

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## GABAPENTINUM

EN

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### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name: Gabapentin  
Gabapentinum  
Gabapentine  
Gabapentine  
Gabapentin

N° CAS: 60142-96-3

N° EC: 262-076-3

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

Identified uses: Active Pharmaceutical Ingredient or Excipient.

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

Company: Magis-Pharma NV  
Neerlandweg 24  
2610 Wilrijk  
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Skin Irrit. 2	H315
Eye Irrit. 2	H319
STOT SE 3	H335
Repr. 1B	H360

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s):

Attention

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### Hazard statements:

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

### Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+352	IF ON SKIN: Wash with plenty of soap solution and water for at least 15 minutes.
P304+340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+351+338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P308+313	If exposed: Call a POISON CENTER or doctor/physician.
P312	Call a POISON CENTER/ doctor if you feel unwell.
P332+313	If skin irritation occurs: Get medical advice/attention.
P337+313	If eye irritation persists get medical advice/attention.
P362+364	Take off contaminated clothing and wash it before reuse.
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Gabapentin
IUPAC name:	2-[1-(aminomethyl)cyclohexyl]acetic acid
Synonyms:	Neurontin Aclonium Fanatrex
N° CAS:	60142-96-3
N° EC:	262-076-3
Molecular Formula:	C <sub>9</sub> H <sub>17</sub> NO <sub>2</sub>
Content:	97.5 per cent to 102.0 per cent (anhydrous substance)

### 3.2 Mixtures

Not applicable.

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### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

General notes:	Remove affected person from source of contamination. General first aid, rest, warmth and fresh air.
After inhalation:	Remove the inhaled person from exposure to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid.
After skin contact:	Flush skin with plenty of soap solution and water for at least 15 minutes after removing contaminated clothing and shoes. Get medical aid. Wash contaminated cloth before reuse.
After eye contact:	Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.
After ingestion:	Never give anything by mouth to an unconscious person. Get medical aid. Do NOT induce vomiting.

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

Adverse effects associated with the therapeutic use include dizziness, tiredness, swelling, and nausea.

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

The active ingredient is not acutely toxic however the dust may cause irritation.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media:	Use fire-extinguishing media appropriate for surrounding materials. Extinguish with foam, carbon dioxide, dry powder or water fog.
Unsuitable extinguishing media:	Not available.

#### 5.2 Special hazards arising from the substance/mixture

Hazardous combustion products: In case of fire, toxic gases (CO, CO<sub>2</sub>, NO<sub>x</sub>) may be formed.

#### 5.3 Advice for firefighters

Surrounding fires:	Keep run-off water out of sewers and water sources. Dike for water control.
Protection against fire:	Self contained breathing apparatus and full protective clothing must be worn in case of fire.
Hazardous combustion products:	In case of fire, toxic gases (CO, CO <sub>2</sub> , NO <sub>x</sub> ) may be formed.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

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

##### For non-emergency personnel

Use proper personal protective equipment as indicated in section 8.

##### For emergency responders

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Not available.

### 6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

### 6.3 Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust. Vacuum or sweep up spillage. Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Wash thoroughly after handling. Use with adequate ventilation. Minimize dust generation and accumulation. Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion and inhalation.
Personal protection:	Not available.
Technical protective measures:	Use with adequate ventilation. Minimize dust generation and accumulation.
Handling:	Wash thoroughly after handling.

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

Storage:	Keep container tightly closed.
Conditions for safe storage, including any incompatibilities:	Store between 15 - 30 °C.
Storage – away from:	Not available.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

The substance has an in-house OEL TWA 8hr of 1.2 mg/m<sup>3</sup>.

### 8.2 Exposure controls

#### Appropriate engineering control

Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits.

#### Individual protection measures

Eye/face protection: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166 or NIOSH.

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Skin protection:	Wear appropriate protective clothing to prevent skin exposure.
Hand protection:	Wear appropriate protective gloves to prevent skin exposure.
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).
Thermal hazards:	Not determined.
<b>Environmental exposure control</b>	
Not available.	

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

Appearance:	White or almost white, crystalline powder.
Odour:	No characteristic odour.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	166 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride. It dissolves in dilute acids and dilute solutions of alkali hydroxides.
Solubility in water:	Sparingly soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

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### 9.2 Other information

Molecular weight: 171.2 g/mol

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

There are no known reactivity hazards associated with this product.

### 10.2 Chemical stability

Stable under normal temperature conditions.

### 10.3 Possibility of hazardous reactions

Not applicable.

### 10.4 Conditions to avoid

Avoid excessive heat for prolonged periods of time.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

Thermal decomposition or combustion may liberate oxides of carbon and nitrogen.

Hazardous polymerization will not occur.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:

Toxicological information:

Toxic Dose 1 - LD 50: > 5000 mg/kg (oral-mouse)

Toxic Dose 2 - LD 50: > 2000 mg/kg (ivn-rat)

Acute toxicity:

Oral LD50 (rat): > 5000 mg/kg

Skin corrosion/irritation:

Causes skin irritation.

Serious eye damage/irritation:

Causes serious eye irritation.

Respiratory/skin sensitisation:

Not available.

Germ cell mutagenicity:

Genotoxicity - In Vitro: Bacterial mutagenicity (Ames): Negative.

Genotoxicity - In Vivo: Chromosome aberration: Chromosome aberration test was negative.

Carcinogenicity:

Oral NOAEL (mouse): 2000 mg/kg/day

Oral NOAEL (male rat): 1000 mg/kg/day

A 2 year oral feed study in mice determined a NOEL of 2000mg/kg/day whereas a 2 year oral feed study in male rats showed evidence of malignant tumours in the pancreas. The corresponding NOEL was 1000 mg/kg/day.

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Reproductive toxicity:	Reproductive Toxicity - Fertility Reproductive & Fertility: NOAEL 500 mg/kg/day Oral Rat Reproductive Toxicity - Development Embryo toxicity: NOAEL 300 mg/kg/day Oral Rat Developmental toxicity was seen but the test concluded that the substance was not teratogenic.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	NOAEL >250 mg/kg/day Oral Rat A 52 week study in rats showed signs of liver and kidney damage whereas a similar 52 week study in monkeys showed no effects at the NOAEL of 250 mg/kg/day. Target organs: Liver and kidneys.
Aspiration Hazard:	Not available.
Other:	May damage fertility or the unborn child. Target organs: Liver and kidneys.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation.
Skin contact:	Causes skin irritation.
Inhalation:	May cause respiratory irritation.
Ingestion:	May cause irritation.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

### 12.6 Other adverse effects

Not available.

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### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

General information: Waste is classified as hazardous waste. Disposal to licensed waste disposal site in accordance with national and local authority regulations.

Waste treatment methods: Product waste, including contaminated materials from spill clean-up, must be handled in accordance with state government regulations. Waste should be incinerated in accordance with regulations.

### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.6 Special precautions for user

Not available.

##### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

##### 14.8 Additional transport information

Not a dangerous good.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant  
Harmful

Risk phrases:

R36/37/38 Irritating to eyes, respiratory system and skin.



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### Safety phrases:

R60 May impair fertility.

R61 May cause harm to the unborn child.

S23 Do not breathe dust/fumes/gas/mist/vapours/spray.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S27 Take off immediately all contaminated clothing;

S28 After contact with skin, wash immediately with plenty of soap solution and water for at least 15 minutes.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S53 Avoid exposure – obtain special instructions before use.

### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.

### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

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### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

Quality Department

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