

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

1 Identification

- **1.1 Product identifier**
- **Trade name:** Amiodarone by HPLC, 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)**



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

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, CAL

(Contd. of page 1)

· **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.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, 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 through 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 and chemical properties**
- **General Information**
- **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:	Undetermined.
Boiling point/Boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not determined.

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, CAL

(Contd. of page 3)

· **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/water):	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.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, CAL

(Contd. of page 4)

· **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 Transport information

- | | |
|----------------------------------------------------------------------------------------|-----------------|
| · 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. |
| · 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | Not applicable. |

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, CAL

(Contd. of page 5)

· 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

· Cancerogenicity 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)

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

Trade name: Amiodarone by HPLC, CAL

(Contd. of page 6)

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

US