

Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

· Product identifier

· Trade name: Amiodarone by HPLC, MP

· Article number: 1955923

· 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
- Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Bio-Rad Laboratories Pty., Ltd. Level 5, 446 Victoria Road

Gladesville, New South Wales 2111

Phone: +61 (2) 9914-2800 Fax: +61 (2) 9914-2888

· Further information obtainable from:

Technical Support:

E-mail: TechSupport.ANZCDG@bio-rad.com

· Emergency telephone number: GBK Gefahrgut Büro GmbH Tel.: 0049(0)6123-84463

### 2 Hazard(s) Identification

· Classification of the substance or mixture

Flam. Liq. 2 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. 2A H319 Causes serious eye irritation. STOT SE 1 H370 Causes damage to organs.

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms







GHS02 GHS06

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

methanol acetonitrile

· Hazard statements

Highly flammable liquid and vapour.

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

Toxic if inhaled.

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)

Causes damage to organs.

#### · Precautionary statements

Do not allow contact with water.

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Store locked up.

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

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

# 3 Composition and Information on Ingredients

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

· Dangerous components:				
75-05-8	acetonitrile	25-50%		
	♠ Flam. Liq. 2, H225; ♠ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2A, H319			
67-56-1	methanol	25-50%		
	<ul> <li>Flam. Liq. 2, H225;</li> <li>Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331;</li> <li>STOT SE 1, H370</li> </ul>			

<sup>·</sup> Additional information: For the wording of the listed hazard phrases refer to section 16.

#### 4 First Aid Measures

- · 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.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- Indication of any immediate medical attention and special treatment needed

No further relevant information available.

# 5 Fire Fighting Measures

- · Extinguishing media
- · Suitable extinguishing agents:

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

(Contd. on page 3)



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 2)

- · For safety reasons unsuitable extinguishing agents: Water
- · Special hazards arising from the substance or mixture

Hydrogen cyanide (HCN)

Carbon monoxide (CO)

- · Advice for firefighters
- · Protective equipment: Mouth respiratory protective device.

#### 6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

Dilute with plenty of water.

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

· 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

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.

### 7 Handling and Storage

- · Handling:
- · 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.

- · 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.

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

### 8 Exposure controls and 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)

#### · Control parameters

Ingredients with limit values that require monitoring at the workplace:				
75-05-8 acetonitrile				
WES Short-term value: 101 mg/m³, 60 ppm				
Long-term value: 67 mg/m³, 40 ppm				
Sk				
67-56-1 methanol				
WES Short-term value: 328 mg/m³, 250 ppm				
Long-term value: 262 mg/m³, 200 ppm				
Sk				

- · Additional information: The lists valid during the making were used as basis.
- · 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)

Physical and Chemical Propertie	es es
Information on basic physical and che General Information	mical properties
Appearance:	
Form:	Fluid
Colour:	Colourless
Odour throat ald	Alcohol-like Not determined.
Odour threshold:	Not determined.
pH-value at 20 °C:	4.5
Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling rang	
Flash point:	5 °C
Flammability (solid, gas):	Not applicable.
Ignition temperature:	455 °C
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
Explosion limits:	
Lower:	3.0 Vol %
Upper:	44.0 Vol %
Vapour pressure at 20 °C:	128 hPa
Density at 20 °C:	0.95 g/cm³
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.
Other information	No further relevant information available.

# 10 Stability and Reactivity

- $\cdot \textit{Reactivity} \ \textit{No further relevant information available}.$
- · Chemical stability
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions

Reacts with acids.

Reacts with alkali (lyes).

Contact with water releases flammable gases.

- · Conditions to avoid No further relevant information available.
- · 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)

· Hazardous decomposition products:

Hydrogen cyanide (prussic acid) Carbon monoxide and carbon dioxide

### 11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity
- Primary irritant effect:
- · Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation Irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.
- · Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

**Toxic** 

Irritant

# 12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · 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.

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

# 13 Disposal considerations

- · 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.

# 14 Transport information

- · UN-Number
- · ADG, IMDG, IATA

UN1992

(Contd. on page 7)



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

	(Contd. of pag
UN proper shipping name	
ADG	1992 FLAMMABLE LIQUID, TOXIC, N.O.S.
HADO LATA	(METHANOL, ACETONITRILE)
IMDG, IATA	FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL ACETONITRILE)
Transport hazard class(es)	
ADG	
3	
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)
Packing group ADG, IMDG, IATA	II
Environmental hazards: Marine pollutant:	No
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.
Transport in bulk according to Annex II of	
and the IBC Code	Not applicable.
Transport/Additional information:	
ADG	11
Limited quantities (LQ)  Excepted quantities (EQ)	1L Code: E2
Excepted quantities (EQ)	Maximum net quantity per inner packaging: 30 ml
Transport category	Maximum net quantity per outer packaging: 500 ml 2
Tunnel restriction code	D/E
	_, <u>_</u>



Printing date 13.02.2017 Version number 14 Revision: 04.01.2017

Trade name: Amiodarone by HPLC, MP

(Contd. of page 7)

· IMDG	
· Limited quantities (LQ)	lL
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 LIQUID, TOXIC, N.O.S. (METHANOL, ACETONITRILE), 3 (6.1), II

## 15 Regulatory information

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

· Australian Inventory of Chemical Substances				
All ingredients are listed.				
· Standard for the Uniform Scheduling of Medicines and Poisons				
67-56-1 methanol	S5, S6			
64-19-7 acetic acid	S2, S5, S6			

#### · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms







GHS02

GHS06

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

methanol

acetonitrile

#### · Hazard statements

Highly flammable liquid and vapour.

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

Toxic if inhaled.

Causes serious eye irritation.

Causes damage to organs.

#### · Precautionary statements

Do not allow contact with water.

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to

do. Continue rinsing. Store locked up.

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

- · 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

(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)

- · Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- · 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.

#### · 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)

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

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

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