

# MATERIAL SAFETY DATA SHEET

Product: **GABAPENTINA (EUR. PH.)**

Product code: 0002443

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Emission date: 09/06/2026

Version: 0002443\_MSDS\_ENG\_0126



## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product name: **GABAPENTINA (EUR. PH.)**  
Product code: 0002443  
Nº CAS: 60142-96-3  
Nº EC: 262-076-3

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

Relevant identified uses: Active pharmaceutical ingredient

### 1.3. Details of the supplier of the safety data sheet

Company: **METAPHARMACEUTICAL INDUSTRIAL SLU**  
JOSEP PLA 163 2º 5ª  
08020 BARCELONA  
SPAIN  
Phone number: (0034) 933 089 976  
Contact e-mail: [info@metaph.es](mailto:info@metaph.es)  
Web page: [www.metaph.com](http://www.metaph.com)

### 1.4. Emergency telephone number

National Institute of Toxicology of Madrid: (0034) 915 620 420

## 2. HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

The product is classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP).

Skin Irrit. 2, H315

Eye Irrit. 2, H319

STOT SE 3, H335

Repr. 1B, H360

### 2.2. Label Elements



Signal word (CLP): WARNING

Hazard statements (CLP)

H315: Causes skin irritation  
H319: Causes serious eye irritation  
H335: May cause respiratory irritation  
H360: May damage fertility or the unborn child

Precautionary statements (CLP)

P264: Wash thoroughly after handling  
P280: Wear protective gloves/protective clothing/eye protection/face protection

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P201: Obtain special instructions before use  
P308+P313: IF exposed or concerned: Get medical advice/attention  
P312: Call a POISON CENTER/doctor if you feel unwell  
P337+P313: If eye irritation persists: Get medical advice/attention

### 2.3. Other hazards

No additional information available.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Product name: GABAPENTINA  
Synonyms: GABAPENTIN, GABAPENTINA  
IUPAC name: (1-Aminomethyl-cyclohexyl)-acetic acid  
N° CAS: 60142-96-3  
N° EC: 262-076-3  
Molecular formula: C<sub>9</sub>H<sub>17</sub>NO<sub>2</sub>

### 3.2. Mixtures

Not applicable.

## 4. FIRST AID MEASURES

### 4.1. Description of first aid measures

General advises: Consult a doctor. Show the safety data sheet to the doctor on duty.  
Inhalation: Take outdoors. If breathing is irregular, call a doctor immediately. Only apply artificial respiration if breathing stops or under medical supervision.  
Skin contact: Wash immediately with plenty of soap and water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.  
Eye contact: Remove contact lenses and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.  
Ingestion: If conscious, give victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

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

The most important known symptoms and effects are described on the label (see section 2.2) and/or in heading 11.

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

In cases of doubt, or if symptoms of discomfort persist, seek medical attention. Never give anything by mouth to an unconscious person.

## 5. FIREFIGHTING MEASURES

### 5.1. Extinguishing media

Suitable extinguishing methods: Foam, dry powder, carbon dioxide, sand, water mist  
Unsuitable extinguishing methods: Direct water jet.  
Neighboring fires (containers exposed to fire): Atomized or nebulized water.

### 5.2. Special hazards arising from the substance or mixture

In the event of fire, fumes that are harmful to health may be produced.

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**5.3. Advice for firefighters**

General information: Cool containers with water to prevent product decomposition and development of potential health hazards. Always use full fire protection. Collect the water that should not enter the sewer. Eliminate the contaminated water used to extinguish and the remains of the second current regulations.

Equipment: Helmet with visor, flame retardant clothing (jacket and trousers with braces around the arms, legs and waist, EN 469), gloves (fire and dielectric proof, EN 659), a mask with a full-face mask. operator's face or car (protective car) in the case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

**6. ACCIDENTAL RELEASE MEASURES****6.1. Personal precautions, protective equipment and emergency procedures**

Avoid the formation of dust by spraying the product with water, provided there are no contraindications. If airborne dust is present, use appropriate respiratory protection.

**6.2. Environmental precautions**

Avoid getting into sewers and water pipes. If the product reaches drains or public water pipes, notify the authorities.

**6.3. Methods and material for containment and cleaning up**

The contaminated area should be cleaned immediately using a suitable decontaminating agent. Apply the decontaminating agent to the spilled material and leave it for several days in an unsealed container until no further reaction occurs.

**6.4. Reference to other sections**

No additional information available.

**7. HANDLING AND STORAGE****7.1. Precautions for safe handling**

Avoid dispersion of the product into the environment. Smoking, eating, and drinking must be prohibited in the application area. Comply with occupational safety and hygiene regulations. Store the product in containers made of material identical to the original.

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

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated area.

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

No data available beyond that provided in Section 1.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1. Exposure controls/personal protection**

The product does NOT contain substances with Occupational Exposure Limit Values (OELs). The product does NOT contain substances with Biological Limit Values.

**8.2. Exposure controls**

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation in the workplace by means of effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE marking that certifies compliance with the applicable regulations. Arrange an emergency shower with a visco-elastic tray.



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Eye and face protection:	Protection masks and safety glasses according to EN 165, EN 166, EN 167, EN 168.
Hands protection:	Handle with gloves. The selected protective gloves must comply with the specifications of the EU Directive 89/686/EEC and the standards EN 374-1, EN 374-2, EN 374-3, EN 420 derived from it.
Respiratory protection:	Where risk assessment shows that air purifying respirators are appropriate, use type N95 (USA) or type P1 (EN 149) dust mask. Use respirators and components tested and approved under the appropriate government standards such as NIOSH (USA) or CEN (EU).
Skin protection:	Choose body protection based on the amount and concentration of the dangerous substance in the workplace.
Hygiene measures:	Handle with adequate industrial hygiene precautions, and respect safety practices. Wash your hands before breaks and after finishing the workday.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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

Aspect:	Solid, powder
Color:	White
Molecular weight ( $\text{g}\cdot\text{mol}^{-1}$ ):	171.24
Melting Point ( $^{\circ}\text{C}$ ):	198 - 200
Water solubility ( $25^{\circ}\text{C}$ ):	4490 mg/L
n-octanol/water partition coefficient:	LogPow -1.10

### 9.2. Other information

No additional information available.

## 10. STABILITY AND REACTIVITY

### 10.1. Reactivity

No special conditions. Stable under the recommended handling and storage conditions (see Section 7).

### 10.2. Chemical stability

Stable under the recommended handling and storage conditions (see Section 7).

### 10.3. Possibility of hazardous reactions

Not known.

### 10.4. Conditions to avoid

Keep away from direct sunlight.

### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be generated.

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## 11. TOXICOLOGICAL INFORMATION

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

Acute Oral Toxicity (Rat, LD50):	> 8000 mg/Kg
Acute Oral Toxicity (Mouse, LD50):	> 8053 mg/Kg
Acute Intravenous Toxicity (Rat, LD50):	> 2000 mg/Kg
Acute Intravenous Toxicity (Mouse, LD50):	> 1000 mg/Kg
Skin Corrosion/Irritation:	Causes skin irritation
Serious Eye Damage/Eye Irritation:	Causes serious eye irritation
Respiratory or Skin Sensitization:	May cause respiratory tract irritation
STOT – single exposure:	May cause respiratory tract irritation
STOT – repeated exposure:	No additional information available (Lack of data)
Carcinogenicity:	No component of this product present at levels greater than or equal to 0.1% is identified as a known, probable, or possible human carcinogen
Reproductive Toxicity:	May damage fertility or the unborn child
Germ Cell Mutagenicity:	No additional information available (Lack of data)
Aspiration Hazard:	No additional information available (Lack of data)

#### Potential Health Effects

Inhalation:	No additional information available (Lack of data)
Ingestion:	No additional information available (Lack of data)
Skin:	No additional information available (Lack of data)
Eyes:	No additional information available (Lack of data)
Signs and Symptoms of Exposure:	No additional information available (Lack of data)

### 11.2. Information on other hazards

No additional information available.

## 12. ECOLOGICAL INFORMATION

Use in accordance with good work practices, avoiding dispersing the product in the environment. Notify the competent authorities if the product has reached water courses or if it has contaminated the soil or vegetation.

### 12.1. Toxicity

This product is not considered harmful to aquatic organisms and is not expected to cause long-term adverse effects in the environment.

### 12.2. Persistence and degradability

No data available.

### 12.3. Bioaccumulative potential

n-Octanol/water partition coefficient: LogPow -1.10

### 12.4. Results of PBT and vPvB assessment

The substance does not meet the criteria for identification as a PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative) substance in accordance with Annex XIII of the REACH Regulation.

### 12.5. Endocrine disrupting properties

No additional information available.

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### 12.6. Other adverse effects

Avoid release to the environment.

## 13. DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

## 14. INFORMACIÓN RELATIVA AL TRANSPORTE

The product should not be considered hazardous according to the applicable regulations for the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code), and air (IATA).

### 14.1. UN Number

Not dangerous for transport.

### 14.2. UN proper shipping name

Not dangerous for transport.

### 14.3. Transport hazard class(es)

Not dangerous for transport.

### 14.4. Packing group

Not dangerous for transport.

### 14.5. Environmental hazards

Not dangerous for transport.

### 14.6. Special precautions for user

Not dangerous for transport.

### 14.7. Maritime transport in bulk according to IMO instruments

No additional information available.

## 15. REGULATORY INFORMATION

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

The Safety Data Sheet complies with the requirements of Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council is modified, relating to the registration, evaluation, authorization and restriction of chemical substances and mixtures (REACH).

### 15.2. Chemical safety assessment

No additional information available.

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**16. OTHER INFORMATION****Abbreviations and acronyms:**

PBT: Persistent, bioaccumulative and toxic

mPmB: Very persistent and very bioaccumulative

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

**Data sources used:**

Regulation (CE) No. 1272/2008 of the European Parliament and of the Council, of December 16, 2008, on the classification, labeling and packaging of substances and mixtures, and by which Directives 67/548/CEE and 1999 are modified and repealed /45/CE and modifies Regulation (CE) No. 1907/2006.

Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council, regarding registration, evaluation, authorization and the restriction of chemical substances and mixtures (REACH)

**Safety Data Sheet according to Annex II of REACH Regulation (EU) 2020/878****Department issuing the Safety Data Sheet:**

Technical Department

The information in this Product Safety Data Sheet is based on current knowledge and current EC and national laws, as far as the working conditions of users are beyond our knowledge and control. The product must not be used for purposes other than those specified, without first having a written instruction on its handling. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established in the legislation.