SAFETY DATA SHEET

Product Name: Vinorelbine Tartrate Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hospira Australia Pty Ltd 1 Lexia Place Mulgrave VIC 3170 AUSTRALIA
Emergency Telephone #'s	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418	
Hospira, Inc., Non-Emergency	224 212-2000	
Product Name	Vinorelbine Tartrate Injection	
Synonyms	3',4'-didehydro-4'-deoxy-*C'*-norvincaleukoblastine [*R*-(*R**,*R**)-2,3-dihydroxy-butanedioate (1:2)(salt)]; Didehydrodeoxynorvincaleukoblastine tartrate.	

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Vinorelbine Tartrate Injection is a solution containing vinorelbine tartrate, a semi-synthetic derivative of vinblastine, with similar general properties. Clinically, it is used to treat some types of cancers. It is a cytotoxic agent, 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, lungs, skin, and gonads.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Germ Cell Mutagenicity	2
	Toxic to Reproduction	2
	STOT – RE	2

Label Element(s)

Pictogram

Signal Word

Warning

Hazard Statement(s)

Suspected of causing genetic defects
Suspected of damaging fertility or the unborn child
May cause damage to organs through prolonged or repeated exposure

Precautionary Statement(s)

Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Vinorelbine Tartrate
Chemical Formula $C_{45}H_{54}N_4O_8 \cdot \bullet\ 2C_4H_6O_6$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Vinorelbine Tartrate	1	125317-39-7	RD2535000

*Non-hazardous ingredients include Water for Injection.

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 None anticipated for this aqueous product.

Fire & Explosion Hazard None anticipated for this aqueous product.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Isolate area around the spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the spilled liquid with a suitable material and clean the affected area with soap and water. Additionally, application of a 50% solution of household bleach (in water) for 10 minutes can be used to further decontaminate the affected spill area. Use care to avoid splashing when applying the bleach solution. Absorb the bleach-treated spill using a suitable material and clean again with soap and water. Dispose of all spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling Vinorelbine tartrate is a cytotoxic anti-neoplastic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic anti-neoplastic agents to minimize potential exposures. Several guidelines on handling cytotoxic anti-neoplastic agents have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate. 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 during the weighing, reconstitution and/or solubilization of this anti-neoplastic agent. 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 anti-neoplastic 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 hypersensitivity to vinorelbine tartrate 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 open containers of this product.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Vinorelbine tartrate	8-hr TWA: Not established	8-hr TWA: Not established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

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 this product. 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

When handling, 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	A clear, colorless to pale yellow solution
Odor	Odorless
Odor Threshold	NA
pH	3.5
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
Relative Density	NA
Solubility	>1,000 mg/mL in distilled water
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	This product is reported to react with strong oxidizing agents and strong bases.
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
*Vinorelbine tartrate	100	LD50	Oral	26-34 77-89	mg/kg mg/kg	Rat Mouse
*Vinorelbine tartrate	100	LD50	Intravenous	11-12 32-42	mg/kg mg/kg	Rat Mouse*
Vinorelbine	100	LD50	Intraperitoneal	26	mg/kg	Mouse

LD50 is the dosage producing 50% mortality. *Sagent Pharmaceuticals, Inc. SDS.

11. TOXICOLOGICAL INFORMATION: continued

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. 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. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. Vinorelbine tartrate is irritating to the skin, eyes, and respiratory tract. Extravasation may cause necrosis, cellulitis, and sloughing. In clinical use, adverse effects include bone-marrow depression, nausea, vomiting, diarrhea, anorexia, headache, paraesthesia, peripheral numbness, myalgia/arthralgia, weakness, and dizziness/vertigo. Shortness of breath occurs in 3% of patients, and is severe in 2%, with interstitial pulmonary changes. Transient elevations of liver enzyme levels may also occur. Like other vinca alkaloids, vinrelbine is a moderate vesicant and injection site reactions include erythema, pain at injection site, and vein discoloration; these occur in about one third of patients and about 5% are severe. Chemical phlebitis along the vein proximal to the site of injection was reported in 10% of patients. Chest pain occurs in about 5% of patients. Systemic allergic reactions may also occur.
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 with redness and discomfort.
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. However, inadvertent eye contact of this product with eyes may produce irritation with stinging, redness, watering, and discomfort.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. However, in clinical use, systemic allergic reactions including anaphylaxis, pruritus, urticaria, angioedema; and flushing have been reported occasionally (about 2% of patients).
Reproductive Effects	None anticipated from normal handling of this product. Vinorelbine did not affect fertility when administered to rats once-weekly at a dosage of 9 mg/m2, or alternate-day schedule at a dosage of 4.2 mg/m2. However, biweekly administration for 13 or 26 weeks in the rat at 2.1 and 7.2 mg/m2 resulted in decreased spermatogenesis and prostate/seminal vesicle secretion. A single dose of vinorelbine has been shown to be embryo- and/or fetotoxic in mice and rabbits at dosages of 9 mg/m2 and 5.5 mg/m2, respectively. At non-maternally-toxic doses, fetal weight was reduced and ossification was delayed.
Mutagenicity	Vinorelbine has been shown to affect chromosome number and possibly structure *in vivo* (polyploidy in bone marrow cells from Chinese hamsters and a positive micronucleus test in mice). It was not mutagenic in the Ames test and gave inconclusive results in the mouse lymphoma TK Locus assay.
Carcinogenicity	The carcinogenic potential of vinorelbine tartrate has not been fully evaluated in animal studies.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs may include the bone marrow, gastrointestinal system, central nervous system, peripheral nervous system, lungs, skin, and gonads.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product. *IC50 > 1000 mg/L for bacteria for vinorelbine.
Persistence/Biodegradability	Not determined for product. *This material is anticipated to degrade when exposed to sunlight. The photodegradation half-life is reported as 9.07 hours.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

*Bedford Laboratories MSDS.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ 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

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP 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	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.

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.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with 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
LD_{50}	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
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