



# SAFETY DATA SHEET

## 1. Identification

Product identifier	Amiodarone Hydrochloride	
Other means of identification		
Catalog number	1027302	
CAS number	19774-82-4	
Chemical name	Methanone, (2-butyl-3-benzofuranyl)[4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl]- hydrochloride	
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	<table><tr><td>Skin corrosion/irritation</td><td>Category 2</td></tr><tr><td>Serious eye damage/eye irritation</td><td>Category 2A</td></tr><tr><td>Reproductive toxicity</td><td>Category 1</td></tr><tr><td>Specific target organ toxicity, single exposure</td><td>Category 1 (cardiovascular system)</td></tr><tr><td>Specific target organ toxicity, repeated exposure</td><td>Category 1 (liver, lung)</td></tr></table>		Skin corrosion/irritation	Category 2	Serious eye damage/eye irritation	Category 2A	Reproductive toxicity	Category 1	Specific target organ toxicity, single exposure	Category 1 (cardiovascular system)	Specific target organ toxicity, repeated exposure	Category 1 (liver, lung)
Skin corrosion/irritation	Category 2											
Serious eye damage/eye irritation	Category 2A											
Reproductive toxicity	Category 1											
Specific target organ toxicity, single exposure	Category 1 (cardiovascular system)											
Specific target organ toxicity, repeated exposure	Category 1 (liver, lung)											
Environmental hazards	Not classified.											
OSHA defined hazards	Not classified.											
Label elements												
Signal word	Danger											
Hazard statement	Causes skin irritation. Causes serious eye irritation. May damage fertility or the unborn child. Causes damage to organs (cardiovascular system). Causes damage to organs (liver, lung) through prolonged or repeated exposure.											
Precautionary statement												
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.											

<b>Response</b>	If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. 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 or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	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** Pharmacologically active material.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Amiodarone Hydrochloride		19774-82-4	100

### 4. First-aid measures

#### Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

#### Skin contact

Remove contaminated clothing. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

#### Eye contact

Rinse with water. If a contact lens is present, DO NOT delay irrigation or attempt to remove the lens. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.

#### Ingestion

Rinse mouth thoroughly. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

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

Liver damage. Heart rhythm abnormalities. Lung damage. Pharmacologically active material.

Occupational exposure may cause physiological effects.

#### Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Treatment of amiodarone may include the following: Support cardiac and respiratory function, as well as conduct ECG monitoring. For bradycardia, a beta-adrenergic agonist or insertion of a temporary pacemaker may be indicated. To decrease absorption following ingestion, perform gastric lavage, only after controlling any seizures. Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Do NOT induce vomiting, since there may be cardiovascular instability. Administer activated charcoal as a slurry (240 mL water/30 grams charcoal). For hypotension, fluids and vasopressors may be helpful. Infuse 10 - 20 mL/kg isotonic fluid. If hypertension persists, administer dopamine or norepinephrine. For torsades de pointes, electrical cardioversion may be required in unstable patients. Treat stable patients with magnesium, isoproterenol, and/or atrial overdrive pacing. Correct electrolyte abnormalities.

#### 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 CO<sub>2</sub>. 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

Keep unnecessary personnel away. 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. Wear appropriate protective equipment and clothing during clean-up. 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

No exposure limits noted for ingredient(s).

### Biological limit values

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

### Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. 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

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 lab coat. 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

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters 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

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.

#### Form

Powder.

#### Color

White.

#### Odor

Odorless.

#### Odor threshold

Not available.

#### pH

Not available.

#### Melting point/freezing point

312.8 °F (156 °C)

<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa at 25 °C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Very slightly soluble.
<b>Solubility (other)</b>	Acetone: Slightly soluble. Chloroform: Soluble. Ethanol: Soluble. Methanol: Soluble.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Benzofuranes.
<b>Dust explosion properties</b>	
<b>Minimum ignition energy (MIE) - dust cloud</b>	> 25 mJ
<b>Molecular formula</b>	C25-H29-I2-N-O3.HCl
<b>Molecular weight</b>	681.78 g/mol
<b>pH in aqueous solution</b>	3.2 - 3.9 Solution: 5%

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	NOx. Cl-. I-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Causes skin irritation.
<b>Eye contact</b>	Causes serious eye irritation.
<b>Ingestion</b>	Based on information from therapeutic use, this material may cause: Cardiac toxicity. Pulmonary toxicity. Liver damage.

<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Difficulty breathing. Cough. Muscle weakness. Fatigue. Irregular heartbeat. Slow heartbeat. Headache. Dizziness. Fainting. Unsteady gait. Tremor. Unusual or uncontrolled body movements. Numbness, pain, tingling, or weakness in hands or feet. Sleep disorders. Decreased sexual desire. Flushing. Fever. Blurred vision. Dry eyes. Nausea. Vomiting. Constipation. Loss of appetite. Unpleasant taste. Blue-gray skin. Skin sensitivity to sunlight. Pain or swelling in scrotum.
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#### Information on toxicological effects

##### Acute toxicity

Product	Species	Test Results
Amiodarone Hydrochloride (CAS 19774-82-4)		
<b>Acute</b>		
Oral		
LD50	Rat	> 3000 mg/kg
<b>Skin corrosion/irritation</b>	Causes skin irritation.	
<b>Serious eye damage/eye irritation</b>	Causes serious eye irritation.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Skin sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.	
<b>Mutagenicity</b>		
Ames test		
Result: Negative.		
Lysogenic induction test		
Result: Negative.		
Micronucleus test		
Result: Negative.		
<b>Carcinogenicity</b>	Knowledge about carcinogenicity is incomplete.	
5 mg/kg/day Carcinogenicity		
Result: Dose-related increase in the incidence of thyroid follicular adenomas and carcinomas.		
Species: Rat		

##### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

##### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

##### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

<b>Reproductive toxicity</b>	May damage fertility or the unborn child. There have been reports of congenital goiter and impaired thyroid status in children whose mothers received amiodarone during pregnancy.
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##### Reproductivity

35 mg/kg/day Reproductivity study, administered during gestation.

Result: Decreased offspring birth weights.

Species: Rat

5 mg/kg/day Reproductivity study

Result: Fetotoxicity.

Species: Mouse

50 - 200 mg/kg/day Reproductivity study

Result: Fetotoxicity (testes displacement, incomplete skeletal formation, decreased body weights, increased fetal resorption).

Species: Rat

75 mg/kg/day Reproductivity study

Result: >90% abortion rate.

Species: Rabbit

90 mg/kg/day Reproductivity study, administered orally.

Result: Reduced fertility.

Species: Rat

<b>Specific target organ toxicity - single exposure</b>	Causes damage to organs (cardiovascular system).
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<b>Specific target organ toxicity - repeated exposure</b>	Causes damage to organs (liver, lung) through prolonged or repeated exposure.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.
<b>Further information</b>	Pharmacologically active material. Occupational exposure may cause physiological effects.

## 12. Ecological information

### Ecotoxicity

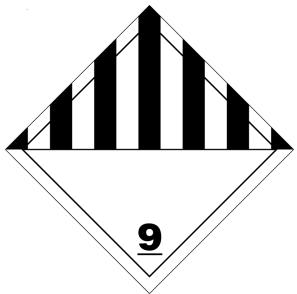
Product	Species	Test Results
Amiodarone Hydrochloride (CAS 19774-82-4)		
<b>Aquatic</b>		
<b>Acute</b>		
Crustacea	EC50	Daphnia magna 0.3 mg/l, 48 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this substance.	
<b>Bioaccumulative potential</b>	No data available.	
<b>Mobility in soil</b>	No data available.	
<b>Other adverse effects</b>	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

<b>Disposal instructions</b>	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. Dispose in accordance with all applicable regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

<b>DOT</b>	
<b>UN number</b>	UN3077
<b>UN proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (Amiodarone Hydrochloride)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>IATA</b>	
<b>UN number</b>	UN3077
<b>UN proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (Amiodarone Hydrochloride)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Other information</b>	
<b>Passenger and cargo aircraft</b>	Allowed with restrictions.
<b>Cargo aircraft only</b>	Allowed with restrictions.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.

**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.

**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**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical**

Yes

**Classified hazard categories** Reproductive toxicity  
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**

**WARNING:** This product can expose you to Amiodarone Hydrochloride, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California Proposition 65 - CRT: Listed date/Developmental toxin**

Amiodarone Hydrochloride (CAS 19774-82-4) Listed: August 26, 1997

**California Proposition 65 - CRT: Listed date/Female reproductive toxin**

Amiodarone Hydrochloride (CAS 19774-82-4) Listed: August 26, 1997

**California Proposition 65 - CRT: Listed date/Male reproductive toxin**

Amiodarone Hydrochloride (CAS 19774-82-4) Listed: August 26, 1997

**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)	No
Canada	Non-Domestic Substances List (NDSL)	No

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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)	Yes
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*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

<b>Issue date</b>	07-01-2007
<b>Revision date</b>	10-30-2019
<b>Version #</b>	04
<b>Further information</b>	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.
<b>Disclaimer</b>	USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.