



MATERIAL SAFETY DATA SHEET

Revision date: 30-Mar-2012

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Material Name: Vinorelbine Tartrate Injection

Trade Name:	Not established
Chemical Family:	Semi-Synthetic Vinca Alkaloid
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Colorless to pale yellow solution
Signal Word: WARNING

Statement of Hazard: Suspected of damaging the unborn child.
Suspected of causing genetic defects.

Additional Hazard Information:

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.
Known Clinical Effects: Bone marrow suppression is the most serious adverse effect seen during clinical use. Adverse effects most commonly reported in clinical use include decreased red blood cell count (anemia), neutropenia, thrombocytopenia, inflammation of the mouth (stomatitis), nausea, liver enzyme changes, fatigue, allergic reaction.

EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic: Category 2

EU Hazard Symbols:



EU Risk Phrases:

R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Vinorelbine Tartrate	125317-39-7	Not Listed	Mut. Cat.2;R46 Repr. Cat.2;R61	1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Vinorelbine Tartrate Pfizer Occupational Exposure Band (OEB):	OEB 5 (control exposure to <1ug/m ³)
Engineering Controls:	General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Colorless to Pale yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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9. PHYSICAL AND CHEMICAL PROPERTIES

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Vinorelbine Tartrate

Mouse Intravenous LD50 28 mg/kg

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Vinorelbine Tartrate

Embryo / Fetal Development	Mouse	Intravenous	9 mg/m2	LOAEL	Embryotoxicity, Fetotoxicity, Teratogenic
Embryo / Fetal Development	Rabbit	Intravenous	5.5 mg/m2	LOAEL	Embryotoxicity, Fetotoxicity, Teratogenic
Reproductive & Fertility	Rat	Intravenous	0.22 mg/kg/day	LOAEL	Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Vinorelbine Tartrate

<i>In Vivo</i> Micronucleus	Mouse	Positive
HGPRT Forward Gene Mutation Assay		Positive
<i>In Vivo</i> Chromosome Aberration	Hamster Bone marrow	Positive
Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic: Category 2

EU Risk Phrases:
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S23 - Do not breathe fumes/vapour/spray.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Suspected of damaging the unborn child.
Suspected of causing genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



Water for Injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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R46 - May cause heritable genetic damage.

R61 - May cause harm to the unborn child.

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet