



Product name: Amiodarone hydrochloride injection

Issue date: 11/12/24

# SDS

## Safety Data Sheet

SDS No. : 24865711122301



Creator: Cairui Chemical Technology (Shanghai) CO.,LTD

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## 1. Product and Company Identification

**Product name** : Amiodarone hydrochloride injection

**Product use** : Antiarrhythmic agent

**Manufacturer/ Supplier** : Zhejiang Poly Pharm. Co., Ltd

**Address** : No. 78, Xinzhou Road, Economic Development Zone, Linping District, Hangzhou, Zhejiang 311199, China (CHN)

**Telephone** : +86 571-89385060

**E-mail** : chencanli@hnpoly.com

**Emergency telephone number of the company** : +86 571-89385060

## 2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

**GHS classification of the product** : Sensitization – skin category 1B  
Eye damage/irritation category 2

### Label elements

Pictogram



Signal word : Warning

**Hazard statement** : May cause an allergic skin reaction  
Causes serious eye irritation

### Precautionary statements

Prevention : Avoid breathing dust/fume/gas/mist/ vapours/spray.  
Contaminated work clothing should not be allowed out of the workplace.  
Wear protective gloves / protective clothing / eye protection / face protection.  
Wash exposed skin thoroughly after handling.

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Response	:	IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Specific treatment (see section 4 on this SDS) Wash contaminated clothing 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.
Disposal	:	Dispose of contents/container in accordance with local/regional/national/international regulations
Hazards not otherwise classified	:	No specific dangers known, if the regulations/notes for storage and handling are considered.

## 3. Composition / Information on Ingredients

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Chemical Name	CAS-No.	Concentration
Sorbitan monooleate, ethoxylated	9005-65-6	55-60%
Amiodarone hydrochloride	19774-82-4	25-30%
Benzyl alcohol	100-51-6	10-15%

## 4. First-Aid Measures

### Description of first aid measures

Inhalation	:	Move person to fresh air; If symptoms persist, consult a physician.
Skin contact	:	Flush skin with large amounts of water immediately. If symptoms persist, seek medical advice.
Eye contact	:	If you use contact lenses, remove the lenses first. Wash affected eyes for at least 15 minutes under running water with eyelids held open. If symptoms occur, consult a physician, preferably an ophthalmologist.
Ingestion	:	Rinse your mouth. If you feel uncomfortable, get medical attention and treatment.
Most important symptoms and effects, both acute and delayed	:	Further important symptoms and effects are so far not known.

Indication of any immediate medical attention and special treatment needed

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**Note to physician** : No information available.

## 5 : Fire-Fighting Measures

**Suitable extinguishing media** : Water fog or fine spray.Dry chemical fire extinguishers.Carbon dioxide fire extinguishers.

**Unsuitable extinguishing media** : No information available.

### Special hazards arising from the substance or mixture

**Hazardous combustion products** : During a fire, smoke may contain the original material in addition to combustion products of varying composition which may be toxic and/or irritating.Combustion products may include and are not limited to: Nitrogen oxides. Sulfur oxides. Carbon monoxide. Carbon dioxide.

### Advice for firefighters

**Special protective equipment for firefighters** : Wear positive-pressure self-contained breathing apparatus (SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat, trousers, boots, and gloves).If protective equipment is not available or not used, fight fire from a protected location or safe distance.

## 6 : Accidental release measures

**Personal precautions, protective equipment and emergency procedures** : Use latex, nitrile, or rubber gloves. Wear lab coat, gown, or smock as appropriate for procedure. Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

**Environmental precautions** : Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.

**Methods and materials for containment and cleaning up** : Collect in suitable and properly labeled containers.Then store and dispose of according to local regulations.

## 7 : Handling and storage

**Advice on safe handling** : Avoid contact with the skin, eyes and clothing. Wear safety glasses with side shields.

**Conditions for safe storage, including any incompatibilities** : Keep tightly closed and protect from light.

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## 8 : Exposure Controls/Personal Protection

**Control parameters** : No data available.

### Personal protective equipment

**Respiratory protection** : None required under normal conditions. Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines.

**Hand protection** : Use latex, nitrile, or rubber gloves.

**Eye protection** : Use safety glasses (with side shields). Depending on conditions of use, a face shield may be necessary.

**Skin and body protection** : Wear protective clothing.

## 9 : Physical and chemical properties

**Form** : liquid

**Color** : light yellow

**Odor** : no data available

**pH** : 3.0~4.0

**Melting point** : no data available

**Boiling point** : no data available

**Flash point** : no data available

**Thermal decomposition temperature** : no data available

**Density** : no data available

**Water solubility** : no data available

**Viscosity, dynamic** : no data available

## 10 : Stability and Reactivity

**Reactivity** : No hazardous reactions if stored and handled as prescribed/indicated.

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**Chemical stability** : The product is stable if stored and handled as prescribed/indicated.

**Possibility of hazardous reactions** : This material is considered stable.

**Conditions to avoid** : No information available.

**Incompatible materials** : Avoid contact with: Strong acids.Strong bases.Strong oxidizers.

**Hazardous decomposition products** : Carbon monoxide. Carbon dioxide. Sulfur oxides. Nitrogen oxides.

## 11 : Toxicological information

### Information on likely routes of exposure

Inhalation, Eye contact, Skin contact, Ingestion.

### Acute toxicity

#### Acute Toxicity Endpoints:

#### Acute oral toxicity

#### Information for the Product:

Shall not be classified as acutely toxic (oral).

As product: Single dose oral LD50 has not been determined.

Based on information for component(s): LD50, > 2 000 mg/kg Estimated.

#### Information for components:

Benzyl alcohol

LD50, rat, 1200 mg/kg bw

Amiodarone hydrochloride

LD50, Rat, >3000 mg/kg

Sorbitan monooleate, ethoxylated

LD50, Mouse, 25000 mg/kg

### Acute dermal toxicity

#### Information for the Product:

Shall not be classified as acutely toxic (dermal).

As product: The dermal LD50 has not been determined.

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Based on information for component(s): LD50, > 2 000 mg/kg Estimated.

## Information for components:

Benzyl alcohol

LC50, rat, 4h, > 4178 mg/m<sup>3</sup> air

Amiodarone hydrochloride

LC50, rat, 1.0-5.0 mg/L air, estimated

Sorbitan monooleate, ethoxylated

LC50, rat, >20 mg/L air, estimated

## Acute inhalation toxicity

Information for the Product:

Shall not be classified as acutely toxic (inhalation).

As product: The LC50 has not been determined.

Information for components:

Benzyl alcohol

LD50, rabbit, > 2 000 mg/kg bw

Amiodarone hydrochloride

LD50, rabbit, 1000-2000 mg/kg bw, estimated

Sorbitan monooleate, ethoxylated

LD50, rabbit, >2000 mg/kg bw, estimated

## Skin corrosion/irritation

Information for the Product:

Shall not be classified as corrosive/irritant to skin.

Information for components:

Benzyl alcohol

Shall not be classified as corrosive/irritant to skin

Amiodarone hydrochloride

Shall not be classified as corrosive/irritant to skin

Sorbitan monooleate, ethoxylated

Shall not be classified as corrosive/irritant to skin

## Serious eye damage/eye irritation

Information for the Product:

Causes serious eye irritation.

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## Information for components:

Benzyl alcohol  
Causes serious eye irritation

Amiodarone hydrochloride  
Shall not be classified as irritant to eye

Sorbitan monooleate, ethoxylated  
Shall not be classified as irritant to eye

## Respiratory or skin sensitisation

### Information for the Product:

May cause an allergic skin reaction.

### Information for components:

Benzyl alcohol  
For skin sensitization:  
May cause an allergic skin reaction  
For respiratory sensitization:  
Shall not be classified as a respiratory sensitiser.

Amiodarone hydrochloride  
For skin sensitization:  
Shall not be classified as a skin sensitiser  
For respiratory sensitization:  
Shall not be classified as a respiratory sensitiser.

Sorbitan monooleate, ethoxylated  
For skin sensitization:  
Shall not be classified as a skin sensitiser  
For respiratory sensitization:  
Shall not be classified as a respiratory sensitiser.

## Germ cell mutagenicity

### Information for the Product:

Shall not be classified as germ cell mutagenic.

### Information for components:

Benzyl alcohol  
Shall not be classified as germ cell mutagenic

Amiodarone hydrochloride  
Shall not be classified as germ cell mutagenic

Sorbitan monooleate, ethoxylated  
Shall not be classified as germ cell mutagenic



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## **Carcinogenicity**

### **Information for the Product:**

Shall not be classified as carcinogenic.

### **Information for components:**

Benzyl alcohol

Shall not be classified as carcinogenic

Amiodarone hydrochloride

Shall not be classified as carcinogenic

Sorbitan monooleate, ethoxylated

Shall not be classified as carcinogenic

## **Reproductive toxicity**

### **Information for the Product:**

Shall not be classified as a reproductive toxicant.

### **Information for components:**

Benzyl alcohol

Shall not be classified as a reproductive toxicant

Amiodarone hydrochloride

Shall not be classified as a reproductive toxicant

Sorbitan monooleate, ethoxylated

Shall not be classified as a reproductive toxicant

## **STOT-single exposure**

### **Information for the Product:**

Shall not be classified as a specific target organ toxicant (single exposure).

### **Information for components:**

Benzyl alcohol

Shall not be classified as a specific target organ toxicant (single exposure)

Amiodarone hydrochloride

Shall not be classified as a specific target organ toxicant (single exposure)

Sorbitan monooleate, ethoxylated

Shall not be classified as a specific target organ toxicant (single exposure)

## **STOT-repeated exposure**

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## Information for the Product:

Shall not be classified as a specific target organ toxicant (repeated exposure).

## Information for components:

Benzyl alcohol

Shall not be classified as a specific target organ toxicant (repeated exposure)

Amiodarone hydrochloride

Shall not be classified as a specific target organ toxicant (repeated exposure)

Sorbitan monooleate, ethoxylated

Shall not be classified as a specific target organ toxicant (repeated exposure)

## Aspiration Hazard

### Information for the Product:

Shall not be classified as presenting an aspiration hazard.

### Information for components:

Benzyl alcohol

Shall not be classified as presenting an aspiration hazard

Amiodarone hydrochloride

Shall not be classified as presenting an aspiration hazard

Sorbitan monooleate, ethoxylated

Shall not be classified as presenting an aspiration hazard

## 12 : Ecological information

### Toxicity

#### Benzyl alcohol

Short-term toxicity to fish

Has a very low toxicity to fish.

LC50, 96h, 460 mg/L

Long-term toxicity to fish

NOEC, 30d, 48.897 mg/L

Short-term toxicity to aquatic invertebrates

EC50, 48h, 230 mg/L

Long-term toxicity to aquatic invertebrates

EC50, 21d, 66 mg/L, OECD Guideline 211

NOEC, 21d, 51 mg/L, OECD Guideline 211

Toxicity to aquatic algae and cyanobacteria

EC50, Pseudokirchnerella subcapitata, 72h, 770 mg/L

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NOEC, Pseudokirchnerella subcapitata, 72h, 310 mg/L.

Toxicity to microorganisms  
EC50, Nitrosomonas, 24h, 390 mg/L

## Persistence and degradability

Benzyl alcohol  
Readily biodegradable  
Biodegradation: 92-96 %  
Exposure time: 14d  
Method: OECD Guideline 301 A

## Bioaccumulative potential

Benzyl alcohol  
BCF: 1.37 L/kg ww

## Mobility in soil

Benzyl alcohol  
Koc: 15.7(20 °C)

## Other adverse effects

### Benzyl alcohol

This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

### Amiodarone hydrochloride

This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

### Sorbitan monooleate, ethoxylated

This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

## 13 : Disposal considerations

<b>Product</b>	:	Observe national and local legal requirements.
<b>Contaminated packaging</b>	:	Packs that cannot be cleaned should be disposed of in the same manner as the contents.

## 14 : Transport Information

### Land transport

#### DOT

Not regulated as dangerous goods

**UN number** : not applicable

**UN proper shipping name :** not applicable

**Transport hazard class(es) :** not applicable

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**Packing group** : not applicable

## Sea transport

### IMDG

Not regulated as dangerous goods

**UN number** : not applicable

**UN proper shipping name :**

**Transport hazard class(es) :**

**Packing group** : not applicable

## Air transport

### IATA/ICAO

Not regulated as dangerous goods

**UN number** : not applicable

**UN proper shipping name :**

**Transport hazard class(es) :**

**Packing group** : not applicable

## 15 : Regulatory information

### Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know Act of 1986) Section 313

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### SARA 311/312 Hazard Categories

Respiratory or skin sensitization;  
Serious eye damage or eye irritation

### Pennsylvania Right To Know Components

No components are subject to the Pennsylvania Right to Know Act.

### California Proposition 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

### United States TSCA Inventory (TSCA)

All components of this product are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

## 16 : Other information

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**SDS Prepared by:**

Cairui Chemical Technology (Shanghai) CO.,LTD

SDS Prepared on: 11/12/24

**NFPA Hazard codes:**

Health : 2      Fire: 0      Reactivity: 0      Special:

**HMIS III rating**

Health: 2      Flammability: 0      Physical hazard: 0

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