SAFETY DATA SHEETS

This SDS packet was issued with item:

078910347

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078910344 078910345 078910346 078931446

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Common/Trade Name: Levetiracetam Tablets

Chemical Name: (2S)-2-(2-oxopyrrolidin-1-yl)butanamide

Synonyms: None

Molecular Formula: $C_8H_{14}N_2O_2$

Molecular Weight: 170.21

CAS No: 102767-28-2

Chemical Family: Anticonvulsant

Product Use: Treatment of epilepsy

Manufacturer's Name: **Boehringer Ingelheim Roxane Inc.**

Address: **1809 Wilson Road**
Columbus, Ohio 43228

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition	CAS#	Exposure Limit
Levetiracetam (active ingredient)	102767-28-2	None established

REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%

3. HAZARDS IDENTIFICATION

Emergency Overview	**Physical State: Round or capsule-shaped tablets** **The 250 mg tablets are blue, film coated, beveled edge, round tablets with "54 875" debossed on one side and a decreasing bisect on the other.** **The 500 mg tablets are yellow, film coated, biconvex, capsule-shaped tablets with "54 284" debossed on one side and a decreasing bisect on the other.** **The 750 mg tablets are light beige, film coated, biconvex, capsule-shaped tablets with "54 636" debossed on one side and a decreasing bisect on the other.** **The 1000 mg tablets are white, film coated, biconvex, capsule-shaped tablets with "54 470" debossed on one side and a decreasing bisect on the other.** **Odor: No data available** **WARNING!** **May be harmful if swallowed.** **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.** **Eye Contact: Not expected to be a hazard to the eye in final pharmaceutical form.** **Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.** **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**

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Effects of Overexposure:	**The potential for exposure is reduced in finished pharmaceutical form. 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.**

5. FIRE AND EXPLOSION HAZARDS

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**

6. ACCIDENTAL RELEASE INFORMATION

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED:
Use appropriate personal protective equipment (see Section 8). Sweep up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.

7. PRECAUTIONS FOR SAFE HANDLING AND USE

Precautions Handling Significant Quantities of Product:	**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.**

8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Exposure Limits	**None**
Engineering Controls	**Not required when handling tablets or containers. Ventilation should be matched to conditions.**
Respiratory Protection	**Not required when handling tablets 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 tablets. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves**
Recommended Facilities	**Eye wash, washing facilities**

9. PHYSICAL / CHEMICAL CHARACTERISTICS

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Appearance	Blue, yellow, light beige or white round or capsule-shaped tablets	Melting point	Not available	Solubility in water	Not available
Odor	Not available	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available

10. STABILITY AND REACTIVITY DATA

Stability	Stable
Incompatibility	None known
Hazardous Decomposition	Oxides of carbon, oxides of nitrogen
Conditions to Avoid	Excessive heat, light
Hazardous Polymerization	Will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Active Ingredient: No data available

Carcinogenicity: Not listed as a carcinogen by NTP, IARC Monographs or OSHA.

12. ENVIRONMENTAL IMPACT INFORMATION

No information is currently available on the environmental impact of this product.

13. DISPOSAL INFORMATION

Waste Disposal Considerations: Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.
At home: Discard away from children's reach.

14. TRANSPORTATION INFORMATION

This product is not subject to the regulations for the safe transport of hazardous chemicals.
DOT: Not regulated
TDG: Not regulated
IATA: Not regulated
IMDG: Not regulated

15. REGULATORY INFORMATION

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.
This material is not listed on the DSL Inventory but is exempt.

16. OTHER DATA

ABBEVIATIONS:
N/A – not applicable

Prepared by: Boehringer Ingelheim Roxane, Inc.

References:

1. **Levetiracetam Tablets, Package Insert, Boehringer Ingelheim Roxane, Inc. , Columbus, Ohio**
2. **RTECS No. UX9656166 - (2S)-2-(2-oxopyrrolidin-1-yl)butanamide**

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3. **Ariel Webinsight. Regulatory and ChemExpert Database.**
4. **PDR – Physicians Desk Reference**

Date: 12/5/2008 - New MSDS

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION

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.

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