

Printing date 13.02.2017 Version number 10 Revision: 13.02.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

· Trade name: Levetiracetam by HPLC, MP

· Article number: 1956694

· 1.2 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

1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Bio-Rad Laboratories Ltd.

Bio-Rad House Maxted Road Hemel Hempstead Hertfordshire HP2 7DX Freephone: 0800 181134 Tel: +44 (0)208 328 2000

· Further information obtainable from:

Technical Support:

techsupport.uk@bio-rad.com

Fax: +44 (0) 208 328 2550

· 1.4 Emergency telephone number:

GBK Gefahrgut Büro GmbH Tel.: 0049(0)6123-84463

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 3 H226 Flammable liquid and vapour.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



- · Signal word Warning
- · Hazard statements

H226 Flammable liquid and vapour.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

P241 Use explosion-proof electrical/ventilating/lighting equipment.

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

P240 Ground/bond container and receiving equipment.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water/shower.

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

regulations.

(Contd. on page 2)



Printing date 13.02.2017 Version number 10 Revision: 13.02.2017

Trade name: Levetiracetam by HPLC, MP

(Contd. of page 1)

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

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
	acetonitrile	1-<10%
EINECS: 200-835-2	Flam. Liq. 2, H225; Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319	

· Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · 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.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- 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.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· 6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· 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.

GR-



Printing date 13.02.2017 Version number 10 Revision: 13.02.2017

Trade name: Levetiracetam by HPLC, MP

(Contd. of page 2)

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling Keep receptacles tightly sealed.
- · Information about fire and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 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: Keep container tightly sealed.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

75-05-8 acetonitrile

WEL Short-term value: 102 mg/m³, 60 ppm Long-term value: 68 mg/m³, 40 ppm

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures: Wash hands before breaks and at the end of work.
- · 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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

GB



Printing date 13.02.2017 Version number 10 Revision: 13.02.2017

Trade name: Levetiracetam by HPLC, MP

(Contd. of page 3)

al properties Il urless racteristic determined. Complete applicable. Il determined. Il determined. Il determined is not selfigniting. Il determined is not explosive. However, formation of explosive air/ur mixtures are possible.
urless racteristic determined. C applicable. determined. duct is not selfigniting. duct is not explosive. However, formation of explosive air/
urless racteristic determined. C applicable. determined. duct is not selfigniting. duct is not explosive. However, formation of explosive air/
urless racteristic determined. C applicable. determined. duct is not selfigniting. duct is not explosive. However, formation of explosive air/
determined. Cupplicable. determined. duct is not selfigniting. duct is not explosive. However, formation of explosive air/
Cupplicable. determined. duct is not selfigniting. duct is not explosive. However, formation of explosive air/
Examplicable. Idetermined. Solution is not selfigniting. Solution is not explosive. However, formation of explosive air/
Examplicable. Idetermined. Solution is not selfigniting. Solution is not explosive. However, formation of explosive air/
Examplicable. Idetermined. Solution is not selfigniting. Solution is not explosive. However, formation of explosive air/
determined. Supplicable of the
npplicable. determined. duct is not selfigniting. duct is not explosive. However, formation of explosive air/
letermined. luct is not selfigniting. luct is not explosive. However, formation of explosive air/
luct is not selfigniting. luct is not explosive. However, formation of explosive air/
luct is not selfigniting. luct is not explosive. However, formation of explosive air/
uct is not explosive. However, formation of explosive air/
determined.
letermined.
Pa
m^3
determined.
determined.
determined.
miscible.
letermined.
determined.
determined.
1

SECTION 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.

(Contd. on page 5)



Printing date 13.02.2017 Version number 10 Revision: 13.02.2017

Trade name: Levetiracetam by HPLC, MP

(Contd. of page 4)

· 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 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 (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.

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

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- · 14.1 UN-Number
- · ADR, IMDG, IATA

UN1993

(Contd. on page 6)



Printing date 13.02.2017 Version number 10 Revision: 13.02.2017

Trade name: Levetiracetam by HPLC, MP

	(Contd. of pa
14.2 UN proper shipping name ADR	1993 FLAMMABLE LIQUID, N.O.S. (ACETONITRILE), special provision 640E
IMDG, IATA	FLAMMABLE LIQUID, N.O.S. (ACETONITRILE)
14.3 Transport hazard class(es)	
ADR, IMDG, IATA	
Class	3 Flammable liquids.
Label	3
14.4 Packing group ADR, IMDG, IATA	III
· · · · · · · · · · · · · · · · · · ·	111
14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user Danger code (Kemler):	Warning: Flammable liquids. 30
EMS Number:	F-E,S- <u>E</u>
Stowage Category	A
14.7 Transport in bulk according to Anne	
Marpol and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
Transport category	3
Tunnel restriction code	D/E
<i>IMDG</i>	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: El
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640E (ACETONITRILE), 3, III

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category P5c FLAMMABLE LIQUIDS
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t

(Contd. on page 7)



Printing date 13.02.2017 Version number 10 Revision: 13.02.2017

Trade name: Levetiracetam by HPLC, MP

(Contd. of page 6)

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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

SECTION 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.

· Relevant phrases

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids - Category 3

Acute Tox. 4: Acute toxicity - Category 4

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

* Data compared to the previous version altered.

- GB