

Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Common/Trade Name: Digoxin Oral Solution

Chemical Name: 3beta-[0-2,6-dideoxy-beta-D-ribo-hexopyranosyl-(1-4)-0-2,6-dideoxy-beta-D-ribo-hexopyranosyl-(1-4)-2,6-dideoxy-beta-d-ribo-hexopyranosyl]oxy)-12beta,14-dihydroxy-5beta-card-20(22)-enolide

Synonyms: None

Molecular Formula: C41H64O14

Molecular Weight: 780.95 CAS No: 20830-75-5

Chemical Family: Cardiac glycosides

Product Use: Treatment of mild to moderate heart failure and chronic atrial fibrillation

Manufacturer's Name: Boehringer Ingelheim Roxane, Inc. 1809 Wilson Road Columbus, Ohio 43228

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition	CAS#	Exposure Limit
Digoxin (active Ingredient)	20830-75-5	None established
Alcohol, ethyl (10 % v/v)	64-17-5	ACGIH TLV-TWA: 1000 ppm OSHA-Z-1 PEL:1000 PPM

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

3. HAZARDS IDEN	ITIFICATION					
Emergency Overview	Physical State: Liquid solution administered orally Colorless, lime flavored solution with 0.05 mg/mL active ingredient Odor: Slight WARNING! Accidental ingestion amounts may be harmful					
Primary Route(s) of Entry	Ingestion					
Potential Health Effects:	 Inhalation: Not expected to be a hazard to the eye. Contact with the 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, 					
	dizziness and weakness.					
Toxicity Data:	See Section 11					
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause changes in vision, loss of appetite, ventricular fibrillation, heart block, renal impairment and irregular heartbeat.					
Target Organs:	Heart					
4. FIRST AID MEA	SURES					
Eye Exposure	sure 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 occur.					
Skin Exposure	Exposure Wash with soap and water. Get medical attention if symptoms occur.					

Ingestion	Call a phys	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				
innaidtion		medical attention immediately.				
5. FIRE AND EXPL	OSION HA	ZARDS				
Flammability		Lower: N/A Upper: N/A				
Flash Point		134 degrees F closed cup				
Extinguishing Media		Use water spray, dry chemical, carbon dioxide, foam or material appropriate for fire in surrounding area				
Special Fire Fighting		Wear full protective clothing and self-contained breathing apparatus. Use water				
Procedures		spray to keep fire-exposed containers cool.				
Unusual Fire/Explosion						
Hazards		For significant quantities of product: Combustible. Prevent build-up of vapors or gases to explosive concentrations.				
Hazardous Combusti Products	on	Carbon dioxide, carbon monoxide				
6. ACCIDENTAL R	ELEASE IN	IFORMATION				
Use appropriate pers	onal protect	CANT QUANTITIES OF LIQUID IS SPILLED: tive equipment (see Section 8). Eliminate ignition sources. Wipe up and containerize				
spill material in a con approved facility is re		tainer. Dispose according to applicable regulations. Incineration the waste at an d.				
7. PRECAUTIONS	FOR SAFE	HANDLING AND USE				
Precautions	Observe	good industrial hygiene practices.				
Handling Significant Quantities of broken						
tablets:						
Storage		Store at 15 to 30 degrees C(59 TO 86 degrees F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.				
8. CONTROL MEASU		PERSONAL PROTECTIVE EQUIPMENT				
Exposure Limits	NONE					
Engineering Controls		Not require when handling liquid or containers. Good ventilation should be used. Ventilaion should be matched to conditions.				
Respiratory Protection	Not requ	ired when handling liquid or containers.				
Personal Protection		Not required when handling final product. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves				
Recommended		h, washing facilities				
Facilities						

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3. Ariel Webinsight. Regulatory and ChemExpert Database.	2. ΚΙΕΟ 3. Δτίρι	Webinsight Regi	Ilatory and Chem	Expert Database				

4. PDR – Physicians Desk Reference

Date: Updated: 01/6/2014

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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.