Annora

SAFETY DATA SHEET

Section 1: Identification	
Material	Linezolid for Oral suspension 100 mg/5 mL
Recommended use	Pharmaceutical product
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) 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
Section 3: Composition/Information on Ingredients	
Active Ingredient	Linezolid
CAS	165800-03-3

Section 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
Section 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	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 firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.	
Section 6: Accidental Release Measures	
Personal Precautions, Protective Equipment and Emergency Procedures Personnel involved in clean-up should wear appropriate personal protective equipment. 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

Section 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. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural wastewater 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

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

Section 9: Physical and Chemical Properties

Physical state	Powder

Description	Linezolid for Oral Suspension is available as a dry, white or off-white to brown granule/powder. When constituted as directed, each bottle will contain 150 mL of a suspension providing the equivalent of 100 mg of linezolid per each 5 mL. Linezolid for Oral Suspension is supplied as follows: 100 mg/5 mL in 250 mL glass bottles NDC 31722-865-25

Section 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	No data available

Section 11: Toxicological Information

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

Linezolid

Rat (F) Oral LD50 5000 mg/kg

Rat (M) Oral LD50 > 5000mg/kg

Dog Oral LD50 > 2000mg/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

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

Linezolid

1Month(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

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

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 72 Hours 1.5 mg/L

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

Linezolid

Activated sludge OECD EC50 > 1000 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:

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

Linezolid

Measured 6-8 Log D 0.55

Mobility in Soil: No data available

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 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.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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

Section 16: Other Information, including date of preparation or last revision

Issue Date: 10-01-2023

Version: 00

Further information

Revision date: NA

Revision note: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.