



SAFETY DATA SHEET

Revision date: 25-Mar-2014

Version: 2.0

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

Product Identifier

Material Name: Linezolid for Oral Suspension

Trade Name: ZYVOX; ZYVOXID

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
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Emergency telephone number:
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Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Physical Hazard: Combustible Dust

EU Classification:

EU Indication of danger: Not classified

Label Elements

Hazard Statements: May form combustible dust concentrations in air

Other Hazards

No data available

Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

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

LINEZOLID FOR ORAL SUSPENSION

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	Not Listed	*
Linezolid	165800-03-3	Not Listed	Xn;R48/22	STOT RE 2 (H373)	2
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Aspartame	22839-47-0	245-261-3	Not Listed	Not Listed	*
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	Not Listed	*
Flavors	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Mannitol	69-65-8	200-711-8	Not Listed	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*
Sodium citrate, anhydrous	68-04-2	200-675-3	Not Listed	Not Listed	*
Xanthan gum	11138-66-2	234-394-2	Not Listed	Not Listed	*
Carboxymethylcellulose sodium	9004-32-4	Not Listed	Not Listed	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 R phrases 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

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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 fire fighting 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 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.

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

Precautions for Safe 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.

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.

Colloidal silicon dioxide

Australia TWA	2 mg/m ³
Austria OEL - MAKs	4 mg/m ³
	0.3 mg/m ³
Czech Republic OEL - TWA	0.1 mg/m ³
	4.0 mg/m ³
Estonia OEL - TWA	2 mg/m ³
Finland OEL - TWA	5 mg/m ³
Germany - TRGS 900 - TWAs	4 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany (DFG) - MAK	4 mg/m ³
Ireland OEL - TWAs	6 mg/m ³
	2.4 mg/m ³
Latvia OEL - TWA	1 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m ³
Switzerland OEL -TWAs	4 mg/m ³
	0.3 mg/m ³
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
Sucrose	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³
Microcrystalline cellulose	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Russia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³
Vietnam OEL - TWAs	10 mg/m ³
	5 mg/m ³

Exposure Controls

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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).
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:	Powder	Color:	White to off-white
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)	

Linezolid

Measured 6-8 Log D 0.55

Microcrystalline cellulose

No data available

Carboxymethylcellulose sodium

No data available

Sucrose

No data available

Sodium citrate, anhydrous

No data available

Aspartame

No data available

Xanthan gum

No data available

Mannitol

No data available

Sodium benzoate

No data available

Colloidal silicon dioxide

No data available

Sodium chloride

No data available

Flavors

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

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Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

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
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.
Short Term: May cause mild eye irritation. (based on components) .
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)

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

Microcrystalline cellulose

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

Carboxymethylcellulose sodium

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

Sucrose

Rat Oral LD50 29.7 g/kg

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11. TOXICOLOGICAL INFORMATION

Xanthan gum

Rat Oral LD50 > 5000 mg/kg

Mannitol

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

Sodium benzoate

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

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 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
Antigenicity- Passive cutaneous anaphylaxis Mouse Negative
Antigenicity- Active anaphylaxis Guinea Pig Negative

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

Carboxymethylcellulose sodium

13 Week(s) Rat Oral 227 g/kg LOAEL Liver, 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))

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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

Sodium benzoate

Embryo / Fetal Development	Rat	Oral	44 g/kg	LOEL	Developmental toxicity
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Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Linezolid

<i>In Vitro</i> Unscheduled DNA Synthesis	Negative
Bacterial Mutagenicity (Ames)	<i>Salmonella</i> Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes Negative
<i>In Vivo</i> Micronucleus	Mouse Negative

Sucrose

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> Negative
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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 (Not Classifiable)

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

<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	> 100 mg/L
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	OECD	LC50	96 Hours	> 1.4 mg/L
<i>Anabaena flos-aquae</i> (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
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Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Linezolid

Measured	6-8	Log D	0.55
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Mobility in Soil: No data available

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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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B



Aspartame

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	245-261-3

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

Colloidal silicon dioxide

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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	231-545-4

Flavors

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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
EU EINECS/ELINCS List	Not Listed

Mannitol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

Sodium benzoate

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	208-534-8

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

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

Sucrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

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15. REGULATORY INFORMATION

Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9
Xanthan gum	
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	234-394-2
Microcrystalline cellulose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9
Carboxymethylcellulose sodium	
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	Not Listed

16. OTHER INFORMATION

Text of R phrases and 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

Xn - Harmful

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.

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

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Product Stewardship Hazard Communication

Prepared by: 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.

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