

13.02.2017

Kit Components

Product code	Description
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1956695	Levetiracetam by HPLC, Control Set
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Components:

1956696	Levetiracetam by HPLC, Control Level 1
1956697	Levetiracetam by HPLC, Control Level 2

Safety Data Sheet according to WHS Regulations

Printing date 13.02.2017

Version number 5

Revision: 13.02.2017

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

1 Identification

- **Product identifier**
- **Trade name:** Levetiracetam by HPLC, Control Level 1
- **Article number:** 1956696
- **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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Safety Data Sheet

according to WHS Regulations

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Trade name: Levetiracetam by HPLC, Control Level 1

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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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according to WHS Regulations

Printing date 13.02.2017

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Trade name: Levetiracetam by HPLC, Control Level 1

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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.
- **Body protection:** Protective work clothing

9 Physical and Chemical Properties

- | | |
|--|---|
| · Information on basic physical and chemical properties | |
| · General Information | |
| · Appearance: | |
| Form: | Solid |
| Colour: | Yellowish |
| · Odour: | Odourless |
| · Odour threshold: | Not determined. |
| · pH-value at 20 °C: 7 | |
| · Change in condition | |
| Melting point/freezing point: | Undetermined. |
| Initial boiling point and boiling range: 100 °C | |
| · Flash point: | Not applicable. |
| · Flammability (solid, gas): | Not determined. |
| · Ignition temperature: | |
| Decomposition temperature: | Not determined. |
| · Auto-ignition temperature: | Product is not selfigniting. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Explosion limits: | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| · Vapour pressure: | Not applicable. |
| · Density: Not determined. | |
| · Relative density Not determined. | |
| · Vapour density Not applicable. | |
| · Evaporation rate Not applicable. | |

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Trade name: Levetiracetam by HPLC, Control Level 1

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- | | |
|--|--|
| · Solubility in / Miscibility with water: | Soluble. |
| · 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:**
- **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.

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Trade name: Levetiracetam by HPLC, Control Level 1

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

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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

- | | |
|---|-----------------|
| · UN-Number | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · ADG, IMDG, IATA | Void |
| · Environmental hazards: | No |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol 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**

 · **Australian Inventory of Chemical Substances**

None of the ingredients is listed.

 · **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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Trade name: Levetiracetam by HPLC, Control Level 1

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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

· 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

AU

Safety Data Sheet according to WHS Regulations

Printing date 13.02.2017

Version number 6

Revision: 13.02.2017

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

1 Identification

- **Product identifier**
- **Trade name:** Levetiracetam by HPLC, Control Level 2
- **Article number:** 1956697
- **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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according to WHS Regulations

Printing date 13.02.2017

Version number 6

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Trade name: Levetiracetam by HPLC, Control Level 2

(Contd. of page 1)

- **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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Version number 6

Revision: 13.02.2017

Trade name: Levetiracetam by HPLC, Control Level 2

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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.
- **Body protection:** Protective work clothing

9 Physical and Chemical Properties

- | | |
|--|---|
| · Information on basic physical and chemical properties | |
| · General Information | |
| · Appearance: | |
| Form: | Solid |
| Colour: | Yellowish |
| · Odour: | Odourless |
| · Odour threshold: | Not determined. |
| · pH-value at 20 °C: 7 | |
| · Change in condition | |
| Melting point/freezing point: | Undetermined. |
| Initial boiling point and boiling range: 100 °C | |
| · Flash point: | Not applicable. |
| · Flammability (solid, gas): | Not determined. |
| · Ignition temperature: | |
| Decomposition temperature: | Not determined. |
| · Auto-ignition temperature: | Product is not selfigniting. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Explosion limits: | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| · Vapour pressure: | Not applicable. |
| · Density: Not determined. | |
| · Relative density Not determined. | |
| · Vapour density Not applicable. | |
| · Evaporation rate Not applicable. | |

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Trade name: Levetiracetam by HPLC, Control Level 2

(Contd. of page 3)

- | | |
|--|--|
| · Solubility in / Miscibility with water: | Soluble. |
| · 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:**
- **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.

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Trade name: Levetiracetam by HPLC, Control Level 2

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

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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

- | | |
|---|-----------------|
| · UN-Number | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · ADG, IMDG, IATA | Void |
| · Environmental hazards: | No |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol 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**

 · **Australian Inventory of Chemical Substances**

None of the ingredients is listed.

 · **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.

AU

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Trade name: Levetiracetam by HPLC, Control Level 2

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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

· 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

AU