity** Several studies were conducted. See Section 11 Target Organs and Symptoms for a description of effects.
Genetic Toxicity	Teniposide **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. N,N-dimethylacetamide **Mutagenicity Assessment** This material was negative in a battery of in vivo and in vitro genotoxicity assays. 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.

11. TOXICOLOGICAL INFORMATION

Carcinogenicity

Teniposide

Carcinogenicity Assessment

This material is probably carcinogenic to humans.

Benzyl Alcohol

2 Years oral (5/week) rat study : Tumor NOAEL = 400 mg/kg No treatment-related tumors were observed.

2 Years oral (5/week) mouse study : Tumor NOAEL = 200 mg/kg No treatment-related tumors were observed.

Carcinogenicity Assessment

This material did not show carcinogenic potential in animal studies.

N,N-dimethylacetamide

2 Years drinking water (daily) rat study : Tumor NOAEL = 100 mg/kg No treatment-related tumors were observed.

2 Years Inhalation (daily) exposure time = 6 H rat study : Tumor NOAEL = 350 mg/kg No treatment-related tumors were observed.

2 Years Inhalation (daily) exposure time = 6 H mouse study : Tumor NOAEL = 350 mg/kg No treatment-related tumors were observed.

Ethyl Alcohol

Carcinogenicity Assessment

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

Carcinogenicity	**ACGIH**	**IARC**	**NTP**
Teniposide	--	2A	--
Benzyl Alcohol	--	--	--
N,N-dimethylacetamide		--	--
Ethyl Alcohol	A3	1	Listed

Reproductive Toxicity

Teniposide

3 Weeks intravenous (3/week) Study of Fertility and Early Embryonic Development (rat) (females) NOAEL = 1 mg/kg

Effects include: decrease in successful matings.

Assessment Reproductive Toxicity

Compound may cause injury to male reproductive organs. Compound may cause injury to female reproductive organs. May impair fertility.

N,N-dimethylacetamide

Assessment Reproductive Toxicity

This substance did not cause adverse effects on male or female reproduction or on the offspring of treated animals. The weight of evidence indicates that this compound is not a reproductive hazard.

Ethyl Alcohol

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.

11. TOXICOLOGICAL INFORMATION

Developmental Toxicity

Teniposide

10 Days intravenous (every other day) Study of Embryo-Fetal Development (rat) (parent, females) NOAEL = 0.3 mg/kg
Maternal effects include: decreased weight gain.

10 Days intravenous (every other day) Study of Embryo-Fetal Development (rat) (embryo/fetus) LOAEL = 0.1 mg/kg
Fetal effects include: developmental delay, malformations, death. Substance was harmful to the fetus at doses that did not produce adverse effects in the maternal animal.

3 Days intraperitoneal (daily) Reproductive and developmental study (mouse) (parent, females) NOAEL = 1 mg/kg
No adverse maternal effects were observed.

3 Days intraperitoneal (daily) Reproductive and developmental study (mouse) (embryo/fetus) NOAEL = 0.5 mg/kg
Fetal effects include: decreased body weight, malformations, death. Substance was harmful to the fetus at doses that did not produce adverse effects in the maternal animal.

Developmental Toxicity Assessment
Birth defects were observed in animal studies. Selective developmental toxicant

Benzyl Alcohol

Developmental Toxicity Assessment
Limited data are available.

N,N-dimethylacetamide

10 Days Inhalation (daily) Study of Embryo-Fetal Development (rat) (parent, females) NOAEL = 100 ppm (embryo/fetus) NOAEL = 100 ppm
Fetal effects include: decreased body weight. Maternal effects include: decreased weight gain.

10 Days Inhalation (daily) Study of Embryo-Fetal Development (rabbit) (parent, females) NOAEL = 570 ppm (embryo/fetus, males and females) NOAEL = 200 ppm
Fetal effects include: changes in skeletal development, malformations. Maternal effects include: decreased weight gain.

13 Days oral (daily) Study of Embryo-Fetal Development (rat) (parent, females) NOAEL = 65 mg/kg (embryo/fetus) NOAEL = 160 mg/kg
Fetal effects include: changes in skeletal development, malformations. Maternal effects include: decreased weight gain.

Developmental Toxicity Assessment
Substance was harmful to the fetus at doses that did not produce adverse effects in the maternal animal.

Ethyl Alcohol

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.

11. TOXICOLOGICAL INFORMATION

Human experience

Clinical Trials

N,N-dimethylacetamide

Dermal - This material was readily absorbed through the skin.

Experiences with Human Exposure

Teniposide

low exposure - acute effects include: nausea, vomiting, diarrhoea, skin flushing, injection site reactions, hypersensitivity, rash, fever, chills, cough, changes in blood pressure. low exposure - long term exposure effects include: bleeding, stool changes, skin effects, hair loss, weakness, dizziness, seizure disorders, inflammation of gastrointestinal tract, back pain, abdominal pain, ulceration, vertigo, skin sensation changes, lethargy, sleepiness, bloody urine, painful urination, inflammation of the mouth, bone marrow suppression, infection, liver disorders, hypotension, congestive heart failure, neurological disorder, peripheral neuropathies, kidney disorders, changes in metabolism, decreased white blood cell count, decreased red blood cell count, decreased platelets, increased blood urea nitrogen.

Benzyl Alcohol

See also symptoms below.

N,N-dimethylacetamide

worker exposure low exposure - long term exposure effects include: liver toxicity, jaundice, increased liver enzymes, increase in blood cholesterol, increase in serum bilirubin.

Clinical trial(s) low exposure - acute effects include: nausea, vomiting, anorexia, depression, lethargy, confusion, hallucinations, delusions.

Ethyl Alcohol

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.

worker exposure low exposure - acute effects include: redness and swelling of eyes, tearing, nasal inflammation, headache, numbness, breathing difficulties, drowsiness, fatigue.

Target Organs

Teniposide

bone marrow, spleen, lymph nodes, liver, gastrointestinal tract, skin, cardiovascular system, central nervous system, testes, ovary

Benzyl Alcohol

central nervous system

N,N-dimethylacetamide

liver, central nervous system

Ethyl Alcohol

central nervous system, liver, heart, gastrointestinal tract

11. TOXICOLOGICAL INFORMATION	
Symptoms	Teniposide See "Human Experience". Benzyl Alcohol nausea, vomiting, diarrhoea, CNS depression, dizziness, headache, vision changes, rash, redness and swelling of skin, vertigo, delirium N,N-dimethylacetamide See "Human Experience". Ethyl Alcohol See "Human Experience".
Pharmacokinetics/ Toxicokinetics	Not available
Other Toxicity Information	Not available

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.

N,N-dimethylacetamide

LC50 (Gambusia affinis, 96 H) : 500 mg/l.

LC50 (Pimephales promelas (fathead minnow)) : > 1,500 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 Invertebrates

Benzyl Alcohol

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

N,N-dimethylacetamide

NOEC (Daphnia magna (Water flea), 48 H) : > 1,000 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 plants

Benzyl Alcohol

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

N,N-dimethylacetamide

EC50 (Scenedesmus subspicatus, 72 H) : > 500 mg/l

Ethyl Alcohol

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

Toxicity to microorganisms

Benzyl Alcohol

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

N,N-dimethylacetamide

EC50 (Photobacterium phosphoreum, 5 Minute) : 4,815 mg/l

EC50 (Photobacterium phosphoreum, 30 Minute) : 2,393 mg/l

Minimum inhibitory concentration (MIC) (E. coli) : 0.425 mg/l

LOEC (Pseudomonas putida) : 4,850 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

N,N-dimethylacetamide

Inherently biodegradable.

Ethyl Alcohol

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

Stability in water

N,N-dimethylacetamide

Hydrolysis (95.0 °C, pH 9.4): Degree of hydrolysis - 140 H (< 0.1 %); Does not undergo hydrolysis

Photolysis: Half-life - 6.1 H

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. Product is classified as a hazardous waste (D001) due to the alcohol content. 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	II
Labelling	3
EmS	F-E, S-D
ICAO/IATA-DGR	
UN/ID No.	ID8000
Proper shipping name	Consumer Commodity
Class	9
Labelling	9
ADR	
UN/ID No.	UN1170
Proper shipping name	Ethanol Solution
Class	3
Packaging group	II
Labelling	3
RID	
UN/ID No.	UN1170
Proper shipping name	Ethanol Solution
Class	3
Packaging group	II
Labelling	3
US DOT	
UN/ID No.	NONE
Proper shipping name	Consumer Commodity
Class	NON
Labelling	NON

15. REGULATORY INFORMATION

EINECS/ELINCS/Number
Teniposide: 249-831-2
Benzyl Alcohol: 202-859-9
N,N-dimethylacetamide: 204-826-4
Ethyl Alcohol: 200-578-6

EU Globally Harmonized System (GHS)

Classification
Flammable Liquid - Category 2
Germ Cell Mutagenicity - Category 1B
Carcinogenicity - Category 1
Toxic To Reproduction - Male Reproductive Toxicity - Category 1A

15. REGULATORY INFORMATION

Toxic To Reproduction - Female 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 or the unborn child (male reproductive toxicity, female reproductive toxicity, Developmental Toxicity) .
Causes damage to organs (bone marrow, spleen, lymph nodes, liver, gastrointestinal tract, skin, cardiovascular system, testes, central nervous system, ovary, heart) through prolonged or repeated exposure.

Precautionary Statements:
Do not breathe dust/fume/gas/mist/vapours/spray.
Ground/Bond container and receiving equipment.
Use explosion proof electrical / ventilating / lighting / equipment.
Use only non-sparking tools.
Take precautionary measures against static discharge.
Wear protective gloves/clothing and eye/face protection.

UN Globally Harmonized System (GHS)

Classification:
Flammable Liquid - Category 2
Skin Corrosion/Irritation - Category 3
Mild Eye Irritation - Category 2B
Germ Cell Mutagenicity - Category 1B
Toxic To Reproduction - Male Reproductive Toxicity - Category 1A
Toxic To Reproduction - Female Reproductive Toxicity - Category 1A
Toxic To Reproduction - Developmental Toxicity - Category 1A
Specific Target Organ Systemic Toxicity (Single Exposure) - Category 3
Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 1

Symbol

Signal Word: Danger

Hazard Statements:
Highly flammable liquid and vapour
Causes mild skin irritation.
Causes eye irritation.
May cause genetic defects.
May damage fertility or the unborn child (male reproductive toxicity, female reproductive toxicity, Developmental toxicant) .
May cause respiratory irritation, May cause drowsiness or dizziness .
Causes damage to organs (bone marrow, spleen, lymph nodes, skin, cardiovascular system, testes, ovary, gastrointestinal tract, liver, central nervous system, heart) through prolonged or repeated exposure.

15. REGULATORY INFORMATION

Precautionary Statements	Refer to HAZARDS IDENTIFICATION section.

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R25: Toxic 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.
R20/22: Harmful by inhalation and if swallowed.
R61: May cause harm to the unborn child.
R11: Highly flammable.

Recommended Restrictions for Use:

Not available

SDS preparation information

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	This Safety Data Sheet has been revised. This data sheet contains changes from the previous version in section(s): 1, 7, and 16.

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