

13.02.2017

**Kit Components**

Product code	Description
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<b>195-5917</b>	<b>Amiodarone by HPLC, Reagent Kit</b>
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## Components:

1955922	Amiodarone by HPLC, REAG 1
1955923	Amiodarone by HPLC, MP
1955920	Amiodarone by HPLC, CAL

## Safety Data Sheet according to WHS Regulations

Printing date 13.02.2017

Version number 15

Revision: 10.02.2017

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

- **Product identifier**
- **Trade name:** Amiodarone by HPLC, REAG 1
- **Article number:** 1955922
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** In-Vitro-laboratory reagent or component
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Bio-Rad Laboratories Pty., Ltd.  
Level 5, 446 Victoria Road  
Gladesville, New South Wales 2111  
Phone: +61 (2) 9914-2800  
Fax: +61 (2) 9914-2888
- **Further information obtainable from:**  
Technical Support:  
E-mail: TechSupport.ANZCDG@bio-rad.com
- **Emergency telephone number:**  
GBK Gefahrgut Büro GmbH  
Tel.: 0049(0)6123-84463

### 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
Flam. Liq. 2 H225 Highly flammable liquid and vapour.  
Acute Tox. 4 H312 Harmful in contact with skin.  
Eye Irrit. 2A H319 Causes serious eye irritation.

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- **Label elements**

- **GHS label elements**

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

- **Hazard pictograms**



GHS02    GHS07

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
acetonitrile
- **Hazard statements**  
Highly flammable liquid and vapour.  
Harmful in contact with skin.  
Causes serious eye irritation.
- **Precautionary statements**  
Keep away from heat/sparks/open flames/hot surfaces. No smoking.  
Use explosion-proof electrical/ventilating/lighting equipment.  
Wear protective gloves/protective clothing/eye protection/face protection.

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Trade name: Amiodarone by HPLC, REAG 1

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

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



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

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

### 3 Composition and Information on Ingredients

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

· **Dangerous components:**

75-05-8	acetonitrile	50-100%
	 Flam. Liq. 2, H225;  Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2A, H319	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First Aid Measures

- **Description of first aid measures**
- **General information:**  
*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 eye contact:**  
*Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.*
- **After swallowing:** *Call for a doctor immediately.*
- **Information for doctor:**  
*Most important symptoms and effects, both acute and delayed* No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
*No further relevant information available.*

### 5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
*CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.*
- **Special hazards arising from the substance or mixture**  
*Hydrogen cyanide (HCN)*  
*Carbon monoxide (CO)*
- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

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### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

75-05-8 acetonitrile

WES	Short-term value: 101 mg/m <sup>3</sup> , 60 ppm
	Long-term value: 67 mg/m <sup>3</sup> , 40 ppm
Sk	

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.

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*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 through 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

**· Information on basic physical and chemical properties****· General Information****· Appearance:**

<b>Form:</b>	Fluid
<b>Colour:</b>	Colourless
<b>· Odour:</b>	Ether-like
<b>· Odour threshold:</b>	Not determined.

<b>· pH-value:</b>	Not determined.
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**· Change in condition**

<b>Melting point/freezing point:</b>	-45.7 °C
<b>Initial boiling point and boiling range:</b>	81 °C

<b>· Flash point:</b>	5 °C
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<b>· Flammability (solid, gas):</b>	Not applicable.
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<b>· Ignition temperature:</b>	524 °C
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<b>· Decomposition temperature:</b>	Not determined.
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· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· <b>Explosion limits:</b> Lower: Upper:	3 Vol % 17 Vol %
· <b>Vapour pressure at 20 °C:</b>	97 hPa
· <b>Density at 20 °C:</b> · <b>Relative density</b> · <b>Vapour density</b> · <b>Evaporation rate</b>	0.79 g/cm <sup>3</sup> Not determined. Not determined. Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b> Dynamic: Kinematic: · <b>Other information</b>	Not determined. Not determined. No further relevant information available.

## 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** Reacts with acids, alkalis and oxidising agents.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**  
Hydrogen cyanide (prussic acid)  
Carbon monoxide and carbon dioxide

## 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** Irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**  
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Harmful  
Irritant

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### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
 Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water  
 Do not allow product to reach ground water, water course or sewage system.  
 Danger to drinking water if even small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
 Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### 14 Transport information

- |   |                             |
|---|-----------------------------|
| · <b>UN-Number</b>  |                             |
| · <b>ADG, IMDG, IATA</b>  | UN1648                      |
| · <b>UN proper shipping name</b>  |                             |
| · <b>ADG</b>  | 1648 ACETONITRILE solution  |
| · <b>IMDG, IATA</b>   | ACETONITRILE solution       |
| · <b>Transport hazard class(es)</b>   |                             |
| · <b>ADG, IMDG, IATA</b>  |                             |
|  |                             |
| · <b>Class</b>  | 3 Flammable liquids.        |
| · <b>Label</b>  | 3                           |
| · <b>Packing group</b>  |                             |
| · <b>ADG, IMDG, IATA</b>  | II                          |
| · <b>Environmental hazards:</b>   |                             |
| · <b>Marine pollutant:</b>  | No                          |
| · <b>Special precautions for user</b>   | Warning: Flammable liquids. |
| · <b>Danger code (Kemler):</b>  | 33                          |

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· <b>EMS Number:</b>	F-E,S-D
· <b>Stowage Category</b>	B
· <b>Stowage Code</b>	SW2 Clear of living quarters.
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b>	2
· <b>Tunnel restriction code</b>	D/E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 1648 ACETONITRILE SOLUTION, 3, II

**15 Regulatory information**

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

· **Australian Inventory of Chemical Substances**

All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **GHS label elements**

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

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** *Danger*

· **Hazard-determining components of labelling:**

acetonitrile

· **Hazard statements**

Highly flammable liquid and vapour.

Harmful in contact with skin.

Causes serious eye irritation.

· **Precautionary statements**

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

Use explosion-proof electrical/ventilating/lighting equipment.

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

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

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**Trade name: Amiodarone by HPLC, REAG 1**

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*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.*

- **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
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## **16 Other information**

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

### · **Relevant phrases**

H225 Highly flammable liquid and vapour.  
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

### · **Contact:**

Technical Support:  
E-Mail: [cts-ce@bio-rad.com](mailto:cts-ce@bio-rad.com)

### · **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)  
ICAO: International Civil Aviation Organisation  
ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)  
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Flam. Liq. 2: Flammable liquids – Category 2  
Acute Tox. 4: Acute toxicity – Category 4  
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

**Safety Data Sheet**  
according to WHS Regulations

Printing date 13.02.2017

Version number 14

Revision: 04.01.2017

Hazardous according to criteria of Australian Safety and Compensation Council.

## 1 Identification

- **Product identifier**
- **Trade name:** Amiodarone by HPLC, MP
- **Article number:** 1955923
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** In-Vitro-laboratory reagent or component
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Bio-Rad Laboratories Pty., Ltd.  
Level 5, 446 Victoria Road  
Gladesville, New South Wales 2111  
Phone: +61 (2) 9914-2800  
Fax: +61 (2) 9914-2888
- **Further information obtainable from:**  
Technical Support:  
E-mail: TechSupport.ANZCDG@bio-rad.com
- **Emergency telephone number:**  
GBK Gefahrgut Büro GmbH  
Tel.: 0049(0)6123-84463

## 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
Flam. Liq. 2 H225 Highly flammable liquid and vapour.  
Water-react. 1 H260 In contact with water releases flammable gases which may ignite spontaneously.  
Acute Tox. 3 H331 Toxic if inhaled.  
Eye Irrit. 2A H319 Causes serious eye irritation.  
STOT SE 1 H370 Causes damage to organs.

### · Label elements

#### · GHS label elements

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

#### · Hazard pictograms



GHS02 GHS06 GHS08

#### · Signal word Danger

#### · Hazard-determining components of labelling:

methanol  
acetonitrile

#### · Hazard statements

Highly flammable liquid and vapour.  
In contact with water releases flammable gases which may ignite spontaneously.  
Toxic if inhaled.  
Causes serious eye irritation.

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## Safety Data Sheet

### according to WHS Regulations

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Trade name: Amiodarone by HPLC, MP

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Causes damage to organs.

- **Precautionary statements**

Do not allow contact with water.

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

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

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

Store locked up.

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

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.






- **vPvB:** Not applicable.

### 3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

75-05-8	acetonitrile	25-50%
	 Flam. Liq. 2, H225;  Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2A, H319	
67-56-1	methanol	25-50%
	 Flam. Liq. 2, H225;  Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331;  STOT SE 1, H370	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First Aid Measures

- **Description of first aid measures**

- **General information:**

Immediately remove any clothing soiled by the product.

Remove breathing equipment only after contaminated clothing have been completely removed.

In case of irregular breathing or respiratory arrest provide artificial respiration.

- **After inhalation:**

Supply fresh air or oxygen; call for doctor.

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

- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:**

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

- **After swallowing:** Do not induce vomiting; call for medical help immediately.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

- **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### 5 Fire Fighting Measures

- **Extinguishing media**

- **Suitable extinguishing agents:**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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# **Safety Data Sheet** according to WHS Regulations

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**Trade name: Amiodarone by HPLC, MP**

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- **For safety reasons unsuitable extinguishing agents:** Water
- **Special hazards arising from the substance or mixture**  
Hydrogen cyanide (HCN)  
Carbon monoxide (CO)
- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

## **6 Accidental Release Measures**

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.  
Do not flush with water or aqueous cleansing agents
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## **7 Handling and Storage**

- **Handling:**
- **Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Open and handle receptacle with care.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.  
Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

## **8 Exposure controls and personal protection**

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

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Trade name: Amiodarone by HPLC, MP

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· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

**75-05-8 acetonitrile**

WES	Short-term value: 101 mg/m <sup>3</sup> , 60 ppm
	Long-term value: 67 mg/m <sup>3</sup> , 40 ppm
Sk	

**67-56-1 methanol**

WES	Short-term value: 328 mg/m <sup>3</sup> , 250 ppm
	Long-term value: 262 mg/m <sup>3</sup> , 200 ppm
Sk	

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

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.  
 Immediately remove all soiled and contaminated clothing  
 Wash hands before breaks and at the end of work.  
 Store protective clothing separately.  
 Avoid contact with the eyes.  
 Avoid contact with the eyes and skin.

· **Respiratory protection:**

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

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
 Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
 Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through 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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**9 Physical and Chemical Properties**

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Fluid
Colour:	Colourless
Odour:	Alcohol-like
Odour threshold:	Not determined.

· **pH-value at 20 °C:** 4.5

· **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	>82 °C

· **Flash point:** 5 °C

· **Flammability (solid, gas):** Not applicable.

· **Ignition temperature:** 455 °C

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· **Explosion limits:**

Lower:	3.0 Vol %
Upper:	44.0 Vol %

· **Vapour pressure at 20 °C:** 128 hPa

Density at 20 °C:	0.95 g/cm <sup>3</sup>
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

· **Solubility in / Miscibility with water:** Fully miscible.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

· **Other information** No further relevant information available.

**10 Stability and Reactivity**

· **Reactivity** No further relevant information available.

· **Chemical stability**

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions**

Reacts with acids.

Reacts with alkali (lyes).

Contact with water releases flammable gases.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

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**Trade name: Amiodarone by HPLC, MP**

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- **Hazardous decomposition products:**  
Hydrogen cyanide (prussic acid)  
Carbon monoxide and carbon dioxide

### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** Irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**  
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Toxic  
Irritant

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### 14 Transport information

- **UN-Number**
- **ADG, IMDG, IATA** UN1992

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<ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>ADG</b></li> <li>· <b>IMDG, IATA</b></li> </ul>	<p>1992 FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL, ACETONITRILE) FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL, ACETONITRILE)</p>
---	---

<ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>ADG</b></li> </ul>	<p>3 Flammable liquids. 3+6.1</p>
---	---------------------------------------



<ul style="list-style-type: none"> <li>· <b>IMDG</b></li> </ul>	<p>3 Flammable liquids. 3/6.1</p>
---	---------------------------------------



<ul style="list-style-type: none"> <li>· <b>IATA</b></li> </ul>	<p>3 Flammable liquids. 3 (6.1)</p>
---	---



<ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>ADG, IMDG, IATA</b></li> </ul>	<p>II</p>
--	-----------

<ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>	<p>No</p>
---	-----------

<ul style="list-style-type: none"> <li>· <b>Special precautions for user</b></li> <li>· <b>Danger code (Kemler):</b></li> <li>· <b>EMS Number:</b></li> <li>· <b>Stowage Category</b></li> <li>· <b>Stowage Code</b></li> </ul>	<p>Warning: Flammable liquids. 339 F-E,S-D B SW2 Clear of living quarters.</p>
---	--

<ul style="list-style-type: none"> <li>· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b></li> </ul>	<p>Not applicable.</p>
---	------------------------

<ul style="list-style-type: none"> <li>· <b>Transport/Additional information:</b></li> <li>· <b>ADG</b></li> <li>· <b>Limited quantities (LQ)</b></li> <li>· <b>Excepted quantities (EQ)</b></li> <li>· <b>Transport category</b></li> <li>· <b>Tunnel restriction code</b></li> </ul>	<p>IL Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml 2 D/E</p>
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**Trade name: Amiodarone by HPLC, MP**

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· <b>IMDG</b>	1L
· <b>Limited quantities (LQ)</b>	Code: E2
· <b>Excepted quantities (EQ)</b>	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 1992 FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL, ACETONITRILE), 3 (6.1), II

### 15 Regulatory information

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

· **Australian Inventory of Chemical Substances**

All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

67-56-1	methanol	S5, S6
64-19-7	acetic acid	S2, S5, S6

· **GHS label elements**

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

· **Hazard pictograms**



· **Signal word** *Danger*

· **Hazard-determining components of labelling:**

methanol

acetonitrile

· **Hazard statements**

Highly flammable liquid and vapour.

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

Toxic if inhaled.

Causes serious eye irritation.

Causes damage to organs.

· **Precautionary statements**

Do not allow contact with water.

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

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

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

Store locked up.

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

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** methanol

· **Seveso category**

H2 ACUTE TOXIC

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

P5c FLAMMABLE LIQUIDS

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**Trade name: Amiodarone by HPLC, MP**

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- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

· **Relevant phrases**

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H332 Harmful if inhaled.

H370 Causes damage to organs.

· **Department issuing SDS:**

Bio-Rad Laboratories GmbH

Heidemannstrasse 164

D-80939 Munich

· **Contact:**

Technical Support:

E-Mail: [cts-ce@bio-rad.com](mailto:cts-ce@bio-rad.com)

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

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

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Water-react. 1: Substances and mixtures which in contact with water emit flammable gases – Category 1

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 4: Acute toxicity – Category 4

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

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

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Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

- **Product identifier**
- **Trade name:** Amiodarone by HPLC, CAL
- **Article number:** 1955920
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** In-Vitro-laboratory reagent or component
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Bio-Rad Laboratories Pty., Ltd.  
Level 5, 446 Victoria Road  
Gladesville, New South Wales 2111  
Phone: +61 (2) 9914-2800  
Fax: +61 (2) 9914-2888
- **Further information obtainable from:**  
Technical Support:  
E-mail: TechSupport.ANZCDG@bio-rad.com
- **Emergency telephone number:**  
GBK Gefahrgut Büro GmbH  
Tel.: 0049(0)6123-84463

### 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
The product is not classified according to the Globally Harmonised System (GHS).
- 
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition and Information on Ingredients

- **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.

### 4 First Aid Measures

- **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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**Trade name: Amiodarone by HPLC, CAL**

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- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.

### 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.

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Trade name: Amiodarone by HPLC, CAL

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- **Respiratory protection:** 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

- |  |                                    |
|--|------------------------------------|
| · <b>Information on basic physical and chemical properties</b>               |                                    |
| · <b>General Information</b>   |                                    |
| · <b>Appearance:</b>   |                                    |
| <b>Form:</b>   | Solid                              |
| <b>Colour:</b>   | According to product specification |
| · <b>Odour:</b>  | Characteristic                     |
| · <b>Odour threshold:</b>  | Not determined.                    |
| · <b>pH-value:</b> Not applicable.   |                                    |
| · <b>Change in condition</b>   |                                    |
| <b>Melting point/freezing point:</b>   | Undetermined.                      |
| <b>Initial boiling point and boiling range:</b>                              | Undetermined.                      |
| · <b>Flash point:</b> Not applicable.  |                                    |
| · <b>Flammability (solid, gas):</b> Not determined.                          |                                    |
| · <b>Ignition temperature:</b>   |                                    |
| <b>Decomposition temperature:</b>  | Not determined.                    |
| · <b>Auto-ignition temperature:</b> Product is not selfigniting.             |                                    |
| · <b>Explosive properties:</b> Product does not present an explosion hazard. |                                    |
| · <b>Explosion limits:</b>   |                                    |
| <b>Lower:</b>  | Not determined.                    |
| <b>Upper:</b>  | Not determined.                    |
| · <b>Vapour pressure:</b> Not applicable.                                    |                                    |
| · <b>Density:</b> Not determined.  |                                    |
| · <b>Relative density</b> Not determined.                                    |                                    |
| · <b>Vapour density</b> Not applicable.                                      |                                    |
| · <b>Evaporation rate</b> Not applicable.                                    |                                    |
| · <b>Solubility in / Miscibility with water:</b> Soluble.                    |                                    |

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Trade name: Amiodarone by HPLC, CAL

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- |  |  |
|--|--|
| · <b>Partition coefficient: n-octanol/water:</b> | Not determined.                            |
| · <b>Viscosity:</b>                              |  |
| <b>Dynamic:</b>                                  | Not applicable.                            |
| <b>Kinematic:</b>                                | Not applicable.                            |
| · <b>Other information</b>                       | No further relevant information available. |

### 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**  
 The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.  
 When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
 Water hazard class 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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

-AU-

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Trade name: Amiodarone by HPLC, CAL

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### 13 Disposal considerations

- **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 Transport information

- |   |                 |
|---|-----------------|
| · <b>UN-Number</b>  |                 |
| · <b>ADG, ADN, IMDG, IATA</b>   | Void            |
| · <b>UN proper shipping name</b>  |                 |
| · <b>ADG, ADN, IMDG, IATA</b>   | Void            |
| · <b>Transport hazard class(es)</b>   |                 |
| · <b>ADG, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>  | Void            |
| · <b>Packing group</b>  |                 |
| · <b>ADG, IMDG, IATA</b>  | Void            |
| · <b>Environmental hazards:</b>   |                 |
| · <b>Marine pollutant:</b>  | No              |
| · <b>Special precautions for user</b>                                       | Not applicable. |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>   | Void            |

### 15 Regulatory information

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

#### · Australian Inventory of Chemical Substances

19774-82-4	2-butyl-3-benzofuryl4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride
1951-25-3	Desethylamiodaron

#### · Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

#### · Directive 2012/18/EU

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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**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](mailto: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)

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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)

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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.**

-AU-