SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product identifier used on the label:

Product Name: **Linezolid Injection**

Other means of identification:

Product Description: 2 mg/mL filled in a 300 mL freeflex bag

Synonyms: Linezolid Injection (freeflex®)

Recommended use of the chemical and restrictions on use:

Product Use/Restriction: Antibacterial Agent

Chemical distributor, or other responsible party Name, address, and telephone number:

Distributor Name: Fresenius Kabi USA, LLC

Address: Three Corporate Drive
Lake Zurich, Illinois 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

SECTION 2 : HAZARD(S) IDENTIFICATION

Classification of the chemical in accordance with CFR 1910.1200(d)(f):

GHS Pictograms:

Signal Word: DANGER.

GHS Class: Specific Target Organ Toxicity -STOT Repeated exposure RE. category 1 (Oral, Blood, Peripheral and Optic Nervous system).
Reproductive toxicity. Effects on or via lactation.

Hazard Statements: Causes damage to organs through prolonged or repeated exposure.
May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
IF exposed or concerned: Get medical advice/attention.
Get medical advice/attention if you feel unwell.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Hazards not otherwise classified that have been identified during the classification process:

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

- Eye: Contact with eyes may cause irritation.
- Skin: May cause skin irritation.
- Inhalation: May cause irritation of respiratory tract.
- Ingestion: May cause irritation.

Signs/Symptoms: Adverse reactions from therapeutic doses include: headache, nausea, diarrhea, vomiting and anemia.

Aggravation of Pre-Existing Conditions: Linezolid is contraindicated for use in patients who have known hypersensitivity to linezolid or any of the other product components
Linezolid should not be used in patients taking any medicinal product which inhibits monoamine oxidases A or B (e.g., phenelzine, isocarboxazid) or within two weeks of taking any such medicinal product.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures:

Chemical Name	CAS#	Ingredient Percent	EC Num.

Linezolid	165800-03-3	2 mg/mL
Dextrose, USP	50-99-7	50.24 mg/mL
Sodium citrate, USP	68-04-2	1.64 mg/mL
Citric acid, USP	77-92-9	0.85 mg/mL
Sodium hydroxide	1310-73-2	- As needed to adjust pH -
Hydrochloric acid	7647-01-0	- As needed to adjust pH -
Water for Injection	7732-18-5	- Quantity Sufficient. -

SECTION 4 : FIRST AID MEASURES

Description of necessary measures:

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed:

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Suitable and unsuitable extinguishing media:

Suitable Extinguishing Media: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards arising from the chemical:

Hazardous Combustion Byproducts: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

Special protective equipment and precautions for fire-fighters:

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Personal Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area.
Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.

Environmental precautions:

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Methods and materials for containment and cleaning up:

Methods for containment: Contain spills with an inert absorbent material such as soil, sand or oil dry.

Methods for cleanup: Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Precautions for safe handling:

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

Conditions for safe storage, including any incompatibilities:

Storage:	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light (Linezolid is sensitive to light). It is recommended that the infusion bags be kept in the overwrap until ready to use. Protect infusion bags from freezing.

Specific end use(s):

Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE GUIDELINES:

Hydrochloric acid :

Guideline ACGIH:	TLV-STEL: 2 ppm(ceiling.)
Guideline OSHA:	OSHA PEL-STEL 5 ppm ceiling./Peak.

Appropriate engineering controls:

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Individual protection measures:

Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.
General Hygiene Considerations:	Wash thoroughly after handling. Do not eat, drink, smoke or apply cosmetics while handling the product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Work should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Liquid.
Color:	Colorless to slightly yellow aqueous solution.
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	177 - 182 °C
Specific Gravity:	Not established.
Solubility:	Insoluble in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
Evaporation Rate:	Not established.
pH:	Not established.
Flash Point:	Not established.
Flash Point Method:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Auto Ignition Temperature:	Not established.

VOC Content:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:

Chemical Stability:	Stable under normal temperatures and pressures.

Possibility of hazardous reactions:

Hazardous Polymerization:	Not reported.

Conditions To Avoid:

Conditions to Avoid:	Excessive heat may cause decomposition.

SECTION 11 : TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Linezolid :

Reproductive Toxicity:	Linezolid did not affect the fertility or reproductive performance of adult female rats. It reversibly decreased fertility and reproductive performance in adult male rats when given at doses ≥ 50 mg/kg/day, with exposures approximately equal to or greater than the expected human exposure level (exposure comparisons are based on AUCs). The reversible fertility effects were mediated through altered spermatogenesis. Affected spermatids contained abnormally formed and oriented mitochondria and were nonviable. Epithelial cell hypertrophy and hyperplasia in the epididymis was observed in conjunction with decreased fertility. Similar epididymal changes were not seen in dogs. (FDA Professional Monograph)
Teratogenicity:	Linezolid was not teratogenic in mice, rats, or rabbits at exposure levels 6.5fold (in mice), equivalent to (in rats), or 0.06fold (in rabbits) the expected human exposure level, based on AUCs.
Other Toxicological Information:	There are no data on the excretion of linezolid into human milk. Linezolid and its metabolites are excreted into rat milk, at concentrations similar to those in maternal plasma. The manufacturer recommends that caution be used when linezolid is administered to nursing women.
Target Organ Repeated Exposures:	In rats administered linezolid orally for 6 months, nonreversible, minimal to mild axonal degeneration of sciatic nerves was observed at 80 mg/kg/day; minimal degeneration of the sciatic nerve was also observed in 1 male at this dose level at a 3month interim necropsy. Sensitive morphologic evaluation of perfusionfixed tissues was conducted to investigate evidence of optic nerve degeneration. Minimal to moderate optic nerve degeneration was evident in 2 male rats after 6 months of dosing, but the direct relationship to drug was equivocal because of the acute nature of the finding and its asymmetrical distribution. The nerve degeneration observed was microscopically comparable to spontaneous unilateral optic nerve degeneration reported in aging rats and may be an exacerbation of common background change. These effects were observed at exposure levels that are comparable to those observed in some human subjects. The hematopoietic and lymphoid effects were reversible, although in some studies, reversal was incomplete within the duration of the recovery period. (FDA Professional Monograph)

Dextrose, USP :

Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: 25800 mg/kg [Behavioral-Coma Lungs, Thorax, or Respiration-Cyanosis Gastrointestinal - Hypermotility, diarrhea] (RTECS)

Citric acid, USP :

Eye:	Administration into the eye - Rabbit Standard Draize test: 750 ug/24H [Severe] (RTECS)
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50 - Lethal dose, 50 percent kill: 11700 mg/kg [Behavioral - Ataxia Cardiac-Change in rate Lungs, Thorax, or Respiration - Respiratory depression] (RTECS)

Sodium hydroxide :

Eye:	Administration into the eye - Rabbit Standard Draize test: 400 ug [Mild] Administration into the eye - Rabbit Standard Draize test: 1 % [Severe] Administration into the eye - Rabbit Standard Draize test: 50 ug/24H [Severe] Administration into the eye - Rabbit Standard Draize test: 1 mg/24H [Severe] Administration into the eye - Rabbit Rinsed with water: 1 mg/30S [Severe] (RTECS)
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H
Ingestion:	Oral - Rabbit LDLo: 500 mg/kg [Details of toxic effects not reported other than lethal dose value]

Hydrochloric acid :

Eye:	Administration into the eye - Rabbit Rinsed with water: 5 mg/30S [Mild] (RTECS)
Skin:	Administration onto the skin - Human Standard Draize test.: 4 %/24H (RTECS)
Inhalation:	Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 3124 ppm/1H [Sense Organs and Special Senses (Olfaction) - effect, not otherwise specified Sense Organs and Special Senses (Eye)-Iritis] Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 45000 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 8300 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 60938 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 7004 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 3700 ppm/30M [Details of toxic effects not reported other than lethal dose value] (RTECS)
Ingestion:	Oral - Rabbit LD50: 900 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Description of waste:

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.
IATA Shipping Name:	Non regulated.
IATA UN Number:	Non regulated.
IMDG UN Number :	Non regulated.
IMDG Shipping Name :	Non regulated.

SECTION 15 : REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product:

Linezolid :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

Dextrose, USP :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

Sodium citrate, USP :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

Citric acid, USP :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.409(80)

Sodium hydroxide :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

Hydrochloric acid :

TSCA Inventory Status:	Listed
SARA:	EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical.
Section 302 EHS:	EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 500 Lbs.
Section 304 RQ:	EPCRA (SARA Title III) Section 304 Extremely Hazardous Substances (EHS) Reportable Quantities (RQ) in pounds.: 5,000 Lbs.
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1*
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	C

Health Hazard	**1***
Fire Hazard	**0**
Reactivity	**0**
Personal Protection	**C**

* **Chronic Health Effects**

SDS Creation Date:	September 24, 2015
SDS Revision Date:	March 18, 2024
SDS Revision Notes:	Overall SDS review - no changes to formulation. Revised HMIS ratings for Health, Flammability, Reactivity, and Personal Protective Equipment (PPE). Removed former co-manufacturer. Added synonym product name.
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