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

Material Name: Linezolid for Oral Suspension  
Trade Name: Zyvox(TM)  
Chemical Family: Mixture  
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
<tr>
<td>Linezolid</td>
<td>165800-03-3</td>
<td>Not listed</td>
<td>2</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>*</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>*</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>*</td>
</tr>
<tr>
<td>Sodium citrate, anhydrous</td>
<td>68-04-2</td>
<td>200-675-3</td>
<td>*</td>
</tr>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
<td>*</td>
</tr>
<tr>
<td>Xanthan gum</td>
<td>11138-66-2</td>
<td>234-394-2</td>
<td>*</td>
</tr>
<tr>
<td>Aspartame</td>
<td>22839-47-0</td>
<td>245-261-3</td>
<td>*</td>
</tr>
<tr>
<td>Flavors</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: White to off-white powder  
Signal Word: WARNING

Statement of Hazard: May cause adverse effects on blood forming organs  
Additional Hazard Information:  
   Short Term: Minimal eye irritant in experimental animals  
   Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system, the developing fetus.
Known Clinical Effects: The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Effects on blood and blood-forming organs have also occurred.

EU Indication of danger: Not classified

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.

4. FIRST AID MEASURES

Eye Contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get 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 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: Avoid breathing dust. Avoid contact with eyes, skin and clothing. Avoid generating airborne dust. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose
  OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
  = 5 mg/m³ TWA
  ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
  Australia TWA = 10 mg/m³ TWA

Linezolid
  Pfizer OEL TWA-8 Hr: 0.75 mg/m³

Sucrose
  OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
  = 5 mg/m³ TWA
  ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
  Australia TWA = 10 mg/m³ TWA

Colloidal silicon dioxide
  OSHA - Final PELs - Table Z-3 Mineral D: = (80)/(% SiO2) mg/m³ TWA
  Australia TWA = 2 mg/m³ TWA

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

Personal Protective Equipment:

  Hands: Wear protective gloves when working with large quantities.
  Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
  Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
  Respiratory protection: None required under normal conditions of use. 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: Powder
  Molecular Formula: Mixture
  Color: White to off-white
  Molecular Weight: Mixture

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)

Linezolid
Rat  Oral  Minimum Lethal Dose  3000 mg/kg

Microcrystalline cellulose
Rat  Oral  LD50  > 5000 mg/kg
Rabbit  Dermal  LD50  > 2000 mg/kg

Citric acid
Rat  Oral  LD50  3000 mg/kg

Carboxymethylcellulose sodium
Mouse  Oral  LD50  > 27,000 mg/kg
Rat  Oral  LD50  27,000 mg/kg
Rabbit  Dermal  LD50  > 2000 mg/kg

Xanthan gum
Rat  Oral  LD50  > 5000 mg/kg

Mannitol
Rat  Oral  LD50  13500 mg/kg
Mouse  Oral  LD 50  22 g/kg

Sodium chloride
Rat  Oral  LD50  3000 mg/kg
Mouse  Oral  LD 50  4000 mg/kg

Sucrose
Rat  Oral  LD50  29.7  g/kg

Sodium benzoate
Rat  Oral  LD50  4,070 mg/kg
Mouse  Oral  LD50  1600 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Linezolid
Eye Irritation  Rabbit  Minimal
Skin Irritation  Rabbit  Minimal

Microcrystalline cellulose
Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Non-irritating

Citric acid
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Mild
Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

**Linezolid**
- Reproductive & Fertility: Rat, Oral, 50 mg/kg/day, LOAEL, Fertility
- Embryo / Fetal Development: Rat, Oral, 15 mg/kg/day, LOAEL, Fetotoxicity, Not Teratogenic
- Embryo / Fetal Development: Rat, Oral, 50 mg/kg/day, LOAEL, Maternal Toxicity
- Embryo / Fetal Development: Mouse, Oral, 450 mg/kg/day, LOAEL, Fetotoxicity, Maternal Toxicity, Not Teratogenic

**Sodium benzoate**
- Embryo / Fetal Development: Rat, Oral, 44 g/kg, LOEL, Developmental toxicity

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

**Linezolid**
- In Vitro Unscheduled DNA Synthesis: Negative
- Bacterial Mutagenicity (Ames): Salmonella, Negative
- In Vitro Chromosome Aberration: Human Lymphocytes, Negative
- In Vivo Micronucleus: Mouse, Negative

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

Colloidal silicon dioxide
- IARC: Group 3

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.

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:
WARNING
May cause adverse effects on blood forming organs

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B

Microcrystalline cellulose
Inventory - United States TSCA - Sect. 8(b): XU
Australia (AICS): Present
EU EINECS List: 232-674-9

Linezolid
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4

Sucrose
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List: 200-334-9

Citric acid
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List: 201-069-1
16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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

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End of Safety Data Sheet