

## 02/13/2017

## **Kit Components**

Product code	Description		
195-5917	Amiodarone by HPLC, Reagent Kit		
Components:			
1955922	Amiodarone by HPLC, REAG 1		
1955923	Amiodarone by HPLC, MP		
1955920	Amiodarone by HPLC, CAL		



Printing date 02/13/2017 Reviewed on 02/10/2017

## 1 Identification

· 1.1 Product identifier

· Trade name: Amiodarone by HPLC, REAG 1

· Article number: 1955922

· 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.

Acute Tox. 5 H303 May be harmful if swallowed.

Acute Tox. 4 H312 Harmful in contact with skin.

Acute Tox. 5 H333 May be harmful if inhaled.

Eye Irrit. 2A H319 Causes serious eye irritation.

- · 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

S02 GHS07

- · Signal word Danger
- · Hazard-determining components of labeling: acetonitrile
- · Hazard statements

H225 Highly flammable liquid and vapor.

H303 May be harmful if swallowed.

H312 Harmful in contact with skin.

H333 May be harmful if inhaled.

H319 Causes serious eye irritation.

· Precautionary statements

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P241 Use explosion-proof electrical/ventilating/lighting/equipment.

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*P280* Wear protective gloves/protective clothing/eye protection/face protection.

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.

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

- · Classification system:
- · NFPA ratings (scale 0 4)



P501

Health = 4 Fire = 3 Reactivity = 0

· HMIS-ratings (scale 0 - 4)



- · 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

50-100%

### 4 First-aid measures

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

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

 ${\it In \ case \ of \ unconsciousness \ place \ patient \ stably \ in \ side \ position \ for \ transportation}.$ 

- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact:

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

- · After swallowing: Immediately call a doctor.
- · 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.

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Trade name: Amiodarone by HPLC, REAG 1

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## 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.

· 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.

· 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
· PAC-2:	
75-05-8 acetonitrile	50 ppm
· PAC-3:	
75-05-8 acetonitrile	150 ppm

### 7 Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 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.

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· 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

· Com	· Components with limit values that require monitoring at the workplace:			
75-0	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			

- · 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.

Wash hands before breaks and at the end of work.

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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

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· Body protection: Protective work clothing

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## 9 Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information	
Appearance:	F1 · 1
Form:	Fluid
Color:	Colorless Ether-like
Odor: Odor threshold:	Einer-like Not determined.
Caor inresnoia:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	-45.7 °C (-50 °F)
Boiling point/Boiling range:	81 °C (178 °F)
Flash point:	5 °C (41 °F)
Flammability (solid, gaseous):	Not applicable.
Ignition temperature:	524 °C (975 °F)
Decomposition temperature:	Not determined.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product is not explosive. However, formation of explosive air/vapo mixtures are possible.
Explosion limits:	
Lower:	3 Vol %
Upper:	17 Vol %
Vapor pressure at 20 °C (68 °F):	97 hPa (73 mm Hg)
Density at 20 °C (68 °F):	0.79 g/cm³ (6.59255 lbs/gal)
Relative density	Not determined.
Vapor density	Not determined.
·	

## · Solubility in / Miscibility with

Water: Fully miscible.

- · Partition coefficient (n-octanol/water): Not determined.
- · Viscosity:

· Evaporation rate

**Dynamic:** Not determined. **Kinematic:** Not determined.

• 9.2 Other information No further relevant information available.

Not determined.

## 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, alkalis and oxidizing agents.
- · 10.4 Conditions to avoid No further relevant information available.

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· 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 if swallowed.

Harmful in contact with skin.

May be harmful 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.
- · 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.

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

Transport information	
14.1 UN-Number DOT, ADR, IMDG, IATA	UN1648
14.2 UN proper shipping name DOT ADR IMDG, IATA	Acetonitrile solution 1648 Acetonitrile solution ACETONITRILE solution
14.3 Transport hazard class(es) DOT	
RAMMAGE DOUD) 3  Class	3 Flammable liquids
Label ADR, IMDG, IATA	3
Class Label	3 Flammable liquids 3
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): EMS Number: Stowage Category Stowage Code	Warning: Flammable liquids 33 F-E,S-D B SW2 Clear of living quarters.
14.7 Transport in bulk according to Anne MARPOL73/78 and the IBC Code	ex II of 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

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1L
Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml
UN 1648 ACETONITRILE SOLUTION, 3, 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):

All ingredients are listed.

· 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:

None of the ingredients is listed.

· Cancerogenity categories

· EPA (Environmental Protection Agency)

75-05-8 acetonitrile

CBD, 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.

· **Department issuing SDS:** Bio-Rad Laboratories GmbH Heidemannstrasse 164 D-80939 Munich

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#### · Contact:

Technical Support:

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

· Date of preparation / last revision 02/13/2017 / 14

#### · 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)

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

Flam. Liq. 2: Flammable liquids - Category 2

Acute Tox. 5: Acute toxicity - Category 5

Acute Tox. 4: Acute toxicity - Category 4

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

\* Data compared to the previous version altered.

US -



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

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

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

- · 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.

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Trade name: Amiodarone by HPLC, MP

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· 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)



\*1 *Health* = \*1 3 *Fire* = 3

REACTIVITY 2 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.

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 $\cdot$  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

<i>PAC-1</i> :		
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
<i>PAC-2:</i>		·
75-05-8	acetonitrile	50 ppm
67-56-1	methanol	2,100 ppi
64-19-7	acetic acid	35 ppm
631-61-8	ammonium acetate	42 mg/m.
PAC-3:		
75-05-8	acetonitrile	150 ppm
67-56-1	methanol	7200* ppi
64-19-7	acetic acid	250 ppm
631-61-8	ammonium acetate	250 mg/m



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## 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.

· Components with limit values that require monitoring at the workplace:

· 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

75-0	75-05-8 acetonitrile		
PEL	Long-term value: 70 mg/m³, 40 ppm		
REL	Long-term value: 34 mg/m³, 20 ppm		
TLV	TLV Long-term value: 34 mg/m³, 20 ppm Skin		
67-5	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.

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Trade name: Amiodarone by HPLC, MP

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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 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

### 9 Physical and chemical properties

· 9.1 Information on basic physical a · General Information	and chemical properties
· 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: Boiling point/Boiling range:	Undetermined. >82 °C (>180 °F)
· Flash point:	5 °C (41 °F)
· Flammability (solid, gaseous):	Not applicable.
· Ignition temperature:	455 °C (851 °F)

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	(Contd. of page
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/cm³ (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/wate	e <b>r):</b> 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.

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Trade name: Amiodarone by HPLC, MP

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- 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	Flammable liquids, toxic, n.o.s. (Methanol, Acetonitrile)	
· ADR	1992 Flammable liquids, toxic, n.o.s. (Methanol,	
	Acetonitrile)	
· IMDG, IATA	FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL,	

ACETONITRILE)

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Trade name: Amiodarone by HPLC, MP

(Contd. of page 7) · 14.3 Transport hazard class(es)  $\cdot$  **DOT** 3 Flammable liquids · Class · Label 3, 6.1  $\cdot$  ADR 3 Flammable liquids · Class · Label 3+6.1 $\cdot$  *IMDG* 3 Flammable liquids · Class 3/6.1 ·Label  $\cdot$  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 Warning: Flammable liquids · Danger code (Kemler): 339 · EMS Number: F-E,S-D· Stowage Category · 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: · Excepted quantities (EQ) Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml



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Trade name: Amiodarone by HPLC, MP

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· 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

· Cancerogenity categories

· EPA (Env	vironmental 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  $\overline{A4}$ 

· 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.

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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.



Printing date 02/13/2017 Reviewed on 02/10/2017

## 1 Identification

· 1.1 Product identifier

· Trade name: Amiodarone by HPLC, CAL

· Article number: 1955920

· 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

  The product is not classified according to the CLP regulation.
- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)

HEALTH 0 Health = 0FIRE 0 Fire = 0REACTIVITY 0 Reactivity = 0

- · 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:** Human source material. Treat as potentially infectious.

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Trade name: Amiodarone by HPLC, CAL

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· Dangerous components: Void

#### 4 First-aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- 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.

### 5 Fire-fighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- · 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

### 6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 Reference to other sections

No dangerous substances are released.

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:

None of the ingredients is listed.

#### · PAC-2:

None of the ingredients is listed.

#### · PAC-3:

None of the ingredients is listed.

### 7 Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- · Information about protection against explosions and fires: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.

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Trade name: Amiodarone by HPLC, CAL

(Contd. of page 2)

- Further information about storage conditions: None.
- · 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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · 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:

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Not required.
- · Protection of hands:

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: Not required.

## 9 Physical and chemical properties

· 9.1 Information on basic physical ar · General Information	nd chemical properties
· Appearance:	
Form:	Solid
Color:	According to product specification
· Odor:	Characteristic
· Odor threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition Melting point/Melting range: Boiling point/Boiling range:	Undetermined. Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.

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Trade name: Amiodarone by HPLC, CAL

		(Contd. of page
Ignition temperature:		
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapor pressure:	Not applicable.	
Density:	Not determined.	
Relative density	Not determined.	
Vapor density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Soluble.	
Partition coefficient (n-octanol/wa	ter): Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
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 No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

### 11 Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity: Based on available data, the classification criteria are not met.
- Primary irritant effect:
- on the skin: Based on available data, the classification criteria are not met.
- on the eye: Based on available data, the classification criteria are not met.
- · Sensitization: Based on available data, the classification criteria are not met.
- · 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.

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Trade name: Amiodarone by HPLC, CAL

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· 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 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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

14.1 UN-Number DOT, ADR, ADN, IMDG, IATA	Void	
14.2 UN proper shipping name DOT, ADR, ADN, IMDG, IATA	Void	
14.3 Transport hazard class(es)		
DOT, ADR, ADN, IMDG, IATA Class	Void	
14.4 Packing group DOT, ADR, IMDG, IATA	Void	
14.5 Environmental hazards: Marine pollutant:	No	
14.6 Special precautions for user	Not applicable.	

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Trade name: Amiodarone by HPLC, CAL

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· UN "Model Regulation":

Void

### 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):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

None of the ingredients is listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

- · Chemicals known to cause reproductive toxicity for females:
- 19774-82-4 2-butyl-3-benzofuryl4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride
- · Chemicals known to cause reproductive toxicity for males:
- 19774-82-4 2-butyl-3-benzofuryl4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride
- · Chemicals known to cause developmental toxicity:

19774-82-4 2-butyl-3-benzofuryl4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride

- · Cancerogenity categories
- · EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· 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.

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 / 5
- · 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)

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Trade name: Amiodarone by HPLC, CAL

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ICAO: International Civil Aviation Organisation

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

 $ADR: Accord \ européen \ sur \ le \ transport \ des \ marchandises \ dangereuses \ par \ Route \ (European \ Agreement \ concerning \ the \ International \ and \ and$ 

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)

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

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

HS.