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 60045 
USA |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospira, Inc., Non-emergency</td>
<td>224 212-2055</td>
</tr>
<tr>
<td>Material Name</td>
<td>Vinblastine Sulfate Injection</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Vincoblastine; Vincaleukoblastine, sulfate (1:1) (salt)</td>
</tr>
</tbody>
</table>

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Vinblastine Sulfate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Formula</td>
<td>C_{46}H_{58}N_{4}O_{9}\cdot H_{2}SO_{4}</td>
</tr>
</tbody>
</table>

<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>

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.

3. HAZARD INFORMATION / CLASSIFICATION

Emergency Overview
Vinblastine Sulfate Injection contains 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 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. This product should also be considered irritating to the eyes and respiratory tract. 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 including 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.

Carcinogen Lists:
IARC: Group 3 - not classifiable as to its carcinogenicity to humans. 
NTP: Not listed 
OSHA: Not listed
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.
7. HANDLING AND STORAGE: continued

Handling: continued
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 USP controlled room temperature 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>OSHA-PEL</td>
</tr>
<tr>
<td>Vinblastine Sulfate</td>
<td>8-hr TWA: Not established</td>
</tr>
</tbody>
</table>

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

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.
Product Name: Vinblastine Sulfate Injection, USP

9. PHYSICAL/CHEMICAL PROPERTIES

**Appearance/Physical State**
Vinblastine Sulfate Injection contains 1 mg/mL of vinblastine sulfate with 0.9% sodium chloride in Water for Injection as a sterile unpreserved solution.

**Odor**
Odorless

**Odor Threshold:**
NA

**pH:**
4.0 to 5.0

**Melting point/Freezing point:**
NA

**Initial Boiling Point/Boiling Point Range:**
NA

**Flash Point:**
NA

**Evaporation Rate:**
NA

**Flammability (solid, gas):**
NA

**Upper/Lower Flammability or Explosive Limits:**
NA

**Vapor Pressure:**
NA

**Vapor Density (Air =1):**
NA

**Evaporation Rate:**
NA

**Specific Gravity:**
NA

**Solubility**
It is 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

**Chemical Stability**
Stable under recommended storage conditions and use.

**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 – Oral:**

<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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<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>
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<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>
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<td></td>
<td></td>
<td>9.5</td>
<td>mg/kg</td>
<td>Mouse</td>
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<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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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2.7</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4.3</td>
<td>mg/kg</td>
<td>Hamster</td>
</tr>
</tbody>
</table>

LD50 is the dosage producing 50% mortality.
11. TOXICOLOGICAL INFORMATION: continued

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 cause burns or permanent damage to the eyes. Following reconstitution, inadvertent contact may produce severe irritation, tearing, pain, and blurred vision.

Dermal or Respiratory Sensitization  None anticipated from normal handling of this product. Instances of allergic reactions have occurred infrequently from 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 anticancer drugs known to be carcinogenic have developed second 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.

Notes:
1. LC50: Concentration in water that produces 50% mortality in fish.
2. EC50: Concentration in water that produces 50% inhibition of growth in algae.
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

DOT STATUS: Not Regulated
Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

ICAO/IATA STATUS Not Regulated
Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

IMDG STATUS Not Regulated
Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

Notes: DOT – US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status Exempt
CERCLA Status Not listed
SARA 302 Status Not listed
SARA 304 Status Not listed
SARA 313 Status Not listed
RCRA Status Not listed
PROP 65 (Calif.) This product is, or contains chemical(s) known to the State of California to cause developmental toxicity.


U.S. OSHA Classification Toxic by Ingestion
Irritant
Reproductive Toxin
Target Organ Toxin
**Product Name: Vinblastine Sulfate Injection, USP**

### 15. REGULATORY INFORMATION: continued

<table>
<thead>
<tr>
<th>GHS Classification</th>
<th>Where medicinal products are not exempt, the recommended GHS classification is as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hazard Class</strong></td>
<td><strong>Acute Oral Toxicity</strong></td>
</tr>
<tr>
<td><strong>Category Symbol</strong></td>
<td>Unclassified</td>
</tr>
<tr>
<td><strong>Signal Word</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Hazard Statement</strong></td>
<td>NA</td>
</tr>
</tbody>
</table>

### GHS Precautionary Statements:

**Prevention:**
- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Use personal protective equipment as required.
- Avoid breathing aerosols or vapors.
- In case of inadequate ventilation wear respiratory protection.
- Wear protective gloves.
- Contaminated work clothing should not be allowed out of the workplace.
- Do not eat, drink or smoke when using this product.
- Wash hands thoroughly after handling.

**Response:**
- IF SWALLOWED: Immediately call a POISON CENTER or doctor. Rinse mouth.
- IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or a doctor.
- IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs, seek medical attention. Take off contaminated clothing and wash before reuse.
- 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.
- IF exposed or concerned, get medical attention.
**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.*

<table>
<thead>
<tr>
<th>Classification(s):</th>
<th>Harmful</th>
<th>Irritant</th>
<th>Toxic to Reproduction Category 2</th>
<th>Carcinogen Category 3</th>
</tr>
</thead>
</table>

**Symbol:**

- Xn
- Xi
- T
- Xn

**Indication of Danger:**

- Xn
- Xi
- T
- Xn

**Risk Phrases:**

- R22 - Harmful if swallowed
- R36/37/38 - Irritating to eyes, respiratory system, and skin
- R40 - Limited evidence of a carcinogenic effect
- R41 - Risk of serious damage to eyes
- R60 - May impair fertility
- R61 - May cause harm to the unborn child
- R64 - May cause harm to breastfed babies

**Safety Phrases:**

- S23: Do not breathe vapor/spray
- S24: Avoid contact with the skin
- S25: Avoid contact with eyes
- S36/37/39: Wear suitable protective clothing, 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: Global Occupational Toxicology
Date Prepared: July 22, 2009

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