

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 14-Oct-2021 Revision Number 1

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

1.1. Product identifier

Product Code(s) TRC-P704820-100MG

Product Name (S)-Pregabalin Lactam

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No -

**CAS No** 181289-23-6

Pure substance/mixture Substance

Formula C8 H15 N O

Molecular weight 141.21

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

#### Supplier

LGC Limited
Queens Road
Teddington
Middlesex TW11 0LY
UNITED KINGDOM
:+44 (0) 20 8943 7000
Fax :+44 (0) 20 8943 2767
eMail : gh@lgcstandards.com

eMail: gb@lgcstandards.com

Web: www.lgcstandards.com

For further information, please contact

E-mail address sds-request@lgcgroup.com

1.4. Emergency telephone number

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### TRC-P704820-100MG - (S)-Pregabalin Lactam

Emergency Telephone For Hazardous Materials or Dangerous Goods Incident

Spill, Leak, Fire Exposure, or Accident

Call CHEMTREC:

USA & Canada 1-800-424-9300 Rest of the world +1 703-741-5970

Emergency Telephone - §4	45 - (EC)1272/2008		
Europe	112		
Austria	No information available		
Bulgaria			
Croatia			
Cyprus			
Czech Republic			
Denmark			
France			
Hungary			
Ireland			
Italy			
Lithuania			
Luxembourg	(+352) 8002 5500 Free telephone number with a 24/7 access in French, Dutch and English.		
Netherlands			
Norway			
Portugal			
Romania			
Slovakia			
Slovenia			
Spain			
Sweden			
Switzerland			

### SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Specific target organ toxicity — single exposure	Category 3 - (H335)

#### 2.2. Label elements

Contains (4S)-4-(2-Methylpropyl)pyrrolidin-2-one

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Signal word Warning

#### **Hazard statements**

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

#### Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves and eye/face protection

P312 - Call a POISON CENTER or doctor if you feel unwell

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

P501 - Dispose of contents/ container to an approved waste disposal plant

### 2.3. Other hazards

No information available.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Chemical name	EU - REACH (1907/2006) - Article 59(1)	EU - REACH (1907/2006) - Endocrine
	- Candidate List of Substances of Very	Disruptor Assessment List of
	High Concern (SVHC) for Authorisation	Substances
(4S)-4-(2-Methylpropyl)pyrrolidin-2-one	-	-

# **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No	Classification according to	Specific concentration	M-Factor	M-Factor (long-term)
		Humber		Regulation (EC) No.	limit (SCL)		(long-term)
				1272/2008 [CLP]			
(4S)-4-(2-Methylpro	100	-	-	Skin Irrit. 2 (H315)			
pyl)pyrrolidin-2-one				Eye Irrit. 2 (H319)			

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181289-23-6		STOT SE 3 (H335)		

#### Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

#### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

**General advice** Show this safety data sheet to the doctor in attendance.

**Inhalation** Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical

attention immediately if symptoms occur.

**Eye contact** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and

persists.

**Skin contact** Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical

attention if irritation develops and persists.

**Ingestion** Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious

person. Call a doctor.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

4.2. Most important symptoms and effects, both acute and delayed

**Symptoms** May cause redness and tearing of the eyes. Burning sensation.

4.3. Indication of any immediate medical attention and special treatment needed

### SECTION 5: Firefighting measures

5.1. Extinguishing media

surrounding environment.

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Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical

No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

# SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate

personnel to safe areas. Avoid contact with skin, eyes or clothing.

**Other information** Refer to protective measures listed in Sections 7 and 8.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up**Take up mechanically, placing in appropriate containers for disposal.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

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Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse. Ensure adequate ventilation. Avoid breathing vapours or mists. In case of insufficient ventilation, wear suitable respiratory

equipment.

General hygiene considerations Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face

protection.

#### 7.2. Conditions for safe storage, including any incompatibilities

Please refer to the manufacturer's certificate for specific storage and transport temperature Storage Conditions

conditions. Store only in the original receptacle unless other advice is given on the CoA.

Keep containers tightly closed in a dry, cool and well-ventilated place.

#### 7.3. Specific end use(s)

Identified uses

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

#### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

This product, as supplied, does not contain any hazardous materials with occupational **Exposure Limits** 

exposure limits established by the region specific regulatory bodies.

#### **Biological occupational exposure limits**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

**Derived No Effect Level (DNEL)** Predicted No Effect Concentration No information available. (PNEC)

No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are

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likely to occur, wear safety glasses with side-shields.

Hand protection The protective gloves to be used must comply with the specifications of EC Directive

89/686/EEC and the related standard EN374.

Gloves					
Duration of contact	PPE - Glove material	Glove thickness	Break through time		
	Wear protective butyl				
	rubber gloves				

Skin and body protection Wear suitable protective clothing. Long sleeved clothing.

No protective equipment is needed under normal use conditions. If exposure limits are Respiratory protection

exceeded or irritation is experienced, ventilation and evacuation may be required.

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this General hygiene considerations

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face

protection.

Do not allow into any sewer, on the ground or into any body of water. **Environmental exposure controls** 

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state Solid

**Appearance** Solid with a low melting point

Colour white

Odour No information available. **Odour threshold** No information available

Property Values Remarks • Method

40 - 41 °C Melting point / freezing point None known No data available None known Boiling point / boiling range Flammability (solid, gas) No data available None known Flammability Limit in Air None known No data available

Upper flammability or explosive

limits

Lower flammability or explosive No data available

limits

No data available Flash point None known **Autoignition temperature** No data available None known **Decomposition temperature** None known

pH (as aqueous solution)

No data available None known No data available No information available

Kinematic viscosity No data available None known

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Dynamic viscosityNo data availableNone knownWater solubilityNo data availableNone known

Solubility(ies) Methanol, Chloroform, Ethyl acetate,

slightly soluble

Partition coefficientNo data availableNone knownVapour pressureNo data availableNone knownRelative densityNo data availableNone known

Bulk density

No data available

No data available

No data available

Relative vapour density

No data available

None known

Particle characteristics

Particle Size No information available Particle Size Distribution No information available

9.2. Other information

Molecular weight 141.21 Molecular formula C8 H15 N O

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

### SECTION 10: Stability and reactivity

10.1. Reactivity

**Reactivity** No information available.

10.2. Chemical stability

**Stability** Stable under normal conditions.

**Explosion data** 

**Sensitivity to mechanical impact** None. **Sensitivity to static discharge** None.

10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

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**Incompatible materials** Strong acids. Strong bases. Strong oxidising agents.

Hazardous decomposition products None known based on information supplied.

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### Information on likely routes of exposure

#### **Product Information**

**Inhalation** Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract.

**Eye contact** Specific test data for the substance or mixture is not available. Causes serious eye irritation.

(based on components). May cause redness, itching, and pain.

**Skin contact** Specific test data for the substance or mixture is not available. Causes skin irritation. (based

on components).

**Ingestion** Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhoea.

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity

No information available

**Acute toxicity** 

Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Skin corrosion/irritation** Classification based on data available for ingredients. Irritating to skin.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

**Respiratory or skin sensitisation** No information available.

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**Germ cell mutagenicity** No information available.

**Carcinogenicity** No information available.

Reproductive toxicity No information available.

**STOT - single exposure** May cause respiratory irritation.

**STOT - repeated exposure**No information available.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

### SECTION 12: Ecological information

12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

12.4. Mobility in soil

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Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

12.7. Other adverse effects

No information available.

### **SECTION 13: Disposal considerations**

13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

## **SECTION 14: Transport information**

14.1 UN number or ID number Not regulated Not regulated 14.2 UN proper shipping name 14.3 Transport hazard class(es) Not regulated 14.4 Packing group Not regulated 14.5 Environmental hazards Not applicable

14.6 Special precautions for user

**Special Provisions** 

None

**IMDG** 

14.1 UN number or ID number Not regulated 14.2 UN proper shipping name Not regulated 14.3 Transport hazard class(es) Not regulated 14.4 Packing group Not regulated 14.5 Marine pollutant Not applicable

14.6 Special precautions for user

**Special Provisions** None No information available

No information available 14.7 Maritime transport in bulk

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according to IMO instruments

#### RID

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special precautions for user

Special Provisions None

#### ADR

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special precautions for user

Special Provisions None

### **SECTION 15: Regulatory information**

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water hazard class (WGK) slightly hazardous to water (WGK 1)

#### **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

**DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors** Not applicable

#### **Persistent Organic Pollutants**

Not applicable

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Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

**International Inventories** 

Contact supplier for inventory compliance status **TSCA DSL/NDSL** Contact supplier for inventory compliance status **EINECS/ELINCS** Contact supplier for inventory compliance status Contact supplier for inventory compliance status **ENCS** Contact supplier for inventory compliance status **IECSC** Contact supplier for inventory compliance status **KECL PICCS** Contact supplier for inventory compliance status **AICS** Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment has been carried out for this substance

### SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value \* Skin designation

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Method Used
Calculation method

#### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

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Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

**End of Safety Data Sheet** 

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