

# 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:** Antiepileptics by HPLC, Control B 2
- **Article number:** 1956502
- **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.

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· **Dangerous components:** Void

### 4 First-aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

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

### 6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**  
No dangerous substances are released.  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

· <b>PAC-1:</b>
None of the ingredients is listed.
· <b>PAC-2:</b>
None of the ingredients is listed.
· <b>PAC-3:</b>
None of the ingredients is listed.

### 7 Handling and storage

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

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- **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:	Yellowish
Odor:	Odorless
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.

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· **Ignition temperature:**

<b>Decomposition temperature:</b>	Not determined.
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· <b>Auto igniting:</b>	Product is not selfigniting.
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· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
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· **Explosion limits:**

<b>Lower:</b>	Not determined.
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<b>Upper:</b>	Not determined.
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· <b>Vapor pressure:</b>	Not applicable.
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· <b>Density:</b>	Not determined.
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· <b>Relative density</b>	Not determined.
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· <b>Vapor density</b>	Not applicable.
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· <b>Evaporation rate</b>	Not applicable.
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· **Solubility in / Miscibility with**

<b>Water:</b>	Soluble.
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· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
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· **Viscosity:**

<b>Dynamic:</b>	Not applicable.
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<b>Kinematic:</b>	Not applicable.
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· <b>9.2 Other information</b>	No further relevant information available.
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## 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**

· <b>IARC (International Agency for Research on Cancer)</b>
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None of the ingredients is listed.
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· <b>NTP (National Toxicology Program)</b>
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630-93-3	Di-phenylhydantonin sodium salt	R
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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 12 Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
 Water hazard class 1 (Self-assessment): slightly hazardous for water  
 Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### 13 Disposal considerations

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

### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>14.1 UN-Number</b><br>· <b>DOT, ADR, ADN, IMDG, IATA</b>                                    | Void            |
| · <b>14.2 UN proper shipping name</b><br>· <b>DOT, ADR, ADN, IMDG, IATA</b>                      | Void            |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>DOT, ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void            |
| · <b>14.4 Packing group</b><br>· <b>DOT, ADR, IMDG, IATA</b>                                     | Void            |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>                               | No              |
| · <b>14.6 Special precautions for user</b>   | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>           | Not applicable. |

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· UN "Model Regulation":

Void

## 15 Regulatory information

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

- Section 355 (extremely hazardous substances):

None of the ingredient is listed.

- Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

- TSCA (Toxic Substances Control Act):

630-93-3 Di-phenylhydantonin sodium salt

- Proposition 65

- Chemicals known to cause cancer:

125-33-7 Primidone

630-93-3 Di-phenylhydantonin sodium salt

- Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

- Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

- Chemicals known to cause developmental toxicity:

298-46-4 Carbamazepine

99-66-1 2-propylvaleric acid

- Cancerogenity categories

- EPA (Environmental Protection Agency)

None of the ingredients is listed.

- TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

- NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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

## 16 Other information

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

- Department issuing SDS:

Bio-Rad Laboratories GmbH  
Heidemannstrasse 164  
D-80939 Munich

- Contact:

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

- Date of preparation / last revision 02/13/2017 / 9

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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  
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