# SAFETY DATA SHEET



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

**Product Identifier**

**Material Name: Linezolid Injection**

**Trade Name:** ZYVOX, ZYVOXID, ZYVOXAM; Relneu IV
**Chemical Family:** Mixture

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against**

**Intended Use:** Pharmaceutical product used as antibiotic agent

**Details of the Supplier of the Safety Data Sheet**

**Pfizer Inc**
**Pfizer Pharmaceuticals Group**
**235 East 42nd Street**
**New York, New York 10017**
**1-800-879-3477**

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

**Pfizer Ltd**
**Ramsgate Road**
**Sandwich, Kent**
**CT13 9NJ**
**United Kingdom**
**+00 44 (0)1304 616161**
**Emergency telephone number:**
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**

**GHS - Classification** Not classified as hazardous

**Label Elements**

**Signal Word:** Not required
**Hazard Statements:** Non-hazardous in accordance with international standards for workplace safety.

**Other Hazards** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**Note:** This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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 | GHS Classification | % |
|---|---|---|---|---|

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| | | | | |
|---|---|---|---|---|
| Linezolid | 165800-03-3 | Not Listed | STOT RE 2 (H373) | 0.2 |

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|---|---|---|---|---|
| Sodium citrate, anhydrous | 68-04-2 | 200-675-3 | Not Listed | * |
| Citric acid, anhydrous | 77-92-9 | 201-069-1 | Not Listed | * |
| Dextrose | 14431-43-7 | Not Listed | Not Listed | * |
| Sodium chloride | 7647-14-5 | 231-598-3 | Not Listed | * |

**Additional Information:** * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16**

## 4. FIRST AID MEASURES

**Description of 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.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**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.

**Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Environmental Precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and Material for Containment and Cleaning Up**

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling**

Avoid breathing vapor or mist. 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.

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

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

**Linezolid**

**Pfizer OEL TWA-8 Hr:** 750µg/$m^3$

**Sodium chloride**

**Latvia OEL - TWA** 5 mg/$m^3$

**Lithuania OEL - TWA** 5 mg/$m^3$

**Sodium chloride**

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/$m^3$ to 3000ug/$m^3$)

**Exposure Controls**

**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.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hands:** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Liquid
**Color:** Clear, colorless
**Odor:** No data available.
**Odor Threshold:** No data available.
**Molecular Formula:** Mixture
**Molecular Weight:** Mixture

**Solvent Solubility:** No data available
**Water Solubility:** No data available
**pH:** No data available.
**Melting/Freezing Point (°C):** No data available
**Boiling Point (°C):** No data available.
**Partition Coefficient: (Method, pH, Endpoint, Value)**
**Sodium citrate, anhydrous**
No data available
**Sodium chloride**
No data available
**Linezolid**
Measured 6-8 Log D 0.55
**Dextrose**
No data available
**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available
**Vapor Pressure (kPa):** No data available
**Vapor Density (g/ml):** No data available
**Relative Density:** No data available
**Viscosity:** No data available

**Flammablity:**
**Autoignition Temperature (Solid) (°C):** No data available
**Flammability (Solids):** No data available
**Flash Point (Liquid) (°C):** No data available
**Upper Explosive Limits (Liquid) (% by Vol.):** No data available
**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

## 10. STABILITY AND REACTIVITY

**Reactivity:** No data available
**Chemical Stability:** Stable under normal conditions of use.
**Possibility of Hazardous Reactions**

## 10. STABILITY AND REACTIVITY

**Oxidizing Properties:** No data available
**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
**Hazardous Decomposition Products:** No data available

## 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**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.

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

**Sodium chloride**
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

**Linezolid**
Rat (F) Oral Minimum Lethal Dose 5000 mg/kg
Rat (M) Oral Minimum Lethal Dose > 5000mg/kg
Dog Oral Minimum Lethal Dose > 2000mg/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)**

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

**Linezolid**
Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Minimal
Antigenicity- Passive cutaneous anaphylaxis Mouse Negative
Antigenicity- Active anaphylaxis Guinea Pig Negative

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

**Linezolid**
1 Month(s) Rat Oral 20 mg/kg/day NOAEL Blood forming organs, Blood
3 Month(s) Rat Oral 10 mg/kg/day NOAEL Blood forming organs, Blood
1 Month(s) Dog Oral 20 mg/kg/day NOAEL Blood forming organs, Blood, Gastrointestinal system
3 Month(s) Dog Oral 20 mg/kg/day NOAEL Blood forming organs, Blood, Gastrointestinal system

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

## 11. TOXICOLOGICAL INFORMATION

**Linezolid**

| | | | | | |
|---|---|---|---|---|---|
| Reproductive & Fertility | Rat | Oral | 50 mg/kg/day | NOAEL | Fertility |
| Embryo / Fetal Development | Rat | Oral | 2.5 mg/kg/day | NOAEL | Fetotoxicity, Not Teratogenic |
| Embryo / Fetal Development | Rat | Oral | 15 mg/kg/day | NOAEL | Maternal Toxicity |
| Embryo / Fetal Development | Mouse | Oral | 150 mg/kg/day | NOAEL | Fetotoxicity, Maternal Toxicity, Not Teratogenic |

**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.

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

**Toxicity:**
**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Linezolid**

| | | | | |
|---|---|---|---|---|
| *Daphnia magna* (Water Flea) | OECD | EC50 | 48 Hours | > 100 mg/L |
| *Oncorhynchus mykiss* (Rainbow Trout) | OECD | LC50 | 96 Hours | > 1.4 mg/L |
| *Anabaena flos-aquae*(Cyanobacteria) Algae | OECD | ErC50 | 72 Hours | 1.5 mg/L |

**Bacterial Inhibition: (Inoculum, Method, End Point, Result)**

**Linezolid**

| | | | |
|---|---|---|---|
| Activated sludge | OECD | EC50 | > 1000 mg/L |

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:**
**Partition Coefficient: (Method, pH, Endpoint, Value)**
**Linezolid**

| | | | |
|---|---|---|---|
| Measured | 6-8 | Log D | 0.55 |

**Mobility in Soil:** No data available

## 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.

## 14. TRANSPORT INFORMATION

**The following refers to all modes of transportation unless specified below.**

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

## 15. REGULATORY INFORMATION

**Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

**Sodium citrate, anhydrous**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS/ELINCS List** | 200-675-3 |

**Citric acid, anhydrous**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS/ELINCS List** | 201-069-1 |

**Dextrose**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **Australia (AICS):** | Present |
| **EU EINECS/ELINCS List** | Not Listed |

**Linezolid**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **Standard for the Uniform Scheduling for Drugs and Poisons:** | Schedule 4 |

## 15. REGULATORY INFORMATION

| | |
|---|---|
| **EU EINECS/ELINCS List** | Not Listed |

**Sodium chloride**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS/ELINCS List** | 231-598-3 |

## 16. OTHER INFORMATION

**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

| | |
|---|---|
| **Data Sources:** | Pfizer proprietary drug development information. Safety data sheets for individual ingredients. |
| **Reasons for Revision:** | Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. |
| **Revision date:** | 15-Jan-2019 |
| | Product Stewardship Hazard Communication |
| **Prepared by:** | Pfizer Global Environment, Health, and Safety Operations |

Pfizer Inc believes that the information contained in this 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**