



IN CASE OF EMERGENCY Emergency Phone: (614) 276-4000

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Fluconazole for Oral Suspension		
Chemical Name: 2,4-difluoro-alpha,alpha'-bis(1H-1,2,4-triazol-1-ylmethyl) benzyl alcohol		
Synonyms: None		
Molecular Formula: C ₁₃ H ₁₂ F ₂ N ₆ O		
Molecular Weight: 306.3		
CAS No: 86386-73-4		
Chemical Family: Synthetic triazole antifungal agents		
Product Use: Treatment of fungal infections		
Manufacturer's Name: Boehringer Ingelheim Roxane Inc.		
Address: 1809 Wilson Road Columbus, Ohio 43228		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Fluconazole (active ingredient)	86386-73-4	None established
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: White, powder used for oral suspension White, orange-flavored powder that provides 350 mg or 1400 mg doses of Fluconazole per bottle. Odor: None WARNING! 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 nausea, vomiting, diarrhea and other systemic effects.	
Toxicity Data:	See Section 11	
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause decreased motility and respiration, salivation, urinary incontinence, cyanosis, and loss of righting reflex.	
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	Move to fresh air and treat symptomatically. 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 available				
Extinguishing Media	Use water spray, carbon dioxide, dry chemical 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 fluoride				
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	Before Reconstitution: Store at 20° and 25°C (68° to 77°F). After Reconstitution: Store suspension at 5° to 25°C (41° to 77°F). Discard unused portion after 2 weeks. Protect from freezing. 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 containers. Good ventilation should be used. Ventilation should be matched to conditions.				
Respiratory Protection	Not required when handling 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				
9. PHYSICAL / CHEMICAL CHARACTERISTICS					
Appearance	White powder	Melting point	Not available	Solubility in water	Soluble
Odor	None	Boiling point	Not available	Specific Gravity	Not available
Taste	Orange	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	Oxidizing material
Hazardous Decomposition	Oxides of carbon, oxides of nitrogen, hydrogen fluoride
Conditions to Avoid	Excessive heat and light
Hazardous Polymerization	Will not occur.
11. TOXICOLOGICAL INFORMATION	
<p>Acute Toxicity:</p> <p>Active Ingredient: LD50 Oral (rat): 1271 mg/kg LD50 Oral (mouse): 1408 mg/kg</p> <p>Carcinogenicity: Not listed as a carcinogen by NTP, IARC Monographs or OSHA.</p>	
12. ENVIRONMENTAL IMPACT INFORMATION	
No information is currently available on the environmental impact of this product.	
13. DISPOSAL INFORMATION	
<p>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.</p>	
14. TRANSPORTATION INFORMATION	
<p>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</p>	
15. REGULATORY INFORMATION	
<p>DEA: Fluconazole is not a controlled substance.</p> <p>FDA: Fluconazole is an approved prescription medication.</p> <p>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.</p>	
16. OTHER DATA	
<p>ABBREVIATIONS: N/A – not applicable</p> <p>Prepared by: Boehringer Ingelheim Roxane Inc.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Fluconazole for Oral Suspension, Package Insert, Boehringer Ingelheim Roxane Inc., Columbus, Ohio 2. RTECS No. XZ4810000 for 1H-1,2,4-Triazole-1-ethanol, alpha-(2,4-difluorophenyl)-alpha-(1H-1,2,4-triazol-1-ylmethyl)- 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.