



MATERIAL SAFETY DATA SHEET

Revision date: 13-Jun-2012

Version: 2.0

Page 1 of 6

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Vincristine Sulfate Injection

Trade Name:	Vincristine Injection
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects: Central nervous system effects such as dizziness, headache, insomnia, irritability and weakness have also been reported. Effects on blood and blood-forming organs have also occurred.

EU Classification
EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Vincristine Sulfate Injection
Revision date: 13-Jun-2012

Page 2 of 6
Version: 2.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Vincristine Sulfate	2068-78-2	218-190-0	Repr. Cat. 2;R61 Mut. Cat. 3;R68	0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*
Water	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: Not applicable

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.

MATERIAL SAFETY DATA SHEET

Material Name: Vincristine Sulfate Injection
Revision date: 13-Jun-2012

Page 3 of 6
Version: 2.0

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 generating airborne dust. Avoid contact with eyes, skin and clothing. 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

Vincristine Sulfate
Pfizer OEL TWA-8 Hr: 0.2 µg/m³

Analytical Method: Analytical method available for Vincristine Sulfate. Contact Pfizer Inc for further information.
Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. 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 the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Aqueous liquid suspension	Color:	Clear, colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Boiling Point (°C):	100		
Specific Gravity:	1.03		

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

MATERIAL SAFETY DATA SHEET

Material Name: Vincristine Sulfate Injection
Revision date: 13-Jun-2012

Page 4 of 6
Version: 2.0

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)

Vincristine Sulfate

Rat Para-periosteal LD 50 1.9 mg/kg
Rat Para-periosteal LD 50 1 mg/kg
Rat Oral LD 50 > 5 mg/kg
Mouse Intraperitoneal LD 50 3 mg/kg
Mouse Intravenous LD 50 1.7 mg/kg

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Vincristine Sulfate

Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Vincristine Sulfate

6 Week(s) Dog Intravenous 0.02 mg/kg/week LOAEL Central nervous system

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

Vincristine Sulfate

Embryo / Fetal Development Rat Intraperitoneal 0.05 mg/kg LOAEL Teratogenic
Embryo / Fetal Development Hamster Intravenous 0.1 mg/kg LOAEL Teratogenic
Embryo / Fetal Development Mouse Intraperitoneal 0.2 mg/kg LOAEL Teratogenic

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

Vincristine Sulfate

Bacterial Mutagenicity (Ames) Negative
In Vivo Micronucleus Mouse Positive
In Vitro Cytogenetics Human Lymphocytes Equivocal
Chromosome Aberration Rodent Negative
Mammalian Cell Mutagenicity Mouse Lymphoma Positive

Carcinogen Status:

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

Vincristine Sulfate

IARC: Group 3 (Not Classifiable)

MATERIAL SAFETY DATA SHEET

Material Name: Vincristine Sulfate Injection
Revision date: 13-Jun-2012

Page 5 of 6
Version: 2.0

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been 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.

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 Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Mannitol

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	200-711-8

MATERIAL SAFETY DATA SHEET

Material Name: Vincristine Sulfate Injection
Revision date: 13-Jun-2012

Page 6 of 6
Version: 2.0

15. REGULATORY INFORMATION

Water

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

Vincristine Sulfate

California Proposition 65	developmental toxicity initial date 7/1/90
Australia (AICS):	Present
EU EINECS/ELINCS List	218-190-0

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.

R68 - Possible risks of irreversible effects.

Data Sources: Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 5 - Fire Fighting Measures.

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