



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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Material Name: Amilomer Suspension for Injection

Trade Name: SPHEREX
Chemical Family: Not determined
Intended Use: Pharmaceutical product used as an adjuvant

2. HAZARDS IDENTIFICATION

Appearance: White suspension

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

Short Term: May cause eye and skin 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 |

| Ingredient | CAS Number | EU EINECS/ELINCS List | Classification | % |
|--------------------------|--------------|-----------------------|----------------|---|
| Amilomer | 42615-49-6 | Not listed | Not Listed | 6 |
| Sodium Chloride Solution | Not Assigned | Not listed | Not Listed | * |

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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. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling.

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 hydroxide

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| | |
|--------------------------------|-------------------------------|
| 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 |

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: | Aqueous suspension | Color: | White |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| pH: | 5.5-7.5 | | |

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)

Sodium hydroxide
Mouse IP LD50 40 mg/kg

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

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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.

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.

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Sodium hydroxide

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| 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 |

Amilomer

| | |
|-------------------|---------|
| Australia (AICS): | Present |
|-------------------|---------|

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