

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

1 Identification

- **1.1 Product identifier**
- **Trade name:** Amiodarone by HPLC, MP
- **Article number:** 1955923
- **Application of the substance / the mixture** *In-Vitro-laboratory reagent or component*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
 Bio-Rad Laboratories, Inc
 4000 Alfred Nobel Drive
 Hercules, California 94547
 USA
 Phone: 510-724-7000
 Toll-Free: 1-800-2-BIORAD (800-224-6723)
 Fax: 510-741-6373
- **Information department:**
 Technical Support:
 Email: support@bio-rad.com
- **1.4 Emergency telephone number:**
 GBK Gefahrgut Büro GmbH
 Tel.: 0049(0)6123-84463

2 Hazard(s) identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Flam. Liq. 2 H225 Highly flammable liquid and vapor.
Water-react. 1 H260 In contact with water releases flammable gases, which may ignite spontaneously.
Acute Tox. 5 H313 May be harmful in contact with skin.
Acute Tox. 3 H331 Toxic if inhaled.
Eye Irrit. 2A H319 Causes serious eye irritation.
STOT SE 1 H370 Causes damage to organs.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labeled according to the CLP regulation.
- **Hazard pictograms**



GHS02 GHS06 GHS07 GHS08

- **Signal word** *Danger*
- **Hazard-determining components of labeling:**
methanol
acetonitrile
- **Hazard statements**
H225 Highly flammable liquid and vapor.
H260 In contact with water releases flammable gases, which may ignite spontaneously.
H313 May be harmful in contact with skin.
H331 Toxic if inhaled.
H319 Causes serious eye irritation.
H370 Causes damage to organs.

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 1)

Precautionary statements

- P223 Do not allow contact with water.
 P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
 P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:

NFPA ratings (scale 0 - 4)



Health = 1
 Fire = 3
 Reactivity = 2

The substance demonstrates unusual reactivity with water.

HMIS-ratings (scale 0 - 4)



Health = *1
 Fire = 3
 Reactivity = 2

2.3 Other hazards

Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

3 Composition/information on ingredients

3.2 Chemical characterization: Mixtures

Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components:

| | | |
|---------|--------------|--------|
| 75-05-8 | acetonitrile | 25-50% |
| 67-56-1 | methanol | 25-50% |

4 First-aid measures

4.1 Description of first aid measures

General information:

Immediately remove any clothing soiled by the product.
 Remove breathing apparatus only after contaminated clothing have been completely removed.
 In case of irregular breathing or respiratory arrest provide artificial respiration.

After inhalation:

Supply fresh air or oxygen; call for doctor.
 In case of unconsciousness place patient stably in side position for transportation.

After skin contact: Immediately wash with water and soap and rinse thoroughly.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing: Do not induce vomiting; immediately call for medical help.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 2)

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

For safety reasons unsuitable extinguishing agents: Water

5.2 Special hazards arising from the substance or mixture

Hydrogen cyanide (HCN)

Carbon monoxide (CO)

5.3 Advice for firefighters

Protective equipment: Mouth respiratory protective device.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

Do not flush with water or aqueous cleansing agents

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

Protective Action Criteria for Chemicals

PAC-1:

| | | |
|----------|------------------|-----------------------|
| 75-05-8 | acetonitrile | 13 ppm |
| 67-56-1 | methanol | 530 ppm |
| 64-19-7 | acetic acid | 5 ppm |
| 631-61-8 | ammonium acetate | 3.8 mg/m ³ |

PAC-2:

| | | |
|----------|------------------|----------------------|
| 75-05-8 | acetonitrile | 50 ppm |
| 67-56-1 | methanol | 2,100 ppm |
| 64-19-7 | acetic acid | 35 ppm |
| 631-61-8 | ammonium acetate | 42 mg/m ³ |

PAC-3:

| | | |
|----------|------------------|-----------------------|
| 75-05-8 | acetonitrile | 150 ppm |
| 67-56-1 | methanol | 7200* ppm |
| 64-19-7 | acetic acid | 250 ppm |
| 631-61-8 | ammonium acetate | 250 mg/m ³ |

US

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 3)

7 Handling and storage

7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.

Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Keep respiratory protective device available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: Store in a cool location.

Information about storage in one common storage facility: Not required.

Further information about storage conditions:

Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.

7.3 Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

Additional information about design of technical systems: No further data; see item 7.

8.1 Control parameters

Components with limit values that require monitoring at the workplace:

75-05-8 acetonitrile

PEL Long-term value: 70 mg/m³, 40 ppm

REL Long-term value: 34 mg/m³, 20 ppm

TLV Long-term value: 34 mg/m³, 20 ppm
Skin

67-56-1 methanol

PEL Long-term value: 260 mg/m³, 200 ppm

REL Short-term value: 325 mg/m³, 250 ppm
Long-term value: 260 mg/m³, 200 ppm
Skin

TLV Short-term value: 328 mg/m³, 250 ppm
Long-term value: 262 mg/m³, 200 ppm
Skin; BEI

Ingredients with biological limit values:

67-56-1 methanol

BEI 15 mg/L
Medium: urine
Time: end of shift
Parameter: Methanol (background, nonspecific)

Additional information: The lists that were valid during the creation were used as basis.

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.

(Contd. on page 5)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 4)

*Wash hands before breaks and at the end of work.**Store protective clothing separately.**Avoid contact with the eyes.**Avoid contact with the eyes and skin.***· Breathing equipment:***In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.***· Protection of hands:**

Protective gloves

*The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.**Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.**Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation***· Material of gloves***The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.***· Penetration time of glove material***The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.***· Eye protection:**

Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

· 9.1 Information on basic physical and chemical properties**· General Information****· Appearance:**

| | |
|------------------------|-----------------|
| Form: | Fluid |
| Color: | Colorless |
| Odor: | Alcohol-like |
| Odor threshold: | Not determined. |

· pH-value at 20 °C (68 °F): 4.5**· Change in condition**

| | |
|-------------------------------------|------------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | >82 °C (>180 °F) |

· Flash point: 5 °C (41 °F)**· Flammability (solid, gaseous):** Not applicable.**· Ignition temperature:** 455 °C (851 °F)

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 5)

| | |
|---|--|
| · Decomposition temperature: | Not determined. |
| · Auto igniting: | Product is not selfigniting. |
| · Danger of explosion: | Product is not explosive. However, formation of explosive air/vapor mixtures are possible. |
| · Explosion limits: | |
| Lower: | 3.0 Vol % |
| Upper: | 44.0 Vol % |
| · Vapor pressure at 20 °C (68 °F): | 128 hPa (96 mm Hg) |
| · Density at 20 °C (68 °F): | 0.95 g/cm ³ (7.92775 lbs/gal) |
| · Relative density | Not determined. |
| · Vapor density | Not determined. |
| · Evaporation rate | Not determined. |
| · Solubility in / Miscibility with Water: | Fully miscible. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| VOC content: | 34.2 % |
| · 9.2 Other information | No further relevant information available. |

10 Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**
 Reacts with acids.
 Reacts with alkali (lyes).
 Contact with water releases flammable gases.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
 Hydrogen cyanide (prussic acid)
 Carbon monoxide and carbon dioxide

11 Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
 May be harmful in contact with skin.
 Toxic if inhaled.
- **Primary irritant effect:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:**
 Causes serious eye irritation.
- **Sensitization:** Based on available data, the classification criteria are not met.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 6)

· **Additional toxicological information:**· **Carcinogenic categories**· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **12.1 Toxicity**· **Aquatic toxicity:** No further relevant information available.· **12.2 Persistence and degradability** No further relevant information available.· **12.3 Bioaccumulative potential** No further relevant information available.· **12.4 Mobility in soil** No further relevant information available.· **Additional ecological information:**· **General notes:**

Water hazard class 2 (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

· **12.5 Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **12.6 Other adverse effects** No further relevant information available.

13 Disposal considerations

· **13.1 Waste treatment methods**· **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**· **Recommendation:** Disposal must be made according to official regulations.· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **14.1 UN-Number**· **DOT, ADR, IMDG, IATA**

UN1992

· **14.2 UN proper shipping name**· **DOT**· **ADR**· **IMDG, IATA**

Flammable liquids, toxic, n.o.s. (Methanol, Acetonitrile)

1992 Flammable liquids, toxic, n.o.s. (Methanol, Acetonitrile)

FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL, ACETONITRILE)

(Contd. on page 8)

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 7)

· **14.3 Transport hazard class(es)**

· **DOT**



· **Class** 3 Flammable liquids
· **Label** 3, 6.1

· **ADR**



· **Class** 3 Flammable liquids
· **Label** 3+6.1

· **IMDG**



· **Class** 3 Flammable liquids
· **Label** 3/6.1

· **IATA**



· **Class** 3 Flammable liquids
· **Label** 3 (6.1)

· **14.4 Packing group**

· **DOT, ADR, IMDG, IATA** II

· **14.5 Environmental hazards:**

· **Marine pollutant:** No

· **14.6 Special precautions for user**

· **Danger code (Kemler):** Warning: Flammable liquids
339
· **EMS Number:** F-E,S-D
· **Stowage Category** B
· **Stowage Code** SW2 Clear of living quarters.

· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

· **Transport/Additional information:**

· **ADR**

· **Excepted quantities (EQ)** Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml

(Contd. on page 9)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 8)

| | |
|-----------------------------------|---|
| · IMDG | |
| · Limited quantities (LQ) | 1L |
| · Excepted quantities (EQ) | Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml |
| · UN "Model Regulation": | UN 1992 FLAMMABLE LIQUIDS, TOXIC, N.O.S. (METHANOL, ACETONITRILE), 3 (6.1), II |

15 Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

| |
|--|
| · Section 355 (extremely hazardous substances): |
|--|

| |
|-----------------------------------|
| None of the ingredient is listed. |
|-----------------------------------|

| |
|--|
| · Section 313 (Specific toxic chemical listings): |
|--|

| | |
|---------|--------------|
| 75-05-8 | acetonitrile |
|---------|--------------|

| | |
|---------|----------|
| 67-56-1 | methanol |
|---------|----------|

| |
|---|
| · TSCA (Toxic Substances Control Act): |
|---|

| |
|-----------------------------|
| All ingredients are listed. |
|-----------------------------|

| |
|-------------------------|
| · Proposition 65 |
|-------------------------|

| |
|---|
| · Chemicals known to cause cancer: |
|---|

| |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

| |
|--|
| · Chemicals known to cause reproductive toxicity for females: |
|--|

| |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

| |
|--|
| · Chemicals known to cause reproductive toxicity for males: |
|--|

| |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

| |
|---|
| · Chemicals known to cause developmental toxicity: |
|---|

| | |
|---------|----------|
| 67-56-1 | methanol |
|---------|----------|

| |
|-------------------------------------|
| · Carcinogenicity categories |
|-------------------------------------|

| |
|--|
| · EPA (Environmental Protection Agency) |
|--|

| | | |
|---------|--------------|--------|
| 75-05-8 | acetonitrile | CBD, D |
|---------|--------------|--------|

| | | |
|----------|------------------|---|
| 631-61-8 | ammonium acetate | D |
|----------|------------------|---|

| |
|---|
| · TLV (Threshold Limit Value established by ACGIH) |
|---|

| | | |
|---------|--------------|----|
| 75-05-8 | acetonitrile | A4 |
|---------|--------------|----|

| |
|---|
| · NIOSH-Ca (National Institute for Occupational Safety and Health) |
|---|

| |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

(Contd. on page 10)

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 9)

· **Department issuing SDS:**

Bio-Rad Laboratories GmbH
Heidemannstrasse 164
D-80939 Munich

· **Contact:**

Technical Support:
E-Mail: cts-ce@bio-rad.com

· **Date of preparation / last revision 02/13/2017 / 13**

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

BEI: Biological Exposure Limit

Flam. Liq. 2: Flammable liquids – Category 2

Water-react. 1: Substances and mixtures which in contact with water emit flammable gases – Category 1

Acute Tox. 5: Acute toxicity – Category 5

Acute Tox. 3: Acute toxicity – Category 3

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

STOT SE 1: Specific target organ toxicity (single exposure) – Category 1

· *** Data compared to the previous version altered.**