



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

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Dexamethasone Oral Solution		
Chemical Name: 9-Fluoro-11-beta,17,21-trihydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione		
Synonyms: None		
Molecular Formula: C ₂₂ H ₂₉ FO ₅		
Molecular Weight: 392.51		
CAS No: 50-02-2		
Chemical Family: Synthetic adrenocortical steroid		
Product Use: Treatment for various inflammatory and autoimmune conditions		
Manufacturer's Name: Boehringer Ingelheim Roxane Inc.		
Address: 1809 Wilson Road Columbus, Ohio 43228		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Dexamethasone (active ingredient)	50-02-2	None established
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: Liquid solution administered orally. Colorless liquid with a cherry-burgundy flavor with 0.5 mg/5 mL active ingredient. 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. 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, increased appetite and glucose intolerance.	
Toxicity Data:	See Section 11	
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause nausea, vomiting, increased appetite, fluid and sodium retention and glucose intolerance. Chronic side effects may include depression of adrenal gland function, increased possibility of severe infections (especially fungal), hypertension and osteoporosis.	
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, 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, hydrogen fluoride				
6. ACCIDENTAL RELEASE INFORMATION					
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.					
7. PRECAUTIONS FOR SAFE HANDLING AND USE					
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.				
8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT					
Exposure Limits	None				
Engineering Controls	Not required when handling liquid or containers. 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				
9. PHYSICAL / CHEMICAL CHARACTERISTICS					
Appearance	Colorless oral solution	Melting point	Not available	Solubility in water	Soluble
Odor	Not available	Boiling point	Not available	Specific Gravity	Not available
Taste	Cherry-burgundy	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, hydrogen fluoride
Conditions to Avoid	Excessive heat, light
Hazardous Polymerization	Will not occur.
11. TOXICOLOGICAL INFORMATION	
Acute Toxicity:	
Active Ingredient: LD50 Oral (rat): >3000 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: 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: Dexamethasone is not a controlled substance.	
FDA: Dexamethasone 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. Dexamethasone Oral Solution, Package Insert, Boehringer Ingelheim Roxane, Inc. , Columbus, Ohio 2. RTECS No. TU3980000 - Pregna-1,4-diene-3,20-dione, 9-fluoro-11-beta,17,21-trihydroxy-16-alpha-methyl- 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.