




<p align="center"><b>IN CASE OF EMERGENCY</b> Emergency Phone: (614) 276-4000</p>
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## Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Diazepam Oral Solution 		
Chemical Name: 2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-		
Synonyms: None		
Molecular Formula: C <sub>16</sub> H <sub>13</sub> ClN <sub>2</sub> O		
Molecular Weight: 284.74		
CAS No: 439-14-5		
Chemical Family: Benzodiazepines, Central Nervous System Agents		
Product Use: Management of anxiety disorders and short-term treatment of anxiety		
Manufacturer's Name: <b>Boehringer Ingelheim Roxane, Inc.</b>		
Address: 1809 Wilson Road Columbus, Ohio 43228		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Diazepam (active ingredient)	439-14-5	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. Orange-colored, wintergreen-spice flavored solution with 5 mg/5 mL active ingredient.  Odor: No data available  <b>WARNING!</b> May be harmful if swallowed. Accidental ingestion of large amounts may be fatal.	
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. Contact with eye may cause irritation, burning and redness.  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 drowsiness, fatigue and impaired coordination.	
Toxicity Data:	See Section 11	
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause drowsiness, confusion, impaired coordination, low blood pressure, coma and even death.	
Target Organs:	Brain, 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.				
<b>5. FIRE AND EXPLOSION HAZARDS</b>					
Flammability	Lower: N/A		Upper: N/A		
Flash Point	Not available				
Extinguishing Media	Use water spray, carbon dioxide, dry chemical, foam 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, hydrogen chloride				
<b>6. ACCIDENTAL RELEASE INFORMATION</b>					
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED: 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 15° to 30°C (59° to 86°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs. Discard opened bottle after 90 days.				
<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	Orange, liquid solution	Melting point	Not available	Solubility in water	Soluble
Odor	Not available	Boiling point	Not available	Specific Gravity	Not available
Taste	Wintergreen-spice	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	Strong bases, mineral acids, oxidizing agents
Hazardous Decomposition	Oxides of carbon, oxides of nitrogen, hydrogen chloride
Conditions to Avoid	Excessive heat and light
Hazardous Polymerization	Will not occur.

**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity:**

**Active Ingredient:**

LD50 Oral (rat): 249 mg/kg

LD50 Oral (rabbit): 328 mg/kg

LD50 Dermal (mouse): 800 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:** Diazepam  Oral Solution is a DEA Schedule IV controlled substance.

**FDA:** Diazepam  Oral Solution 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. Diazepam  Oral Solution, Package Insert, Boehringer Ingelheim Roxane Inc., Columbus, Ohio
2. RTECS No. DF1575000 for 2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-
3. Ariel Webinsight. Regulatory and ChemExpert Database.
4. PDR – Physicians Desk Reference

**Date:** 09/13/2008 - 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.*