

## 13.02.2017

## **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 13.02.2017 Version number 15 Revision: 10.02.2017

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

· 1.1 Product identifier

· Trade name: Amiodarone by HPLC, REAG 1

· Article number: 1955922

· 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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Acute Tox. 4 H312 Harmful in contact with skin.

Eye Irrit. 2 H319 Causes serious eye irritation.

- · 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

GHS07

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

H225 Highly flammable liquid and vapour.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. 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.

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: |  |         |
|-------------------------|--|---------|
| CAS: 75-05-8            | acetonitrile   | 50-100% |
| EINECS: 200-835-2       | ♠ Flam. Liq. 2, H225; ♠ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319 |         |

<sup>·</sup> 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:

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.

In case of unconsciousness place patient stably in side position for transportation.

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

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

- · After swallowing: Call for a doctor 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.

#### **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.

· 5.2 Special hazards arising from the substance or mixture

Hydrogen cyanide (HCN)

Carbon monoxide (CO)

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Trade name: Amiodarone by HPLC, REAG 1

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· 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.

· 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.

Prevent formation of aerosols.

· Information about fire - and explosion protection:

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 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.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

#### 75-05-8 acetonitrile

WEL Short-term value: 102 mg/m³, 60 ppm Long-term value: 68 mg/m³, 40 ppm

- · 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

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Wash hands before breaks and at the end of work.

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

### SECTION 9: Physical and chemical properties

| <ul> <li>9.1 Information on basic physical ar</li> <li>General Information</li> </ul> | nd chemical properties |
|---|------------------------|
| · Appearance:   | F1: 1                  |
| Form:   | Fluid                  |
| Colour:   | Colourless             |
| · Odour:  | Ether-like             |
| · Odour threshold:  | Not determined.        |
| · pH-value:   | Not determined.        |
| · Change in condition   | -45.7 °C               |
| Melting point/freezing point:   |                        |
| Initial boiling point and boiling ra  | nge: 81°C              |
| · Flash point:  | 5 °C                   |
| · Flammability (solid, gas):  | Not applicable.        |
| · Ignition temperature:   | 524 °C                 |
| · Decomposition temperature:  | Not determined.        |

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Trade name: Amiodarone by HPLC, REAG 1

|   | (Contd. of page   |
|---|---|
| · 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 Vol %   |
| Upper:                                    | 17 Vol %  |
| · Vapour pressure at 20 °C:               | 97 hPa  |
| · Density at 20 °C:                       | $0.79 \text{ g/cm}^3$   |
| · 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, alkalis and oxidising agents.
- · 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

#### SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity

Harmful in contact with skin.

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

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· 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.

### SECTION 14: Transport information

| · 14.1 UN-Number<br>· ADR, IMDG, IATA                   | UN1648   |  |
|---|--|--|
| · 14.2 UN proper shipping name<br>· ADR<br>· IMDG, IATA | 1648 ACETONITRILE solution ACETONITRILE solution |  |
| · 14 3 Transport hazard class(es)                       |  |  |

- l 4.3 Transport hazard class(es)
- ADR, IMDG, IATA



| · Class<br>· Label                                   | 3 Flammable liquids.<br>3 |  |
|--|---------------------------|--|
| · 14.4 Packing group<br>· ADR, IMDG, IATA            | II                        |  |
| · 14.5 Environmental hazards:<br>· Marine pollutant: | No                        |  |

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|   | (Contd. of                                       |
|---|--|
| 14.6 Special precautions for user       | Warning: Flammable liquids.                      |
| Danger code (Kemler):                   | 33   |
| EMS Number:                             | F- $E$ , $S$ - $D$                               |
| Stowage Category                        | B  |
| Stowage Code                            | SW2 Clear of living quarters.                    |
| 14.7 Transport in bulk according to Ann | ex II of   |
| Marpol and the IBC Code                 | Not applicable.                                  |
| Transport/Additional information:       |  |
| ADR                                     |  |
| 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 |
| Transport category                      | 2  |
| Tunnel restriction code                 | D/E  |
| <i>IMDG</i>                             |  |
| 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 1648 ACETONITRILE SOLUTION, 3, 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 None of the ingredients is listed.
- · Seveso category P5c FLAMMABLE LIQUIDS
- Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · 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.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

### · 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

#### · 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

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

Acute Tox. 4: Acute toxicity - Category 4

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

\* Data compared to the previous version altered.



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)



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Trade name: Amiodarone by HPLC, MP

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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  |        |

<sup>·</sup> 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



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Trade name: Amiodarone by HPLC, MP

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### **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.

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Trade name: Amiodarone by HPLC, MP

(Contd. of page 3)

#### · 8.1 Control parameters

| Ingredients with limit values that require monitoring at the workplace: |  |
|---|--|
| 75-05-8 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



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Trade name: Amiodarone by HPLC, MP

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| SECTION 9: Physical and chemi           | cui properues   |
|---|---|
| 9.1 Information on basic physical and c | hemical properties  |
| General Information                     |   |
| Appearance:                             | F1 · 1  |
| Form:                                   | Fluid<br>Colourless   |
| Colour:<br>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 |   |
| 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:                       | $0.95 \text{ g/cm}^3$   |
| 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.

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· 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



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| 14.1 UN-Number   | UNIOO2   |
|--|--|
| ADR, IMDG, IATA  | UN1992   |
| 14.2 UN proper shipping name<br>ADR                                | 1992 FLAMMABLE LIQUID, TOXIC, N.O.S.                     |
|  | (METHANOL, ACETONITRILE)                                 |
| IMDG, IATA   | FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL, ACETONITRILE) |
| 14.3 Transport hazard class(es)                                    |  |
| ADR  |  |
|  |  |
| Class  | 3 Flammable liquids.                                     |
| Label  | 3+6.1  |
| IMDG   |  |
| Class  | 3 Flammable liquids.                                     |
| Label  | 3/6.1  |
| Class<br>Label   | 3 Flammable liquids.<br>3 (6.1)                          |
| 14.4 Packing group   | J (V.1)  |
| ADR, IMDG, IATA  | II   |
| 14.5 Environmental hazards:  |  |
| Marine pollutant:  | No   |
| 14.6 Special precautions for user                                  | Warning: Flammable liquids.                              |
| Danger code (Kemler):  | 339<br>E E S D   |
| EMS Number:  | F-E,S-D<br>B   |
| Stowage Category<br>Stowage Code                                   | SW2 Clear of living quarters.                            |
| 14.7 Transport in bulk according to Ann<br>Marpol and the IBC Code |  |
|  |  |
| Transport/Additional information:                                  |  |
| Transport/Additional information: ADR                              |  |



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|                            | (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  |
| 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 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

- 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)

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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



Printing date 13.02.2017 Version number 6 Revision: 10.02.2017

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

· 1.1 Product identifier

· Trade name: Amiodarone by HPLC, CAL

· Article number: 1955920

· 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

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

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- · 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.
- $\cdot$  4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- 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.

#### SECTION 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.

#### SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- · Information about fire and explosion protection: 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.
- · Further information about storage conditions: None.
- · 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.
- · 8.1 Control parameters
- · Ingredients 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 valid during the making were used as basis.
- · 8.2 Exposure controls
- Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Not required.

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#### 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.

| 9.1 Information on basic physical and ch | nemical properties                            |
|--|---|
| General Information                      | 1 1   |
| Appearance:                              |   |
| 1 0                                      | Solid   |
|  | According to product specification            |
| Odour:                                   | Characteristic                                |
| Odour threshold:                         | Not determined.                               |
| pH-value:                                | Not applicable.                               |
| Change in condition                      |   |
| Melting point/freezing point:            | Undetermined.                                 |
| Initial boiling point and boiling range: | Undetermined.                                 |
| Flash point:                             | Not applicable.                               |
| Flammability (solid, gas):               | Not determined.                               |
| Ignition temperature:                    |   |
| Decomposition temperature:               | Not determined.                               |
| Auto-ignition temperature:               | Product is not selfigniting.                  |
| Explosive properties:                    | Product does not present an explosion hazard. |
| Explosion limits:                        |   |
|  | Not determined.                               |
| Upper:                                   | Not determined.                               |
| Vapour pressure:                         | Not applicable.                               |
| Density:                                 | Not determined.                               |
| •  | Not determined.                               |
|  | Not applicable.                               |
|  | Not applicable.                               |
| Solubility in / Miscibility with         |   |
|  | Soluble.                                      |
| Partition coefficient: n-octanol/water:  | Not determined.                               |

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· Viscosity:

**Dynamic:** Not applicable. **Kinematic:** Not applicable.

• 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 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.

### SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · 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 Based on available data, the classification criteria are not met.
- · 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 1 (German Regulation) (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.

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## SECTION 13: Disposal considerations

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

| · 14.1 UN-Number<br>· ADR, ADN, IMDG, IATA                           | Void                        |  |
|--|-----------------------------|--|
| · 14.2 UN proper shipping name<br>· ADR, ADN, IMDG, IATA             | Void                        |  |
| · 14.3 Transport hazard class(es)                                    |                             |  |
| · ADR, ADN, IMDG, IATA<br>· Class                                    | Void                        |  |
| · 14.4 Packing group<br>· ADR, IMDG, IATA                            | Void                        |  |
| · 14.5 Environmental hazards:<br>· Marine pollutant:                 | No                          |  |
| · 14.6 Special precautions for user                                  | Not applicable.             |  |
| · 14.7 Transport in bulk according to Ann<br>Marpol and the IBC Code | ex II of<br>Not applicable. |  |
| · UN "Model Regulation":   | Void                        |  |

### **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 None of the ingredients is listed.
- · 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.

Department issuing SDS:

Bio-Rad Laboratories GmbH Heidemannstrasse 164 D-80939 Munich

· Contact:

Technical Support:

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

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#### · 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

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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

\* Data compared to the previous version altered.

GD.