



MATERIAL SAFETY DATA SHEET

Revision date: 03-Jan-2012

Version: 1.0

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

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Material Name: Cladribine Injection

Trade Name:	Not applicable
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Colorless solution
Signal Word: DANGER

Statement of Hazard: Suspected of causing genetic defects.

Additional Hazard Information:

Short Term: May cause eye and skin irritation (based on components) .

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 seen in clinical use include gastrointestinal discomfort, dizziness, and headache.

EU Indication of danger: Mutagenic: Category 2

EU Hazard Symbols:



EU Risk Phrases:

R46 - May cause heritable genetic damage.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Cladribine	4291-63-8	Not Listed	Mut. Cat.2;R46 Repr. Cat.2;R61	0.1
Phosphoric acid	7664-38-2	231-633-2	C;R34	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	**

Additional Information:

* Proprietary

** to adjust pH

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.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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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

Refer to available public information for specific member state Occupational Exposure Limits.

Sodium chloride

Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

Phosphoric acid

ACGIH Threshold Limit Value (TWA)	1 mg/m ³
ACGIH Threshold Limit Value (STEL)	3 mg/m ³
Australia STEL	3 mg/m ³
Australia TWA	1 mg/m ³
Austria OEL - MAKs	1 mg/m ³
Belgium OEL - TWA	1 mg/m ³
Bulgaria OEL - TWA	1.0 mg/m ³
Cyprus OEL - TWA	1 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Denmark OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
Finland OEL - TWA	1 mg/m ³
France OEL - TWA	0.2 ppm 1 mg/m ³
Germany - TRGS 900 - TWAs	2 mg/m ³
Germany (DFG) - MAK	2 mg/m ³ inhalable fraction
Greece OEL - TWA	1 mg/m ³
Hungary OEL - TWA	1 mg/m ³
Ireland OEL - TWAs	1 mg/m ³
Italy OEL - TWA	1 mg/m ³
Latvia OEL - TWA	1 mg/m ³
Lithuania OEL - TWA	1 mg/m ³
Luxembourg OEL - TWA	1 mg/m ³
Malta OEL - TWA	1 mg/m ³
Netherlands OEL - TWA	1 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OSHA - Final PELs - TWAs:	1 mg/m ³
Poland OEL - TWA	1 mg/m ³
Portugal OEL - TWA	1 mg/m ³
Romania OEL - TWA	1 mg/m ³
Slovakia OEL - TWA	1 mg/m ³
Slovenia OEL - TWA	1 mg/m ³
Spain OEL - TWA	1 mg/m ³
Sweden OEL - TWAs	1 mg/m ³

Cladribine

Pfizer Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of >1ug/m³ to <10ug/m³)

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 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:	Solution	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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)

Sodium chloride

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11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Cladribine

Mouse IP LD50 150 mg/kg

Phosphoric acid

Rat Oral LD50 1530 mg/kg
Rabbit Dermal LD 50 2730 mg/kg

Sodium phosphate, dibasic

Rat Oral LD 50 17 g/kg

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

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Phosphoric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Sodium phosphate, dibasic

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

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

Cladribine

Embryo / Fetal Development Rabbit Intravenous 1 mg/kg/day NOAEL Fetotoxicity, Teratogenic
Embryo / Fetal Development Mouse Intravenous 0.5 mg/kg/day NOAEL Fetotoxicity, Teratogenic

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

Cladribine

In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive
In Vivo Micronucleus Mouse Bone Marrow Positive

Carcinogen Status:

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

12. ECOLOGICAL INFORMATION

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

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Phosphoric acid

Gambusia affinis (Mosquitofish) LC50 96 Hours 3-3.5 mg/L
Daphnia magna (Water Flea) EC-50 12 Hours 4.6 mg/L

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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 Symbol: T
EU Indication of danger: Mutagenic: Category 2

EU Risk Phrases: R46 - May cause heritable genetic damage.

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:
DANGER
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

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15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Sodium chloride	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3
Cladribine	
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
Phosphoric acid	
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-633-2
Sodium phosphate, dibasic	
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R46 - May cause heritable genetic damage.

R61 - May cause harm to the unborn child.

R34 - Causes burns.

Data Sources: Publicly available toxicity 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