

## 13.02.2017

## **Kit Components**

Product code	Description
1956690R	Levetiracetam by HPLC, Reagent Set
Components:	
1955894	Levetiracetam by HPLC, DISP COL
1955992	Levetiracetam by HPLC; REAG 1
1956693	Levetiracetam by HPLC, REAG 2
1956694	Levetiracetam by HPLC, MP



Printing date 13.02.2017 Version number 4 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, DISP COL

· Article number: 1955894

· 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: Mixture of substances listed below with nonhazardous additions.
- · 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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- · 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: No special measures required.
- · 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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· 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: Not required.

Information on basic physical and c	rhemical properties	
General Information		
Appearance:		
Form:	Solid	
Colour:	Whitish	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not applicable.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling ra	unge: 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.	
Solubility in / Miscibility with		
water:	Insoluble.	

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Trade name: Levetiracetam by HPLC, DISP COL

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· 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: Generally not hazardous for water
- · 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 Disposal must be made according to official regulations.

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· Uncleaned packaging:

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

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

### 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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Trade name: Levetiracetam by HPLC, DISP COL

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· 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) ICAO: International Civil Aviation Organisation

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



Printing date 13.02.2017 Version number 16 Revision: 13.02.2017

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

· Product identifier

· Trade name: Levetiracetam by HPLC; REAG 1

· Article number: 1955992

• 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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Acute Tox. 3 H331 Toxic if inhaled.

STOT SE 1 H370 Causes damage to organs.

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms







GHS02

GHS06

GHS08

- · Signal word Danger
- · Hazard-determining components of labelling: methanol
- · Hazard statements

Highly flammable liquid and vapour.

Toxic if inhaled.

Causes damage to organs.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

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

Do not breathe dust/fume/gas/mist/vapours/spray.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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Store locked up.

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

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

#### 3 Composition and Information on Ingredients

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

67-56-1 methanol

50-100%

Flam. Liq. 2, H225; Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; STOT SE 1, H370

· 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:

*Immediately remove any clothing soiled by the product.* 

Remove breathing equipment only after contaminated clothing have been completely removed.

In case of irregular breathing or respiratory arrest provide artificial respiration.

· After inhalation:

Supply fresh air or oxygen; call for 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: Do not induce vomiting; call for medical help immediately.
- · 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:

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

- · Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment: Mouth respiratory protective device.

#### 6 Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

Dilute with plenty of water.

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Trade name: Levetiracetam by HPLC; REAG 1

(Contd. of page 2)

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

· Methods and material for containment and cleaning up:

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

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

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.

Open and handle receptacle with care.

Prevent formation of aerosols.

· Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Keep respiratory protective device available.

- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: Store in a cool location.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

· 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:

#### 67-56-1 methanol

WES Short-term value: 328 mg/m<sup>3</sup>, 250 ppm Long-term value: 262 mg/m³, 200 ppm

- · Additional information: The lists valid during the making 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.

Store protective clothing separately.

Avoid contact with the eyes and skin.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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Trade name: Levetiracetam by HPLC; REAG 1

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#### 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 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

Information on basic physical and General Information	chemical properties
Appearance:	
Form:	Fluid
Colour:	Colourless
Odour:	Characteristic
Odour threshold:	Not determined.
pH-value:	Not determined.
Change in condition Melting point/freezing point:	-98 °C
Initial boiling point and boiling re	
Flash point:	11 °C
Flammability (solid, gas):	Not applicable.
Ignition temperature:	455 °C
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
Explosion limits: Lower:	5.5 Vol %

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Trade name: Levetiracetam by HPLC; REAG 1

		(Contd. of page 4
Upper:	44 Vol %	
· Vapour pressure at 20 °C:	128 hPa	
· Density at 20 °C:	$0.79 \text{ g/cm}^3$	
Relative density	Not determined.	
· Vapour density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
water:	Fully miscible.	
Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
· 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 shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

Toxic

#### 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

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Trade name: Levetiracetam by HPLC; REAG 1

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

### 13 Disposal considerations

- · 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.

Transport information		
UN-Number ADG, IMDG, IATA	UN1230	
UN proper shipping name ADG IMDG, IATA	1230 METHANOL solution METHANOL solution	
Transport hazard class(es)		
ADG		
Class	3 Flammable liquids.	
Label	3+6.1	
IMDG		
Class	3 Flammable liquids.	
Label	3/6.1	
IATA		
Class	3 Flammable liquids.	
Label	3 (6.1)	
Packing group ADG, IMDG, IATA	II	



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Trade name: Levetiracetam by HPLC; REAG 1

	(Contd. of p
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	336
EMS Number:	F-E,S-D
Stowage Category	B
Stowage Code	SW2 Clear of living quarters.
Transport in bulk according to Annex II	of Marpol
and the IBC Code	Not applicable.
Transport/Additional information:	
ADG	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E
<i>IMDG</i>	
Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1230 METHANOL SOLUTION, 3 (6.1), II

## 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Chemical Substances

All ingredients are listed.

Standard for the Uniform Scheduling of Medicines and Poisons

67-56-1 methanol

S5, S6

GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms







GHS02

GHS06

· Signal word Danger

- · Hazard-determining components of labelling:
- methanol
- · Hazard statements

Highly flammable liquid and vapour.

Toxic if inhaled.

Causes damage to organs.

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Trade name: Levetiracetam by HPLC; REAG 1

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#### · Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

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

Do not breathe dust/fume/gas/mist/vapours/spray.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Store locked up.

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

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I methanol
- · Seveso category

H2 ACUTE TOXIC

P5c FLAMMABLE LIQUIDS

- · Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- · 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.

#### · Relevant phrases

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

H370 Causes damage to organs.

#### 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

Flam. Liq. 2: Flammable liquids - Category 2

Acute Tox. 3: Acute toxicity – Category 3

STOT SE 1: Specific target organ toxicity (single exposure) – Category 1



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, REAG 2

· Article number: 1956693

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: Mixture of substances listed below with nonhazardous additions.
- · 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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Printing date 13.02.2017 Version number 6 Revision: 13.02.2017

Trade name: Levetiracetam by HPLC, REAG 2

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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:

Dilute with plenty of water.

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

· Methods and material for containment and cleaning up:

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

· 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.

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- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

- · 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: Goggles recommended during refilling
- · **Body protection:** Protective work clothing

## 9 Physical and Chemical Properties · Information on basic physical and chemical properties · General Information · Appearance:

4

Form: Fluid Colour: Colourless · Odour: Characteristic · Odour threshold: Not determined.

· pH-value at 20 °C:

· Change in condition

Melting point/freezing point:  $0 \, {}^{\circ}C$ Initial boiling point and boiling range: 100 °C

Not applicable. · Flash point:

· Flammability (solid, gas): Not applicable.

· Ignition temperature:

Not determined. Decomposition temperature: · Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

23 hPa

· Explosion limits:

Not determined. Lower: Not determined. Upper:

· Vapour pressure at 20 °C:

· Density at 20 °C:  $1 g/cm^3$ 

· Relative density Not determined.



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		(Contd. of page 3)
· Vapour density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
water:	Fully miscible.	
Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
· 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, REAG 2

(Contd. of page 4)

· Other adverse effects No further relevant information available.

## 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.

Transport information		
UN-Number ADG, ADN, IMDG, IATA	Void	
· UN proper shipping name · ADG, ADN, IMDG, IATA	Void	
Transport hazard class(es)		
· ADG, ADN, IMDG, IATA · Class	Void	
Packing group ADG, IMDG, IATA	Void	
Environmental hazards: Marine pollutant:	No	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex In and the IBC Code	<b>I of Marpol</b> 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

All ingredients are 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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### 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



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Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

· Product identifier

· Trade name: Levetiracetam by HPLC, MP

· Article number: 1956694

· 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

Flam. Liq. 3 H226 Flammable liquid and vapour.

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS02

- · Signal word Warning
- · Hazard-determining components of labelling: acetonitrile
- · Hazard statements

Flammable liquid and vapour.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

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

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

Ground/bond container and receiving equipment.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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

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Trade name: Levetiracetam by HPLC, MP

(Contd. of page 1)

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

#### 3 Composition and Information on Ingredients

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

75-05-8 acetonitrile

1-<10%

♦ Flam. Liq. 2, H225; ♦ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eve Irrit. 2A, H319

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

### 4 First Aid Measures

- · 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.
- · 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:

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

- 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

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

Dilute with plenty of water.

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

Methods and material for containment and cleaning up:

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

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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Trade name: Levetiracetam by HPLC, MP

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See Section 13 for disposal information.

#### 7 Handling and Storage

- · Handling:
- · 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.

- · 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.
- · 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:

#### 75-05-8 acetonitrile

WES Short-term value: 101 mg/m³, 60 ppm Long-term value: 67 mg/m³, 40 ppm

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- · Additional information: The lists valid during the making were used as basis.
- · 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



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Trade name: Levetiracetam by HPLC, MP

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· Body protection: Protective work clothing

Information on basic physical and chen	nical properties
General Information	
Appearance: Form:	Fluid
rorm. Colour:	Colourless
Odour:	Characteristic
Odour threshold:	Not determined.
pH-value at 20°C:	4
Change in condition	
Melting point/freezing point:	0 °C
Initial boiling point and boiling range	: 78 °C
Flash point:	43 °C
Flammability (solid, gas):	Not applicable.
Ignition temperature:	
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure at 20 °C:	23 hPa
Density at 20 °C:	1 g/cm³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
water:	Fully miscible.

## 10 Stability and Reactivity

- $\cdot \textit{Reactivity} \ \textit{No further relevant information available}.$
- · Chemical stability

· Viscosity:

Dynamic: Kinematic:

· Other information

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Not determined.

Not determined.

No further relevant information available.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.

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Trade name: Levetiracetam by HPLC, MP

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- · 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.

### 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.
- · Other adverse effects No further relevant information available.

### 13 Disposal considerations

- · 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.

## 14 Transport information

· UN-Number	
· ADG, IMDG, IATA	UN1993

· UN proper shipping name

· ADG

1993 FLAMMABLE LIQUID, N.O.S.

(ACETONITRILE), special provision 640E

· IMDG, IATA

FLAMMABLE LIQUID, N.O.S. (ACETONITRILE)

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Trade name: Levetiracetam by HPLC, MP

	(Contd. of pa
Transport hazard class(es)	
ADG, IMDG, IATA	
Class	3 Flammable liquids.
Label	3
Packing group ADG, IMDG, IATA	III
Environmental hazards: Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler): EMS Number:	30 F-E,S-E
Stowage Category	Г-Е, <u>S-Е</u> А
Transport in bulk according to Annex II	
and the IBC Code	Not applicable.
Transport/Additional information:	
ADG	
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
Transport category	3
Tunnel restriction code	D/E
IMDG	
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
UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL

## 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Chemical Substances

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

- · GHS label elements
- The product is classified and labelled according to the Globally Harmonised System (GHS).

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Trade name: Levetiracetam by HPLC, MP

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#### · Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:

acetonitrile

· Hazard statements

Flammable liquid and vapour.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Use explosion-proof electrical/ventilating/lighting equipment.

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

Ground/bond container and receiving equipment.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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

- · 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
- · 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.

#### · 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

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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Trade name: Levetiracetam by HPLC, MP

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