

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, Test Mix
- **Article number:** 1955898
- **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**
Acute Tox. 4 H302 Harmful if swallowed.
Eye Irrit. 2A H319 Causes serious eye irritation.
Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Carc. 1B H350 May cause cancer.
Repr. 2 H361 Suspected of damaging fertility or the unborn child.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labeled according to the CLP regulation.
- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Danger
- **Hazard-determining components of labeling:**
Zonisamide
Di-phenylhydantonin sodium salt
Carbamazepine
Lamotrigine
- **Hazard statements**
H302 Harmful if swallowed.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.

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H350 May cause cancer.

H361 Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

P284 [In case of inadequate ventilation] wear respiratory protection.

P261 Avoid breathing dust/fume/gas/mist/vapors/spray

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

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

Health = 1

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = *1

Fire = 0

Reactivity = 0

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

3 Composition/information on ingredients

· **3.2 Chemical characterization: Mixtures**· **Description:** Mixture of the substances listed below with nonhazardous additions.· **Dangerous components:**

68291-97-4	Zonisamide	10-25%
52584-39-1	5-Ethyl-5-P-tolylbarbituric acid	10-25%
630-93-3	Di-phenylhydantonin sodium salt	10-25%
298-46-4	Carbamazepine	1-<10%
84057-84-1	Lamotrigine	1-<10%

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 and to be sure call for a 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. Then consult a doctor.· **After swallowing:** Immediately call a doctor.

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- **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:**
Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

· **PAC-1:**

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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of dust.
- **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.
- **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.

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- **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:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.
- **Body protection:** Protective work clothing

9 Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Solid
Color:	Whitish
Odor:	Odorless
Odor threshold:	Not determined.

· pH-value:	Not applicable.
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· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· Flash point:	Not applicable.
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· Flammability (solid, gaseous):	Not determined.
· 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:	Insoluble.
· 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:**
Harmful if swallowed.
- **Primary irritant effect:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:**
Causes serious eye irritation.
- **Sensitization:**
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.

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· **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

630-93-3 Di-phenylhydantonin sodium salt

R

· **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 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Other adverse effects** No further relevant information available.

13 Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

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

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- | | |
|---|-----------------|
| · 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 MARPOL73/78 and the IBC Code | Not applicable. |
| · 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):
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None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

630-93-3 Di-phenylhydantonin sodium salt
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· Proposition 65

· Chemicals known to cause cancer:

630-93-3 Di-phenylhydantonin sodium salt
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· Chemicals known to cause reproductive toxicity for females:
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None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:
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None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

298-46-4 Carbamazepine

· Cancerogenity categories

· EPA (Environmental Protection Agency)
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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

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· **Contact:**

Technical Support:

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

· **Date of preparation / last revision 02/13/2017 / 11**

· **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

Acute Tox. 4: Acute toxicity – Category 4

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

Resp. Sens. 1: Respiratory sensitisation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

Carc. 1B: Carcinogenicity – Category 1B

Repr. 2: Reproductive toxicity – Category 2

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