



MATERIAL SAFETY DATA SHEET

Revision date: 24-Oct-2011

Version: 2.1

Page 1 of 7

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:
International CHEMTREC (24 hours): +1-703-527-3887

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

Material Name: Linezolid Injection

Trade Name: ZYVOX, ZYVOXID, ZYVOXAM
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution

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

Additional Hazard Information:
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

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	EU Classification	%
------------	------------	-----------------------	-------------------	---

LINEZOLID INJECTION

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Injection
Revision date: 24-Oct-2011

Page 2 of 7
Version: 2.1

3. COMPOSITION/INFORMATION ON INGREDIENTS

Linezolid	165800-03-3	Not Listed	Xn;R48/22	0.2
Citric acid	77-92-9	201-069-1	Xi; R36	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium citrate, anhydrous	68-04-2	200-675-3	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.

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.

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.

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 spill with absorbent material. 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.

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Injection
Revision date: 24-Oct-2011

Page 3 of 7
Version: 2.1

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. 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.

Linezolid
Pfizer OEL TWA-8 Hr: 750µg/m³

Sodium chloride
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

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.

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:	Liquid	Color:	Clear, colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Injection
Revision date: 24-Oct-2011

Page 4 of 7
Version: 2.1

10. STABILITY AND REACTIVITY

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)

Citric acid

Rat Oral LD50 3000 mg/kg

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 > 5000 mg/kg
Dog Oral Minimum Lethal Dose > 2000 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)

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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))

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

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Injection
Revision date: 24-Oct-2011

Page 5 of 7
Version: 2.1

11. TOXICOLOGICAL INFORMATION

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.

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 EC-50 72 Hours 1.5 mg/L

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

Linezolid

Activated sludge OECD EC50 > 1000 mg/L

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

EU Indication of danger: Not classified

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Injection
Revision date: 24-Oct-2011

Page 6 of 7
Version: 2.1

15. REGULATORY INFORMATION

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

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.

Linezolid

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

Citric acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

Sodium citrate, anhydrous

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

Dextrose

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

Sodium chloride

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R36 - Irritating to eyes.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources:

Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Injection
Revision date: 24-Oct-2011

Page 7 of 7
Version: 2.1

Reasons for Revision:

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 5 - Fire Fighting Measures. Updated Section 4 - First Aid Measures. Updated Section 10 - Stability and Reactivity. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Prepared by:

Product Stewardship Hazard Communication
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