



MATERIAL SAFETY DATA SHEET

Revision date: 14-Apr-2008

Version: 1.2

Page 1 of 5

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd,
Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Fibrinolysin Ointment

Trade Name: FIBROLAN; ELASE
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for topical wound dressing

2. HAZARDS IDENTIFICATION

Appearance: Yellow, brown ointment

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

Known Clinical Effects: This product contains protein of bovine origin. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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	%
Sucrose	57-50-1	200-334-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Fibrinuclease powder	Not assigned	Not listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Ointment base	Not assigned	Not listed	Not Listed	*

MATERIAL SAFETY DATA SHEET

Material Name: Fibrinolysin Ointment
Revision date: 14-Apr-2008

Page 2 of 5
Version: 1.2

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

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 determined

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. Use absorbent material to wipe up spill and place in a sealed 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 contact with eyes, skin and clothing. Use appropriate ventilation.

Storage Conditions: Store as directed by product packaging.

MATERIAL SAFETY DATA SHEET

Material Name: Fibrinolysin Ointment
Revision date: 14-Apr-2008

Page 3 of 5
Version: 1.2

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sucrose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	= 10 mg/m ³ TWA
Bulgaria OEL - TWA	= 10.0 mg/m ³ TWA
Estonia OEL - TWA	= 10 mg/m ³ TWA
France OEL - TWA	= 10 mg/m ³ VME
Ireland OEL - TWAs	= 10 mg/m ³ TWA
Lithuania OEL - TWA	= 10 mg/m ³ IPRV
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
	= 5 mg/m ³ TWA
Portugal OEL - TWA	= 10 mg/m ³ TWA
Slovakia OEL - TWA	= 6 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED

Sodium chloride

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

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

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.
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:	Ointment	Color:	Yellow, brown
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Not determined
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.
----------------------	---

MATERIAL SAFETY DATA SHEET

Material Name: Fibrinolysin Ointment
Revision date: 14-Apr-2008

Page 4 of 5
Version: 1.2

11. TOXICOLOGICAL INFORMATION

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

Sucrose

Rat Oral LD50 29.7 g/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg

Mouse Oral LD50 4000 mg/kg

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

Sodium chloride

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild

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

Sodium chloride

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

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 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.

MATERIAL SAFETY DATA SHEET

Material Name: Fibrinolysin Ointment
Revision date: 14-Apr-2008

Page 5 of 5
Version: 1.2

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:

None required

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.

Sucrose

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	200-334-9

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

16. OTHER INFORMATION

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 4 - First Aid Measures.

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