

Section 1: Identification

Product Name	Digoxin Micronized USP	
Commercial Name	N/A	
Product Use	N/A	
Restrictions On Use	N/A	
Product Code	50-5045	
Company	<p>PCCA</p> <p>9901 South Wilcrest</p> <p>Houston, TX 77099</p> <p>Phone: 1-800-331-2498</p> <p>Fax: 1-800-874-5760</p>	<p>In case of emergency contact:</p> <p>CHEMTREC (24hr) 1-800-424-9300</p>

Section 2: Hazard(s) Identification

OSHA Haz Com: Acute toxicity oral: Cat. 2 Acute toxicity inhalation: cat. 2 Serious eye damage/Eye Irrit.: cat. 2A
CFR 1910.1200: Carcinogenicity Category 2 STOT SE: cat.1 (Cardiovascular system)

Signal Word DANGER

Hazard Statement(s) Fatal if swallowed. Fatal if inhaled.

Pictogram(s) or Symbol(s)


Precautionary Statement(s):

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation wear respiratory protection.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. 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 advice/attention. If exposed: Call a poison center/doctor.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations

Section 3: Composition/Information on Ingredients

Substance/Mixture	Substance
Components	Digoxin
% By Weight	N/A
CAS#	20830-75-5
Molecular Weight	780,95 g/mol
Chemical Formula	C41H64O14
Synonym(s)	N/A

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Digoxin	20830-75-5	N/A	N/A	N/A

Section 4: First-Aid Measures

Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if the substance is inhaled. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.
Skin Contact	Wash off with soap and water. Get medical attention if irritation develops and persists
Eye Contact	Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. Do not use mouth-to-mouth method if substance is ingested. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device
Symptoms/Effects	
Acute	Cardiovascular effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Delayed	Cardiovascular effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Immediate Medical Attention

Provide general supportive measures and treat symptomatically.

Section 5: Fire-Fighting Measures
Suitable Extinguishing Media

Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials

Unsuitable Extinguishing Media

N/A

Products of Combustion

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

Firefighters Special Equipment and Precautions

Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Methods and materials for containment and cleaning up: Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS. Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

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. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. 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 Controls/Personal Protection
Exposure Limits

TWA 2 micrograms/m³

Engineering Controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Personal Protection

Eye/face protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. **Skin protection Hand protection:** Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. **Other:** Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. **Respiratory protection:** Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls. **Thermal hazards:** Wear appropriate thermal protective clothing, when necessary. **General hygiene considerations:** Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

Section 9: Physical and Chemical Properties

Appearance	White. Translucent. Crystalline powder. Crystals.		
Odor	Odorless		
Odor Threshold	N/A		
Melting Point	446 - 509 °F (230 - 265 °C) (pH	N/A
Freezing Point	N/A	Vapor Pressure	< 0.0000001 kPa (77 °F (25 °C))
Boiling Point/Range	N/A	Vapor Density	N/A
Decomposition temperature	N/A	Viscosity	N/A
Partition Coefficient: n-octanol/water	1.26	Evaporation Rate	N/A
Flash Point	N/A	Autoignition temperature	635 °F (335 °C) BAM fluidized dus
Flammability	N/A	Flammability or Explosive Limits:	
		Lower	N/A
		Upper	N/A
Solubility(ies)	Practically insoluble in water.		
Other	Acetone: Practically insoluble. Chloroform: Slightly soluble. Diluted alcohol: Slightly soluble. Ether: Practically insoluble. Ethyl acetate: Practically insoluble. Mixture of chloroform and alcohol: Soluble. Pyridine: Freely soluble. Chemical family Cardenolide. Dust explosion properties Kst > 300 bar.m/s Molecular formula C41H64O14 Molecular weight 780.94		

Section 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
Hazardous Polymerization	No dangerous reaction known under conditions of normal use
Conditions to Avoid	Contact with incompatible materials
Incompatible Materials	Acids. Oxidizing agents
Hazardous Decomposition Products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions

Section 11: Toxicological Information

RTECS	No data available
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Acute Toxicity

Fatal if inhaled. Fatal if swallowed. Oral LD50 Mouse 17780 microg/kg Rat 28270 µg/kg Acute Inhalation LC50 Rat < 0.5 mg/l/4h

Skin Corrosion/Irritation

No data available

Serious Eye Damage/Irritation

Causes serious eye irritation

Respiratory or Skin Sensitization

No data available

Germ Cell Mutagenicity

No data available

Carcinogenicity

Suspected of causing cancer. In epidemiological studies a positive association has been observed between this material and cancer of the breast.

Reproductive Toxicity

Knowledge about health hazard is incomplete. Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects

Routes of Entry

Inhalation. Eye. Ingestion.

Symptoms Related to Exposure

For cardiac glycosides: Loss of appetite. Gastrointestinal disturbances. Fatigue. Weakness. Irregular heartbeat. Visual disturbances. Drowsiness. Confusion. Depression. Headache. Anxiety.

Potential Health Effects

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects

Target Organ(s) Causes damage to organs (Cardiovascular system)

Section 12: Ecological Information**Ecotoxicity**

Very toxic to aquatic life Aquatic Acute Fish LC50 Fuppy (Poecilia reticulata) 0.25 mg/l, 96 hours Chronic Algae NOEC Algae 0.1 mg/l, 72 hours

Persistence and Degradability

Not readily biodegradable

Bioaccumulative Potential

Not available

Mobility in Soil

Not available

Other Adverse Effects

Not available

Section 13: Disposal Considerations**Waste Disposal**

Dispose of contents/container in accordance with local/regional/national/international regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner

Disposal of Container

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Other Considerations

Not available

Section 14: Transport Information**DOT Classification**

UN number: UN2811 UN proper shipping name: Toxic solid, organic, n.o.s. (Digoxin) Transport hazard class(es) Class 6.1

Subsidiary risk - Packing group II

Section 15: Regulatory Information**Regulations**



Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Digoxin Micronized USP

50-5045

US federal regulations: This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200 Toxic Substances Control Act (TSCA) TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification DIGOXIN (CAS 20830-75-5) 10 LBS OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053) Not listed. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Chemical name CAS number Reportable quantity (pounds) Threshold planning quantity (pounds) Threshold planning quantity, lower value (pounds) Threshold planning quantity, upper value (pounds) Digoxin 20830-75-5 10 10 10000 YESSARA 311/312 Hazardous chemical Acute toxicity (any route of exposure) Serious eye damage or eye irritation Carcinogenicity Specific target organ toxicity (single or repeated exposure) Classified hazard categories SARA 313 (TRI reporting) Not regulated. Other federal regulations 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. Not regulated. Safe Drinking Water Act (SDWA) US state regulations 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. For more information go to www.P65Warnings.ca.gov.

Other

N/A

Section 16: Other Information

Key literature references and sources for data Regulation (EC) No. 1272/2008 and No. 487/2013 IATA-DGR Römpf, Merck, STN, RTECS