



|   |
|---|
| <b>IN CASE OF EMERGENCY</b><br><b>Emergency Phone: (614) 276-4000</b> |
|---|

## Material Safety Data Sheet

| 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION                                     |  |                  |
|--|--|------------------|
| Common/Trade Name: Levetiracetam Oral Solution                                     |  |                  |
| Chemical Name: (2S)-2-(2-oxopyrrolidin-1-yl)butanamide                             |  |                  |
| Synonyms: None   |  |                  |
| Molecular Formula: C <sub>8</sub> H <sub>14</sub> N <sub>2</sub> O <sub>2</sub>    |  |                  |
| Molecular Weight: 170.21   |  |                  |
| CAS No: 102767-28-2  |  |                  |
| Chemical Family: Anticonvulsant  |  |                  |
| Product Use: Treatment of epilepsy   |  |                  |
| Manufacturer's Name: <b>Boehringer Ingelheim Roxane Inc.</b>                       |  |                  |
| Address: <b>1809 Wilson Road<br/>Columbus, Ohio 43228</b>                          |  |                  |
| 2. COMPOSITION / INFORMATION ON INGREDIENTS  |  |                  |
| Composition  | CAS#   | Exposure Limit   |
| Levetiracetam (active ingredient)  | 102767-28-2  | None established |
| <i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as &lt;1%</i> |  |                  |
| 3. HAZARDS IDENTIFICATION  |  |                  |
| Emergency Overview   | Physical State: Liquid solution administered orally.<br>Clear, colorless, cherry-flavored solution with 100 mg of Levetiracetam per mL.<br><br>Odor: No data available<br><br><b>WARNING!</b><br>May be harmful if swallowed.<br>Accidental ingestion of large amounts may be harmful.   |                  |
| Primary Route(s) of Entry  | Ingestion  |                  |
| Potential Health Effects:  | Inhalation: Not expected to be an inhalation hazard in final pharmaceutical form.<br><br>Eye Contact: Not expected to be a hazard to the eye. Contact with eye may cause irritation, burning and redness.<br><br>Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.<br><br>Ingestion: May be harmful if ingested. Ingestion may cause central nervous system effects such as somnolence, fatigue, coordination difficulties and behavioral abnormalities. |                  |
| Toxicity Data:   | See Section 11   |                  |
| Effects of Overexposure:   | The potential for exposure is reduced in finished pharmaceutical form.<br>Overexposure by ingestion may cause somnolence, agitation, aggression, depressed level of consciousness, respiratory depression and coma.  |                  |
| Target Organs:   | Gastrointestinal tract   |                  |
| 4. FIRST AID MEASURES  |  |                  |
| Eye Exposure   | Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.   |                  |

|   |   |                |               |                     |               |
|---|---|----------------|---------------|---------------------|---------------|
| Skin Exposure   | Wash with soap and water. Get medical attention if symptoms occur.  |                |               |                     |               |
| Ingestion   | Call a physician or poison control center immediately.  |                |               |                     |               |
| Inhalation  | Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.  |                |               |                     |               |
| <b>5. FIRE AND EXPLOSION HAZARDS</b>  |   |                |               |                     |               |
| Flammability  | Lower: N/A  |                | Upper: N/A    |                     |               |
| Flash Point   | Not Applicable  |                |               |                     |               |
| Extinguishing Media   | Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area  |                |               |                     |               |
| Special Fire Fighting Procedures  | Wear full protective clothing and self-contained breathing apparatus.   |                |               |                     |               |
| Unusual Fire/Explosion Hazards  | Not Applicable  |                |               |                     |               |
| Hazardous Combustion Products   | Carbon dioxide, carbon monoxide, nitrogen oxides  |                |               |                     |               |
| <b>6. ACCIDENTAL RELEASE INFORMATION</b>  |   |                |               |                     |               |
| STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED:<br>Use appropriate personal protective equipment (see Section 8). Wipe up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended. |   |                |               |                     |               |
| <b>7. PRECAUTIONS FOR SAFE HANDLING AND USE</b>   |   |                |               |                     |               |
| Precautions Handling Significant Quantities of Liquid:  | Observe good industrial hygiene practices.  |                |               |                     |               |
| Storage   | Store at 20° to 25°C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.   |                |               |                     |               |
| <b>8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT</b>  |   |                |               |                     |               |
| Exposure Limits   | None  |                |               |                     |               |
| Engineering Controls  | Not required when handling liquid or containers. Good ventilation should be used. Ventilation should be matched to conditions.  |                |               |                     |               |
| Respiratory Protection  | Not required when handling liquid or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions. |                |               |                     |               |
| Personal Protection   | Not required when handling final product. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves   |                |               |                     |               |
| Recommended Facilities  | Eye wash, washing facilities  |                |               |                     |               |
| <b>9. PHYSICAL / CHEMICAL CHARACTERISTICS</b>   |   |                |               |                     |               |
| Appearance  | Clear, colorless solution   | Melting point  | Not available | Solubility in water | Not available |
| Odor  | Not available   | Boiling point  | Not available | Specific Gravity    | Not available |
| Taste   | Cherry  | Vapor Pressure | Not available | Flashpoint          | Not available |
| pH  | Not available   | Density        | Not available | Flammability Limits | Not available |
| <b>10. STABILITY AND REACTIVITY DATA</b>  |   |                |               |                     |               |

|   |                                      |
|---|--------------------------------------|
| Stability   | Stable                               |
| Incompatibility   | None known                           |
| Hazardous Decomposition   | Oxides of carbon, oxides of nitrogen |
| Conditions to Avoid   | Excessive heat, light                |
| Hazardous Polymerization  | Will not occur.                      |
| <b>11. TOXICOLOGICAL INFORMATION</b>  |                                      |
| Acute Toxicity:   |                                      |
| Active Ingredient: No data available  |                                      |
| Carcinogenicity: Not listed as a carcinogen by NTP, IARC Monographs or OSHA.  |                                      |
| <b>12. ENVIRONMENTAL IMPACT INFORMATION</b>   |                                      |
| No information is currently available on the environmental impact of this product.  |                                      |
| <b>13. DISPOSAL INFORMATION</b>   |                                      |
| Waste Disposal Considerations: Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.<br>At home: Discard away from children's reach.   |                                      |
| <b>14. TRANSPORTATION INFORMATION</b>   |                                      |
| This product is not subject to the regulations for the safe transport of hazardous chemicals.<br>DOT: Not regulated<br>TDG: Not regulated<br>IATA: Not regulated<br>IMDG: Not regulated   |                                      |
| <b>15. REGULATORY INFORMATION</b>   |                                      |
| DEA: Levetiracetam is not a controlled substance.   |                                      |
| FDA: Levetiracetam is an approved prescription medication.  |                                      |
| Inventory Status: This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.<br>This material is not listed on the DSL Inventory but is exempt.   |                                      |
| <b>16. OTHER DATA</b>   |                                      |
| ABBREVIATIONS:<br>N/A – not applicable  |                                      |
| Prepared by: Boehringer Ingelheim Roxane, Inc.  |                                      |
| References:<br>1. Levetiracetam Oral Solution, Package Insert, Boehringer Ingelheim Roxane, Inc. , Columbus, Ohio<br>2. RTECS No. UX9656166 - (2S)-2-(2-oxopyrrolidin-1-yl)butanamide<br>3. Ariel Websight. Regulatory and ChemExpert Database.<br>4. PDR – Physicians Desk Reference |                                      |
| Date: 12/5/2008 - New MSDS  |                                      |
| <b>SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION</b>   |                                      |

*The information provided is believed to be complete and accurate. If this product is combined with other materials, deteriorates or becomes contaminated, it may pose hazards not mentioned in this MSDS. It is the users' responsibility to use the information according to the application. Boehringer Ingelheim Roxane, Inc. assumes no responsibility or liability resulting from the use of this information.*