SAFETY DATA SHEET



1. Identification

Product identifier Amiodarone Related Compound H

Other means of identification

Catalog number 1027380 869-24-9 **CAS** number

Chemical name 2-chloro-N,N-diethylethanamine 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

U. S. Pharmacopeia Company name **Address** 12601 Twinbrook Parkway

> Rockville MD 20852-1790 **United States**

RS Technical Services 301-816-8129 Telephone

Website www.usp.org E-mail RSTECH@usp.org

CHEMTREC within US & **Emergency phone number** 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 2

> Acute toxicity, dermal Category 2 Acute toxicity, inhalation Category 2 Skin corrosion/irritation Category 1 Serious eye damage/eye irritation Category 1 Sensitization, skin Category 1

Environmental hazards Not classified. **OSHA** defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled. Causes severe skin burns and eye

damage. May cause an allergic skin reaction.

Precautionary statement

Prevention Do not breathe dust/fume. Do not get in eyes, on skin, or on clothing. Wash thoroughly after

handling. Use only outdoors or in a well-ventilated area. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eve protection/face

protection. In case of inadequate ventilation wear respiratory protection.

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If exposed: Immediately call a poison center/doctor. If swallowed: Rinse mouth. Do NOT induce Response

vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

Storage Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Pharmaceutical related compound of unknown potency.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Amiodarone Related Compound H		869-24-9	100

4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Do not use mouth-to-mouth method if the substance is inhaled.

Call a physician or poison control center immediately.

Remove contaminated clothing immediately and wash skin with soap and water. Call a physician Skin contact

or poison control center immediately. Chemical burns must be treated by a physician. Wash

contaminated clothing before reuse.

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if Eye contact

present and easy to do. Continue rinsing. Call a physician or poison control center immediately.

Ingestion Call a physician or poison control center immediately. Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if

substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a

one-way valve or other proper respiratory medical device.

Most important

symptoms/effects, acute and delayed

Indication of immediate medical attention and special

General information

treatment needed

Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.

Provide general supportive measures and treat symptomatically. Chemical burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital.

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 CO2. Use fire-extinguishing media appropriate for surrounding

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

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.

USP SDS US

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Wear appropriate personal protective equipment. 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. 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

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. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.

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. Consider double gloves.

Other

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. Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task.

Respiratory protection

Choose respiratory protection appropriate to the task and the level of existing engineering controls. Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup.

cover for spill clearlup.

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. Pharmacological effects may be seen with occupational exposure.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.
Form Powder.
Color Off-white.

Odor Not available.

Ph Not available.

Not available.

Melting point/freezing point 406.4 - 413.6 °F (208 - 212 °C)

Initial boiling point and boiling

range

Not available.

Flash point Not available.

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Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure 0.0000002 kPa at 25 °C

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Very soluble
Solubility (other) Ethanol: Soluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Molecular formulaC6H14Cl2N . HClMolecular weight172.08 g/molpH in aqueous solution5 Solution: 10%

Specific gravity 1.12

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong bases. Strong oxidizing agents.

Hazardous decomposition

products

NOx. CI-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation Fatal if inhaled.

Skin contact Fatal in contact with skin. Causes severe skin burns. May cause an allergic skin reaction.

Eye contact Causes serious eye damage.

Ingestion Fatal if swallowed. Causes digestive tract burns.

Symptoms related to the physical, chemical, and

toxicological characteristics

Burning pain and severe corrosive skin damage. Coughing. Wheezing. Rash. Permanent eye

damage including blindness could result.

Information on toxicological effects

Acute toxicity Fatal if inhaled. Fatal in contact with skin. Fatal if swallowed.

Product Species Test Results

Amiodarone Related Compound H (CAS 869-24-9)

Dermal

LD50 Rabbit 125 mg/kg

Inhalation

LC50 Rat 103 mg/m3, 4 hours

Material name: Amiodarone Related Compound H 1027380 Version #: 04 Revision date: 10-29-2019 Issue date: 12-30-2009 Product Species Test Results

Oral

LD50 Rat 24 mg/kg

Skin corrosion/irritation Causes severe skin burns and eye damage.

Serious eye damage/eye

irritation

Causes serious eye damage.

Local effects

100 mg Draize
Result: Irritation
Species: Rabbit
Organ: Eye
Severity: Severe
500 mg Draize
Result: Irritation
Species: Rabbit
Organ: Skin
Severity: Severe

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization May cause an allergic skin reaction.

Maximisation test

Result: Delayed contact hypersensitivity

Species: Guinea pig Organ: Skin.

Germ cell mutagenicityKnowledge about mutagenicity is incomplete.
Carcinogenicity
Knowledge about carcinogenicity is incomplete.

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.

Reproductive toxicity Knowledge about health hazard is incomplete.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Pharmaceutical related compound of unknown potency. It is not known if occupational exposure

may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this substance.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects 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

Disposal instructions Dispose in accordance with all applicable regulations. 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused products

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).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number UN2928

UN proper shipping name Toxic, solid, corrosive, organic, n.o.s. (Amiodarone Related Compound H)

Transport hazard class(es)

Class 6.1 Subsidiary risk 8 Packing group II

IATA

UN number UN2928

UN proper shipping name Transport hazard class(es) Toxic, solid, corrosive, organic, n.o.s. (Amiodarone Related Compound H)

Class 6.1 Subsidiary risk 8 Packing group II

Other information

Passenger and cargo

aircraft

Allowed with restrictions.

Cargo aircraft only
Transport in bulk according to

Annex II of MARPOL 73/78 and

Allowed with restrictions. Not applicable.

the IBC Code





IATA



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 Yes

chemical

Acute toxicity (any route of exposure)

categories

Skin corrosion or irritation Serious eve damage or eve irritation

Respiratory or skin sensitization

SARA 313 (TRI reporting)

Classified hazard

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

Not regulated.

Inventory name

(SDWA)

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region

Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
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)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

^{*}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

16. Other information, including date of preparation or last revision

Issue date 12-30-2009 10-29-2019 **Revision date**

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On inventory (yes/no)*

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