

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): **VINCRISTINE SULFATE**

PRODUCT USE: Medical Treatment; Cytotoxic 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: 1-714-855-8210

Common Names: KYOCRISTINE; LILLY 37231; NSC-67574; ONCOVIN; VCR SULFATE; VINCRISUL

Chemical Name: For Active Ingredient: 22-Oxovincal leukoblastine Sulfate

Chemical Formula: For Active Ingredient: $C_{46}H_{56}N_4O_{10} \cdot H_2SO_4$

Chemical Family: For Active Ingredient: Vinca Rosa Alkaloid

How Supplied: 1 mg/2mL, 2 mg/mL, 5 mg/5mL vials.

DATE OF PREPARATION: January 8, 1998

2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% by weight	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA		IDLH	OTHER
			TLV	STEL	PEL	STEL		
VINCRISTINE SULFATE	2068-78-2	< 1	NE	NE	NE	NE	NE	Manufacturer Exposure Guideline [Lilly]: 0.14 :g/m ³ per 12 hours Carcinogen: IARC - Group 3
MANNITOL	69-65-8	10	NE	NE	NE	NE	NE	NE
WATER FOR INJECTION	7732-18-5	Balance	NE	NE	NE	NE	NE	NE

NE = Not Established

C = Ceiling Limit

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 Z400.1-1993 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, odorless liquid. The primary health hazard associated with exposure to this product during an emergency response situation would be irritation of contaminated skin or eyes. Vincristine Sulfate is a potential reproductive toxin. 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:

Vincristine Sulfate is generally intended for intravenous injection under the supervision of physicians experienced in cancer chemotherapy. Dose-dependent adverse effects associated with therapeutic treatments include headache, fever, drowsiness, fatigue, changes in blood pressure, leukopenia (depression of the bone marrow), anemia, changes in urine volume, painful urination, nausea, vomiting, constipation, abdominal pain, hair loss, rash, and adverse effects on the neuromuscular system (e.g., tremors, loss of reflexes, sensory impairment, neuritic pain, muscle weakness) and kidneys. This product must be considered a reproductive toxin, based on human exposure evidence and animal data. Anaphylactic reactions, consisting of hypotension, fever, chills, mental confusion, and wheezing, may also occur. The extent of entry into the body by most routes has not been fully investigated. Occupational exposures to this product may cause severe acute or chronic effects in humans, as described in the following paragraphs.

INHALATION: Inhalation of mists or sprays of this product may mildly irritate the nose and throat. Symptoms of such exposure may include coughing and sneezing. Symptoms of such overexposure may also include the toxic effects described in "Symptoms of Overexposure by Route of Exposure". Because of the small size of individual containers, inhalation of significant amounts of the product is not anticipated to occur.

CONTACT WITH SKIN or EYES: Contact of this product with the skin can cause redness and irritation. Contact of this product with the eyes may cause severe irritation, redness, and tearing. Vinca alkaloids do not cause a direct chemical burn of eye tissue, but interfere with the reproduction of the eye epithelium (outer layer of eye tissue), which occurs continuously. The result can be a delayed burn. While very painful, all cases have recovered completely without any loss of eye function.

SKIN ABSORPTION: Skin absorption is not reported to be a significant route of exposure to the components of this product.

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 "Symptoms of Overexposure by Route of Exposure".

INJECTION: Local redness and pain are the primary symptoms of accidental injection, in terms of anticipated occupational overexposure effects. Symptoms of such overexposure may also include the toxic effects described in "Symptoms of Overexposure by Route of Exposure".

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, neuromuscular problems and a variety of other health effects may occur. Death may occur in the event of an accidental over-dose.

CHRONIC: Based on human and animal data, Vincristine Sulfate must be considered a potential reproductive toxin. Refer to Section 11 (Toxicological Information) for additional information on this product.

TARGET ORGANS: Skin, eyes (anticipated occupational exposures). Cardiovascular system, neuromuscular system, reproductive system, kidneys (therapeutic doses).

HAZARDOUS MATERIAL INFORMATION SYSTEM			
HEALTH		(BLUE)	3
FLAMMABILITY		(RED)	0
REACTIVITY		(YELLOW)	0
PROTECTIVE EQUIPMENT			X
EYES	RESPIRATORY	HANDS	BODY
See Section 8 of this MSDS.			
PPE used during 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 VINCRISTINE SULFATE MUST RECEIVE PROMPT MEDICAL ATTENTION!

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 gentle 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. Remove or cover gross contamination to avoid exposure to rescuers.

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. Victim should drink milk, egg whites, or large quantities of water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow.

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.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not flammable.

AUTOIGNITION TEMPERATURE: Not applicable.

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

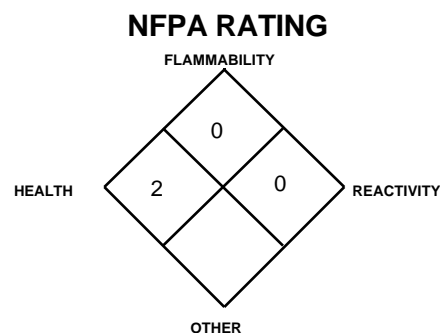
FIRE EXTINGUISHING EQUIPMENT:

Water Spray: OK Carbon Dioxide: OK Foam: OK
Dry Chemical: OK Halon: OK Other: Any "ABC"
Class

UNUSUAL FIRE and EXPLOSION HAZARDS: At extremely high temperatures, this product will decompose to produce irritating vapors and toxic gases (carbon oxides, sulfur oxides, and 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: For small releases of this product (1 vial) wear double latex or nitrile gloves, and safety glasses. Large or uncontrolled releases should be responded to by trained personnel using pre-planned procedures. 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.

In case of a spill, clear the affected area, protect people, and respond with trained personnel. Clean-up spilled liquid with a damp sponge, polypad, or other appropriate materials. If necessary, decontaminate area with a bleach solution. 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 Federal, State, and local waste disposal regulations.

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

7. HANDLING and STORAGE

WORK and HYGIENE PRACTICES: VINCRISTINE SULFATE 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. Wash hands after handling the product. Do not eat or drink while handling the product. Wash hands thoroughly after handling this product or equipment and containers which contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with product.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Operations of high risk associated with the use of this product include:

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

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 a designated area for working with hazardous drugs;
- Containment devices, such as a Biological Safety Cabinet, should be used;
- Contaminated waste must be properly handled; and,
- Work areas must be regularly decontaminated.

STORAGE and HANDLING PRACTICES: Employees must be trained to properly use this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Operations of high risk associated with the use of this product include withdrawal of needles from drug vials, drug transfers using syringes and needles, and expulsion of air from drug-filled syringes. Use of this product should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated. Ensure vials are properly labeled. Store this product away from incompatible materials. Refrigerate this product in original container at 2-8°C (36-46°F). Protect from light.

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. Wash equipment with soap and 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 regularly cleaned following the manufacturer's recommendations, but no less frequently than 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. Technicians should be aware of the risks associated with this drug via training, and should use the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS for the clean-up of large spills. 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 of use with a Biological Safety Cabinet.

EYE PROTECTION: Chemical splash goggles, or regular splash goggles, with a full face-shield.

HAND PROTECTION: Double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff.

BODY PROTECTION: A full body gown which is closed at the front and has long sleeves. The gown should be made of Tyvek^(TM), PE-Coated Tyvek^(TM), or SARANEX^(TM).

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: Approximately 1.

SOLUBILITY IN WATER: Soluble.

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

ODOR THRESHOLD: Not determined.

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

EVAPORATION RATE (n-BuAc=1): > 1

MELTING/FREEZING POINT: Not determined

BOILING POINT: Approximately 100°C (212°F)

pH: 3.5 - 5.5

APPEARANCE and COLOR: This is a clear, colorless, odorless liquid.

HOW TO DETECT THIS SUBSTANCE (warning properties): The odor may be a distinguishing characteristics associated with this product.

10. STABILITY and REACTIVITY

STABILITY: This product is stable (when refrigerated and protected from light).

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

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 (i.e., oxides of carbon and nitrogen). 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 the components of this product.

VINCRIStINE SULFATE:

DNA Inhibition-Human: Oncogenic Transformation: 69,120 pmol/L

Micronucleus Test-Hamster-Intraperitoneal 200 ug/kg

Oncogenic Transformation - Hamster: embryo 1 ug/L

Sister Chromatid Exchange-Hamster :ovary 50 ug/L

Sex Chromosome Loss and Nondisjunction - Hamster: embryo 3 ug/L

Intraperitoneal-Mouse TDLo: 250 ug/kg (female 9 days post): Teratogenic effects

Intraperitoneal-Mouse TDLo: 250 ug/kg (female 9 days post): Reproductive effects

Intraperitoneal-Rat LD50: 1900 ug/kg

Intravenous-Rat LD50: 1010 ug/kg

VINCRIStINE SULFATE (continued):

Intraperitoneal-Mouse LD50: 3 mg/kg

Intravenous-Mouse LD50: 2100 ug/kg

MANNITOL:

oms-other microorganisms 1 mol/L

DNA Inhibition-Human: lymphocyte 50 mmol/L

Intravenous-Man TDLo: 17,143 mg/kg/2D-C: Cardiovascular effects, Gastrointestinal tract effects, kidney effects

Oral-Rat LD₅₀: 13,500 mg/kg

Intravenous-Rat LD50: 9690 mg/kg

Oral-Mouse LD₅₀: 22 g/kg

Intraperitoneal-Mouse LD₅₀: 14 g/kg

Intravenous-Mouse LD50: 7470 mg/kg

SUSPECTED CANCER AGENT: Vincristine Sulfate is listed as follows:

IARC-Group 3: Not Classifiable as to Carcinogenicity to Humans.

This product's other ingredients are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, CAL/OSHA, and therefore the ingredients are not considered to be, nor suspected to be, cancer-causing agents by these agencies.

IRRITANCY OF PRODUCT: This product is moderately to severely irritating to contaminated skin, eyes, and other tissue.

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

REPRODUCTIVE TOXICITY INFORMATION: Vincristine Sulfate has rating of Pregnancy Category D (Positive Evidence of Risk) and is suspected of being a human reproductive toxin, based on animal data. Listed below is information concerning the effects of Vincristine Sulfate on the human reproductive system.

Mutagenicity: Human mutation data are reported for Vincristine Sulfate.

Embryotoxicity: Vincristine Sulfate may cause human embryotoxic effects. Refer to "Teratogenicity" for additional information.

11. TOXICOLOGICAL INFORMATION (Continued)

Teratogenicity: Vincristine Sulfate can cause fetal harm when administered to a pregnant woman during therapeutic treatments. Pregnant mice and hamsters were given doses of Vincristine Sulfate which caused the resorption of 23% to 85% of fetuses, and fetal malformations were produced in those that survived. Five monkeys were given single doses of Vincristine Sulfate during pregnancy; 3 of the fetuses were normal at term and 2 had grossly evident malformations at term. In several animal species, Vincristine Sulfate can induce teratogenesis and embryo death at doses non-toxic to the pregnant animal.

Reproductive Toxicity: Vincristine Sulfate can induce human reproductive effects (e.g., changes in sperm production and development, amenorrhea) during therapeutic treatments.

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.

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

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: Vincristine Sulfate is a potent, cytotoxic drug. It should only be used by persons experienced in management of patients receiving this type of therapy. In the event of an occupational exposure, treat symptoms and eliminate exposure. In case of eye contact, a steroid eye ointment or drops can be used to minimize inflammation.

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 Vincristine Sulfate 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 Vincristine Sulfate and its effects on test animals.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of Vincristine Sulfate on 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: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. 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. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Reusable equipment should be cleaned with soap and water. Incineration is recommended.

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

14. TRANSPORTATION INFORMATION

THIS MATERIAL IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: Not applicable.

HAZARD CLASS NUMBER and DESCRIPTION: Not applicable.

UN IDENTIFICATION NUMBER: Not applicable.

PACKING GROUP: Not applicable.

DOT LABEL(S) REQUIRED: Not applicable.

14. TRANSPORTATION INFORMATION (Continued)

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. Refer to the above paragraph for additional information.

15. REGULATORY INFORMATION

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.

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

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

U.S. SARA THRESHOLD PLANNING QUANTITY: Not applicable.

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

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): Vincristine Sulfate is frequently used in combination chemotherapy for lymphomas. "Certain Combined Chemotherapy for Lymphomas" is on the California Proposition 65 lists. **WARNING**: This product contains a chemical known to the State of California to cause cancer.

OTHER U.S. FEDERAL REGULATIONS: Based on this product's use, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) are applicable. Employers should refer to the OSHA Technical Instructions, TED 1.15, when employees are working with hazardous drugs.

U.S. STATE REGULATORY INFORMATION: The components of this product are not covered under the following specific State regulations (NONE indicates no special regulations were noted).

Alaska - Designated Toxic and Hazardous Substances: None.
California - Permissible Exposure Limits for Chemical Contaminants: None.
Florida - Substance List: None.
Illinois - Toxic Substance List: None.
Kansas - Section 302/313 List: None.
Massachusetts - Substance List: None.

Michigan - Critical Materials Register: None.
Minnesota - List of Hazardous Substances: None.
Missouri - Employer Information/Toxic Substance List: None.
New Jersey - Right to Know Hazardous Substance List: None.
North Dakota - List of Hazardous Chemicals, Reportable Quantities: None.

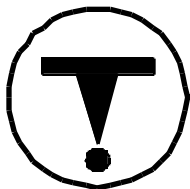
Pennsylvania - Hazardous Substance List: None.
Rhode Island - Hazardous Substance List: None.
Texas - Hazardous Substance List: None.
West Virginia - Hazardous Substance List: None.
Wisconsin - Toxic and Hazardous Substances: None.

LABELING (Precautionary Statements): **DANGER!** CYTOTOXIC AGENT. Vincristine Sulfate should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available. Avoid exposure. Wash hands and arms thoroughly after handling Vincristine Sulfate. Do not eat, drink, or smoke when handling Vincristine Sulfate. Clean-up spills promptly. Store containers in a cool location, tightly closed, away from direct light. Aluminum needles or intravenous sets should not be used for preparation or administration of Vincristine Sulfate.

In addition to standard pharmacy labeling practices, all syringes and IV bags containing this product should be labeled as follows:

SPECIAL HANDLING AND DISPOSAL REQUIRED

CANADIAN WHMIS SYMBOLS: **Class D2A/D2B**: Materials Causing Other Toxic Effects



16. OTHER INFORMATION

PREPARED BY:

CHEMICAL SAFETY ASSOCIATES, Inc.
9163 Chesapeake Drive, San Diego, CA 92123-1002
(619) 565 - 0302
May 8, 2000

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: 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).

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:

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. Data from several sources are used to evaluate the cancer-causing potential of the material. 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 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 death. **BEI** - 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.

REGULATORY INFORMATION:

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively. **Superfund Amendments and Reauthorization Act (SARA)**; the Canadian **Domestic Substances List (DSL)**; the U.S. **Toxic Substance Control Act (TSCA)**; Marine Pollutant status according to the **DOT**; California's Safe Drinking Water Act (**Proposition 65**); the **Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund)**; and various state regulations. This section also includes information on the precautionary warnings which appear on the material's package label.