



MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.1

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

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

Material Name: Linezolid Tablets

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	*
Magnesium stearate	557-04-0	209-150-3	*
Corn Starch	9005-25-8	232-679-6	*
Linezolid	165800-03-3	Not listed	70
Titanium dioxide	13463-67-7	236-675-5	*

Ingredient	CAS Number	EU EINECS List	%
Carnauba wax	8015-86-9	232-399-4	*
Polyethylene glycol	25322-68-3	Not listed	*
Sodium starch glycolate	9063-38-1	Not listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: White tablets
Signal Word: WARNING

Statement of Hazard: May cause adverse effects on blood forming organs

Additional Hazard Information:

Short Term: May cause minimal eye irritation (based on animal data). May cause negligible skin irritation (based on animal data). Not acutely toxic (based on animal data). May cause stomach irritation, diarrhea, nausea, or vomiting.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Tablets
Revision date: 05-Jan-2007

Page 2 of 7
Version: 1.1

EU Indication of danger: Harmful

EU Hazard Symbols:



EU Risk Phrases:

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

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: Due to the nature of this material first aid is not normally required.

Ingestion: In the event of swallowing this material, seek medical advice.

Inhalation: Due to the nature of this material first aid is not normally required.

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: Not applicable

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

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Tablets
Revision date: 05-Jan-2007

Page 3 of 7
Version: 1.1

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid generating airborne dust. Wash thoroughly after handling.

Storage Conditions: No special precautions required.

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

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Corn Starch

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

Titanium dioxide

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

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

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:	Tablet	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Tablets
Revision date: 05-Jan-2007

Page 4 of 7
Version: 1.1

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The following information is available for 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

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD 50 50 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

Polyethylene glycol

Eye Irritation Rabbit Mild

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

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

Linezolid

Reproductive & Fertility Rat Oral 50 mg/kg/day LOAEL Fertility

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Tablets
Revision date: 05-Jan-2007

Page 5 of 7
Version: 1.1

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

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

Carcinogen Status: See below

Titanium dioxide

IARC:	Group 2B
OSHA:	Present

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 Symbol:	Xn
EU Indication of danger:	Harmful

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

EU Safety Phrases: S22 - Do not breathe dust.
S24 - Avoid contact with skin.

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Tablets
Revision date: 05-Jan-2007

Page 6 of 7
Version: 1.1

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

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Linezolid

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

Carnauba wax

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-399-4

Polyethylene glycol

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

Sodium starch glycolate

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

Hydroxypropyl cellulose

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

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

MATERIAL SAFETY DATA SHEET

Material Name: Linezolid Tablets
Revision date: 05-Jan-2007

Page 7 of 7
Version: 1.1

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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

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.

End of Safety Data Sheet