MATERIAL SAFETY DATA SHEET

Product Name: Digoxin Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency 224-212-2000

Product Name
Digoxin Injection, USP

Synonyms
(3β, 5β, 12β)-3-[(0-2,6-dideoxy-β-D-ribo-hexopyranosyl-(1→4)-2,6-dideoxy-β-D-ribo-hexopyranosyl-(1→4)-2,6-dideoxy-β-D-ribo-hexopyranosyl)oxy]-12,14-dihydroxy-card-20(22)-enolide.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Digoxin

Chemical Formula
C_{41}H_{64}O_{14}

Preparation
Non-hazardous ingredients include Water for Injection (>49%). Hazardous ingredients present at less than 1% include sodium phosphate and citric acid which are added as buffers to adjust the pH.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin</td>
<td>0.025</td>
<td>20830-75-5</td>
<td>IH6125000</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>40</td>
<td>57-55-6</td>
<td>TY2000000</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>10</td>
<td>64-17-5</td>
<td>KQ6300000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Digoxin Injection, USP, contains digoxin, a cardiac glycoside used for treatment of heart failure, atrial flutter, atrial fibrillation and paroxysmal atrial tachycardia. In the workplace, this material should be considered a potent drug, potentially irritating to the eyes and respiratory tract, and harmful by ingestion and by skin absorption. Inadvertent over-exposure can lead to cardiotoxicity including cardiac arrest. Based on clinical use, possible target organs include the heart, kidneys, nervous system, liver, testes, and eyes.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. However, limited information suggests that digoxin may be absorbed through the skin. Avoid
### Product Name: Digoxin Injection, USP

Liquid aerosol generation and skin contact.

#### Signs and Symptoms

No signs or symptoms from occupational exposure are known. In clinical use, side effects include tachycardia, nausea, vomiting, anorexia, diarrhea, facial pain, blurred vision, altered color vision, headaches, hypokalemia and weakness. Use can also result in cardiac arrest. Direct contact with the eyes could result in irritation.

#### Medical Conditions Aggravated by Exposure

Data suggest hypersensitivity to cardiac glycosides. Prescription medications for heart conditions and certain antibiotics, corticosteroids and sympathomimetics. Pre-existing renal, ocular, gastrointestinal ailments, skin and hematopoietic system.

### 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
</tbody>
</table>

#### Notes to Physician:

Severe digitalis intoxication can cause a massive shift of potassium from inside to outside the cell, leading to life-threatening hyperkalemia. The administration of potassium supplements in the setting of massive intoxication may be hazardous and should be avoided. Hyperkalemia caused by massive digitalis toxicity is best treated with DIGIBIND; initial treatment with glucose and insulin may also be required if hyperkalemia itself is acutely life-threatening.

Massive Digitalis Overdosage: Manifestations of life-threatening toxicity include ventricular tachycardia or ventricular fibrillation, or progressive bradyarrhythmias, or heart block. The administration of more than 10 mg of digoxin in a previously healthy adult, or more than 4 mg in a previously healthy child, or a steady-state serum concentration greater than 10 ng/mL often results in cardiac arrest. DIGIBIND should be used to reverse the toxic effects of ingestion of a massive overdose. The decision to administer DIGIBIND to a patient who has ingested a massive dose of digoxin but who has not yet manifested life-threatening toxicity should depend on the likelihood that life-threatening toxicity will occur (see above).

DIGIBIND to a patient who has ingested a massive dose of digoxin but who has not yet manifested life-threatening toxicity should depend on the likelihood that life-threatening toxicity will occur (see above).

Patients with massive digitalis ingestion should receive large doses of activated charcoal to prevent absorption and bind digoxin in the gut during enteroenteric recirculation. Emesis or gastric lavage may be indicated especially if ingestion has occurred within 30 minutes of the patient’s presentation at the hospital. Emesis should not be induced in patients who are obtunded. If a patient presents more than 2 hours after ingestion or already has toxic manifestations, it may be unsafe to induce vomiting or attempt passage of a gastric tube, because such maneuvers may induce an acute vagal episode that can worsen digitalis-related arrhythmias.
If a rhythm disturbance is a symptomatic bradyarrhythmia or heart block, consideration should be given to the reversal of toxicity with DIGIBIND® [Digoxin Immune Fab (Ovine)]; the use of atropine, or the insertion of a temporary cardiac pacemaker. However, asymptomatic bradycardia or heart block related to digoxin may require only temporary withdrawal of the drug and cardiac monitoring of the patient.

If the rhythm disturbance is a ventricular arrhythmia, consideration should be given to the correction of electrolyte disorders, particularly if hypokalemia (see below) or hypomagnesemia is present. DIGIBIND is a specific antidote for digoxin and may be used to reverse potentially life-threatening ventricular arrhythmias due to digoxin overdosage.

Administration of Potassium: Every effort should be made to maintain the serum potassium concentration between 4 and 5.5 mmol/L. Potassium is usually administered orally, but when correction of the arrhythmia is urgent and the serum potassium concentration is low, potassium may be administered cautiously by the intravenous route. The electrocardiogram should be monitored for any evidence of potassium toxicity (e.g., peaking of T waves) and to observe the effect on the arrhythmia. Potassium salts may be dangerous in patients who manifest bradycardia or heart block due to digoxin (unless primarily related to supraventricular tachycardia) and in the setting of massive digitalis overdosage.

5. FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Flashpoint: 51.7°C (125°F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fire &amp; Explosion Hazard</td>
<td>Combustible Liquid. Keep away from flames, sparks, or other sources of ignition.</td>
</tr>
<tr>
<td>Extinguishing media</td>
<td>As with any fire, use extinguishing media appropriate for primary cause of fire.</td>
</tr>
<tr>
<td>Special Fire Fighting Procedures</td>
<td>No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.</td>
</tr>
</tbody>
</table>

6. ACCIDENTAL RELEASE MEASURES

| Spill Cleanup and Disposal | Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Isolate any sources of ignition away from the spill. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations. |

7. HANDLING AND STORAGE

| Handling | No special handling required under conditions of normal product use. |
| Storage | No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert. |
| Special Precautions | No special precautions required for hazard control. |
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>ACGIH 8 Hr TLV</td>
<td>mg/m3 ppm µg/m3</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>US OSHA 8 Hr PEL</td>
<td>N/A</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>Australia NOHSC</td>
<td>N/A</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>AIHA WEEL</td>
<td>10 N/A</td>
</tr>
<tr>
<td>Digoxin</td>
<td>Hospira EEL</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Respiratory protection
Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection
If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection
Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls
Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State: Liquid
Color: Clear, colorless aqueous based solution
Odor: None
Odor Threshold: NA
pH: 6.8 to 7.2
Melting point/Freezing point: NA
Initial Boiling Point/Boiling Point Range: NA
Evaporation Rate: NA
Flammability (solid, gas): Combustible
Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: NA
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA
Product Name: Digoxin Injection, USP

10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Strong oxidizers, acids.

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx).

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>28.3</td>
<td>mg/kg</td>
<td>Rat, Mouse, Guinea Pig</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>17.8</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.5</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td>Digoxin</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>25</td>
<td>mg/kg</td>
<td>Rat, Mouse, Rabbit</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7.7</td>
<td>mg/kg</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.6</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>10,400 - 29,536</td>
<td>mg/kg</td>
<td>Rat, Mouse, Rabbit, Dog, Guinea Pig</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>20,800</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>3450 - 11,500</td>
<td>mg/kg</td>
<td>Guinea Pig, Rat, Mouse, Dog</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LC50 (10h)</td>
<td>Inhalation</td>
<td>20,000</td>
<td>ppm</td>
<td>Rat</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LC50 (4h)</td>
<td>Inhalation</td>
<td>39,000</td>
<td>mg/m3</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product. However, inadvertent inhalation of the product aerosol may produce respiratory irritation.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. Ethanol may produce mild skin irritation with redness and dryness.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation. Exposure to ethanol has produced severe eye irritation in studies in animals.
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Dermal or Respiratory Sensitization

None anticipated from normal handling of this product.

Reproductive Effects

Animal reproduction studies have not been conducted with digoxin to assess its potential to affect fertility. Ethanol has been shown to produce fetotoxicity in the embryo or fetus of laboratory animals. Chronic prenatal exposure to ethanol has been associated with a distinct pattern of congenital malformations that have collectively been termed the "fetal alcohol syndrome".

Mutagenicity

No studies been conducted to assess the mutagenic potential of digoxin.

Carcinogenicity

There have been no long-term studies performed in animals to evaluate carcinogenic potential of digoxin.

Target Organ Effects

Based on clinical use, possible target organs include the heart, kidneys, nervous system, liver, testes, and eyes.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Not determined for the product. Information for ingredients is provided below:

LC50 (24 hr) = 12,900 - 15,300 mg/L in rainbow trout for ethanol
LC50 (24 hr) = 11,200 mg/L in fingerling trout for ethanol
LC50 (48 hr) = 9,268 - 14,221 mg/L in Daphnia magna for ethanol
EC50 = 9310 mg/L in Chlorella pyrenoidosa (green algae) for ethanol

LC50 (96 hr) = 51,600 mg/L in rainbow trout for propylene glycol
LC50 (48 hr) = 34,400 - 43,500 mg/L in Daphnia magna for propylene glycol
EC50 (14 day) = 19,000 mg/L in algae for propylene glycol

Persistence/Biodegradability

Not determined for the product. Information for ingredients is provided below: Ethanol was reported to be degraded between 45% and 74% in five days in two aqueous biodegradation assays. Propylene glycol was reported to be 100% biodegradable after 24-hours in activated sludge.

Bioaccumulation

Not determined for the product. Information for ingredients is provided below: Because of its low octanol : water partition coefficient, ethanol is not anticipated to bioaccumulate.

Mobility in Soil

Not determined.

13. DISPOSAL CONSIDERATIONS

Waste Disposal

Disposal should be performed in accordance with the federal, state or local regulatory requirements. Product classified as hazardous waste (D001) based on flashpoint testing.

Container Handling and Disposal

Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION
Product Name: Digoxin Injection, USP

ADR/ADG/ DOT STATUS: Not regulated
IMDG STATUS: Not regulated
ICAO/IATA STATUS: Not regulated
Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Listed</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

RCRA Status: Classified as D001 hazardous waste based on ignitability.

U.S. OSHA Classification
- Target Organ Toxin
- Possible Irritant
- Combustible Liquid

GHS Classification
- *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:
- Hazard Class: Not Applicable
- Hazard Category: Not Applicable
- Signal Word: Not Applicable
- Symbol: Not Applicable
- Prevention: P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
- Hazard Statement: Not Applicable
- Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.
- Get medical attention if you feel unwell.

EU Classification*
- *Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Digoxin
  - Classification(s): Not Applicable
  - Symbol: Not Applicable
  - Indication of Danger: Not Applicable
**Product Name:** Digoxin Injection, USP

**Risk Phrases:**  
R00 - Not Applicable

**Safety Phrases:**  
S23 - Do not breathe vapor.  
S24/25 - Avoid contact with skin and eyes.  
S37/39 - Wear suitable gloves and eye/face protection.

### 16. OTHER INFORMATION:

**Notes:**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
<td>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
</tr>
<tr>
<td>EEL</td>
<td>Employee Exposure Limit</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>LD50</td>
<td>Dosage producing 50% mortality</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable/Not available</td>
</tr>
<tr>
<td>NE</td>
<td>Not established</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
</tr>
<tr>
<td>Prop 65</td>
<td>California Proposition 65</td>
</tr>
<tr>
<td>RCRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
</tr>
<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
</tr>
</tbody>
</table>

**MSDS Coordinator:** Hospira GEHS  
**Date Prepared:** 09/15/2011  
**Obsolete Date:** 07/10/2008

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