




<p align="center">IN CASE OF EMERGENCY Emergency Phone: (614) 276-4000</p>

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Zolpidem Tartrate Tablets USP 		
Chemical Name: N,N,6-trimethyl-2-p-tolylimidazo[1,2-a] pyridine-3-acetamide L-(+)-tartrate (2:1)		
Synonyms: None		
Molecular Formula: $(C_{19}H_{21}N_3O)_2 \cdot C_4H_6O_6$		
Molecular Weight: 764.88		
CAS No: 99294-93-6		
Chemical Family: Non-benzodiazepine hypnotic		
Product Use: Short-term treatment of insomnia		
Manufacturer's Name: Boehringer Ingelheim Roxane Inc.		
Address: 1809 Wilson Road Columbus, Ohio 43228		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Zolpidem Tartrate (active ingredient)	99294-93-6	None established
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: Round, biconvex, film-coated tablets The 5 mg tablets are pink with "54 371" debossed on one side and blank on the other. The 10 mg tablets are white with "54 553" debossed on one side and blank on the other. Odor: None 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 headache, dizziness, short-term memory impairment, hallucinations, impaired coordination and nausea.	
Toxicity Data:	See Section 11	
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause various central nervous system effects ranging from drowsiness to coma, as well as other systemic effects including: headache, dizziness, short-term memory impairment, hallucinations, impaired coordination and nausea.	
Target Organs:	Central Nervous System	
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 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, oxides of nitrogen				
6. ACCIDENTAL RELEASE INFORMATION					
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT ARE 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 product. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves				
Recommended Facilities	Eye wash, washing facilities				
9. PHYSICAL / CHEMICAL CHARACTERISTICS					
Appearance	Round, biconvex, film-coated tablets	Melting point	196°C (active)	Solubility in water	23 mg/mL (active) at 20°C
Odor	None	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:

Oral LD50 (rat): 2700 mg/kg

Oral LD50 (mouse): 695 mg/kg

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: Drug Enforcement Administration controlled substances must be destroyed following DEA Guidelines for witnessed destruction of the product beyond reclamation. 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: Zolpidem Tartrate  is a DEA Schedule IV controlled substance.

FDA: Zolpidem Tartrate  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

ABBREVIATIONS:

N/A – not applicable

Prepared by: Boehringer Ingelheim Roxane, Inc.

References:

1. Zolpidem Tartrate Tablets USP , Package Insert, Boehringer Ingelheim Roxane Laboratories, Inc. , Columbus, Ohio
2. RTECS No. NJ5109800 - Imidazo(1,2-a)pyridine-3-acetamide, N,N,6-trimethyl-2-(4-methylphenyl)-,(R-(R*,R*))-2,3-dihydroxybutanedioate (2:1)
3. Ariel Webinsight. Regulatory and ChemExpert Database.
4. PDR – Physicians Desk Reference

Date: 09/14/2008 - 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.