



MATERIAL SAFETY DATA SHEET

Revision date: 12-Feb-2008

Version: 1.0

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

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CHEMTREC (24 hours): 1-800-424-9300
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Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Epargriseovit Solution for Injection

Trade Name: Epargriseovit
Chemical Family: Not determined
Intended Use: Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: Liquid solution

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

Additional Hazard Information:

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

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium hydroxide	1310-73-2	215-185-5	C;R35	<1
Cyanocobalamin (Vitamin B12)	68-19-9	200-680-0	Not Listed	*

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Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Ascorbic acid (Vitamin C)	50-81-7	200-066-2	Not Listed	*
Folic Acid	59-30-3	200-419-0	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.

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.

Measures for Cleaning / Collecting: Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

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.

Storage Conditions: Store as directed by product packaging.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	= 2 mg/m ³ Ceiling
Australia PEAK	= 2 mg/m ³ Peak
Austria OEL - MAKs	= 2 mg/m ³ MAK
Belgium OEL - TWA	= 2 mg/m ³ TWA
Bulgaria OEL - TWA	= 2.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 1 mg/m ³ TWA
Finland OEL - TWA	= 2 mg/m ³ TWA
France OEL - TWA	= 2 mg/m ³ VME
Greece OEL - TWA	= 2 mg/m ³ TWA
Hungary OEL - TWA	= 2 mg/m ³ TWA
Latvia OEL - TWA	= 0.5 mg/m ³ TWA
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	= 0.5 mg/m ³ NDS
Slovakia OEL - TWA	= 2 mg/m ³ TWA
Slovenia OEL - TWA	= 2 mg/m ³ TWA
Sweden OEL - TWAs	= 1 mg/m ³ LLV

Cyanocobalamin (Vitamin B12)

ACGIH Threshold Limit Value (TWA)	= 0.02 mg/m ³ TWA
Australia TWA	= 5 mg/m ³ TWA
Bulgaria OEL - TWA	= 0.1 mg/m ³ TWA
Czech Republic OEL - TWA	= 0.05 mg/m ³ TWA
Denmark OEL - TWA	= 0.01 mg/m ³ TWA
Estonia OEL - TWA	= 0.05 mg/m ³ TWA
Finland OEL - TWA	= 0.05 mg/m ³ TWA
France OEL - TWA	= 5 mg/m ³ TWA
Greece OEL - TWA	= 5 mg/m ³ VME
Hungary OEL - TWA	= 0.1 mg/m ³ TWA
Ireland OEL - TWAs	= 5 mg/m ³ TWA
Lithuania OEL - TWA	= 0.1 mg/m ³ TWA
OSHA - Final PELs - TWAs:	= 5 mg/m ³ TWA
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption
Portugal OEL - TWA	= 0.02 mg/m ³ TWA
Slovakia OEL - TWA	= 2 mg/m ³ TWA
Slovenia OEL - TWA	= 5 mg/m ³ TWA
Spain OEL - TWA	= 0.02 mg/m ³ VLA-ED
Sweden OEL - TWAs	= 0.05 mg/m ³ LLV

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.

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Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
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:	Liquid solution	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
pH:	5.7-5.9		

10. STABILITY AND REACTIVITY

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)

Folic Acid

Mouse Oral LD 50 10 g/kg

Ascorbic acid (Vitamin C)

Rat Oral LD 50 11.9 g/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

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

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Carcinogen Status: None of the other components of this mixture are listed as a carcinogen by IARC, NTP or OSHA.

Cyanocobalamin (Vitamin B12)

IARC: Group 2B
OSHA: Present

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12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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:
Non-controlled
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	= 454 kg final RQ
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	215-185-5

Ascorbic acid (Vitamin C)	
Inventory - United States TSCA - Sect. 8(b)	Present

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Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-066-2
Folic Acid	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 4
	200-419-0
Cyanocobalamin (Vitamin B12)	
CERCLA/SARA 313 Emission reporting	= 0.1 % de minimis concentration
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-680-0
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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R35 - Causes severe burns.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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