

02/13/2017

Kit Components

Product code	Description
1956500	Antiepileptics by HPLC, CONTROL B Set
Components:	
1956501	Antiepileptics by HPLC, Control B 1
1956502	Antiepileptics by HPLC, Control B 2



Printing date 02/13/2017 Reviewed on 02/10/2017

1 Identification

· 1.1 Product identifier

· Trade name: Antiepileptics by HPLC, Control B 1

· Article number: 1956501

· 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)



Health = 0 Fire = 0Reactivity = 0

· 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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Printing date 02/13/2017 Reviewed on 02/10/2017

Trade name: Antiepileptics by HPLC, Control B 1

(Contd. of page 1)

· Dangerous components: Void

4 First-aid measures

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

No further relevant information available.

5 Fire-fighting measures

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

6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 Reference to other sections

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

· Protective Action Criteria for Chemicals

· PAC-1:

None of the ingredients is listed.

· PAC-2:

None of the ingredients is listed.

· PAC-3:

None of the ingredients is listed.

7 Handling and storage

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

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Trade name: Antiepileptics by HPLC, Control B 1

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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 trough 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 a General Information	na cnemicai properties	
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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Trade name: Antiepileptics by HPLC, Control B 1

		(Contd. of pag
Ignition temperature:		
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapor pressure:	Not applicable.	
Density:	Not determined.	
Relative density	Not determined.	
Vapor density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Soluble.	
Partition coefficient (n-octanol/wa	ter): Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
9.2 Other information	No further relevant information available.	

10 Stability and reactivity

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

11 Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity: Based on available data, the classification criteria are not met.
- Primary irritant effect:
- on the skin: Based on available data, the classification criteria are not met.
- on the eye: Based on available data, the classification criteria are not met.
- · Sensitization: Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · Carcinogenic categories
- None of the ingredients is listed.
 - · NTP (National Toxicology Program)

630-93-3 Di-phenylhydantonin sodium salt

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Printing date 02/13/2017 Reviewed on 02/10/2017

Trade name: Antiepileptics by HPLC, Control B 1

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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.

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ot applicable.

(Contd. on page 6)



Printing date 02/13/2017 Reviewed on 02/10/2017

Trade name: Antiepileptics by HPLC, Control B 1

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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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Trade name: Antiepileptics by HPLC, Control B 1

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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.

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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)



Health = 0 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



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

3 Composition/information on ingredients

- · 3.2 Chemical characterization: Mixtures
- · **Description:** Human source material. Treat as potentially infectious.

(Contd. on page 2)



Printing date 02/13/2017 Reviewed on 02/10/2017

Trade name: Antiepileptics by HPLC, Control B 2

(Contd. of page 1)

· Dangerous components: Void

4 First-aid measures

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

No further relevant information available.

5 Fire-fighting measures

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

6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 Reference to other sections

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

· Protective Action Criteria for Chemicals

· PAC-1:

None of the ingredients is listed.

PAC-2:

None of the ingredients is listed.

· PAC-3:

None of the ingredients is listed.

7 Handling and storage

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

(Contd. on page 3)



Printing date 02/13/2017 Reviewed on 02/10/2017

Trade name: Antiepileptics by HPLC, Control B 2

(Contd. of page 2)

- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · 8.1 Control parameters
- · Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists that were valid during the creation were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Not required.
- · Protection of hands:

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

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

· Material of gloves

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

· Penetration time of glove material

The exact break trough 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

and chemical properties
Solid
Yellowish
Odorless
Not determined.
Not applicable.
Undetermined.
Undetermined.
Not applicable.
Not determined.

(Contd. on page 4)



Printing date 02/13/2017 Reviewed on 02/10/2017

Trade name: Antiepileptics by HPLC, Control B 2

		(Contd. of pag
Ignition temperature:		
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapor pressure:	Not applicable.	
Density:	Not determined.	
Relative density	Not determined.	
Vapor density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Soluble.	
Partition coefficient (n-octanol/wa	ter): Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
9.2 Other information	No further relevant information available.	

10 Stability and reactivity

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

11 Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity: Based on available data, the classification criteria are not met.
- Primary irritant effect:
- on the skin: Based on available data, the classification criteria are not met.
- on the eye: Based on available data, the classification criteria are not met.
- · Sensitization: Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

 None of the ingredients is listed.
 - · NTP (National Toxicology Program)

630-93-3 Di-phenylhydantonin sodium salt

(Contd. on page 5)



Printing date 02/13/2017 Reviewed on 02/10/2017

Trade name: Antiepileptics by HPLC, Control B 2

(Contd. of page 4)

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

13 Disposal considerations

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

Void	
Void	
Void	
Void	
No	
Not applicable.	
	Void Void Void No

(Contd. on page 6)



Printing date 02/13/2017 Reviewed on 02/10/2017

Trade name: Antiepileptics by HPLC, Control B 2

(Contd. of page 5)

· UN "Model Regulation":

Void

15 Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- ·Sara
- · Section 355 (extremely hazardous substances):

None of the ingredient is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

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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Printing date 02/13/2017 Reviewed on 02/10/2017

Trade name: Antiepileptics by HPLC, Control B 2

(Contd. of page 6)

· 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)

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.

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