

SAFETY DATA SHEET according
to GB/T 16483 and GB/T 17519Version 8.1
Revision Date 2022/10/18
Print Date 2025/04/09
Date of first issue 24.08.2022SDS No. Sigma - SML3167
Product Number Sigma - SML3167**Pregabalin****SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifiers**

Product name : Pregabalin

Product Number : SML3167
Brand : Sigma
CAS-No. : 148553-50-8**1.2 Details of the supplier of the safety data sheet**Company : Sigma-Aldrich (Shanghai) Trading Co.Ltd.
509 Renqing Road
Zhangjiang High Tech East Park, Pudong
SHANGHAI
201201 SHANGHAI
CHINA西格玛奥德里奇（上海）贸易有限公司
上海市浦东新区仁庆路 509 号 10 幢
邮政编码：201201Merck KGaA
64271 Darmstadt
Germany
Phone: +49 6151 72-0Telephone : +86 21 6141-5566
Fax : +86 21 6141-5567**1.3 Emergency telephone**Emergency Phone # : +86 532 83889090 (NRCC) 400 120 4937
(CHEMTREC)**1.4 Relevant identified uses of the substance or mixture and uses advised against**Identified uses : For R&D use only. Not for pharmaceutical, household or other
uses.**SECTION 2: Hazards identification**

Summary of emergency

off-white, white May cause drowsiness or dizziness., Suspected of damaging fertility or the unborn child. Show this material safety data sheet to the doctor in attendance. After inhalation: fresh air. Call in physician. In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower., Consult a physician. After eye contact: rinse out with plenty of water., Call in ophthalmologist., Remove contact lenses. After swallowing: immediately make victim drink water (two glasses at most)., Consult a physician. Combustible. Development of hazardous combustion gases or vapours possible in the event of fire.

2.1 GHS Classification

Reproductive toxicity (Category 2), H361

Specific target organ toxicity - single exposure (Category 3), Narcotic effects, H336

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal Word

Warning

Hazard statement(s)

H336

May cause drowsiness or dizziness.

H361

Suspected of damaging fertility or the unborn child.

Precautionary statement(s)

Prevention

P201

Obtain special instructions before use.

P202

Do not handle until all safety precautions have been read and understood.

P261

Avoid breathing dust.

P271

Use only outdoors or in a well-ventilated area.

P280

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

Response

P304 + P340 + P312

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.

P308 + P313

IF exposed or concerned: Get medical advice/ attention.

Storage

P403 + P233

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

P405

Store locked up.

Disposal

P501

Dispose of contents/ container to an approved waste disposal plant.

Reduced Labeling (<= 125 ml)

Pictogram



Signal Word

Warning

Hazard statement(s)

H336

May cause drowsiness or dizziness.

H361

Suspected of damaging fertility or the unborn child.

Precautionary

none

statement(s)

2.3 Physical and chemical hazards

Referring to current information, no physical or chemical hazard.

2.4 Health hazards

H361 Suspected of damaging fertility or the unborn child.
H336 May cause drowsiness or dizziness.

2.5 Environmental hazards

Referring to current information, no environmental hazard.

2.6 Other hazards - none

SECTION 3: Composition/information on ingredients

Substance / Mixture : Substance

3.1 Substances

Synonyms : Lyrica
(S)-3-(Aminomethyl)-5-methylhexanoic acid
(S)-Pregabalin

Formula : C₈H₁₇NO₂
Molecular weight : 159.23 g/mol
CAS-No. : 148553-50-8
EC-No. : 604-639-1

Hazardous ingredients

Component	Classification	Concentration
Pregabalin		
	Reproductive toxicity Category 2; Specific target organ toxicity - single exposure Category 3; H361, H336	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice

Show this material safety data sheet to the doctor in attendance.

If inhaled

After inhalation: fresh air. Call in physician.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.

In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

If swallowed

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

4.4 Notes to physician

No data available

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Nature of decomposition products not known.

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

In the event of fire, wear self-contained breathing apparatus.

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling****Advice on safe handling**

Work under hood. Do not inhale substance/mixture.

Hygiene measures

Change contaminated clothing. Wash hands after working with substance.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.

Storage stability

Recommended storage temperature
-20 °C

Storage class

Storage class (TRGS 510): 11: Combustible Solids

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

Change contaminated clothing. Wash hands after working with substance.

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

Handle with gloves.

Body Protection

protective clothing

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- | | |
|---------------------------------|-----------------------------------|
| a) Physical state | solid |
| b) Color | off-white, white |
| c) Odor | No data available |
| d) Melting point/freezing point | Melting point: 195 °C - (solvent) |
| e) Initial boiling point | No data available |

- and boiling range
- | | |
|---|--|
| f) Flammability (solid, gas) | No data available |
| g) Upper/lower flammability or explosive limits | No data available |
| h) Flash point | Not applicable |
| i) Autoignition temperature | No data available |
| j) Decomposition temperature | No data available |
| k) pH | No data available |
| l) Viscosity | Viscosity, kinematic: No data available
Viscosity, dynamic: No data available |
| m) Water solubility | No data available |
| n) Partition coefficient: n-octanol/water | No data available |
| o) Vapor pressure | No data available |
| p) Density | No data available |
| Relative density | No data available |
| q) Relative vapor density | No data available |
| r) Particle characteristics | No data available |
| s) Explosive properties | No data available |
| t) Oxidizing properties | none |

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .
Stable under recommended storage conditions.

10.2 Possibility of hazardous reactions

No data available

10.3 Conditions to avoid

no information available

10.4 Incompatible materials

Strong oxidizing agents

10.5 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - > 5,000 mg/kg

Remarks: (External MSDS)

Inhalation: No data available

Dermal: No data available

Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitization

Buehler Test - Guinea pig

Result: negative

Remarks: (External MSDS)

Germ cell mutagenicity

Test Type: Chromosome aberration test in vitro

Test system: Chinese hamster ovary cells

Result: negative

Remarks: (External MSDS)

Test Type: unscheduled DNA synthesis assay

Species: Rat

Result: negative

Remarks: (External MSDS)

Carcinogenicity

No data available

Reproductive toxicity

Suspected human reproductive toxicant

Specific target organ toxicity - single exposure

May cause drowsiness or dizziness.

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Additional Information

RTECS: MO6452000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

12.1 Toxicity

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Toxicity to fish	LC50 - Oncorhynchus mykiss (rainbow trout) - > 1,000 mg/l - 96 h Remarks: (External MSDS)
Toxicity to daphnia and other aquatic invertebrates	EC50 - Daphnia magna (Water flea) - > 1,000 mg/l - 48 h Remarks: (External MSDS)
Toxicity to algae	EbC50 - Scenedesmus quadricauda (Green algae) - > 300 mg/l - 72 h Remarks: (External MSDS)
	ErC50 - Scenedesmus quadricauda (Green algae) - > 300 mg/l - 72 h Remarks: (External MSDS)

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

SECTION 14: Transport information

14.1 UN number

ADR/RID: -

IMDG: -

IATA-DGR: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA-DGR: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA-DGR: -

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA-DGR: -

14.5 Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA-DGR: no

14.6 Special precautions for user

14.7 Incompatible materials

Strong oxidizing agents

Further information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

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

National regulatory information

Measures on the Environmental Administration of New Chemical Substances Registration

Registration/Notification number : B1A222212760

Downstream users need to comply with the conditions of safe use of the chemical, understand the environmental and health hazard and risk management measures identified on the SDS as well as the local/national regulations concerning the chemical.

Other regulations

Please pay attention on the waste treatment should also comply with local regulations requirement.

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H336 May cause drowsiness or dizziness.

H361 Suspected of damaging fertility or the unborn child.

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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