



SAFETY DATA SHEET

1. Identification

Product identifier Digoxin

Other means of identification

Catalog number 1200000

CAS number 20830-75-5

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]-12,14-dihydroxy-, (3beta,5beta,12beta)-

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
United States

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Acute toxicity, oral	Category 2
Acute toxicity, inhalation	Category 2
Serious eye damage/eye irritation	Category 2A
Carcinogenicity	Category 2
Specific target organ toxicity, single exposure	Category 1 (Cardiovascular system)

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Fatal if swallowed. Fatal if inhaled. Causes serious eye irritation. Suspected of causing cancer. Causes damage to organs (Cardiovascular system).

Precautionary statement

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.

Hazard(s) not otherwise classified (HNOC) This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

Supplemental information Potent pharmacologically active material.

3. Composition/information on ingredients

Chemical name	Common name and synonyms	CAS number	%
Digoxin		20830-75-5	100

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.

Most important symptoms/effects, acute and delayed Cardiovascular effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

General information Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

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

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical 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.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire fighting equipment/instructions 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.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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. For personal protection, see section 8 of the SDS.

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.

7. Handling and storage

Precautions for safe 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.

Conditions for safe storage, including any incompatibilities

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

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

Material	Type	Value
Digoxin (CAS 20830-75-5)	TWA	2 micrograms/m ³

Biological limit values:

No biological exposure limits noted for the ingredient(s).

Appropriate 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.

Individual protection measures, such as personal protective equipment

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.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Material name: Digoxin

1200000 Version #: 04 Revision date: 06-30-2020 Issue date: 11-14-2007

USP SDS US

3 / 8

Form

Crystalline powder. Crystals.

Color

White. Translucent

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

446 - 509 °F (230 - 265 °C) (decomposes)

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

< 0.0000001 kPa (77 °F (25 °C))

Vapor density

Not available.

Relative density

Not available.

Solubility(ies)

Solubility (water)

Practically insoluble.

Solubility (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.

Partition coefficient (n-octanol/water)

1.26

Auto-ignition temperature

635 °F (335 °C) BAM fluidized dust

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Chemical family

Cardenolide.

Dust explosion properties

Kst

> 300 bar.m/s

Molecular formula

C₄₁H₆₄O₁₄

Molecular weight

780.94

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.

Incompatible materials

Acids. Oxidizing agents.

Hazardous decomposition products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Material name: Digoxin

1200000 Version #: 04 Revision date: 06-30-2020 Issue date: 11-14-2007

USP SDS US

4 / 8

11. Toxicological information

Information on likely routes of exposure

Inhalation	Fatal if inhaled.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Causes serious eye irritation.
Ingestion	Fatal if swallowed. Based on information from therapeutic use, this material may cause: Cardiovascular effects.

Symptoms related to the physical, chemical and toxicological characteristics
For cardiac glycosides: Loss of appetite, Gastrointestinal disturbances, Fatigue, Weakness, Irregular heartbeat, Visual disturbances, Drowsiness, Confusion, Depression, Headache, Anxiety.

Information on toxicological effects

Acute toxicity	Fatal if inhaled. Fatal if swallowed.	
Product	Species	Test Results
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Digoxin (CAS 20830-75-5)		
Oral		
LD50	Mouse	17780 microg/kg
	Rat	28270 µg/kg
Acute		
Inhalation		
LC50	Rat	< 0.5 mg/l/4h
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Causes serious eye irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about health hazard is incomplete.	
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity		
Ames assay	Result: Negative.	
In vitro mouse lymphoma assay	Result: Negative.	
Carcinogenicity	Suspected of causing cancer. In epidemiological studies a positive association has been observed between this material and cancer of the breast.	
IARC Monographs. Overall Evaluation of Carcinogenicity	Digoxin (CAS 20830-75-5) 2B Possibly carcinogenic to humans.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)	Not listed.	
US. National Toxicology Program (NTP) Report on Carcinogens	Not listed.	
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.	
Reproductivity		
1.75 mg/kg Developmental study	Result: No increase in birth defects.	
Species: Rat		
10 mg/kg Developmental study	Result: Increased rates of fetal death.	
Species: Rabbit		
Intramuscular injection, domestic animals	Result: Single dose led to abnormalities.	
Specific target organ toxicity - single exposure	Causes damage to organs (Cardiovascular system).	

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

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

12. Ecological information

Ecotoxicity	Very toxic to aquatic life.		
Product	Species	Test Results	
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Digoxin (CAS 20830-75-5)			
Aquatic			
Acute			
Fish	LC50	Guppy (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	No data available.		
Mobility in soil	No data available.		
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.		

13. Disposal considerations

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

14. Transport information

DOT	
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
IATA	
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
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

DOT; IATA



General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

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.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

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

SARA 311/312 Hazardous chemical

Classified hazard categories Acute toxicity (any route of exposure)
Serious eye damage or eye irritation
Carcinogenicity
Specific target organ toxicity (single or repeated exposure)

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.

Safe Drinking Water Act (SDWA)

Not regulated.

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.

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

Country(s) or region	Inventory name	On inventory (yes/no)*
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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply 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

Issue date 11-14-2007

Revision date 06-30-2020

Version # 04

Further information

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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