

# SAFETY DATA SHEET

## Digoxin Tablets



### Section 1. Identification

<b>GHS product identifier</b>	: Digoxin Tablets
<b>Synonyms</b>	: Not available.
<b>Product code</b>	: NDC 0143-1240-01; NDC 0143-1240-10; NDC 0143-1240-51 NDC 0143-1241-01; NDC 0143-1241-10; NDC 0143-1241-51
<b>Chemical family</b>	: Cardiovascular drugs. Regulated prescription drug.
<b>Product type</b>	: Drug.
<b>Container information</b>	: Not available.
<b>Identified uses</b>	: Treatment of heart failure.
<b>Supplier's details</b>	: West-Ward Pharmaceuticals 401 Industrial Way Eatontown NJ 07724 Phone (732 542 1191) Fax (732 720 6220)
<b>Emergency telephone number (with hours of operation)</b>	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7

### Section 2. Hazards identification

<b>OSHA/HCS status</b>	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
<b>Classification of the substance or mixture</b>	: ACUTE TOXICITY (oral) - Category 4 ACUTE TOXICITY (inhalation) - Category 3 CARCINOGENICITY - Category 2 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 1 AQUATIC HAZARD (ACUTE) - Category 3

#### GHS label elements

##### Hazard pictograms



##### Signal word

: Danger

##### Hazard statements

: H331 - Toxic if inhaled.  
H302 - Harmful if swallowed.  
H351 - Suspected of causing cancer.  
H372 - Causes damage to organs through prolonged or repeated exposure.  
H402 - Harmful to aquatic life.

##### Precautionary statements

## Section 2. Hazards identification

<b>Prevention</b>	: P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves. Wear eye or face protection. Wear protective clothing. P271 - Use only outdoors or in a well-ventilated area. P273 - Avoid release to the environment. P260 - Do not breathe dust. P270 - Do not eat, drink or smoke when using this product. P264 - Wash hands thoroughly after handling.
<b>Response</b>	: P314 - Get medical attention if you feel unwell. P308 + P313 - IF exposed or concerned: Get medical attention. P304 + P340 + P311 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician. P301 + P312 + P330 - IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth.
<b>Storage</b>	: P405 - Store locked up.
<b>Disposal</b>	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
<b>Hazards not otherwise classified</b>	: None known.
<b>Hazards not otherwise classified (HNOC)</b>	: None known.

## Section 3. Composition/information on ingredients

<b>Substance/mixture</b>	: Mixture
<b>Other means of identification</b>	: Not available.
<b>CAS number/other identifiers</b>	
<b>CAS number</b>	: Not applicable.
<b>Product code</b>	: NDC 0143-1240-01; NDC 0143-1240-10; NDC 0143-1240-51 NDC 0143-1241-01; NDC 0143-1241-10; NDC 0143-1241-51

Ingredient name	%	CAS number
Digoxin	1 - 5	20830-75-5
D-Glucose, 4-O-β-D-galactopyranosyl-, hydrate (1:1)	10 - 30	64044-51-5
Aluminium, 6-hydroxy-5-[(4-sulfophenyl)azo]-2-naphthalenesulfonic acid complex	0.1 - 1	15790-07-5
Silica, amorphous, fumed, cryst.-free	1 - 5	112945-52-5
Starch	10 - 30	9005-25-8
Lactose	30 - 60	63-42-3
Magnesium distearate	1 - 5	557-04-0
C.I. Pigment Yellow 115	0.1 - 1	68814-04-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

## Section 4. First aid measures

### Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Flush contaminated skin with plenty of water. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Toxic if inhaled.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : Harmful if swallowed.

#### Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

### Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

## Section 5. Fire-fighting measures

### Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

**Specific hazards arising from the chemical** : This material is harmful to aquatic life. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
metal oxide/oxides

**Special protective actions for fire-fighters** : No special measures are required.

**Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

**Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

### Methods and materials for containment and cleaning up

- Spill** : Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

## Section 7. Handling and storage

### Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid release to the environment. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

## Section 7. Handling and storage

- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

## Section 8. Exposure controls/personal protection

### Control parameters

#### Occupational exposure limits

None.

- Appropriate engineering controls** : Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

### Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

### Skin protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

## Section 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	: Solid. [Round scored tablet.]
<b>Color</b>	: Not available.
<b>Odor</b>	: Odorless.
<b>Odor threshold</b>	: Not available.
<b>pH</b>	: Not available.
<b>Melting point</b>	: 265°C (509°F)
<b>Boiling point</b>	: Not available.
<b>Flash point</b>	: Not applicable.
<b>Evaporation rate</b>	: Not available.
<b>Flammability (solid, gas)</b>	: Not applicable.
<b>Lower and upper explosive (flammable) limits</b>	: Not applicable.
<b>Vapor pressure</b>	: Not available.
<b>Vapor density</b>	: Not available.
<b>Relative density</b>	: Not available.
<b>Solubility in water</b>	: Not available.
<b>Partition coefficient: n-octanol/water</b>	: 1.26
<b>Auto-ignition temperature</b>	: Not applicable.
<b>Decomposition temperature</b>	: Not available.
<b>Viscosity</b>	: Not available.

## Section 10. Stability and reactivity

<b>Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>Chemical stability</b>	: The product is stable.
<b>Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>Conditions to avoid</b>	: No specific data.
<b>Incompatible materials</b>	: Reactive or incompatible with the following materials: oxidizing materials, acids and alkalis.
<b>Hazardous decomposition products</b>	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Digoxin	LD50 Oral	Rat	28270 µg/kg	-

#### Irritation/Corrosion

There is no data available.

#### Sensitization

There is no data available.

#### Mutagenicity

There is no data available.

#### Carcinogenicity

##### Classification

Product/ingredient name	OSHA	IARC	NTP	ACGIH	EPA	NIOSH
Starch	-	-	-	A4	-	-
Digoxin	-	2B	-	-	-	-
Silica, amorphous, fumed, cryst.-free	-	3	-	-	-	-
Magnesium distearate	-	-	-	A4	-	-

#### Reproductive toxicity

There is no data available.

#### Teratogenicity

There is no data available.

#### Specific target organ toxicity (single exposure)

There is no data available.

#### Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
Digoxin	Category 1	Not determined	Not determined

#### Aspiration hazard

There is no data available.

**Information on the likely routes of exposure** : Dermal contact. Eye contact. Inhalation. Ingestion.

#### Potential acute health effects

**Eye contact** : No known significant effects or critical hazards.  
**Inhalation** : Toxic if inhaled.  
**Skin contact** : No known significant effects or critical hazards.  
**Ingestion** : Harmful if swallowed.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : No known significant effects or critical hazards.  
**Inhalation** : No known significant effects or critical hazards.  
**Skin contact** : No known significant effects or critical hazards.  
**Ingestion** : No known significant effects or critical hazards.

## Section 11. Toxicological information

### Delayed and immediate effects and also chronic effects from short and long term exposure

#### Short term exposure

**Potential immediate effects** : No known significant effects or critical hazards.

**Potential delayed effects** : No known significant effects or critical hazards.

#### Long term exposure

**Potential immediate effects** : No known significant effects or critical hazards.

**Potential delayed effects** : No known significant effects or critical hazards.

#### Potential chronic health effects

**General** : Causes damage to organs through prolonged or repeated exposure.

**Carcinogenicity** : Suspected of causing cancer. Risk of cancer depends on duration and level of exposure.

**Mutagenicity** : No known significant effects or critical hazards.

**Teratogenicity** : No known significant effects or critical hazards.

**Developmental effects** : No known significant effects or critical hazards.

**Fertility effects** : No known significant effects or critical hazards.

### Numerical measures of toxicity

#### Acute toxicity estimates

Route	ATE value
Oral	1401 mg/kg
Inhalation (vapors)	2.5 mg/L

## Section 12. Ecological information

### Toxicity

There is no data available.

### Persistence and degradability

There is no data available.

### Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
Digoxin Tablets	1.26	-	low
Digoxin	1.26	-	low

### Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : Not available.




**Other adverse effects** : No known significant effects or critical hazards.



## Section 13. Disposal considerations

**Disposal methods** : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

## Section 14. Transport information

	DOT	IMDG	IATA
<b>UN number</b>	UN2811	UN2811	UN2811
<b>UN proper shipping name</b>	TOXIC SOLID, ORGANIC, N.O.S. (Digoxin)	TOXIC SOLID, ORGANIC, N.O.S. (Digoxin)	TOXIC SOLID, ORGANIC, N.O.S. (Digoxin)
<b>Transport hazard class(es)</b>	6.1 	6.1 	6.1 
<b>Packing group</b>	III	III	III
<b>Environmental hazards</b>	No.	No.	No.
<b>Additional information</b>	-	-	-

**AERG** : 154

**Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** : Not available.

## Section 15. Regulatory information

**U.S. Federal regulations** : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined  
**United States inventory (TSCA 8b):** All components are listed or exempted.

**Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)** : Not listed

**Clean Air Act Section 602 Class I Substances** : Not listed

## Section 15. Regulatory information

**Clean Air Act Section 602 Class II Substances** : Not listed

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

**DEA List II Chemicals (Essential Chemicals)** : Not listed

### SARA 302/304

#### Composition/information on ingredients

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Digoxin	≥1.5 - <2.5	Yes.	10 / 10000	-	10	-

**SARA 304 RQ** : 500 lbs / 227 kg

### SARA 311/312

**Classification** : Immediate (acute) health hazard  
Delayed (chronic) health hazard

#### Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Digoxin	≥1.5 - <2.5	Yes.	No.	No.	Yes.	Yes.

### SARA 313

No products were found.

### State regulations

**Massachusetts** : The following components are listed: Starch; Digoxin

**New York** : The following components are listed: Digoxin

**New Jersey** : The following components are listed: Digoxin

**Pennsylvania** : The following components are listed: Starch; Digoxin

### California Prop. 65

No products were found.

## Section 16. Other information

### History

**Date of issue mm/dd/yyyy** : 09/15/2015

**Version** : 1

**Prepared by** : KMK Regulatory Services Inc.

### Key to abbreviations

: ATE = Acute Toxicity Estimate  
 BCF = Bioconcentration Factor  
 GHS = Globally Harmonized System of Classification and Labelling of Chemicals  
 IATA = International Air Transport Association  
 IBC = Intermediate Bulk Container  
 IMDG = International Maritime Dangerous Goods  
 LogPow = logarithm of the octanol/water partition coefficient  
 MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

## Section 16. Other information

UN = United Nations

**Notice to reader**

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.