

SAFETY DATA SHEETS

This SDS packet was issued with item:

078342777

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078930579



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

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Digoxin Oral Solution		
Chemical Name: 3 β -[O-2,6-dideoxy- β -D-ribo-hexopyranosyl-(1 \rightarrow 4)-O-2, 6-dideoxy- β -D-ribo-hexopyranosyl-(1 \rightarrow 4)-2, 6-dideoxy- β -D-ribo-hexopyranosyl]oxy]-12 β , 14-dihydroxy-5 β -card-20(22)-enolide		
Synonyms: None		
Molecular Formula: C ₄₁ H ₆₄ O ₁₄		
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.		
Address: 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	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 IDENTIFICATION		
Emergency Overview	Physical State: Liquid solution administered orally. Colorless, lime flavored solution with 0.05 mg/mL active ingredient. Odor: Slight 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, 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 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	N/A		
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. Use water 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 Combustion Products	Carbon dioxide, carbon monoxide		
6. ACCIDENTAL RELEASE INFORMATION			
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED: Use appropriate personal protective equipment (see Section 8). Eliminate ignition sources. 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 15° to 30°C (59° to 86°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. 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		
9. PHYSICAL / CHEMICAL CHARACTERISTICS			

Appearance	Colorless liquid solution	Melting point	Not available	Solubility in water	Soluble
Odor	Slight	Boiling point	Not available	Specific Gravity	Not available
Taste	Lime	Vapor Pressure	Not available	Flashpoint	
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				
Conditions to Avoid	Excessive heat, light				
Hazardous Polymerization	Will not occur.				
11. TOXICOLOGICAL INFORMATION					
Acute Toxicity:					
Active Ingredient:					
LD50 Oral (rat): 28.27 mg/kg					
LD50 Oral (mouse): 17.78 mg/kg					
Carcinogenicity: Not listed as a carcinogen or potential 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					
DOT: Limited Quantity of liquids and solids containing ethyl alcohol are exempt from provisions of 49CR by DOT granting Special Permit DOT-SP-9275					
TDG: Not Regulated					
IATA: : Limited Quantity of liquids and solids containing ethyl alcohol are exempt from provisions of 49CR by DOT granting Special Permit DOT-SP-9275					
IMDG: Not Regulated					
15. REGULATORY INFORMATION					
DEA: Digoxin is not a controlled substance.					
FDA: Digoxin 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. Digoxin Oral Solution, Package Insert, Boehringer Ingelheim Roxane, Inc. , Columbus, Ohio					
2. RTECS No. IH6125000 - Digoxin					

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| 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.



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

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: C ₄₁ H ₆₄ O ₁₄		
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 IDENTIFICATION		
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 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 occur.	
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	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 Procedures	Wear full protective clothing and self-contained breathing apparatus. Use water 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 Combustion Products	Carbon dioxide, carbon monoxide
6. ACCIDENTAL RELEASE INFORMATION	
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED: Use appropriate personal protective equipment (see Section 8). Eliminate ignition sources. Wipe up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration the waste at an approved facility is recommended.	
7. PRECAUTIONS FOR SAFE HANDLING AND USE	
Precautions Handling Significant Quantities of broken tablets:	Observe good industrial hygiene practices.
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 MEASURES AND 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 required 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 Facilities	Eye wash, washing facilities

9. PHYSICAL / CHEMICAL CHARACTERISTICS					
Appearance	Colorless liquid solution	Melting point	Not available	Solubility in water	Soluble
Odor	Slight	Boiling point	Not available	Specific Gravity	Not available
Taste	Lime	Vapor Pressure	Not available	Flashpoint	134 degrees F
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				
Conditions to Avoid	Excessive heat, light				
Hazardous Polymerization	Will not occur				
11. TOXICOLOGICAL INFORMATION					
Acute Toxicity:					
Active Ingredient:					
LD50 Oral (RAT): 28.27 mg/kg					
LD50 Oral (mouse): 17.78 mg/kg					
Carcinogenicity: Not listed as a carcinogen or potential 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					
DOT: Consult 49CFR					
IATA: Consult current version of IATA regulations					
IMDG: Consult current version of IMO					
15. REGULATORY INFORMATION					
DEA: Digoxin is not a controlled substance					
FDA: Digoxin 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. Digoxin Oral Solution,, Package Insert, Boehringer Ingelheim Roxane, Inc. , Columbus, Ohio					
2. RTECS No. IH612500 - Digoxin					
3. Ariel Webinsight. Regulatory and ChemExpert Database.					

4. PDR – Physicians Desk Reference

Date: Updated: 01/6/2014

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION

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