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  
Ramsgate Road  
Sandwich, 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  

Material Name: Somatropin Placebo Solution For Injection  
Trade Name: Not established  
Chemical Family: Mixture  
Intended Use: Placebo

2. HAZARDS IDENTIFICATION

Appearance: White sterile lyophilized powder plus sterile diluent  
Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.  
Additional Hazard Information: May cause eye irritation (based on components)


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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>m-Cresol</td>
<td>108-39-4</td>
<td>203-577-9</td>
<td>C;R34 T;R24/25</td>
<td>*</td>
</tr>
</tbody>
</table>

PZ01361
4. FIRST AID MEASURES

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: No data available

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not available

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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: Minimize dust generation and accumulation. Avoid breathing dust. 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.

Glycine
- Latvia OEL - TWA: Listed

m-Cresol
- ACGIH Threshold Limit Value (TWA): 5 ppm TWA
- ACGIH OELs - Notice of Intended Changes: Listed
- ACGIH - Skin Absorption Designation: Listed
- Australia TWA: 22 mg/m³
  - 5 ppm
- Austria OEL - MAKs: Listed
- Belgium OEL - TWA: Listed
- Bulgaria OEL - TWA: Listed
- Cyprus OEL - TWA: Listed
- Czech Republic OEL - TWA: Listed
- Denmark OEL - TWA: Listed
- Estonia OEL - TWA: Listed
- Finland OEL - TWA: Listed
- France OEL - TWA: Listed
- Greece OEL - TWA: Listed
- Hungary OEL - TWA: Listed
- Ireland OEL - TWAs: Listed
- Latvia OEL - TWA: Listed
- Lithuania OEL - TWA: Listed
- Luxembourg OEL - TWA: Listed
- Malta OEL - TWA: Listed
- OSHA - Final PELS - TWAs: 22 mg/m³
  - 5 ppm
- OSHA - Final PELs - Skin Notations: Listed
- Poland OEL - TWA: Listed
- Portugal OEL - TWA: Listed
- Romania OEL - TWA: Listed
- Slovenia OEL - TWA: Listed
- Spain OEL - TWA: Listed
- Sweden OEL - TWAs: Listed

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. 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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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: Lyophilized powder plus sterile diluent
Molecular Formula: Mixture
Color: White
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: No data available
Incompatible Materials: None identified

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)

Glycine
- Rat Oral LD 50 7930 mg/kg
- Mouse Oral LD 50 4920 mg/kg

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

m-Cresol
- Rat Oral LD 50 242 mg/kg
- Rabbit Dermal LD 50 2050 mg/kg

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

m-Cresol
- Skin Irritation Rabbit Severe
- Eye Irritation Rabbit Severe
11. TOXICOLOGICAL INFORMATION

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

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.

m-Cresol
RCRA - U Series Wastes Listed

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

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.
15. REGULATORY INFORMATION

Glycine
- Inventory - United States TSCA - Sect. 8(b) Listed
- Australia (AICS): Listed
- EU EINECS/ELINCS List 200-272-2

Mannitol
- Inventory - United States TSCA - Sect. 8(b) Listed
- Australia (AICS): Listed
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List 200-711-8

m-Cresol
- CERCLA/SARA 313 Emission reporting 1.0% de minimis concentration
- CERCLA/SARA Hazardous Substances and their Reportable Quantities: 100 lb final RQ 45.4 kg final RQ
- Inventory - United States TSCA - Sect. 8(b) Listed
- Australia (AICS): Listed
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 6
- EU EINECS/ELINCS List 203-577-9

Sodium Phosphate
- Inventory - United States TSCA - Sect. 8(b) Listed
- Australia (AICS): Listed
- EU EINECS/ELINCS List 231-558-5

Water
- Inventory - United States TSCA - Sect. 8(b) Listed
- Australia (AICS): Listed
- 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
R34 - Causes burns.
R24/25 - Toxic in contact with skin and if swallowed.

Data Sources: Publicly available toxicity information.

Prepared by: Product Stewardship Hazard Communications
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