

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 6.5

Revision Date 23.08.2024

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GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifiers

Product name : Amiodarone Hydrochloride, United States Pharmacopeia (USP) Reference Standard

Product Number : 1027302

Brand : US Pharmacopeia

REACH No. : A registration number is not available for this substance as the substance or its uses are exempted from registration or the annual tonnage does not require a registration.

CAS-No. : 19774-82-4

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

### 1.3

### 1.4 Emergency telephone

Emergency Phone # : 000 800 1007 141 (CHEMTREC)

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

|                                     |                                                                                     |
|-------------------------------------|-------------------------------------------------------------------------------------|
| Skin irritation, (Category 2)       | H315: Causes skin irritation.                                                       |
| Eye irritation, (Category 2)        | H319: Causes serious eye irritation.                                                |
| Carcinogenicity, (Category 2)       | H351: Suspected of causing cancer.                                                  |
| Reproductive toxicity, (Category 2) | H361fd: Suspected of damaging fertility.<br>Suspected of damaging the unborn child. |
| Effects on or via lactation         | H362: May cause harm to breast-fed                                                  |

children.

Specific target organ toxicity -  
single exposure, (Category 3),  
Respiratory system

H335: May cause respiratory irritation.

Short-term (acute) aquatic  
hazard, (Category 1)

H400: Very toxic to aquatic life.

Long-term (chronic) aquatic  
hazard, (Category 1)

H410: Very toxic to aquatic life with long  
lasting effects.

## 2.2 Label elements

### Labelling according Regulation (EC) No 1272/2008

Pictogram

|                                |                                                                                                                                  |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Signal Word                    | Warning                                                                                                                          |
| Hazard Statements              |                                                                                                                                  |
| H315                           | Causes skin irritation.                                                                                                          |
| H319                           | Causes serious eye irritation.                                                                                                   |
| H335                           | May cause respiratory irritation.                                                                                                |
| H351                           | Suspected of causing cancer.                                                                                                     |
| H361fd                         | Suspected of damaging fertility. Suspected of damaging the unborn child.                                                         |
| H362                           | May cause harm to breast-fed children.                                                                                           |
| H410                           | Very toxic to aquatic life with long lasting effects.                                                                            |
| Precautionary Statements       |                                                                                                                                  |
| P260                           | Do not breathe dust.                                                                                                             |
| P263                           | Avoid contact during pregnancy and while nursing.                                                                                |
| P273                           | Avoid release to the environment.                                                                                                |
| P302 + P352                    | IF ON SKIN: Wash with plenty of water.                                                                                           |
| P305 + P351 + P338             | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P308 + P313                    | IF exposed or concerned: Get medical advice/ attention.                                                                          |
| Supplemental Hazard Statements | none                                                                                                                             |

### Reduced Labeling (<= 125 ml)

Pictogram

|                          |                                                                          |
|--------------------------|--------------------------------------------------------------------------|
| Signal Word              | Warning                                                                  |
| Hazard Statements        |                                                                          |
| H351                     | Suspected of causing cancer.                                             |
| H362                     | May cause harm to breast-fed children.                                   |
| H361fd                   | Suspected of damaging fertility. Suspected of damaging the unborn child. |
| Precautionary Statements |                                                                          |
| P308 + P313              | IF exposed or concerned: Get medical advice/ attention.                  |
| Supplemental Hazard      | none                                                                     |

## Statements

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

#### Ecological information:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### Toxicological information:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Formula : C<sub>25</sub>H<sub>29</sub>I<sub>2</sub>NO<sub>3</sub> · HCl  
Molecular weight : 681,8 g/mol  
CAS-No. : 19774-82-4  
EC-No. : 243-293-2

| Component                       |            | Classification                                                                                                                                                                                                                  | Concentration |
|---------------------------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| <b>Amiodarone hydrochloride</b> |            |                                                                                                                                                                                                                                 |               |
| CAS-No.                         | 19774-82-4 | Skin Irrit. 2; Eye Irrit. 2;<br>Carc. 2; Repr. 2; Lact. ;<br>STOT SE 3; Aquatic Acute<br>1; Aquatic Chronic 1;<br>H315, H319, H351,<br>H361fd, H362, H335,<br>H400, H410<br>M-Factor - Aquatic Acute:<br>1 - Aquatic Chronic: 1 | <= 100 %      |
| EC-No.                          | 243-293-2  |                                                                                                                                                                                                                                 |               |

For the full text of the H-Statements mentioned in this Section, see Section 16.

## SECTION 4: First aid measures

### 4.1 Description of first-aid measures

#### General advice

Show this material safety data sheet to the doctor in attendance.

#### If inhaled

After inhalation: fresh air. Call in physician.

#### In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.

#### In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

**If swallowed**

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

**4.2 Most important symptoms and effects, both acute and delayed**

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

**4.3 Indication of any immediate medical attention and special treatment needed**

No data available

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**SECTION 5: Firefighting measures****5.1 Extinguishing media****Suitable extinguishing media**

Water Foam Carbon dioxide (CO<sub>2</sub>) Dry powder

**Unsuitable extinguishing media**

For this substance/mixture no limitations of extinguishing agents are given.

**5.2 Special hazards arising from the substance or mixture**

Carbon oxides

Nitrogen oxides (NO<sub>x</sub>)

Hydrogen chloride gas

Hydrogen iodide

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

**5.3 Advice for firefighters**

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

**5.4 Further information**

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

**6.2 Environmental precautions**

Do not let product enter drains.

**6.3 Methods and materials for containment and cleaning up**

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

**6.4 Reference to other sections**

For disposal see section 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

#### Advice on safe handling

Work under hood. Do not inhale substance/mixture.

#### Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

For precautions see section 2.2.

### 7.2 Conditions for safe storage, including any incompatibilities

#### Storage conditions

Tightly closed. Dry.

#### Storage stability

Recommended storage temperature  
2 - 8 °C

#### Storage class

Storage class (TRGS 510): 11: Combustible Solids

### 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Ingredients with workplace control parameters

### 8.2 Exposure controls

#### Personal protective equipment

##### Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

##### Skin protection

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: [www.kcl.de](http://www.kcl.de)).

##### Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: KCL 741 Dermatril® L

##### Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: KCL 741 Dermatril® L

##### Body Protection

protective clothing

**Respiratory protection**

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter type: Filter type P3

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

**Control of environmental exposure**

Do not let product enter drains.

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**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

|                                                 |                                                                                  |
|-------------------------------------------------|----------------------------------------------------------------------------------|
| a) Physical state                               | solid                                                                            |
| b) Color                                        | No data available                                                                |
| c) Odor                                         | No data available                                                                |
| d) Melting point/freezing point                 | No data available                                                                |
| e) Initial boiling point and boiling range      | No data available                                                                |
| f) Flammability (solid, gas)                    | No data available                                                                |
| g) Upper/lower flammability or explosive limits | No data available                                                                |
| h) Flash point                                  | No data available                                                                |
| i) Autoignition temperature                     | No data available                                                                |
| j) Decomposition temperature                    | No data available                                                                |
| k) pH                                           | No data available                                                                |
| l) Viscosity                                    | Viscosity, kinematic: No data available<br>Viscosity, dynamic: No data available |
| m) Water solubility                             | No data available                                                                |
| n) Partition coefficient: n-octanol/water       | No data available                                                                |
| o) Vapor pressure                               | No data available                                                                |
| p) Density                                      | No data available                                                                |
| Relative density                                | No data available                                                                |
| q) Relative vapor density                       | No data available                                                                |
| r) Particle characteristics                     | No data available                                                                |

- s) Explosive properties Not classified as explosive.
- t) Oxidizing properties none

## **9.2 Other safety information**

No data available

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## **SECTION 10: Stability and reactivity**

### **10.1 Reactivity**

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

### **10.2 Chemical stability**

The product is chemically stable under standard ambient conditions (room temperature) .

### **10.3 Possibility of hazardous reactions**

Violent reactions possible with:  
Strong oxidizing agents

### **10.4 Conditions to avoid**

no information available

### **10.5 Incompatible materials**

Strong oxidizing agents

### **10.6 Hazardous decomposition products**

In the event of fire: see section 5

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## **SECTION 11: Toxicological information**

### **11.1 Information on toxicological effects**

#### **Acute toxicity**

Oral: No data available  
Inhalation: No data available  
Dermal: No data available

#### **Skin corrosion/irritation**

No data available

#### **Serious eye damage/eye irritation**

No data available

#### **Respiratory or skin sensitization**

No data available

#### **Germ cell mutagenicity**

No data available

#### **Carcinogenicity**

Suspected of causing cancer.

#### **Reproductive toxicity**

Suspected of damaging the unborn child.  
Suspected of damaging fertility.  
Studies indicating a hazard to babies during the lactation period

#### **Specific target organ toxicity - single exposure**

May cause respiratory irritation.

**Specific target organ toxicity - repeated exposure**

No data available

**Aspiration hazard**

No data available

**11.2 Additional Information**

**Endocrine disrupting properties**

**Product:**

Assessment

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

prolonged or repeated exposure can cause:, Damage to the lungs., Liver injury may occur., Damage to the heart.

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**SECTION 12: Ecological information**

**12.1 Toxicity**

Toxicity to daphnia and other aquatic invertebrates

EC50 - Daphnia magna (Water flea) - 0,3 mg/l - 48 h  
Remarks: (External MSDS)

**12.2 Persistence and degradability**

Biodegradability

Result: - Not readily biodegradable.  
Remarks: (External MSDS)

**12.3 Bioaccumulative potential**

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Endocrine disrupting properties**

**Product:**

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**12.7 Other adverse effects**

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

No data available

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## SECTION 14: Transport information

### 14.1 UN number

ADR/RID: 3077

IMDG: 3077

IATA: 3077

### 14.2 UN proper shipping name

ADR/RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amiodarone hydrochloride)

IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amiodarone hydrochloride)

IATA: Environmentally hazardous substance, solid, n.o.s. (Amiodarone hydrochloride)

### 14.3 Transport hazard class(es)

ADR/RID: 9

IMDG: 9

IATA: 9

### 14.4 Packaging group

ADR/RID: III

IMDG: III

IATA: III

### 14.5 Environmental hazards

ADR/RID: yes

IMDG Marine pollutant: yes

IATA: yes

### 14.6 Special precautions for user

Tunnel restriction code : (-)

#### Further information

EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids. Packages smaller than or equal to 5 kg / L , not dangerous goods of Class 9

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## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

#### National legislation

Seveso III: Directive 2012/18/EU of the E1 ENVIRONMENTAL HAZARDS  
European Parliament and of the Council  
on the control of major-accident hazards  
involving dangerous substances.

#### Other regulations

Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.

Take note of Dir 94/33/EC on the protection of young people at work.

### 15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

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## SECTION 16: Other information

### Full text of H-Statements

|        |                                                                          |
|--------|--------------------------------------------------------------------------|
| H315   | Causes skin irritation.                                                  |
| H319   | Causes serious eye irritation.                                           |
| H335   | May cause respiratory irritation.                                        |
| H351   | Suspected of causing cancer.                                             |
| H361fd | Suspected of damaging fertility. Suspected of damaging the unborn child. |
| H362   | May cause harm to breast-fed children.                                   |
| H400   | Very toxic to aquatic life.                                              |
| H410   | Very toxic to aquatic life with long lasting effects.                    |

### Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

The information is believed to be correct but is not exhaustive and will be used solely as a guideline, which is based on current knowledge of the chemical substance or mixture and is applicable to appropriate safety precautions for the product. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact

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