

MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI and Canadian WHMIS Standards

PART I What is the material and what do I need to know in an emergency?

1. PRODUCT IDENTIFICATION

PRODUCT NAME (AS LABELED): VINORELBINE TARTRATE INJECTION
PRODUCT USE: Antineoplastic Agent
SUPPLIER/MANUFACTURER'S NAME: GensiaSicor Pharmaceuticals, Inc.
ADDRESS: 17 Hughes,
 Irvine, CA 92618
CHEMTREC EMERGENCY NO.: 1-800-424-9300 (United States)**
 1-202-483-7616 (International Collect)
BUSINESS PHONE: 1-800-729-9991
FAX: 1-949-855-8210
Common Names: Navelbine Tartrate, 5'-Noranhydrovinoblastine Tartrate, KW-2307, Vinorelbine Ditartrate
Chemical Name: For Active Ingredient: 3',4'-didehydro-4'-deoxy-C'-norvincal leukoblastine [R-(R*,R*)-2,3-dihydroxybutanedioate (1:2) (salt)]
Chemical Formula: For Active Ingredient: C₄₅H₅₄N₄O₈•2C₄H₆O₆
Chemical Family: For Active Ingredient: Vinca Alkaloid
How Supplied: 10 mg/mL solution in a 2 mL vial
 50 mg/5 mL solution in a 5 mL vial
DATE OF PREPARATION: December 7, 1999

2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% by weight	EXPOSURE LIMITS IN AIR					
			ACGIH-TLV		OSHA-PEL		IDLH mg/m ³	OTHER
			TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³		
Vinorelbine Tartrate	125317-39-7	1	VINORELBINE TARTRATE IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.					
Water for Injection	7732-18-5	Balance	NE	NE	NE	NE	NE	NE

NE = Not Established C = Ceiling Limit mppcf: Millions of Particles per Cubic Foot See Section 16 for Definitions of Terms Used

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1-1998 format.

**CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this chemical.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This is a clear, colorless to pale yellow, odorless liquid. The primary health hazard associated with exposure to this product during an emergency response situation would be mild irritation of contaminated skin or eyes. Vinorelbine Tartrate is a potential reproductive toxin, based on animal data. This product is neither flammable nor reactive. Emergency responders must wear adequate personal protective equipment for the situation to which they are responding.

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: This material is a powerful cytotoxic and antineoplastic agent. The extent of entry into the body by most routes has not been fully investigated. Since the toxicological properties of this compound have not been fully investigated, all exposures must be minimized. Occupational exposures to this product may cause acute or chronic effects in humans, as described in the following paragraphs.

INHALATION: Inhalation of mists or sprays of this product may irritate the nose and throat. Symptoms of such exposure may include coughing, sneezing, and other toxic effects described in "Other Potential Health Effects".

3. HAZARD IDENTIFICATION (Continued)

CONTACT WITH SKIN or EYES: Contact of this product with the skin may cause redness, discomfort, and irritation. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Contact of this product with the eyes may cause irritation, redness, and tearing.

SKIN ABSORPTION: This product is not known to be absorbed through intact skin.

INGESTION: Ingestion is not anticipated to be a likely route of occupational exposure. If this product is swallowed, it may cause gastrointestinal distress and diarrhea. Symptoms of such overexposure may also include the toxic effects described in "Other Potential Health Effects".

INJECTION: In terms of anticipated occupational overexposure effects, local redness and pain are the primary symptoms of accidental injection. Symptoms of such overexposure may also include the toxic effects described in "Other Potential Health Effects".



OTHER POTENTIAL HEALTH EFFECTS: Vinorelbine Tartrate is a pharmacological product used in the treatment of cancer. The most common dose-dependent adverse effects associated with therapeutic treatments include hair loss, nausea, constipation, vomiting, diarrhea, loss of appetite, inflammation of the mouth, difficulty swallowing, sleepiness, shortness of breath, chest pain, jaw pain, headache, rash, muscle weakness, muscle or joint pain, partial paralysis of the lower limbs, impaired reflexes, loss of deep tendon reflexes, decreased granulocyte, red blood, and platelet cell counts, elevation of liver enzymes, and fever. An acute overdose of Vinorelbine Tartrate can cause irreversible bone marrow suppression and peripheral nerve damage.

HEALTH EFFECTS OR RISKS FROM EXPOSURE (An explanation in lay terms).

ACUTE: The primary health effects that may be experienced by medical personnel exposed to this product are irritation of contaminated skin and eyes or pain, redness, and local swelling after accidental injection. In the event of exposures via injection to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result.

CHRONIC: Vinorelbine Tartrate is a potential carcinogen and reproductive toxin, based on animal data. This compound has been rated as a Category D Reproductive Toxin, with possible reproductive effects in humans. Refer to Section 11 (Toxicological Information) for additional information on this product.

TARGET ORGANS: Skin, eyes (anticipated occupational exposures). Blood system, nervous system, skin, and reproductive system (therapeutic doses).

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM			
HEALTH		(BLUE)	2
FLAMMABILITY		(RED)	0
REACTIVITY		(YELLOW)	0
PROTECTIVE EQUIPMENT			X
EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8
For medical treatment of cancer.			

See Section 16 for Definition of Ratings

PART II *What should I do if a hazardous situation occurs?*

4. FIRST-AID MEASURES

PERSONS ACCIDENTALLY EXPOSED TO VINOURELBINE TARTRATE MUST RECEIVE PROMPT MEDICAL ATTENTION!

Victims of chemical exposure must be taken for medical attention. Rescuers should be taken for medical attention, if they have been exposed to this product. Take copy of label and MSDS to physician or health professional with victim.

SKIN EXPOSURE: If the product contaminates the skin, immediately begin decontamination with running water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. The minimum recommended flushing time is 15 minutes. Victims must seek immediate medical attention, especially if an adverse reaction occurs.

EYE EXPOSURE: If this product contaminates the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 15 minutes. If necessary, consult an ophthalmologist.

INHALATION: If this product is inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

INGESTION: If the product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, **DO NOT** induce vomiting. Have victim rinse mouth with water, if conscious. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain an open airway and prevent aspiration. If contaminated individual is convulsing, maintain an open airway and obtain immediate medical attention.

4. FIRST-AID MEASURES (Continued)

INJECTION: In the event of accidental injection, wash contaminated area with soap and water.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Disorders involving the Target Organs of this product (see Section 3, Hazard Information) can be aggravated by exposures to this product (especially in doses approaching therapeutic levels for this product).

RECOMMENDATIONS TO PHYSICIANS: Vinorelbine Tartrate is a potent cytotoxic antineoplastic drug. It should only be administered under the supervision of physicians experienced in cancer chemotherapy. Employees should receive routine medical surveillance before job placement, periodically (especially following acute exposures) and the termination of job or transfer. If necessary, cardiac evaluations, blood tests should be conducted. Consult the Package Insert for additional information which can assist with treatment of overexposure.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable.

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS (in air by volume, %): Lower: Not applicable.
Upper: Not applicable.

FIRE EXTINGUISHING EQUIPMENT:

Water Spray: OK

Foam: OK

Halon: OK

Carbon Dioxide: OK

Dry Chemical: OK

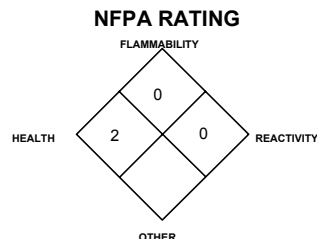
Other: Any "ABC" Class

UNUSUAL FIRE and EXPLOSION HAZARDS: This substance must be viewed

as a potential irritant, presenting a contact hazard to firefighters. Vinorelbine Tartrate is a potential carcinogen and reproductive toxin, based on animal data. Thermal decomposition of this product will produce irritating vapors and toxic gases (carbon oxides, nitrogen oxides).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.



**See Section 16 for
Definition of Ratings**

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation.

6. ACCIDENTAL RELEASE MEASURES

SPILL AND LEAK RESPONSE: **Cleanup of Small Spills.** Spills of less than 5 mL or 5 gm outside a hood should be cleaned immediately by personnel wearing gowns and double surgical latex gloves and eye protection. Liquids should be wiped with absorbent gauze pads; solids should be wiped with wet absorbent gauze. The spill areas should then be cleaned (three times) using a detergent solution followed by clean water. **Cleanup of Large Spills.** For spills of amounts larger than 5 mL or 5 gm, spread should be limited by gently covering with absorbent sheets or spill-control pads or pillows or, if a powder is involved, with damp cloths or towels. Be sure not to generate aerosols. Access to the spill areas should be restricted. Protective apparel should be used with the addition of a respirator when there is any danger of airborne powder or an aerosol being generated. The dispersal of mists into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Chemical inactivators may produce hazardous by-products and should not be applied to the absorbed Vinorelbine Tartrate. Proper protective equipment should be used, including double latex or nitrile gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator. All contaminated surfaces should be thoroughly cleaned with detergent solution and then wiped with clean water. All contaminated absorbents and other materials should be disposed of in the cytotoxic compound disposal bag. **Spills in Hoods.** Decontamination of all interior hood surfaces may be required after the above procedures have been followed. If the HEPA filter of a hood is contaminated, the unit must be labeled "Do not use--contaminated," and the filter must be changed and disposed of properly as soon as possible by trained personnel wearing protective equipment. Protective goggles should be cleaned with an alcohol wipe after the cleanup. Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12 x 12) of absorbent material, 250-mL and 1-liter spill control pillows and a small scoop to collect glass fragments (if applicable). Absorbents should be incinerable. Finally, the kit should contain two large cytotoxic compound waste-disposal bags.

6. ACCIDENTAL RELEASE MEASURES

SPILL AND LEAK RESPONSE (continued): Avoid generating airborne dusts of this product during spill response procedures. Decontaminate the area of the spill thoroughly by using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with U.S. Federal, State, and local or Canadian waste disposal regulations (refer to Section 13, Disposal Considerations).

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and STORAGE

WORK and HYGIENE PRACTICES: VINORELBINE TARTRATE IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL. As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat, smoke or drink while handling this product. Wash thoroughly after handling this product or equipment and containers that contain this product. In addition, smokers who do not take simple protective measures such as gloving and handwashing may take in additional amounts of the drug orally through contaminated cigarettes, resulting in exposure. Particular care in working with this product must be practiced in pharmacies and other preparation areas, and while manufacturing this product. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials;
- Drug transfers using syringes and needles or filter straws; and
- Expulsion of air from drug-filled syringes.
- Opening vials.

DO NOT CLIP OR CRUSH NEEDLE WITH WHICH THIS PRODUCT WAS IN CONTACT. Use of this product should meet the following provisions.

- Work should be performed in an appropriate, designated area;
- Contaminated waste must be properly handled; and,
- If necessary, work areas must be regularly decontaminated.

STORAGE and HANDLING PRACTICES: Employees must be trained to properly use this product. Contaminated waste must be properly handled. Work areas must be regularly decontaminated. Ensure vials are properly labeled. Store this product away from incompatible materials. Store containers at 2-8°C (36-46°F) and protect from light. DO NOT FREEZE.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Decontaminate equipment with a soapy water. All needles, syringes, vials, and other disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION and ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. Admixtures or manipulations of this drug should be carried out in a cytotoxic drug safety cabinet. The cabinet should be cleaned regularly following the manufacturer's recommendations, at least weekly. All surfaces should be thoroughly washed with water and detergent and triple rinsed. During decontamination, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS for the clean up of a large spill. HEPA filters on the cytotoxic drug safety cabinet should be changed every six months. The safety cabinet should be tested and certified as recommended by the National Sanitation Foundation in Standard Number 49.

RESPIRATORY PROTECTION: A full-face respirator with a HEPA filter should be used until a Biological Safety Cabinet is installed. A respirator is not required for routine conditions if used in a Biological Safety Cabinet. If respiratory protection is needed, use only protection authorized in the U.S. Federal OSHA Standard (29 CFR 1910.134), applicable U.S. State regulations, or the Canadian CSA Standard Z94.4-93 and applicable standards of Canadian Provinces. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134-1998).

EYE PROTECTION: Chemical splash goggles, or regular splash goggles, with a full face-shield. An eyewash station must be available in areas where this compound is used.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

HAND PROTECTION: Double glove, using latex, nitrile, or rubber gloves (powderless). Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if they are torn or punctured.

BODY PROTECTION: A protective disposable gown made of lint-free low permeability fabric with a closed front, long sleeves, and elastic or knit-closed cuffs must be worn, with the cuffs tucked under the gloves. The gown should be made of Tyvek^(TM), PE-Coated Tyvek^(TM), or SARANEX^(TM). Gowns and gloves in use should not be worn outside the preparation area.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

9. PHYSICAL and CHEMICAL PROPERTIES

RELATIVE VAPOR DENSITY (air = 1): Not determined.

SPECIFIC GRAVITY: Not determined.

SOLUBILITY IN WATER: Soluble.

VAPOR PRESSURE, mm Hg @ 25°C: Not determined.

ODOR THRESHOLD: Odorless.

COEFFICIENT OF OIL/WATER DISTRIBUTION (Partition Coefficient): Not determined.

APPEARANCE, ODOR and COLOR: This is a clear, colorless to pale yellow, odorless liquid.

HOW TO DETECT THIS SUBSTANCE (warning properties): There are no distinguishing characteristic associated with this product.

EVAPORATION RATE (n-BuAc=1): Not determined.

MELTING/FREEZING POINT: Not determined.

BOILING POINT: Not determined.

pH: Approximately 3.5

10. STABILITY and REACTIVITY

STABILITY: This product is stable, when stored at the recommended temperature and protected from light.

DECOMPOSITION PRODUCTS: When heated to decomposition temperatures, this product will emit carbon oxides and nitrogen oxides.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. This product would not be compatible with strong oxidizers.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Heat may cause this product to decompose, destroying the product and producing irritating vapors and toxic gases (e.g., carbon oxides, nitrogen oxides). Avoid contact with incompatible chemicals.

PART IV *Is there any other useful information about this material?*

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA: The following data are available for Vinorelbine Tartrate, the active ingredient in this product.

VINORELBINE TARTRATE:

TDLo (intravenous, rat) = 2 mg/kg/female 7-16 days after conception; Reproductive: Specific Developmental Abnormalities: musculoskeletal system

VINORELBINE TARTRATE (continued):

LD₅₀ (oral, rat) = 26-34 mg/kg
LD₅₀ (intravenous, rat) = 11-12 mg/kg

VINORELBINE TARTRATE(continued):

LD₅₀ (oral, mouse) = 77-89 mg/kg
LD₅₀ (intravenous, mouse) = 32-42 mg/kg
LD (intravenous, beagle) = 1-2 mg/kg

SUSPECTED CANCER AGENT: Vinorelbine Tartrate is cytotoxic, DNA-damaging, and should be handled as a suspect carcinogen.

This product's ingredients are not found on the following lists: U.S. FEDERAL OSHA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

IRRITANCY OF PRODUCT: This product may be irritating to contaminated skin, eyes, and other tissue.

SENSITIZATION TO THE PRODUCT: This product may cause allergic reactions in sensitive individuals.

REPRODUCTIVE TOXICITY INFORMATION: Vinorelbine Tartrate is rated as Pregnancy Category D (Risk to Pregnancy Cannot Be Ruled Out). Listed below is information concerning the effects of Vinorelbine Tartrate, the active ingredient of this product, on animal or human reproductive systems.

Mutagenicity: Vinorelbine Tartrate has been shown to affect chromosome number and possibly structure in vivo.

Embryotoxicity: A single dose of Vinorelbine Tartrate has been shown to be embryotoxic in mice and rabbits at doses of 9 mg/m² and 5.5 mg/m², respectively (1/3 and 1/6 the human dose). Refer to "Teratogenicity" for additional information.

Teratogenicity: At non-maternotoxic doses, fetal weight was reduced and ossification was delayed. There are no adequate and well-controlled studies in pregnant women.

Reproductive Toxicity: Biweekly administration of Vinorelbine Tartrate for 13 or 26 weeks in the rat at 2.1 and 7.2 mg/m² resulted in decreased spermatogenesis and prostate/seminal vesicle secretion.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

A mutagen is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An embryotoxin is a chemical which causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical which causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance which interferes in any way with the reproductive process.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently there are no ACGIH Biological Exposure Indices (BEIs) associated with the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: This product will be relatively stable under ambient environmental conditions.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: No specific information is currently available on the effect of Vinorelbine Tartrate on plants or animals in the environment. This product may be harmful or fatal to contaminated plant and animal life. Refer to Section 11 (Toxicological Information) for additional information on Vinorelbine Tartrate and its effects on test animals.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of Vinorelbine Tartrate on aquatic plants or animals in the environment. This product may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Cytotoxic waste must be disposed in sealable plastic or wire tie bags of 4-mil thick polyethylene or 2-mil polypropylene, labeled with a cytotoxic hazard label, colored differently from other hospital trash bags, and used for the routine accumulation and collection of used containers, syringes, discarded gloves, gowns, goggles and any other disposable material. All Vinorelbine Tartrate-related wastes should be placed in approved bags only. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Incineration is recommended for the product and disposable equipment contaminated with this product. Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or those of Canada and its Provinces. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

14. TRANSPORTATION INFORMATION

THIS MATERIAL IS NOT HAZARDOUS, PER THE U.S. DEPARTMENT OF TRANSPORTATION (49 CFR 172.101)

PROPER SHIPPING NAME: Not Regulated

HAZARD CLASS NUMBER and DESCRIPTION: Not Applicable

UN IDENTIFICATION NUMBER: Not Applicable

PACKING GROUP: Not Applicable

DOT LABEL(S) REQUIRED: Not Applicable

NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (1996): Not Applicable

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B).

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: THIS MATERIAL IS NOT CONSIDERED AS DANGEROUS GOODS.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. TSCA STATUS: Vinorelbine Tartrate is a "drug" as defined by the Federal Food, Drug and Cosmetic Act (21 USC 321 et. Seq.); therefore, it is not a chemical substance under TSCA (40 CFR 720.3 (e)).

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lbs. (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

15. REGULATORY INFORMATION (Continued)

ADDITIONAL U.S. REGULATIONS(continued):

OTHER U.S. FEDERAL REGULATIONS: Requirements under FDA regulations may apply to this compound. In addition, when used as an injectable drug, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) are applicable. Employers should refer to OSHA Technical Instructions, TED 1.15, when employees are working with hazardous drugs.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No component of this product is on the California Proposition 65 lists.

U.S. STATE REGULATORY INFORMATION: The components of this product are covered under the following specific State regulations (NONE indicates no special regulations were noted).

Alaska - Designated Toxic and Hazardous Substances: None.	Minnesota - List of Hazardous Substances: None.	Pennsylvania - Hazardous Substance List: None.
California - Permissible Exposure Limits for Chemical Contaminants: None.	Missouri - Employer Information/Toxic Substance List: None.	Rhode Island - Hazardous Substance List: None.
Florida - Substance List: None.	New Jersey - Right to Know Hazardous Substance List: None.	Texas - Hazardous Substance List: None.
Illinois - Toxic Substance List: None.	North Dakota - List of Hazardous Chemicals, Reportable Quantities: None.	West Virginia - Hazardous Substance List: None.
Kansas - Section 302/313 List: None.		Wisconsin - Toxic and Hazardous Substances: None.
Massachusetts - Substance List: None.		
Michigan - Critical Materials Register: None.		

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): **DANGER!** CYTOTOXIC AGENT. ALL EXPOSURE MUST BE MINIMIZED. ACCIDENTAL INJECTION CAN CAUSE SERIOUS HEALTH EFFECTS. MAY BE HARMFUL IF SWALLOWED. MAY CAUSE RESPIRATORY SYSTEM, EYE, AND SKIN IRRITATION. MAY CAUSE REPRODUCTIVE EFFECTS, BASED ON ANIMAL DATA, AND CAN CAUSE HARM DURING PREGNANCY. CAN CAUSE NERVOUS SYSTEM AND BLOOD EFFECTS. Do not taste or swallow. Do not accidentally get on skin, in eyes, or on clothes. Avoid prolonged or repeated skin contact. Avoid breathing mists or sprays. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. If necessary, wear gloves, goggles, and appropriate body protection. Store containers in a cool location, tightly closed, away from direct light. **FIRST-AID:** In case of contact, immediately flush skin or eyes with plenty of water. If inhaled, remove to fresh air. If ingested, do not induce vomiting. Get medical attention if necessary. **IN CASE OF FIRE:** Use water fog, dry chemical, CO₂, or "alcohol" foam. **IN CASE OF SPILL:** Absorb spill with poly pads and place in suitable container. Consult Material Safety Data Sheet for additional information.

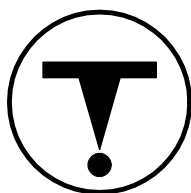
ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL STATUS: Vinorelbine Tartrate is regulated by the Food and Drug Administration of Health Canada; it is exempt from the requirements of CEPA.

OTHER CANADIAN REGULATIONS: Not Applicable.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

CANADIAN WHMIS SYMBOLS: **Class D2A:** Materials Causing Other Toxic Effects (Irritant, Nervous System Effects)



16. OTHER INFORMATION

PREPARED BY:

CHEMICAL SAFETY ASSOCIATES, Inc.
9163 Chesapeake Drive, San Diego, CA 92123-1002
(619) 565 - 0302
February 7, 2003

DATE OF PRINTING:

DEFINITIONS OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these which are commonly used include the following:

CAS #: This is the Chemical Abstract Service Number which uniquely identifies each constituent. It is used for computer-related searching.

EXPOSURE LIMITS IN AIR:

ACGIH - American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

TLV - Threshold Limit Value - an airborne concentration of a substance which represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour **Time Weighted Average (TWA)**, the 15-minute **Short Term Exposure Limit**, and the instantaneous **Ceiling Level**. Skin absorption effects must also be considered.

OSHA - U.S. Occupational Safety and Health Administration.

PEL - Permissible Exposure Limit - This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL," is placed next to the PEL which was vacated by Court Order.

IDLH - Immediately Dangerous to Life and Health - This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury. **The DFG - MAK** is the Republic of Germany's Maximum Exposure Level, similar to the U.S. PEL. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (**OSHA**). NIOSH issues exposure guidelines called **Recommended Exposure Levels (RELs)**. When no exposure guidelines are established, an entry of **NE** is made for reference.

HAZARD RATINGS:

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM: This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards. Health Hazard: **0** (minimal acute or chronic exposure hazard); **1** (slight acute or chronic exposure hazard); **2** (moderate acute or significant chronic exposure hazard); **3** (severe acute exposure hazard; onetime overexposure can result in permanent injury and may be fatal); **4** (extreme acute exposure hazard; onetime overexposure can be fatal). Flammability Hazard: **0** (minimal hazard); **1** (materials that require substantial pre-heating before burning); **2** (combustible liquid or solids; liquids with a flash point of 38-93°C [100-200°F]); **3** (Class IB and IC flammable liquids with flash points below 38°C [100°F]); **4** (Class IA flammable liquids with flash points below 23°C [73°F] and boiling points below 38°C [100°F]). Reactivity Hazard: **0** (normally stable); **1** (material that can become unstable at elevated temperatures or which can react slightly with water); **2** (materials that are unstable but do not detonate or which can react violently with water); **3** (materials that can detonate when initiated or which can react explosively with water); **4** (materials that can detonate at normal temperatures or pressures). PPE Rating X: Special attention should be given to PPE, based on product use.

NATIONAL FIRE PROTECTION ASSOCIATION: Health Hazard: **0** (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); **1** (materials that on exposure under fire conditions could cause irritation or minor residual injury); **2** (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury); **3** (materials that can on short exposure could cause serious temporary or residual injury); **4** (materials that under very short exposure could cause death or major residual injury). Flammability Hazard and Reactivity Hazard: Refer to definitions for "Hazardous Materials Identification System".

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the **National Fire Protection Association (NFPA)**. Flash Point - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. Autoignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD₅₀** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC₅₀** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m³** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, and **LDo**, or **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** The sources are: **IARC** - the International Agency for Research on Cancer; **NTP** - the National Toxicology Program, **RTECS** - the Registry of Toxic Effects of Chemical Substances, **OSHA** and **CAL/OSHA**. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** **BEI** - ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV. **Ecological Information:** **EC** is the effect concentration in water. **BCF** = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. Coefficient of Oil/Water Distribution is represented by **log K_{ow}** or **log K_{oc}** and is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

This section explains the impact of various laws and regulations on the material. **U.S.:** **EPA** is the U.S. Environmental Protection Agency. **DOT** is the U.S. Department of Transportation. **SARA** is the Superfund Amendments and Reauthorization Act. **TSCA** is the U.S. Toxic Substance Control Act. **CERCLA (or Superfund)** refers to the Comprehensive Environmental Response, Compensation, and Liability Act. Labeling is per the American National Standards Institute (**ANSI Z129.1**). **CANADA:** **CEPA** is the Canadian Environmental Protection Act. **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **TC** is Transport Canada. **DSL/NDL** are the Canadian Domestic/Non-Domestic Substances Lists.