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_{4}O_{9}\cdot H_{2}SO_{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.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vinblastine Sulfate</td>
<td>0.1</td>
<td>143-67-9</td>
<td>YY8400000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vinblastine Sulfate</td>
<td>3</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

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
Product Name: Vinblastine Sulfate Injection

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

<table>
<thead>
<tr>
<th>Exposure Guidelines</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component</td>
<td>Type</td>
</tr>
<tr>
<td>Vinblastine Sulfate</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

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

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

### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>Stable under recommended storage conditions and use.</td>
</tr>
<tr>
<td>Hazardous Reactions</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Incompatibilities</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>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).</td>
</tr>
<tr>
<td>Hazardous Polymerization</td>
<td>Not anticipated to occur with this product.</td>
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</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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

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

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.
Product Name: Vinblastine Sulfate Injection

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vinblastine Sulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Listed</td>
</tr>
</tbody>
</table>

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
**Product Name:** Vinblastine Sulfate Injection

**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.*

**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.

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**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
Date Prepared: 11/08/2011
Obsolete Date: 07/22/2009
Product Name: Vinblastine Sulfate Injection

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