

1. PRODUCT AND COMPANY INFORMATION

Distributed By: WG Critical Care, LLC.
 120 Route 17 North
 Suite 115
 Paramus, NJ 07652 USA

Product Name:

TENIPOSIDE INJECTION

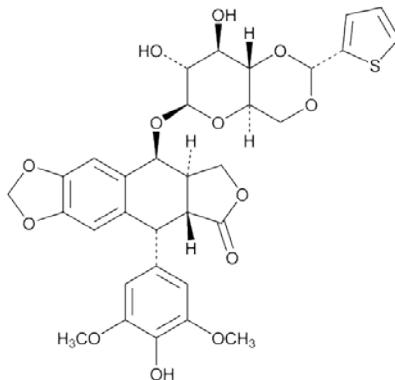
Product Code:

50mg / 5ml Vial: 44567-507-01

Common / Trade Name:

Teniposide

Structure:



Chemical Name:

5,8,8a,9-Tetrahydro-5-(4-hydroxy-3,5-dimethoxyphenyl)-9-((4, 6-O-(2-thienylmethylene)-B-D-glucopyranosyl)oxy)furo(3',4':6,7)-(naphtho(2,3,-d)-1,3-di-2-thenylidene-B-D-glucopyranoside

Molecular Formula:

C₃₂H₃₂O₁₃S

UNII Code:

957E6438QA

CAS Number:

29767-20-2

Chemical Family:

Antineoplastic

Product Use:

Pharmaceutical

Product Type:

Prescription Drug

Container Information:

Vials

General Phone Number:

+1-847-549-3200

Customer Service Phone Number:

+1-888-493-0861

Emergency Phone Number:

+1-866-562-4708 (Prosar)

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2. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>
TENIPOSIDE	1	29767-20-2
Benzyl Alcohol	<5	100-51-6
N,N Dimethylacetamide	<10	127-19-5
Dehydrated Alcohol	<50	64-17-5
Non-Hazardous Ingredient	<55%	N/A

3. HAZARDS IDENTIFICATION
EMERGENCY OVERVIEW

APPEARANCE:	Liquid, clear, colorless solution
SIGNAL WORD	Danger
HAZARD STATEMENTS:	Flammable liquid Toxic if swallowed Causes mild skin irritation Causes serious eye irritation May cause respiratory irritation May cause genetic defects May cause cancer May damage fertility May damage the unborn child Causes damage to organs through prolonged or repeated exposure Target Organs: bone marrow, spleen, lymph nodes, skin cardiovascular system, testes, ovary, gastrointestinal tract, liver, central nervous system, heart

PRIMARY PHYSICAL AND HEALTH HAZARDS:

HAZARDS:	Do not breathe dust/fume/gas/mist/vapours/spray. Keep away from heat, sparks and open flame - No smoking. Store container tightly closed in well-ventilated place. Ground/Bond container and receiving equipment. Use explosion proof electrical / ventilating / lighting / equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Avoid contact during pregnancy/while nursing.
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ROUTES OF ENTRY:

EYES	Causes serious eye irritation
SKIN	Causes mild skin irritation
INGESTION	Toxic if swallowed
INHALATION	May cause respiratory irritation
TARGET ORGANS	Bone marrow, spleen, lymph nodes, skin, cardiovascular system, ovary, gastrointestinal tract, liver, central nervous system, heart

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3. HAZARDS IDENTIFICATION (CONTINUED)

SIGNS & SYMPTOMS OF EXPOSURE:	Refer to Section 11 "Human Experience"		
CHEMICAL LISTED AS CARCINOGEN:	NTP: NO	IARC: 2A	OSHA: LISTED

4. FIRST AID MEASURES

EYE EXPOSURE:	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention.
SKIN EXPOSURE:	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. IF exposed or concerned: Get medical attention/advice.
INGESTION:	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician. Rinse mouth.
INHALATION:	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention. IF exposed or concerned: Get medical attention/advice.
NOTE TO PHYSICIAN:	This product has been reported to interact with the following medications: cyclosporine. Material not fully tested. Refer to Section 11. Pregnant or nursing women should avoid exposure.
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 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

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5. FIRE FIGHTING MEASURES

FLASH POINT:	127°C (closed cup)
AUTO-IGNITION TEMPERATURE:	N/A
FLAMMABLE LIMITS IN AIR:	N/A
FLAMMABLE LIMITS:	N/A
EXTINGUISHING MEDIA:	Foam, Dry Chemical Powder
UNUSUAL FIRE / EXPLOSION	Explosive Limits, LEL: 3.3%(V), for ethanol component
HAZARDS:	Explosive Limits, UEL 19.0%(V) for ethanol component

6. ACCIDENTAL RELEASE MEASURE

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
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

GENERAL HANDLING:	Highly potent material. Avoid exposure - obtain special instructions before use. Avoid formation of dust and aerosols. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
STORAGE CONDITIONS:	Store at room temperature. Protect against light. Keep away from heat, sparks and flames. Keep in a dry place. Protect from moisture.
CONTAINER REQUIREMENTS:	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROL BAND:	5sc -- Material is assigned to Exposure Control Band 5, Special Case (range < 0.1 µg/m ³).
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 to control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges 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) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR when exposures are 50-100 times the exposure control guideline. Wear a hood-shroud HEPA PAPR or full facepiece supplied air respirator 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. Face shields or chemical safety goggles 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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION (CONTINUED)**VENTILATION**

Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. 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 5 grams should be handled in a containment facility using appropriate containment isolation technology with isolator/glove box systems, glove bags, double/split butterfly valves, remote operations, direct process connections and systems, or automated systems. For manufacturing and pilot plant operations, the containment level should be to keep exposures as low as reasonable achievable. Barrier/containment technology with isolator/glove bags, remote operations, direct process connections and systems, or automated systems should be used. Isolated work areas are required with rooms to provide thorough secondary containment.

SKIN PROTECTION:

For quantities up to 5 grams: wear disposable labcoat or coverall of low permeability; disposable wrist gauntlets/sleeves unless working in glove box. For quantities > 5 grams: wear full disposable coverall of low permeability; 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 may be required as associated with advanced respiratory protection.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION (CONTINUED)**OTHER PROTECTIVE EQUIPMENT:** Wear double gloves.

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.

ADDITIONAL EXPOSURE**PRECAUTIONS:**

Wash hands and face before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES**PHYSICAL STATE:**

Solid,

SPECIFIC GRAVITY: N/A**APPEARANCE AND**

White, Crystalline

EVAPORATION RATE: N/A**ODOR:****BOILING POINT:**

N/A

MELTING POINT: 242-246 °C**VAPOR PRESSURE:**

Negligible

SOLUBILITY IN WATER: practically insoluble**VAPOR DENSITY:**

N/A

pH: N/A**10. STABILITY AND REACTIVITY****STABILITY:**

Stable under normal conditions. Unstable in very high and very low pH environments.

INCOMPATIBILITY :

N/A

(MATERIALS TO AVOID)**HAZARDOUS POLYMERIZATION:**

N/A

HAZARDOUS DECOMPOSITION:

Hazardous decomposition products formed under fire conditions.carbon oxides(COx), sulphur oxides (SOx)

10. STABILITY AND REACTIVITY (CONTINUED)

Other Statements: Although material has not been specifically tested, fine dust suspended in air in sufficient concentration and in the presence of an ignition source may pose a potential explosion hazard. Provide appropriate bonding and grounding protection to control static charge. Powder handling equipment such as dust collectors, dryers, and mills may require additional protective measures (e.g. explosion venting, inerting, etc.).

11. TOXICOLOGICAL INFORMATION

Acute Toxicity Study:	Acute Oral LD50 (dog, males and females): > 300 mg/kg Acute toxicity (other routes of administration) 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
Repeated Dose Toxicity:	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, diarrhea, 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.
Genetic Toxicity:	Mutagenicity Assessment This material was positive in a battery of in vivo and in vitro genotoxicity assays.
Carcinogenicity:	Carcinogenicity Assessment This material is probably carcinogenic to humans. Teniposide: Group 2A (IARC)

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11. TOXICOLOGICAL INFORMATION (CONTINUED)

Reproductive Toxicity:	<p>3 Weeks intravenous (3/week) Study of Fertility and Early Embryonic Development (rat) (females) NOAEL = 1 mg/kg Effects include: decrease in successful matings.</p> <p>Assessment Reproductive Toxicity</p> <p>Compound may cause injury to male reproductive organs. Compound may cause injury to female reproductive organs. May impair fertility.</p>
Developmental Toxicity:	<p>10 Days intravenous (every other day) Study of Embryo-Fetal Development (rat) (parent, females) NOAEL = 0.3 mg/kg</p> <p>Maternal effects include: decreased weight gain.</p> <p>10 Days intravenous (every other day) Study of Embryo-Fetal Development (rat) (embryo/fetus) LOAEL = 0.1 mg/kg</p> <p>Fetal effects include: developmental delay, malformations, death.</p> <p>Substance was harmful to the fetus at doses that did not produce adverse effects in the maternal animal.</p> <p>3 Days Intraperitoneal (daily) Reproductive and developmental study (mouse) (parent, females) NOAEL = 1 mg/kg</p> <p>No adverse maternal effects were observed.</p> <p>3 Days Intraperitoneal (daily) Reproductive and developmental study (mouse) (embryo/fetus) NOAEL = 0.5 mg/kg</p> <p>Fetal effects include: decreased body weight, malformations, death.</p> <p>Substance was harmful to the fetus at doses that did not produce adverse effects in the maternal animal.</p> <p>Developmental Toxicity Assessment</p> <p>Birth defects were observed in animal studies. Selective developmental toxicant.</p>
Human experience:	<p>Experiences with Human Exposure</p> <p>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.</p>

11. TOXICOLOGICAL INFORMATION (CONTINUED)

Target Organs:	bone marrow, spleen, lymph nodes, liver, gastrointestinal tract, skin, cardiovascular system, central nervous system, testes, ovary
Symptoms:	See "Human Experience".
Pharmacokinetics/Toxicokinetics:	Not Available
Other Toxicity Information:	Not Available

12. ECOLOGICAL INFORMATION

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) : 12,900 mg/l. LC50 (fingerling trout, 24 H) : 11,200 mg/l. LC50 (Pimephales promelas (fathead minnow), 96 H) : 14,200 mg/l. flow-through
Acute Toxicity to Aquatic Invertabrates:	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.

12. ECOLOGICAL INFORMATION (CONTINUED)

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
Ecotoxicological Information (Terrestrial)	N/A
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



13. DISPOSAL CONSIDERATIONS

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.

WASTE DISPOSAL: Disposal by incineration is recommended.

14. TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

DOT: None Hazard Class or Division: 6.1

ID: UN3249 PG: III

Label Codes: 6.1

Special Provisions: T1, TP33

Packaging Exceptions: 153 Packaging: Non-bulk 213

Packaging Exceptions: 153 Quantity Limitations: 5kg

Passenger aircraft/rail: Quantity Limitations: Cargo

5kg Vessel Storage: Location: C aircraft only: Vessel

Stowage: Other: 40

Hazardous Materials descriptions and proper shipping names: Medicine, solid, toxic, n.o.s

ICAO / IATA: 6.1 Subrisk: None

UN / ID Number: 3249 Packing Group: III

Special Provisions: A3

Cargo Only

Packing Instructions: 200kg Max; Qty / Pack: 677

Passenger /Cargo Passenger/ Cargo Packing

Instructions: 100kg Max; Qty/Pack: 670

Shipping Name: Medicine, Solid, Toxic, N.O.S

IMO: Not Regulated



15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Worldgen Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

US Regulations

TS CA – No
CERCLA-No
SARA 302 – No
SARA 313 – No
OSHA Substance Specific - No

16. OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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