

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/13/2017

Reviewed on 02/10/2017

1 Identification

- **Product identifier**
- **Trade name:** Antiepileptics by HPLC, Test Mix
- **Article number:** 1955898
- **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 (Canada) Ltd.
2403 Guenette Street
Montreal, Quebec H4R 2E9
Phone: (514) 334-4372
Freephone: 1 (800) 361-1808
Fax: (514) 334-0872
- **Information department:**
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E-mail: cdg_canada_salesmarketing@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**
Acute Toxicity (Oral) - Category 4 H302 Harmful if swallowed.
Eye Irritation - Category 2A H319 Causes serious eye irritation.
Respiratory Sensitizer - Category 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.
Carcinogenicity - Category 1B H350 May cause cancer.
Reproductive Toxicity - Category 2 H361 Suspected of damaging fertility or the unborn child.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07 GHS08

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

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Suspected of damaging fertility or the unborn child.

Precautionary statements

[In case of inadequate ventilation] wear respiratory protection.

Avoid breathing dust/fume/gas/mist/vapours/spray.

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

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.

Hazard description:**WHMIS-symbols:**

D2A - Very toxic material causing other toxic effects

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

Health = 1

Fire = 0

Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = *1

Fire = 0

Reactivity = 0

3 Composition/information on ingredients

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

68291-97-4	Zonisamide	10-30% w/w
	⚠ Acute Toxicity (Oral) - Category 4, H302	
52584-39-1	5-Ethyl-5-P-tolylbarbituric acid	10-30% w/w
	⚠ Eye Irritation - Category 2A, H319	
630-93-3	Di-phenylhydantonin sodium salt	10-13% w/w
	⚠ Carcinogenicity - Category 1B, H350; Reproductive Toxicity - Category 2, H361; ⚠ Acute Toxicity (Oral) - Category 4, H302; Skin Sensitizer - Category 1, H317	
298-46-4	Carbamazepine	3-7% w/w
	⚠ Respiratory Sensitizer - Category 1, H334; ⚠ Acute Toxicity (Oral) - Category 4, H302; Skin Sensitizer - Category 1, H317	
84057-84-1	Lamotrigine	1-5% w/w
	⚠ Acute Toxicity (Oral) - Category 3, H301	

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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 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.
- **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 fighting measures that suit the environment.
- **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:**
Dispose contaminated material as waste according to item 13.
- **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 dust.
- **Information about protection against explosions and fires:** 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.

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8 Exposure controls/personal protection

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

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

- **General Information**

- **Appearance:**

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

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range:	Undetermined.
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Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· 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.
· 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** 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:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:**
- Sensitization possible through inhalation.
- Sensitization possible through skin contact.
- **Additional toxicological information:**
- The product shows the following dangers according to internally approved calculation methods for preparations:

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Harmful

Irritant

· 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

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12 Ecological information

· Toxicity

· Aquatic toxicity: No further relevant information available.

· Persistence and degradability No further relevant information available.

· Behavior 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 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.

· 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 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

· UN-Number

· DOT, TDG, ADN, IMDG, IATA Void

· UN proper shipping name

· DOT, TDG, ADN, IMDG, IATA Void

· Transport hazard class(es)

· DOT, TDG, ADN, IMDG, IATA

· Class Void

· Packing group

· DOT, TDG, IMDG, IATA Void

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|--|-----------------|
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **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

· Canadian substance listings:

· Canadian Domestic Substances List (DSL)

298-46-4 Carbamazepine

· Canadian Ingredient Disclosure list (limit 0.1%)

None of the ingredients is listed.

· Canadian Ingredient Disclosure list (limit 1%)

None of the ingredients is listed.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



GHS07 GHS08

· Signal word Danger

· Hazard-determining components of labeling:

Zonisamide

Di-phenylhydantonin sodium salt

Carbamazepine

Lamotrigine

· Hazard statements

Harmful if swallowed.

Causes serious eye irritation.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause cancer.

Suspected of damaging fertility or the unborn child.

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· Precautionary statements*[In case of inadequate ventilation] wear respiratory protection.**Avoid breathing dust/fume/gas/mist/vapours/spray.**Wear protective gloves/protective clothing/eye protection/face protection.**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.***· 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***· Abbreviations and acronyms:***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)**IMDG: International Maritime Code for Dangerous Goods**DOT: US Department of Transportation**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)**NFPA: National Fire Protection Association (USA)**HMIS: Hazardous Materials Identification System (USA)**WHMIS: Workplace Hazardous Materials Information System (Canada)**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative***· * Data compared to the previous version altered.**

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