MATERIAL SAFETY DATA SHEET

Product Name: Vinblastine Sulfate Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira Inc. 275 North Field Drive Lake Forest, Illinois USA 60045
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880
Hospira, Inc., Non-Emergency	224-212-2000
Product Name	Vinblastine Sulfate Injection
Synonyms	Vincoblastine; Vincaleukoblastine, sulfate (1:1) (salt).

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name	Vinblastine Sulfate
Chemical Formula	$C_{46}H_{58}N_4O_9 \cdot H_2SO_4$
Preparation	Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride. Sodium hydroxide and/or sulfuric acid are added to adjust the pH.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Vinblastine Sulfate	0.1	143-67-9	YY8400000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Vinblastine Sulfate	3	Not Listed	Not Listed

Emergency Overview	Vinblastine Sulfate Injection is a solution containing vinblastine sulfate, an anti-neoplastic agent that binds to microtubule proteins of the spindle, arresting cellular mitosis. Clinically, it is used to treat some types of cancers. It is cytotoxic, neurotoxic, and in the workplace, should be considered potentially irritating to the eyes and respiratory tract, a potential occupational reproductive hazard, harmful to the fetus, and a potential human carcinogen. Based on clinical use, possible target organs may include the bone marrow, gastrointestinal system, central nervous system, peripheral nervous system, cardiovascular system, lungs, skin, gonads, and the fetus.
Occupational Exposure Potential	There are scientific studies that suggest that personnel (e.g. nurses, pharmacists, etc.) who prepare and administer parenteral antineoplastics (e.g. in hospitals) may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these materials if workplace exposures are not properly controlled. The actual risk in the workplace is not known.
Signs and Symptoms	None known from workplace exposure. In clinical use, vinblastine sulfate is irritating to the

	skin and mucous membranes and extravasation may cause necrosis, cellulitis, and sloughing. Other adverse effects may include bone-marrow depression, gastrointestinal bleeding, stomatitis, nausea and vomiting, and dyspnea and bronchospasm. Vinblastine may also produce central and peripheral neurotoxicity, malaise, weakness, headache, depression, paraesthesia and numbness, loss of deep tendon reflexes, peripheral neuropathies, constipation, jaw pain, and convulsions. Damage to the eighth cranial nerve may result in vestibular and auditory toxicity leading to dizziness, nystagmus, vertigo, and partial or total deafness. Other adverse effects include skin reactions, alopecia, ischemic cardiac toxicity, hypertension, and bone and tumor pain. Aspermia has been reported in men following treatment.
Medical Conditions Aggravated by Exposure	Pre-existing hypersensitivity to vinblastine sulfate or other vinca alkaloids. Pre-existing bone marrow, gastrointestinal, central nervous system, peripheral nervous system, pulmonary, neuromuscular, gonadal, auditory (hearing) or skin ailments; pregnancy.

4. FIRST AID MEASURES

Eye contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability	Not anticipated for this aqueous product.
Fire & Explosion Hazard	Not anticipated for this aqueous product.
Extinguishing media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	Firefighters should wear self-contained breathing apparatus. Protective equipment and clothing should be worn to minimize contact with the respiratory tract, skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb liquid with suitable material. Clean affected area with soap and water. Additionally, application of a 10% solution of household bleach in water for 10 minutes can be used to clean the affected spill areas. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling

Vinblastine sulfate is a cytotoxic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic antineoplastics agents to minimize potential exposures. Several guidelines on handling cytotoxic antineoplastic agents have been published. Consult your hygienist or safety professional for your site requirements.

Avoid ingestion, inhalation, skin contact, and eye contact. When handling, precautions may include the use of a containment cabinet. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials is required when working with this product.

Storage

No special storage is required for hazard control. However, employees should be trained on the proper storage procedures for antineoplastic agents. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions

Persons with known hypersensitivities to vinblastine sulfate or other vinca alkaloids, women who are pregnant, or women who want to become pregnant, should consult a health and/or safety professional prior to handling this product.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits				
Component	**Type**	**mg/m3**	**ppm**	**µg/m3**	**Note**
Vinblastine Sulfate	Not Applicable	N/A	N/A	N/A	None Established

Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N99 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection

When handling this product, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to chemotherapeutic agents. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.

Eye protection

As a minimum, the use of chemical safety goggles is recommended when handling this product.

Engineering Controls

Good local exhaust ventilation is recommended to minimize employee exposure. The use of an enclosure, such as an approved ventilated cabinet designed to minimize airborne exposures, is also recommended.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Liquid
Color	Sterile, Unpreserved Solution
Odor	Odorless
Odor Threshold:	NA
pH:	NA
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	NA
Solubility:	Soluble in water and methyl alcohol, slightly soluble in chloroform and alcohol and practically insoluble in ether.
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under recommended storage conditions and use.
Hazardous Reactions	Not determined.
Conditions to avoid	Not determined.
Incompatibilities	Not determined.
Hazardous decomposition products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and sulfur oxides (SOx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Vinblastine Sulfate	100	LD50	Oral	305 423	mg/kg mg/kg	Rat Mouse
Vinblastine Sulfate	100	LD50	Intravenous	37 9.5	mg/kg mg/kg	Rat Mouse
Vinblastine Sulfate	100	LD50	Intraperitoneal	1 2.7 4.3	mg/kg mg/kg mg/kg	Rat Mouse Hamster

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent skin contact with this product may produce irritation and redness.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent eye contact with this product may produce severe irritation, redness, tearing and pain.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. Allergic reactions have occurred infrequently during clinical use of this product.

Reproductive Effects
Vinblastine sulfate has been shown to impair fertility and to be embryocidal and teratogenic in mice, rats, hamsters, rabbits and monkeys at very low dosages (lowest LOAEL = 0.05 mg/kg). In monkeys, a single injection of vinblastine at a dosage of 0.15-0.175 mg/kg on day 27 or 29 of gestation produced one fetus with encephalocele (skull defect) and one with syndactyly (webbing of fingers or toes). In rats, a single injection of vinblastine at a dosage of 0.05-0.075 mg/kg on day 9 of gestation produced a high incidence of eye defects and some microcephaly and neural tube closure defects.

Mutagenicity
Vinblastine sulfate was not mutagenic in Salmonella typhimurium, with or without microsomal activation produced no chromosomal aberrations in CHO cells or in a Syrian hamster fibroblast cell line and failed to transform C3H/10T½ clone 8 cells. However, this material did increase numerical and/or structural chromosomal aberrations in mouse bone-marrow cells and embryonic tissues. It also increased micronuclei formation in mouse bone-marrow cells and increased sister chromatid exchanges in a hamster cell line and human lymphocytes.

Carcinogenicity
Vinblastine sulfate was negative in one cancer study in rats and mice although the study was limited. Some patients who received chemotherapy with vinblastine in combination with anti-cancer drugs known to be carcinogenic have developed secondary malignancies.

Target Organ Effects
This product should be considered irritating to the skin, eyes and respiratory tract. Based on clinical use, possible target organs may include the bone marrow, gastrointestinal system, central nervous system, peripheral nervous system, cardiovascular system, lungs, skin, gonads, and the fetus.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity Not determined for product.

Persistence/Biodegradability Vinblastine degraded about 10% in a 28-day biodegradation assay; it is not considered biodegradable.

Bioaccumulation Not determined for product.

Mobility in Soil Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of containers and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Vinblastine Sulfate	Not Listed	Not Listed	Not Listed	Not Listed	Listed

RCRA Status Not Listed

U.S. OSHA Classification
Target Organ Toxin
Reproductive Toxin
Possible Irritant

GHS Classification *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class Not Applicable

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapours/spray.

Hazard Statement Not Applicable

Response: 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 attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Vinblastine Sulfate

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Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
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