

SAFETY DATA SHEET



Product Name: Digoxin Injection, USP

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	Digoxin Injection, USP
Synonyms	(3 β , 5 β , 12 β)-3-[(0-2,6-dideoxy- β -D-ribo-hexopyranosyl-(1 \rightarrow 4)-0-2,6-dideoxy- β -D-ribo-hexopyranosyl-(1 \rightarrow 4)-2,6-dideoxy- β -D-ribo-hexopyranosyl)oxy]-12,14-dihydroxy-card-20(22)-enolide.

2. HAZARD(S) IDENTIFICATION

Emergency Overview Digoxin Injection, USP, is a solution containing 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 flammable liquid, a potent drug, potentially irritating to the eyes and respiratory tract, and potentially harmful by ingestion. 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.

U.S. OSHA GHS Classification

Physical Hazards	Hazard Class	Hazard Category
	Flammable Liquid	3
Health Hazards	Hazard Class	Hazard Category
	Eye Damage/Irritation	2A
	STOT - RE	2

Label Element(s)

Pictogram



Signal Word

Warning

Hazard Statement(s)

Flammable liquid and vapor
Causes serious eye irritation
May cause damage to organs through prolonged or repeated exposure

2. HAZARD(S) IDENTIFICATION: continued

Precautionary Statement(s)

Prevention

Keep away from heat/sparks/open flames/hot surfaces.– No smoking
 Keep container tightly closed
 Ground/bond container and receiving equipment
 Use explosion-proof equipment
 Use only non-sparking tools
 Take precautionary measures against static discharge
 Do not breathe vapor or spray
 Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.

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.

IF ON SKIN (OR HAIR): Take off immediately all contaminated clothing. Rinse skin with water/shower.

IN CASE OF FIRE: For small fires, use water fog or fire extinguishing media suitable for Class B fires (e.g. dry chemical, carbon dioxide or foam). For large fires, apply water from as far away as possible; use very large quantities of water applied as a mist or spray.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name	Digoxin	Propylene Glycol	Ethyl Alcohol
Chemical Formula	C ₄₁ H ₆₄ O ₁₄	C ₃ H ₈ O ₂	C ₂ H ₆ O

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Digoxin	0.025	20830-75-5	IH6125000
Propylene Glycol	40	57-55-6	TY2000000
Ethyl Alcohol	≤ 10	64-17-5	KQ6300000

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.

4. FIRST AID MEASURES

Eye Contact

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.

Skin Contact

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.

Inhalation

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

4. FIRST AID MEASURES: continued

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary

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).

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

Flammability Flashpoint: 51.7°C (125°F)

Fire & Explosion Hazard GHS Flammable Liquid - Category 3. Keep away from flames, sparks, or other sources of ignition. When heated, product may produce combustible vapors due to the alcohol content.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control 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 for hazard control 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

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Digoxin	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: Not Established	8 hr TWA: Not Established
Propylene Glycol	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: 10 mg/m3	8 hr TWA: Not Established
Ethyl Alcohol	8 hr TWA: 1000 ppm; 1900 mg/m3	8 hr TWA: 1000 ppm	8-hr TWA: Not Established	8 hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 AIHA WEEL: Workplace Environmental Exposure Level
 EEL: Employee Exposure Limit.
 TWA: 8 hour Time Weighted Average.

Respiratory Protection Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols or vapors 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) with an organic vapor cartridge 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	Clear colorless aqueous-based solution in a syringe.
Odor	NA
Odor Threshold	NA
pH	6.8 to 7.2
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	51.7°C (125°F)
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	NA
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

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:

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

LD 50: Dosage that produces 50% mortality. LC50: Air concentration that produces 50% mortality.

11. TOXICOLOGICAL INFORMATION: continued

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 liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. 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.
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.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product.
Reproductive Effects	None anticipated from normal handling of this product. 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.
Carcinogen Lists	IARC: Not listed NTP: Not listed OSHA: Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	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 for product.

Notes:

1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EC50: Concentration in water that produces 50% inhibition of growth in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements. Product classified as D001 hazardous waste based on ignitability.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt. However, digoxin is listed on the TSCA inventory.
US CERCLA Status	Not listed
US SARA 302 Status	The Threshold Planning Quantity (TPQ) is 10/10,000 lbs.
US SARA 304 Status	The Reportable Quantity (RQ) is 10 lbs.
US SARA 313 Status	Not listed
US RCRA Status	Product classified as D001 hazardous waste based on ignitability.
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

15. REGULATORY INFORMATION: continued

GHS/CLP 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	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Keep away from heat/sparks/open flames/hot surfaces.– No smoking
 Keep container tightly closed
 Ground/bond container and receiving equipment
 Use explosion-proof equipment
 Use only non-sparking tools
 Take precautionary measures against static discharge
 Do not breathe vapor or spray
 Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.
 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.
 IF ON SKIN (OR HAIR): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 IN CASE OF FIRE: For small fires, use water fog or fire extinguishing media suitable for Class B fires (e.g. dry chemical, carbon dioxide or foam). For large fires, apply water from as far away as possible; use very large quantities of water applied as a mist or spray.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s)
Symbol
Indication of Danger
Risk Phrases
Safety Phrases

NA
 NA
 NA
 NA
 S23: Do not breathe vapor/spray
 S24: Avoid contact with the skin
 S25: Avoid contact with eyes
 S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

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

MSDS Coordinator: Hospira GEHS
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Disclaimer:

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