



**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 <sub>41</sub> H <sub>64</sub> O <sub>14</sub>   |   |  |
| 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   |   |  |
| <b>Manufacturer's Name: Boehringer Ingelheim Roxane, Inc.</b><br><b>1809 Wilson Road</b><br><b>Columbus, Ohio 43228</b>  |   |  |
| 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<br>OSHA-Z-1 PEL:1000 PPM |
| <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<br>Colorless, lime flavored solution with 0.05 mg/mL active ingredient<br>Odor: Slight<br><b>WARNING!</b><br>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.<br><br>Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.<br><br>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.<br>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.                  |
| <b>5. FIRE AND EXPLOSION HAZARDS</b>  |   |
| 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   |
| <b>6. ACCIDENTAL RELEASE INFORMATION</b>  |   |
| <b>STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED:</b><br>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. |   |
| <b>7. PRECAUTIONS FOR SAFE HANDLING AND USE</b>   |   |
| 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. |
| <b>8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT</b>  |   |
| 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.<br>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.<br>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**

*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.*