



Material Safety Data Sheet

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Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

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DIGITOXIN

Catalog Number: 1199002

Revision Date:

November 14, 2008

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Digitoxin

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW: Poison. Irritant.

Adverse Effects: Adverse effects on the heart may include slow and/or irregular heartbeat, palpitations, and fainting. Other adverse effects may include anxiety, apathy, blurred or yellow vision, breast enlargement in men, confusion, dizziness, hallucinations, headache, mental depression, weakness, abdominal pain, loss of appetite, diarrhea, nausea, and vomiting. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Overdose effects are similar to adverse effects at therapeutic or high doses, except in cases of massive overdose. Effects of massive overdose may include progressive irregularity and slowing of the heartbeat and cardiac arrest. The estimated lethal dose of digitoxin is 3 to 10 mg.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization and enlargement of breast tissue in males.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, heart problems (or history of), severe lung disease, impaired liver or kidney function, metabolic disorders, and electrolyte imbalance (especially hypercalcemia, hypocalcemia, hypokalemia, and hypomagnesemia).

Cross Sensitivity: Persons sensitive to other cardiac glycosides may be sensitive to this material also.

Target Organs: Heart

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

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Common Name: Digitoxin

Formula: C₄₁H₆₄O₁₃

Synonym: Digitoxoside

Chemical Name: Card-20(22)-enolide, 3-[(O-2,6-dideoxy-beta-D-ribo-hexopyranosyl-(1 to 4)-O-2,6-dideoxy-beta-D-ribo-hexopyranosyl-(1 to 4)-2,6-dideoxy-beta-D-ribo-hexopyranosyl)oxy]-14-hydroxy, (3beta,5beta)-

CAS: 71-63-6

RTECS Number: IH2275000

Chemical Family: Cardenolide

Therapeutic Category: Cardiotonic

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation and possibly life-threatening effects. Avoid inhalation. Remove to fresh air.

Eye: Causes irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

Skin: May cause irritation and possibly life-threatening effects. Avoid contact. Flush with copious quantities of soap and water.

Ingestion: May cause irritation, possibly life-threatening effects, and bitter taste. Avoid ingestion. Flush out mouth with water. This material is readily and completely absorbed from the gastrointestinal tract. Effects begin in 30 minutes to 4 hours with peak effect at 12 hours. Duration of action is 2 to 3 weeks.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Overdose treatment should be symptomatic and supportive and may include the following:

1. For massive (acute) overdose: Emesis is generally NOT recommended EXCEPT prior to presentation at the hospital. Gastric lavage may be used only if ingestion occurred within 1 hour, but should not be used in patients who are obtunded or exhibit toxic symptoms. Emesis or gastric lavage also is NOT recommended in patients with underlying heart disease or arrhythmias because it may provoke arrhythmias by augmenting vagal tone.
2. Previous adjunctive treatments in the management of non-life threatening digitalis intoxication, such as repetitive doses of activated charcoal, cholestyramine, and/or colestipol have not been shown to be clinically effective. Previous strategies for treatment of hyperkalemia and ventricular arrhythmias have been replaced by more clinically safe and effective treatment with Fab antibody fragments. Digoxin immune Fab is NOT recommended for mild digitalis toxicity.
3. For symptomatic sinus bradycardia or AV block: administer atropine and/or digoxin immune Fab. Cardiac pacing has been associated with complications and is only recommended if digoxin immune Fab therapy is unsuccessful.
4. For ventricular arrhythmias: correct electrolyte disorders (especially potassium and magnesium); administer digoxin immune Fab.
5. For hypokalemia: in cases of low or normal serum potassium concentrations, administration of potassium may help to antagonize the digitalis toxic effects; however, because severe digitalis intoxication can cause a redistribution of potassium from inside to outside the cell, resulting in hyperkalemia, administration of potassium may be dangerous in cases of massive overdose.
6. For hyperkalemia: In cases of high serum potassium concentrations, further increases in serum potassium may result in complete AV block or cardiac arrest. If potassium concentrations exceed 5 mgEq per L, digoxin immune Fab should be used.
7. Constant electrocardiogram monitoring is recommended to guide therapy and to monitor for potassium toxicity (T-wave peaking) during administration of potassium.
8. Subtle signs or symptoms of digitalis toxicity should be managed by identifying and correcting other factors that contribute to toxic effects (such as electrolyte disturbances or drug interactions). [USP DI 2003]

SECTION 5 - FIREFIGHTING MEASURES

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Extinguisher Media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site. Digitoxin has been shown to be absorbed onto glass and plastic in substantial amounts from simple aqueous solutions.

SECTION 7 - HANDLING AND STORAGE

Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety goggles or glasses

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White or pale buff, microcrystalline powder; odorless.

Odor Threshold: n/f

pH: n/f

Melting Range: 240 - 270° C

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Practically insoluble

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Fat Solubility: n/f**Other Solubility:** Freely soluble in mixture of equal volumes of methanol and methylene chloride; slightly soluble in alcohol and in methanol; sparingly soluble in chloroform; very slightly soluble in ether.**Partition Coefficient: n-octanol/water:** 1.85**Percent Volatile:** n/f**Reactivity in Water:** n/f**Explosive Properties:** n/f**Oxidizing Properties:** n/f**Formula:** C₄₁H₆₄O₁₃**Molecular Weight:** 764.94

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SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: n/f

Incompatibilities: Strong oxidizing agents and strong acids.

Decomposition Products: When heated to decomposition, material emits acrid smoke and irritating fumes. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 23750 micrograms/kg (23.75 mg/kg)

Oral Mouse: LD50: 4950 micrograms/kg (4.95 mg/kg)

Other Toxicity Data: n/f

Irritancy Data: Dog/eye: irritant

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: No

Mutagenicity Data: n/f

Reproductive and Developmental Effects: Therapeutic use of digitoxin during the first trimester of pregnancy has not been associated with adverse effects in pregnancy. Low birth-weight has been observed in infants of mothers receiving digitalis glycosides.
Studies using rats and rabbits did not show digoxin to induce birth defects.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: Very toxic to aquatic organisms.
Very toxic to mammals.
Fish LC50: 0.59 mg/L/96 h

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State, and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: Toxic, solid, organic, n.o.s. (Digitoxin)

Class: 6.1

UN Number: UN2811

Packing Group: II

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: EINECS#: 200-760-5
Hazard code: T
Risk phrases: R23/25, R33

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SECTION 16 - OTHER INFORMATION

Revision: 14-Nov-08**Previous Revision Date:** 05-Sep-03