

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078930579

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

078342777

# SAFETY DATA SHEET

## 1. Identification

**Product identifier** Digoxin Oral Solution USP  
**Other means of identification** None.  
**Recommended use** Treatment of mild to moderate heart failure  
**Recommended restrictions** None known.  
**Manufacturer/Importer/Supplier/Distributor information**  
**Company name** Boehringer Ingelheim Roxane Inc.  
**Address** 1809 Wilson Road  
 Columbus, Ohio 43228  
**Telephone** (614) 276-4000  
**Emergency phone number** (614) 276-4000

## 2. Hazard(s) identification

**Physical hazards** Not classified.  
**Health hazards** Carcinogenicity Category 2  
**OSHA defined hazards** Not classified.  
**Label elements**



**Signal word** Warning

**Hazard statement** This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Suspected of causing cancer.

### Precautionary statement

**Prevention** Observe good industrial hygiene practices. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** Wash hands after handling. If exposed or concerned: Get medical advice/attention.

**Storage** Store away from incompatible materials. Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). Protect from light. Store locked up.

**Disposal** Incineration of waste at an approved USEPA incinerator is recommended.

**Hazard(s) not otherwise classified (HNOC)** None known.

## 3. Composition/information on ingredients

### Substances

Chemical name	Common name and synonyms	CAS number	%
Digoxin		20830-75-5	0.05 mg/mL

**Composition comments** Refer to Physician's Desk Reference for common components present at <1%

## 4. First-aid measures

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact** Wash off with soap and water. Get medical attention if irritation develops and persists.

**Eye contact** Rinse with water. Get medical attention if irritation develops and persists.

<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Product has been associated with abdominal pain, intestinal ischemia, and hemorrhagic necrosis of the intestines. Symptoms include nausea, vomiting, and diarrhea.
<b>Indication of immediate medical attention and special treatment needed</b>	Patients who have intentionally or accidentally ingested massive doses should receive activated charcoal orally or by nasogastric tube.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).
<b>Methods and materials for containment and cleaning up</b>	Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.
<b>Conditions for safe storage, including any incompatibilities</b>	Store away from incompatible materials (see Section 10 of the SDS). Protect from light. Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F).

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Ventilation should be matched to conditions.

### Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.
<b>Skin protection</b>	
<b>Hand protection</b>	For consumer use, no unusual precautions are necessary.
<b>Other</b>	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

**Respiratory protection** None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

**Appearance** Clear, colorless solution.

**Physical state** Liquid.

**Form** Liquid.

**Color** Clear colorless.

**Odor** Not available.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Explosive limit - lower (%)** Not available.

**Explosive limit - upper (%)** Not available.

**Vapor pressure** Not available.

**Vapor density** Not available.

**Relative density** Not available.

**Relative density temperature** estimated

**Solubility(ies)**

**Solubility (water)** Insoluble

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

## 10. Stability and reactivity

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Contact with incompatible materials. Exposure to light.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** Not expected to be hazardous in final pharmaceutical form.  
**Skin contact** Not expected to be hazardous in final pharmaceutical form.  
**Eye contact** Not expected to be hazardous in final pharmaceutical form. Direct contact with eyes may cause temporary irritation.  
**Ingestion** Ingestion may cause irritation and malaise.

**Symptoms related to the physical, chemical and toxicological characteristics** Product has been associated with abdominal pain, intestinal ischemia, and hemorrhagic necrosis of the intestines. Symptoms also include nausea, vomiting, and diarrhea.

### Information on toxicological effects

**Acute toxicity** May be harmful if swallowed in large quantities.  
**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.  
**Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation.  
**Respiratory or skin sensitization**  
**Respiratory sensitization** Not a respiratory sensitizer.  
**Skin sensitization** Rash and other skin reactions have been observed.  
**Germ cell mutagenicity** No mutagenicity studies have been conducted  
**Carcinogenicity** Suspected of causing cancer. In finished product form, risk of occupational exposure is expected to be limited.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Digoxin (CAS 20830-75-5) 2B Possibly carcinogenic to humans.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

**Reproductive toxicity** Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women.  
There should be no pharmacologic effect upon the infant, nevertheless, caution should be exercised when administered to a nursing woman.

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - repeated exposure** Not classified.

**Aspiration hazard** Not classified.

**Further information** See package insert.

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

#### Partition coefficient n-octanol / water (log Kow)

Digoxin (CAS 20830-75-5) 1.26

**Mobility in soil** No data available.

**Other adverse effects** None.

## 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging**

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. Transport information****DOT**

Not regulated as dangerous goods.

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

**15. Regulatory information****US federal regulations**

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.

OSHA GHS: GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****Hazard categories**

Immediate Hazard - No  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Chemical name	CAS number	Reportable quantity	Threshold planning quantity	Threshold planning quantity, lower value	Threshold planning quantity, upper value
Digoxin	20830-75-5	10		10 lbs	10000 lbs

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations**

Drug Enforcement Administration (DEA): Digoxin is not a controlled substance.

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

Not listed.

**US state regulations****US. Massachusetts RTK - Substance List**

Digoxin (CAS 20830-75-5)

**US. New Jersey Worker and Community Right-to-Know Act**

Digoxin (CAS 20830-75-5)

**US. Pennsylvania Worker and Community Right-to-Know Law**

Digoxin (CAS 20830-75-5)

**US. Rhode Island RTK**

Digoxin (CAS 20830-75-5)

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

<b>Issue date</b>	05-December-2014
<b>Revision date</b>	-
<b>Version #</b>	01
<b>References</b>	1) Digoxin Oral Solution USP, Package Insert, Roxane Laboratories, Inc. , Columbus, Ohio 2) PDR – Physicians Desk Reference. 3) Ariel Webinsight. Regulatory and ChemExpert Database.

**Disclaimer** Boehringer Ingelheim Roxane Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.