

**VINBLASTINE SULFATE INJECTION**

**1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

Product Identifier: Vinblastine  
General Use: Antineoplastic

**MANUFACTURER**

American Pharmaceutical Partners, Inc.  
1101 Perimeter Drive  
Schaumburg, IL 60173-5837  
(847) 969-2700

**EMERGENCY TELEPHONE NUMBER:**

(708) 450-7500

**2. COMPOSITION/INFORMATION ON INGREDIENTS**

Component: **Benzyl Alcohol**

CAS Registry #: 100-51-6

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: NG Note: 9 mg/mL

Component: **Sodium Chloride**

CAS Registry #: 7647-14-5

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: NG Note: 9 mg/ml

Component: **Vinblastine Sulfate**

CAS Registry #: 143-67-9

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: NG Note: 1 mg/ml

Component: **Water for Injection**

CAS Registry #: 7732-18-5

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: NG Note: QS to volume

**3. HAZARD IDENTIFICATION**

PRIMARY ROUTES OF EXPOSURE - Inhalation, Eye/Skin Absorption and Ingestion.

See also section 14.

California Proposition 65, Reproductive Toxin  
CHEMICAL LISTING AS CARCINOGEN:

<u>COMPONENT</u>	<u>CAS No.</u>	<u>NTP</u>	<u>IARC</u>	<u>OSHA</u>
Benzyl Alcohol	100-51-6	NO	NO	NO
Sodium Chloride	7647-14-5	NO	NO	NO
Vinblastine Sulfate	143-67-9	NO	3	NO

**COMPONENT**

Water for Injection

**CAS No.**

7732-18-5

**NTP**

NO

**IARC**

NO

**OSHA**

NO

---

**4. EMERGENCY AND FIRST AID PROCEDURES**

**INHALATION:** Move person to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if necessary. Seek medical attention, if cough or difficulty in breathing persists.

**INGESTION:** Flush mouth out with water. This product is not reliably absorbed from the gastro-intestinal (GI) tract after ingestion. Seek medical attention.

**SKIN CONTACT:** Remove contaminated clothing immediately. Wash affected area with soap and water for at least 15 minutes. If irritation, pain, redness or swelling persist after washing seek medical attention. This product is not absorbed through the skin.

**EYE CONTACT:** Immediately flush with water for at least 15 minutes. If irritation, pain, redness and swelling persist, seek medical attention.

---

**5. FIRE FIGHTING MEASURES**

Fire and Explosion Data:

Closed Cup Flash Pt.	NE
Open Cup Flash Pt.	NE
Fire Point	NE
Autoignition	NE
Lower Explosion Limit	NE
Upper Explosion Limit	NE

**GENERAL HAZARD:** When heated to decomposition it emits toxic fumes.

**FIRE FIGHTING INSTRUCTION:** Water spray, dry chemical, carbon dioxide or foam as appropriate.

**FIRE FIGHTING EQUIPMENT:** Wear self-contained breathing apparatus and protective clothing.

**HAZARDOUS COMBUSTION PRODUCTS:** Smoke, and toxic fumes of SO<sub>x</sub> and NO<sub>x</sub>.

---

**6. ACCIDENTAL RELEASE MEASURES**

**CLEAN-UP:** Wear recommended personal protective equipment. Use absorbent towels or booms to contain spill. Material may be decomposed using a basic (pH approximately 10) sodium hypochlorite (bleach) solution prior to clean-up. Wipe surfaces clean and wash with soap and water.

---

**7. HANDLING AND STORAGE**

When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Vials should be stored under refrigeration, 2 - 8 C (36 - 46 F).

---

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**ENGINEERING CONTROLS:**

Use local exhaust ventilation when preparing solution for administration.

**PERSONAL PROTECTION:**

Respirators - With satisfactory ventilation, respiratory protection not usually required. Use NIOSH approved respirators when preparing solutions.

Eyes - Safety glasses or goggles recommended.

Gloves - Disposable latex gloves recommended.

Clothing - Disposable garments if direct skin contact is anticipated.

---

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Odor other characteristics: Clear, colorless, odorless solution.

Boiling Point:	NE	Vapor Density:	NE
Melting Point:	284-285C*	Percent Volatiles:	NE
Freezing Point:	NE	pH:	3.5-5.0
Vapor Pressure:	NE	Molecular Weight:	909.16
Note:	*Refers to raw material	Solubility:	Freely Water Soluble

---

## 10. STABILITY AND REACTIVITY

Stability - Stable.

Conditions/Materials to Avoid - Exposure to excessive light or heat may cause decomposition.

Hazardous Polymerization - Will not occur.

---

## 11. TOXICOLOGY INFORMATION

SIGNS & SYMPTOMS OF OVEREXPOSURE MAY INCLUDE:

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert and include: leukopenia, anemia, thrombocytopenia, alopecia, constipation, loss of appetite, nausea, vomiting, abdominal pain, ileus, oral ulceration, pharyngitis, diarrhea, rectal bleeding, numbness of digits, loss of deep tendon reflexes, peripheral neuritis, mental depression, headache, convulsions, hypertension, malaise, bone pain, weakness, dizziness and jaw pain. Occupational exposure has not been fully investigated.

LD50: 305 mg/kg oral rat

MEDICAL CONDITIONS GENERALLY RECOGNIZED AS BEING AGGRAVATED BY EXPOSURE:

Pre-existing skin and respiratory conditions.

IMMEDIATE EFFECTS: Eye, skin and respiratory irritation, bone marrow suppression, loss of hair, and nausea may occur. Direct eye contact can lead to severe irritation and ulceration. Extravasation may cause tissue irritation and damage.

DELAYED EFFECTS: Hypersensitivity reactions may occur ranging from mild to severe.

---

## 12. TRANSPORT INFORMATION

UN/NA Number: NA

DOT Hazard Class: NA

Shipping Name: NA

Shipping Label: NA

---

## 13. WASTE DISPOSAL

Waste Disposal - Waste product should be incinerated in accordance with federal, state and local regulations.

---

## 14. OTHER INFORMATION

### KEY TO ABBREVIATIONS:

ACGIH - American Conference of Governmental Industrial Hygienists

HEPA - High-Efficiency Particulate Air

IARC - International Agency for Research on Cancer

NA - Not Applicable

NE - Not Established

NG - Not Given

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PEL - Permissible Exposure Limit

PPM - Parts Per Million

QS - Quantity Sufficient

RCRA - Resource Conservation and Recovery Act

STEL - Short Term Exposure Limit

TLV - Threshold Limit Value

There is limited but increasing evidence and concern that personnel involved in preparation and administration of parenteral antineoplastics may be at some risk because of the potential mutagenicity, teratogenicity, and/or carcinogenicity of these agents, although the actual risk is unknown. USP advisory panels recommend cautious handling both in preparation and disposal of antineoplastic agents. Precautions that have been suggested include:

- Use of biological containment cabinet during reconstitution and dilution of parenteral medications and wearing of disposable surgical gloves and masks.
- Use of proper technique to prevent contamination of the medication, work area, and operator during transfer between containers (including proper training of personnel in this technique).
- Cautious and proper disposal of needles, syringes, vials, ampuls, and unused medication.

Vinblastine is teratogenic in animals and in humans and is not recommended for use during pregnancy (FDA Pregnancy Category D)

---