

Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

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

· 1.1 Product identifier

· Trade name: Amiodarone by HPLC, MP

· Article number: 1955923

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

No further relevant information available.

- · 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 Ltd.

Bio-Rad House Maxted Road Hemel Hempstead

Hertfordshire HP2 7DX Freephone: 0800 181134 Tel: +44 (0)208 328 2000 Fax: +44 (0) 208 328 2550

· Further information obtainable from:

Technical Support:

techsupport.uk@bio-rad.com

· 1.4 Emergency telephone number:

GBK Gefahrgut Büro GmbH Tel.: 0049(0)6123-84463

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

H225 Highly flammable liquid and vapour.

Water-react. 1 H260 In contact with water releases flammable gases which may ignite spontaneously.

Acute Tox. 3 H331 Toxic if inhaled.

Eye Irrit. 2 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 labelled according to the CLP regulation.

· Hazard pictograms







GHS02

GHS06

GHS08

- · Signal word Danger
- · Hazard-determining components of labelling:

methanol

acetonitrile

· Hazard statements

H225 Highly flammable liquid and vapour.

H260 In contact with water releases flammable gases which may ignite spontaneously.

H331 Toxic if inhaled.

H319 Causes serious eye irritation.

(Contd. on page 2)



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 1)

H370 Causes damage to organs.

· 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.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

• **PBT:** Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

	Dangerous components:			
		acetonitrile	25-50%	
	EINECS: 200-835-2	♠ Flam. Liq. 2, H225; ♠ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319		
ĺ		methanol	25-50%	
	EINECS: 200-659-6	♠ Flam. Liq. 2, H225; ♠ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; ♠ STOT SE 1, H370		

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information:

Immediately remove any clothing soiled by the product.

Remove breathing equipment 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; call for medical help immediately.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

- GB



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 2)

SECTION 5: Firefighting measures

- 5.1 Extinguishing media
- Suitable extinguishing agents:

CO2, 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.

SECTION 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.

SECTION 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 fire - and explosion protection:

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 container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

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

SECTION 8: Exposure controls/personal protection

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

(Contd. on page 4)



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 3)

· 8.1 Control parameters

·Ingre	Ingredients with limit values that require monitoring at the workplace:				
75-03	5-8 acetonitrile				
WEL	Short-term value: 102 mg/m³, 60 ppm Long-term value: 68 mg/m³, 40 ppm				
67-56-1 methanol					
WEL	Short-term value: 333 mg/m³, 250 ppm Long-term value: 266 mg/m³, 200 ppm Sk				

- · Additional information: The lists valid during the making 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

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.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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 trough 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



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 4)

SECTION 9: Physical and chemical properties				
9.1 Information on basic physical and c	hemical properties			
General Information				
Appearance:				
Form:	Fluid			
Colour:	Colourless			
Odour:	Alcohol-like			
Odour threshold:	Not determined.			
pH-value at 20 °C:	4.5			
Change in condition				
Melting point/freezing point:	Undetermined.			
Initial boiling point and boiling range	:>82 °C			
Flash point:	5 °C			
Flammability (solid, gas):	Not applicable.			
Ignition temperature:	455 °C			
Decomposition temperature:	Not determined. Product is not selfigniting. Product is not explosive. However, formation of explosive air/vapour mixtures are possible.			
Auto-ignition temperature:				
Explosive properties:				
Explosion limits:				
Lower:	3.0 Vol %			
Upper:	44.0 Vol %			
Vapour pressure at 20 °C:	128 hPa			
Density at 20 °C:	0.95 g/cm^3			
Relative density	Not determined.			
Vapour 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.			
9.2 Other information	No further relevant information available.			

SECTION 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.

(Contd. on page 6)



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 5)

· 10.6 Hazardous decomposition products:

Hydrogen cyanide (prussic acid) Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity

Toxic if inhaled.

- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation

Causes serious eye irritation.

- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure

Causes damage to organs.

- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 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 (German Regulation) (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.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

GB



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 6)

14.1 UN-Number ADR, IMDG, IATA	UN1992
14.2 UN proper shipping name	
ADR	1992 FLAMMABLE LIQUID, TOXIC, N.O.S.
IMDC 14T4	(METHANOL, ACETONITRILE) FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL,
IMDG, IATA	ACETONITRILE)
14.3 Transport hazard class(es)	
ADR	
Class	3 Flammable liquids.
Label	3+6.1
<i>IMDG</i>	
Class	3 Flammable liquids.
Label	3/6.1
Class Label	3 Flammable liquids. 3 (6.1)
14.4 Packing group	
ADR, IMDĞ, İATA	II
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler): EMS Number:	339 F-E,S-D
EMS Number: Stowage Category	F-E,S-D B
Stowage Code	SW2 Clear of living quarters.
14.7 Transport in bulk according to Ann Marpol and the IBC Code	e x II of Not applicable.
Transport/Additional information:	
ADR	



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

	(Contd. of
Excepted quantities (EQ)	Code: E2
• • •	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E
<i>IMDG</i>	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
1 1 ~ ~ ~	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1992 FLAMMABLE LIQUID, TOXIC, N.O.S.
· ·	(METHANOL, ACETONITRILE), 3 (6.1), II

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I methanol
- · Seveso category

H2 ACUTE TOXIC

O2 Substances and mixtures which in contact with water emit flammable gases P5c FLAMMABLE LIQUIDS

- \cdot Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 40
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.

· Relevant phrases

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H332 Harmful if inhaled.

H370 Causes damage to organs.

Department issuing SDS:

Bio-Rad Laboratories GmbH

Heidemannstrasse 164

D-80939 Munich

· Contact:

Technical Support:

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

· 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)

(Contd. on page 9)



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 8)

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

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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. 3: Acute toxicity – Category 3

Acute Tox. 4: Acute toxicity - Category 4

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

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

* * Data compared to the previous version altered.

CD