# MATERIAL SAFETY DATA SHEET



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

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**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

**Hazardous**

| Ingredient | CAS Number | EU EINECS List | % |
|---|---|---|---|
| Microcrystalline cellulose | 9004-34-6 | 232-674-9 | * |
| Linezolid | 165800-03-3 | Not listed | 2 |
| Sucrose | 57-50-1 | 200-334-9 | * |
| Citric acid | 77-92-9 | 201-069-1 | * |
| Colloidal silicon dioxide | 7631-86-9 | 231-545-4 | * |

| Ingredient | CAS Number | EU EINECS List | % |
|---|---|---|---|
| Sodium chloride | 7647-14-5 | 231-598-3 | * |
| Sodium citrate, anhydrous | 68-04-2 | 200-675-3 | * |
| Mannitol | 69-65-8 | 200-711-8 | * |
| Sodium benzoate | 532-32-1 | 208-534-8 | * |
| Xanthan gum | 11138-66-2 | 234-394-2 | * |
| Aspartame | 22839-47-0 | 245-261-3 | * |
| Flavors | NOT ASSIGNED | Not listed | * |
| Carboxymethylcellulose sodium | 9004-32-4 | Not listed | * |

**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/m$^3$ TWA<br>= 5 mg/m$^3$ TWA | total |
| **ACGIH Threshold Limit Value (TWA)** | = 10 mg/m$^3$ TWA | |
| **Australia TWA** | = 10 mg/m$^3$ TWA | |

**Linezolid**

| | |
|---|---|
| **Pfizer OEL TWA-8 Hr:** | 0.75 mg/m$^3$ |

**Sucrose**

| | | |
|---|---|---|
| **OSHA - Final PELS - TWAs:** | = 15 mg/m$^3$ TWA<br>= 5 mg/m$^3$ TWA | total |
| **ACGIH Threshold Limit Value (TWA)** | = 10 mg/m$^3$ TWA | |
| **Australia TWA** | = 10 mg/m$^3$ TWA | |

**Colloidal silicon dioxide**

| | |
|---|---|
| **OSHA - Final PELs - Table Z-3 Mineral D:** | (80)/(% SiO2) mg/m$^3$ TWA<br>= 20 mppcf TWA |
| **Australia TWA** | = 2 mg/m$^3$ 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 | **Color:** | White to off-white |
| **Molecular Formula:** | Mixture | **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 LD 50 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

**Sodium chloride**
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

**Linezolid**
1 Day(s) Rat Intravenous >400 mg/kg/day NOEL Blood forming organs, Blood
14 Day(s) Rat Intravenous 40 mg/kg/day NOAEL Blood forming organs, Blood
14 Day(s) Dog Intravenous 60 mg/kg/day LOAEL Blood forming organs, Blood
14 Day(s) Dog Intravenous 30 mg/kg/day NOAEL Blood forming organs, Blood
3 Month(s) Dog Oral 20 mg/kg/day NOAEL Blood forming organs, Blood

**Carboxymethylcellulose sodium**
13 Week(s) Rat Oral 227 g/kg LOAEL Liver, Kidney, Ureter, Bladder

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

**Sodium benzoate**
10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

**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 |

**Sodium chloride**

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

**Sodium citrate, anhydrous**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS List** | 200-675-3 |

**Mannitol**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS List** | 200-711-8 |

**Sodium benzoate**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS List** | 208-534-8 |

**Colloidal silicon dioxide**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS List** | 231-545-4 |

**Xanthan gum**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | XU |
| **Australia (AICS):** | Present |
| **EU EINECS List** | 234-394-2 |

**Aspartame**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS List** | 245-261-3 |

**Carboxymethylcellulose sodium**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | XU |
| **Australia (AICS):** | Present |

## 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**