




# HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.  
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250  
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

## SAFETY DATA SHEET

| Section 1: Identification                                      |  |
|--|--|
| <b>Material</b>  | <b>Linezolid Tablets 600 mg</b>  |
| <b>Manufacturer</b>  | <b>Hetero labs limited, Unit V, Polepally, Jadcherla , Mahaboob Nagar -509 301, India.</b>   |
| <b>Distributor</b>   | <b>Camber Pharmaceuticals, Inc, Piscatway, NJ 08854</b>  |
| Section 2: Hazard(s) Identification                            |  |
| Classification according to Directive 67/548/EEC or 1999/45/EC | Carc.Cat.3; R40  |
| Hazard pictograms (CLP)  | <br>None  |
| CLP Signal word  | Warning  |
| Hazard statements (CLP)  | H302 - Harmful if swallowed<br>H332 - Harmful if inhaled   |
| Precautionary statements (CLP)                                 | P102 - Keep out of reach of children<br>P103 - Read label before use<br>P202 - Do not handle until all safety precautions have been read and understood<br>P232 - Protect from moisture<br>P233 - Keep container tightly closed<br>P234 - Keep only in original container<br>P235+P410 - Keep cool. Protect from sunlight<br>P403 - Store in a well-ventilated place<br>P410 - Protect from sunlight |
| EUH phrases  | EUH210 - Safety data sheet available on request  |
| Section 3: Composition/Information on Ingredients              |  |
| Composition/information on ingredients                         | CAS number   |
| Linezolid (Form- III)  | 165800-03-3  |
| Colloidal Silicon Dioxide (Aerosil-200) USP-NF                 | 7631869  |
| Lactose Monohydrate USP - NF (Impalpable)                      | 64044515   |
| Lactose Monohydrate USP - NF (Supertab 11 SD)                  | 64044515   |



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|  |  |
|--|--|
| Hypromellose, USP 2910 5cps<br>(Methocel E5 LV Premium)                    | 9004653  |
| Polacrilin Potassium, USP-NF<br>(Kyron T 314)                              | 39394-76-5   |
| Magnesium Stearate USP-NF  | 557040   |
| <b>Section 4: First-Aid Measures</b>                                       |  |
| <b>Section 4, First-aid measures</b>                                       |  |
| <b>Description of First Aid Measures</b>                                   | <p>Eye contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.</p> <p>Skin contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.</p> <p>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</p> <p>Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.</p> |
| <b>Section 5: Fire-Fighting Measures</b>                                   |  |
| <b>Section 5, Fire-fighting measures</b>                                   |  |
| <b>Extinguishing Media</b>   | Extinguish fires with CO <sub>2</sub> , extinguishing powder, foam, or water.  |
| <b>Special Hazards Arising from the Substance or Mixture</b>               |  |
| <b>Hazardous Combustion Products</b>                                       | Formation of toxic gases is possible during heating or fire.   |
| <b>Fire / Explosion Hazards</b>  | Fine particles (such as dust and mists) may fuel fires/explosions.   |
| <b>Advice for Fire-Fighters</b>  | During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.  |
| <b>Section 6: Accidental Release Measures</b>                              |  |
| <b>Section 6, Accidental release measures</b>                              |  |
| <b>Personal Precautions, Protective Equipment and Emergency Procedures</b> | Personnel involved in clean-up should wear appropriate personal protective equipment Minimize exposure.  |
| <b>Environmental protection</b>  | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release  |
| <b>Methods and Material for Containment and Cleaning Up</b>                |  |
| <b>Measures for Cleaning / Collecting</b>                                  | 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.   |



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|  |   |
|--|---|
| <b>Additional Consideration for Large Spills</b>   | Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.  |
| <b>Section 7: Handling and Storage</b>   |   |
| <b>Precautions for Safe Handling</b>   | Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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 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.   |
| <b>Storage</b>   | Store at 25°C; excursions permitted between 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature.]   |
| <b>Section 8: Exposure Controls/Personal Protection</b>  |   |
| <b>Engineering Controls:</b><br><br>Personal Protective equipment<br><br>Hands<br>Eyes<br><br>Skin<br><br>Respiratory protection | <ul style="list-style-type: none"> <li>• 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</li> <li>• Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).</li> <li>• Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.</li> <li>• Wear safety glasses or goggles if eye contact is possible.</li> <li>• Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.</li> <li>• 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.</li> </ul> |
| <b>Section 9: Physical and Chemical Properties</b>   |   |
| <b>Physical State</b>  | Tablet  |
| <b>Appearance</b>  | White to off-white crystalline powder.  |
| <b>Molecular mass</b>  | 337.346 g/mol   |
| <b>Melting point</b>   | 177.0-182.0 °C  |
| <b>Description</b>   | Linezolid Tablets, 600 mg are white to off white, oval shaped, bevel edged, biconvex film coated tablets, debossed with 'I' on one side and '22' on other side.   |



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|                     |   |                  |
|---------------------|---|------------------|
| <b>Availability</b> | 20 tablets in HDPE bottle                 | NDC 31722-749-20 |
|                     | 30 tablets in HDPE bottle                 | NDC 31722-749-30 |
|                     | 100 tablets in HDPE bottle                | NDC 31722-749-01 |
|                     | Unit-dose packages of 150 (15x10) tablets | NDC 31722-749-31 |

## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

### Carcinogenesis, Mutagenesis, Impairment of Fertility

Lifetime studies in animals have not been conducted to evaluate the carcinogenic potential of linezolid. Neither mutagenic nor clastogenic potential was found in a battery of tests including: assays for mutagenicity (Ames bacterial reversion and CHO cell mutation), an in vitro unscheduled DNA synthesis (UDS) assay, an in vitro chromosome aberration assay in human lymphocytes, and an in vivo mouse micronucleus assay.

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  $\geq 50$  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 non-viable. Epithelial cell hypertrophy and hyperplasia in the epididymis was observed in conjunction with decreased fertility. Similar epididymal changes were not seen in dogs.

In sexually mature male rats exposed to drug as juveniles, mildly decreased fertility was observed following treatment with linezolid through most of their period of sexual development (50 mg/kg/day from days 7 to 36 of age, and 100 mg/kg/day from days 37 to 55 of age), with exposures up to 1.7-fold greater than mean AUCs observed in pediatric patients aged 3 months to 11 years. Decreased fertility was not observed with shorter treatment periods, corresponding to exposure in utero through the early neonatal period (gestation day 6 through postnatal day 5), neonatal exposure (postnatal days 5 to 21), or to juvenile exposure (postnatal days 22 to 35). Reversible reductions in sperm motility and altered sperm morphology were observed in rats treated from postnatal day 22 to 35.

## Section 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



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*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

## Section 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.

## Section 14: Transport Information

### IATA/ICAO - Not Regulated

IATA Proper shipping Name : N/A

IATA UN/ID No : N/A

IATA Hazard Class : N/A

IATA Packaging Group : N/A

IATA Label : N/A

### IMDG - Not Regulated

IMDG Proper shipping Name : N/A

IMDG UN/ID No : N/A

IMDG Hazard Class : N/A

IMDG Flash Point : N/A

IMDG Label : N/A

### DOT - Not Regulated

DOT Proper shipping Name : N/A

DOT UN/ID No : N/A



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|                   |       |
|-------------------|-------|
| DOT Hazard Class  | : N/A |
| DOT Flash Point   | : N/A |
| DOT Packing Group | : N/A |
| DOT Label         | : N/A |

## Section 15: Regulatory Information

This Section contains Information relevant to compliance with other Federal and/or state laws.

## Section 16: Other Information

### Section 16, Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

Hetero labs limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero labs limited reserves the right to revise this MSDS.