



# SAFETY DATA SHEET

Revision date 18-Mar-2022

Version 2

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Linezolid Injection (Hospira, Inc.)  
**Product Code(s)** PZ03154  
**Trade Name:** Not applicable  
**Chemical Family:** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as antibiotic agent

### 1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

### 2.2. Label elements

**Signal word** Not required

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

### 2.3. Other hazards

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

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**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

**Section 3: COMPOSITION/INFORMATION ON INGREDIENTS**

**3.1 Substances**  
**Substances**

Not applicable

**3.2 Mixtures**

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Linezolid (CAS #: 165800-03-3)	0.2		Not Listed	STOT RE 2 (H373) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)	Not Listed	No data available	No data available
Citric acid (CAS #: 77-92-9)	*		201-069-1	Eye Irrit. 2A (H319)SE 3 (H335)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Dextrose	*		Not Listed	Not classified	Not Listed	No data	No data

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(CAS #: 14431-43-7)				as hazardous		available	available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

## Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Citric acid 77-92-9	5400	>2000	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available

## Additional information

+ Substance with a Union workplace exposure limit

\* Proprietary

\*\* to adjust pH

Non-hazardous ingredients provided for completeness. 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.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.

### 4.2. Most important symptoms and effects, both acute and delayed

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

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## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO2, alcohol-resistant foam or water spray.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Fine particles (such as dust and mists) may fuel fires/explosions.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

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

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

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

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

#### Advice on 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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

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

### 7.3. Specific end use(s)

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**Specific use(s)** Pharmaceutical drug product.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure Limits

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

#### Linezolid

Pfizer OEL TWA-8 Hr: 750 µg/m<sup>3</sup>

#### Citric acid

Czech Republic	4 mg/m <sup>3</sup>
Germany	2 mg/m <sup>3</sup>
	Ceiling / Peak: 4 mg/m <sup>3</sup>
Germany	2 mg/m <sup>3</sup>
Russia	MAC: 1 mg/m <sup>3</sup>
Switzerland	2 mg/m <sup>3</sup>
	STEL: 4 mg/m <sup>3</sup>

#### Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m <sup>3</sup>
ACGIH TLV	Ceiling: 2 mg/m <sup>3</sup>
Austria	2 mg/m <sup>3</sup>
	STEL 4 mg/m <sup>3</sup>
Bulgaria	2.0 mg/m <sup>3</sup>
Czech Republic	1 mg/m <sup>3</sup>
	Ceiling: 2 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup>
Estonia	1 mg/m <sup>3</sup>
	STEL: 2 mg/m <sup>3</sup>
Finland	Ceiling: 2 mg/m <sup>3</sup>
France	2 mg/m <sup>3</sup>
Hungary	1 mg/m <sup>3</sup>
	STEL: 2 mg/m <sup>3</sup>
Ireland	STEL: 2 mg/m <sup>3</sup>
Ceiling Limit Value	2 mg/m <sup>3</sup>
Latvia	0.5 mg/m <sup>3</sup>
Poland	STEL: 1 mg/m <sup>3</sup>
	0.5 mg/m <sup>3</sup>
Romania	1 mg/m <sup>3</sup>
	STEL: 3 mg/m <sup>3</sup>
Slovakia	2 mg/m <sup>3</sup>
Spain	STEL: 2 mg/m <sup>3</sup>
Switzerland	2 mg/m <sup>3</sup>
	STEL: 2 mg/m <sup>3</sup>
OSHA PEL	2 mg/m <sup>3</sup>
	(vacated) Ceiling: 2 mg/m <sup>3</sup>
United Kingdom	STEL: 2 mg/m <sup>3</sup>

#### + Hydrochloric Acid

ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	5 ppm
	8 mg/m <sup>3</sup>
	STEL 10 ppm
	STEL 15 mg/m <sup>3</sup>
Bulgaria	STEL: 10 ppm
	STEL: 15.0 mg/m <sup>3</sup>
	5 ppm
	8.0 mg/m <sup>3</sup>

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Czech Republic	8 mg/m <sup>3</sup> Ceiling: 15 mg/m <sup>3</sup>
Estonia	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
European Union	TWA: 5 ppm TWA: 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Finland	STEL: 5 ppm STEL: 7.6 mg/m <sup>3</sup>
Germany	2 ppm 3.0 mg/m <sup>3</sup> Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m <sup>3</sup>
Germany	2 ppm 3 mg/m <sup>3</sup>
Hungary	8 mg/m <sup>3</sup> STEL: 16 mg/m <sup>3</sup>
Ireland	8 mg/m <sup>3</sup> 5 ppm STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Italy	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Ceiling Limit Value	2 ppm 3.0 mg/m <sup>3</sup>
Latvia	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Netherlands	8 mg/m <sup>3</sup> STEL: 15 mg/m <sup>3</sup>
Poland	STEL: 10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Romania	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Russia	MAC: 5 mg/m <sup>3</sup>
Slovakia	5 ppm 8.0 mg/m <sup>3</sup>
Spain	5 ppm 7.6 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Switzerland	2 ppm 3 mg/m <sup>3</sup> STEL: 4 ppm STEL: 6 mg/m <sup>3</sup>
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m <sup>3</sup>
OSHA PEL	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m <sup>3</sup> Ceiling: 5 ppm Ceiling: 7 mg/m <sup>3</sup>
United Kingdom	TWA: 1 ppm

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	TWA: 2 mg/m <sup>3</sup> STEL: 5 ppm STEL: 8 mg/m <sup>3</sup>
<b>SODIUM CHLORIDE</b> Latvia Russia	5 mg/m <sup>3</sup> MAC: 5 mg/m <sup>3</sup>
<b>SODIUM CHLORIDE</b> Pfizer Occupational Exposure Band (OEB):	OEB 1 (control exposure to the range of 1000ug/m <sup>3</sup> to 3000ug/m <sup>3</sup> )
<b>8.2. Exposure controls</b>	
<b>Engineering controls</b>	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.
<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	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.
<b>Eye/face protection</b>	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.).
<b>Hand protection</b>	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.).
<b>Skin and body protection</b>	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.).
<b>Respiratory protection</b>	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.)
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Liquid
<b>Color</b>	Clear, colorless
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture
<b>Property</b>	<b>Values</b>
<b>pH</b>	4.4-5.2
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available

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<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## **Partition Coefficient: (Method, pH, Endpoint, Value)**

Linezolid  
Measured 6-8 Log D 0.55

## **9.2. Other information**

No information available

### **9.2.1. Information with regard to physical hazard classes**

No information available

### **9.2.2. Other safety characteristics**

No information available

## **Section 10: STABILITY AND REACTIVITY**

### **10.1. Reactivity**

**Reactivity** No data available.

### **10.2. Chemical stability**

**Stability** Stable under normal conditions.

#### **Explosion data**

**Sensitivity to Mechanical Impact** No data available.

**Sensitivity to Static Discharge** No data available.

### **10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** No information available.

### **10.4. Conditions to avoid**

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

### **10.5. Incompatible materials**

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

### **10.6. Hazardous decomposition products**

**Hazardous decomposition products** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**



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## 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Long Term:</b>	Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system the developing fetus.
<b>Known Clinical Effects:</b>	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.
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

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

#### 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

#### Citric acid

Mouse Oral LD50 5400 mg/kg

#### Sodium hydroxide

Mouse IP LD50 40 mg/kg

#### SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>  
Rat Oral LD 50 3 g/kg  
Mouse Oral LD 50 4 g/kg  
Rabbit Dermal LD 50 > 10 g/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Citric acid	= 3 g/kg ( Rat )	> 2000 mg/kg ( Rat )	-
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-
+ Hydrochloric Acid	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h
SODIUM CHLORIDE	= 3 g/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h

**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

#### Citric acid

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

#### Sodium hydroxide

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Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

## **+ Hydrochloric Acid**

Skin irritation Severe  
Eye irritation Severe

## **SODIUM CHLORIDE**

Skin irritation Rabbit Mild  
Eye irritation Rabbit Mild

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

### **Linezolid**

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

## **Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Linezolid**

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

### **+ Hydrochloric Acid**

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vivo* Micronucleus Rat Negative

## **Carcinogenicity**

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### **+ Hydrochloric Acid**

IARC Group 3 (Not Classifiable)

## **11.2. Information on other hazards**

### **11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** No information available.

### **11.2.2. Other information**

**Other adverse effects** No information available.

## **Section 12: ECOLOGICAL INFORMATION**

### **Environmental Overview:**

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

## **12.1. 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 96 hours 2.0 mg/L

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*Anabaena flos-aquae* (Cyanobacteria) OECD NOEC 96 hours 1.0 mg/L

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

### **Linezolid**

Activated sludge OECD EC50 / EC15 > 1000 mg/L

*Aspergillus niger* (Fungus) OECD MIC 600 mg/L

*Trichoderma viride* (Fungus) OECD MIC > 1000 mg/L

*Clostridium perfringens* (Bacterium) OECD MIC 2 mg/L

*Bacillus subtilis* (Bacterium) OECD MIC 0.4 mg/L

## **Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**

### **Linezolid**

*Pimephales promelas* (Fathead Minnow) OECD 32 Day(s) NOEC 9.9 mg/L Sublethal effects

*Daphnia magna* (Water Flea) OECD 21 Day(s) NOEC 24 mg/L Reproduction

*Ceriodaphnia dubia* (Daphnids) OECD 7 Day(s) NOEC 31 mg/L Reproduction, Survival

## **12.2. Persistence and degradability**

### **Persistence and degradability**

## **Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)**

### **Linezolid**

OECD Activated sludge Die-away, Mineralization (CO<sub>2</sub> Evolution) 84 % in 28 Day(s)

OECD Activated sludge Mineralization (CO<sub>2</sub> Evolution) -3.4% Not readily biodegradable

OECD Water - Sediment (various) Mineralization (CO<sub>2</sub> Evolution) 44 - 52.7 % in 102 Day(s)

OECD Water - Sediment (various) Total System DT50 23 - 24.7 Day(s)

## **12.3. Bioaccumulative potential**

### **Bioaccumulation**

## **Partition Coefficient: (Method, pH, Endpoint, Value)**

### **Linezolid**

Measured 6-8 Log D 0.55

## **12.4. Mobility in soil**

### **Mobility in soil**

### **Sorption:**

#### **Linezolid (165800-03-3)**

#### **Method**

#### **Inoculum**

#### **End Point**

#### **Result**

OECD

Activated sludge

Kd

3.0

OECD

Activated sludge

Koc

8.6

OECD

Soil (various)

Kd (Geometric mean)

18.8

OECD

Soil (various)

Koc (Geometric mean)

922

## **12.5. Results of PBT and vPvB assessment**

### **PBT and vPvB assessment**

Chemical name	PBT and vPvB assessment
Citric acid	The substance is not PBT / vPvB
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
+ Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does not apply
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply

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## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. Other adverse effects

No information available.

## **Section 13: DISPOSAL CONSIDERATIONS**

### 13.1. 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 wastewater 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.

## **Section 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.**

<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group:</b>	Not applicable
<b>Environmental Hazard(s):</b>	Not applicable
<b>Special precautions for user:</b>	Not applicable

## **Section 15: REGULATORY INFORMATION**

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

Dextrose

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present

Linezolid

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4

Citric acid

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<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	201-069-1
<b>AICS</b>	Present
Sodium hydroxide	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6
+ Hydrochloric Acid	
<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-595-7
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6
SODIUM CHLORIDE	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present

## France

### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
SODIUM CHLORIDE 7647-14-5	RG 78	-

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Citric acid - 77-92-9	Use restricted. See item 75.	
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

### Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid - 7647-01-0	25	250

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## Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

## EU - Biocides

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure. Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation. Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage. Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life. Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects.

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

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**Prepared By** Pfizer Global Environment, Health, and Safety

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