



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 24-Nov-2021

Revision Number 1

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

1.1. Product identifier

Product Code(s) CAT 532
Product Name Amiodarone hydrochloride Assay Standard

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No 243-293-2
CAS No 19774-82-4
Chemical name Amiodarone Hydrochloride
Pure substance/mixture Substance
Formula C₂₅H₂₉I₂NO₃.ClH
Molecular weight 681.81

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

Recommended use Laboratory use
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier

British Pharmacopoeia Commission
MHRA
10 South Colonnade
Canary Wharf
London E14 4PU
United Kingdom

Tel : +44 (0)20 3080 6561
eMail: bpcrs@mhra.gov.uk

For further information, please contact



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E-mail address bpcrs@mhra.gov.uk

1.4. Emergency telephone number

Emergency Telephone +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

| Emergency Telephone - §45 - (EC)1272/2008 | |
|---|---|
| Europe | 112 |
| Austria | No information available |
| Bulgaria | |
| Croatia | |
| Cyprus | |
| Czech Republic | |
| Denmark | |
| France | |
| Hungary | |
| Ireland | |
| Italy | |
| Lithuania | |
| Luxembourg | (+352) 8002 5500 Free telephone number with a 24/7 access in French, Dutch and English. |
| Netherlands | |
| Norway | |
| Portugal | |
| Romania | |
| Slovakia | |
| Slovenia | |
| Spain | |
| Sweden | |
| Switzerland | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

| | |
|--|----------------------|
| Skin corrosion/irritation | Category 2 - (H315) |
| Serious eye damage/eye irritation | Category 2 - (H319) |
| Reproductive toxicity | Category 1B - (H360) |
| Effects on or via lactation | Yes - (H362) |
| Specific target organ toxicity — repeated exposure | Category 2 - (H373) |



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2.2. Label elements

Contains Amiodarone Hydrochloride



Signal word
Danger

Hazard statements

H315 - Causes skin irritation
H319 - Causes serious eye irritation
H360 - May damage fertility or the unborn child
H362 - May cause harm to breast-fed children
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use
P260 - Do not breathe dust/fume/gas/mist/vapours/spray
P263 - Avoid contact during pregnancy and while nursing
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical advice/attention

2.3. Other hazards

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information

| Chemical name | EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation | EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances |
|--------------------------|---|--|
| Amiodarone Hydrochloride | - | - |

SECTION 3: Composition/information on ingredients



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3.1 Substances

| Chemical name | Weight-% | REACH registration number | EC No | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|--|----------|---------------------------|-----------|--|------------------------------------|----------|----------------------|
| Amiodarone Hydrochloride 19774-82-4 | 100 | - | 243-293-2 | Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Repr. 1B (H360) Lact. (H362) STOT RE 2 (H373) | | | |

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

| Chemical name | Oral LD50 mg/kg | Dermal LD50 mg/kg | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapour - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|--|-----------------|-------------------|---|--|--------------------------------------|
| Amiodarone Hydrochloride 19774-82-4 | 3000 | No data available | No data available | No data available | No data available |

Additional information

This component contains a stable isotope.

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance.

Inhalation

Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and



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|---|--|
| | persists. |
| Skin contact | Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists. |
| Ingestion | Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a doctor. |
| Self-protection of the first aider | Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8). |

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

Symptoms May cause redness and tearing of the eyes. Burning sensation.

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

Note to doctors Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate



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|---|--|
| | personnel to safe areas. Avoid contact with skin, eyes or clothing. |
| Other information | Refer to protective measures listed in Sections 7 and 8. |
| For emergency responders | Use personal protection recommended in Section 8. |
| <u>6.2. Environmental precautions</u> | |
| Environmental precautions | Prevent further leakage or spillage if safe to do so. |
| <u>6.3. Methods and material for containment and cleaning up</u> | |
| Methods for containment | Prevent further leakage or spillage if safe to do so. |
| Methods for cleaning up | Take up mechanically, placing in appropriate containers for disposal. |
| Prevention of secondary hazards | Clean contaminated objects and areas thoroughly observing environmental regulations. |
| <u>6.4. Reference to other sections</u> | |
| Reference to other sections | See section 8 for more information. See section 13 for more information. |

SECTION 7: Handling and storage

7.1. Precautions for safe handling

| | |
|---------------------------------------|---|
| Advice on safe handling | Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Ensure adequate ventilation. Take off contaminated clothing and wash it before reuse. |
| General hygiene considerations | Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product. |

7.2. Conditions for safe storage, including any incompatibilities

| | |
|---------------------------|---|
| Storage Conditions | Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. |
|---------------------------|---|

7.3. Specific end use(s)

| | |
|--------------------------------------|--|
| Risk Management Methods (RMM) | The information required is contained in this Safety Data Sheet. |
|--------------------------------------|--|



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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL)

No information available.

Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection

Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields.

Hand protection

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear suitable gloves. Impervious gloves.

| Gloves | | | |
|---------------------|-------------------------------------|-----------------|--------------------|
| Duration of contact | PPE - Glove material | Glove thickness | Break through time |
| | Wear protective butyl rubber gloves | | |

Skin and body protection

Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face



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protection. Wash hands before breaks and immediately after handling the product.

Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|-----------------|---------------------------|
| Physical state | Solid |
| Appearance | Solid |
| Colour | white |
| Odour | No information available. |
| Odour threshold | No information available |

| Property | Values | Remarks • Method |
|--|--|--------------------------|
| Melting point / freezing point | 154 - 158 °C | None known |
| Boiling point / boiling range | No data available | None known |
| Flammability (solid, gas) | No data available | None known |
| Flammability Limit in Air | | None known |
| Upper flammability or explosive limits | No data available | |
| Lower flammability or explosive limits | No data available | |
| Flash point | No data available | None known |
| Autoignition temperature | No data available | None known |
| Decomposition temperature | | None known |
| pH | No data available | None known |
| pH (as aqueous solution) | No data available | No information available |
| Kinematic viscosity | No data available | None known |
| Dynamic viscosity | No data available | None known |
| Water solubility | Insoluble in water 700mg/L | None known |
| Solubility(ies) | Chloroform, Methanol, slightly soluble | |
| Partition coefficient | 4.92 | None known |
| Vapour pressure | No data available | None known |
| Relative density | No data available | None known |
| Bulk density | No data available | |
| Liquid Density | No data available | |
| Relative vapour density | No data available | None known |
| Particle characteristics | | |
| Particle Size | No information available | |
| Particle Size Distribution | No information available | |

9.2. Other information

| | |
|-------------------|---|
| Molecular weight | 681.81 |
| Molecular formula | C ₂₅ H ₂₉ I ₂ NO ₃ .ClH |



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9.2.1. Information with regards to physical hazard classes
Not applicable

9.2.2. Other safety characteristics
No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong acids. Strong bases. Strong oxidising agents.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of



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| | |
|---------------------|---|
| | respiratory tract. |
| Eye contact | Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain. |
| Skin contact | Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components). |
| Ingestion | Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. |

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity

Acute toxicity

Component Information

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|--------------------------|------------------|-------------|-----------------|
| Amiodarone Hydrochloride | > 3 g/kg (Rat) | | |

Delayed and immediate effects as well as chronic effects from short and long-term exposure

| | |
|--|--|
| Skin corrosion/irritation | Classification based on data available for ingredients. Irritating to skin. |
| Serious eye damage/eye irritation | Classification based on data available for ingredients. Causes serious eye irritation. |
| Respiratory or skin sensitisation | No information available. |
| Germ cell mutagenicity | No information available. |
| Carcinogenicity | No information available. |



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Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child. May cause harm to breast-fed children.

STOT - single exposure No information available.

STOT - repeated exposure May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

| Chemical name | Partition coefficient |
|--------------------------|-----------------------|
| Amiodarone Hydrochloride | 4.92 |



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12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

| | |
|-----------------------------------|----------------|
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Environmental hazards | Not applicable |
| 14.6 Special precautions for user | |
| Special Provisions | None |

IMDG

| | |
|---------------------------------|---------------|
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |



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| | |
|--|-------------------------------|
| 14.5 Marine pollutant | Not applicable |
| 14.6 Special precautions for user | |
| Special Provisions | None No information available |
| 14.7 Maritime transport in bulk according to IMO instruments | No information available |

RID

| | |
|-----------------------------------|----------------|
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Environmental hazards | Not applicable |
| 14.6 Special precautions for user | |
| Special Provisions | None |

ADR

| | |
|-----------------------------------|----------------|
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Environmental hazards | Not applicable |
| 14.6 Special precautions for user | |
| Special Provisions | None |

SECTION 15: Regulatory information

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

National regulations

Germany

Water hazard class (WGK) slightly hazardous to water (WGK 1)

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)



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DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

| | |
|---------------|--|
| TSCA | Contact supplier for inventory compliance status |
| DSL/NDL | Contact supplier for inventory compliance status |
| EINECS/ELINCS | Contact supplier for inventory compliance status |
| ENCS | Contact supplier for inventory compliance status |
| IECSC | Contact supplier for inventory compliance status |
| KECL | Contact supplier for inventory compliance status |
| PICCS | Contact supplier for inventory compliance status |
| AICS | Contact supplier for inventory compliance status |

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment has been carried out for this substance

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet



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Full text of H-Statements referred to under section 3

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H360 - May damage fertility or the unborn child

H362 - May cause harm to breast-fed children

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

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average)

Ceiling Maximum limit value

STEL

*

STEL (Short Term Exposure Limit)

Skin designation

| Classification procedure | |
|---|--------------------|
| Classification according to Regulation (EC) No. 1272/2008 [CLP] | Method Used |
| Acute oral toxicity | Calculation method |
| Acute dermal toxicity | Calculation method |
| Acute inhalation toxicity - gas | Calculation method |
| Acute inhalation toxicity - Vapour | Calculation method |
| Acute inhalation toxicity - dust/mist | Calculation method |
| Skin corrosion/irritation | Calculation method |
| Serious eye damage/eye irritation | Calculation method |
| Respiratory sensitisation | Calculation method |
| Skin sensitisation | Calculation method |
| Mutagenicity | Calculation method |
| Carcinogenicity | Calculation method |
| STOT - single exposure | Calculation method |
| STOT - repeated exposure | Calculation method |
| Acute aquatic toxicity | Calculation method |
| Chronic aquatic toxicity | Calculation method |
| Aspiration hazard | Calculation method |
| Ozone | Calculation method |

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals



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Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 24-Nov-2021

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

Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

End of Safety Data Sheet