SAFETY DATA SHEET

Version 5.4 Revision Date 07/19/2017 Print Date 11/10/2018

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name : Amiodarone hydrochloride

Product Number : A8423 Brand : Sigma

CAS-No. : 19774-82-4

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

Identified uses : Laboratory chemicals, Synthesis of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich

3050 Spruce Street SAINT LOUIS MO 63103

USA

Telephone : +1 800-325-5832 Fax : +1 800-325-5052

1.4 Emergency telephone number

Emergency Phone # : +1-703-527-3887 (CHEMTREC)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Inhalation (Category 4), H332 Acute toxicity, Dermal (Category 4), H312 Skin irritation (Category 2), H315

Eye irritation (Category 2A), H319
Reproductive toxicity (Category 2), H361

Specific target organ toxicity - repeated exposure (Category 2), H373

Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410

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

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word Warning

Hazard statement(s)

H312 + H332 Harmful in contact with skin or if inhaled

H315 Causes skin irritation.
H319 Causes serious eye irritation.

H361 Suspected of damaging fertility or the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

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Precautionary statement(s)

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and

understood.

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

P264 Wash skin thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face

protection.

P302 + P352 + P312 IF ON SKIN: Wash with plenty of water.Call a POISON CENTER/doctor if

you feel unwell.

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for

breathing. Call a POISON CENTER/doctor if you feel unwell.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Get medical advice/ attention. If skin irritation occurs: Get medical advice/ attention.

P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

P391 Collect spillage. P405 Store locked up.

P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS

Photosensitizer.

P308 + P313

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms : 2-Butyl-3-benzofuranyl-4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl

ketonehydrochloride

Formula : $C_{25}H_{29}I_2NO_3 \cdot HCI$

Molecular weight : 681.77 g/mol CAS-No. : 19774-82-4 EC-No. : 243-293-2

Hazardous components

Component	Classification	Concentration		
Amiodarone hydrochloride				
	Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2A; Repr. 2; STOT RE 2; Aquatic Acute 1; Aquatic Chronic 1; H312 + H332, H315, H319, H361, H373, H410	90 - 100 %		

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

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

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In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. 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

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

No data available

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature 2 - 8 °C

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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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values. Hazardous components without workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a)	Appearance	Form: solid	
b)	Odour	No data available	
c)	Odour Threshold	No data available	
d)	рН	No data available	
e)	Melting point/freezing point	No data available	
f)	Initial boiling point and boiling range	No data available	
g)	Flash point	No data available	
h)	Evaporation rate	No data available	
i)	Flammability (solid, gas)	No data available	
j)	Upper/lower flammability or explosive limits	No data available	
k)	Vapour pressure	No data available	
l)	Vapour density	No data available	
m)	Relative density	No data available	

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n) Water solubility No data available o) Partition coefficient: n-No data available

octanol/water

No data available p) Auto-ignition temperature

q) Decomposition temperature

No data available

Viscosity No data available r) s) Explosive properties No data available Oxidizing properties No data available

9.2 Other safety information

No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride gas, Hydrogen iodide

Other decomposition products - No data available

In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - > 3,000 mg/kg

Inhalation: No data available Dermal: No data available

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Sigma - A8423 Page 5 of 8 IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a

known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a

carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

No data available

Reproductive toxicity - Rat - Oral

Effects on Fertility: Pre-implantation mortality (e.g., reduction in numbe corpora lutea). Effects on Fertility: Other measures of fertility Effects on Newborn: Growth statistics (e.g., reduced weight gain).

Reproductive toxicity - Rat - Oral

Effects on Fertility: Litter size (e.g.; # fetuses per litter; measured before birth).

Reproductive toxicity - Rat - Oral Effects on Newborn: Physical.

No data available

Suspected human reproductive toxicant

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: OB1361000

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

Stomach - Irregularities - Based on Human Evidence Stomach - Irregularities - Based on Human Evidence

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life with long lasting effects.

No data available

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13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

Not dangerous goods

IMDG

UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amiodarone hydrochloride)

Marine pollutant:yes

IATA

UN number: 3077 Class: 9 Packing group: III

Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Amiodarone hydrochloride)

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.

15. REGULATORY INFORMATION

SARA 302 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

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.

CAS-No.

Revision Date

SARA 311/312 Hazards

Acute Health Hazard, Chronic Health Hazard

Massachusetts Right To Know Components

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

Pennsylvania Right To Know Components

Amiodarone hydrochloride	19774-82-4	2009-07-17
Amiodarone hydrochloride	CAS-No. 19774-82-4	Revision Date 2009-07-17
New Jersey Right To Know Components		
	CAS-No.	Revision Date
Amiodarone hydrochloride	19774-82-4	2009-07-17
California Prop. 65 Components		
WARNING: This product contains a chemical known to the	CAS-No.	Revision Date
State of California to cause birth defects or other reproductive	19774-82-4	1997-08-26
harm.		
Amiodarone hydrochloride		

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16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

Acute Tox. Acute toxicity

Aquatic Acute Acute aquatic toxicity
Aquatic Chronic Chronic aquatic toxicity

Eye Irrit. Eye irritation

H312 Harmful in contact with skin.

H312 + H332 Harmful in contact with skin or if inhaled

H315 Causes skin irritation. H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H361 Suspected of damaging fertility or the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

HMIS Rating

Health hazard: 2
Chronic Health Hazard: *
Flammability: 0
Physical Hazard 0

NFPA Rating

Health hazard: 2
Fire Hazard: 0
Reactivity Hazard: 0

Further information

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Preparation Information

Sigma-Aldrich Corporation Product Safety – Americas Region 1-800-521-8956

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