

# Material Safety Data Sheet

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

## BACLOFENUM

EN

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

#### 1.1 Product identifier

Product name: Baclofen  
Baclofenum  
Baclofen  
Baclofène  
Baclofen  
N° CAS: 1134-47-0  
N° EC: 214-486-9

#### 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: FAC SECUNDUM ARTEM NV  
Oostmalsebaan 1c (unit 5)  
2960 Sint-Lenaarts  
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

Acute toxicity, oral (Category 3)	H301
Skin irritation (Category 2)	H315
Skin sensitization (Category 1)	H317
Eye irritation (Category 2)	H319
Respiratory Sensitization, (Category 1)	H334
STOT-SE (Cat 3)	H335

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Danger

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### Hazard statements:

H301	Toxic if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.

### Precautionary statements:

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/...
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Baclofen
IUPAC name:	(3RS)-4-Amino-3-(4-chlorophenyl)butanoic acid.
Synonyms:	Lioresal. Baclon.
N° CAS:	1134-47-0
N° EC:	214-486-9
Molecular Formula:	C <sub>10</sub> H <sub>12</sub> ClNO <sub>2</sub>
Content:	98.0 per cent to 101.0 per cent (anhydrous substance).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Instantly remove any clothing soiled by the product. In case of irregular breathing or respiratory arrest, provide artificial respiration.
After inhalation:	Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. In case of unconsciousness bring patient into stable side position for transport.

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After skin contact:	Instantly wash with water and soap and rinse thoroughly.
After eye contact:	Rinse opened eye for several minutes (10 – 15 min) under running water. Then consult doctor.
After ingestion:	Rinse out mouth and then drink plenty of water (200 -300 ml). induce vomiting, only if person affected is fully conscious. Administer medicinal carbon. Call a doctor immediately.

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

Dizziness; Dyspnoea, wheezing, respiratory depression; Spasm, convulsions; Confusion; Unconsciousness; Headache; Dazed, lightheadedness; Sleep disturbances; Hallucinations; Visual defect / blurred vision; Nausea, vomiting, diarrhea; Drowsiness, fatigue

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

If swallowed, induce vomiting (patient is conscious)

If swallowed, gastric irrigation with added, activated carbon.

Monitoring or correction of vital functions.

No specific antidote available. Treat symptomatically and supportively.

In case of cramps, give hydantoine or benzodiazepine (caution: danger of respiratory depression!)

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water or alcohol-resistant foam.

Unsuitable extinguishing media: Do not use a heavy water stream.

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

Formation or toxic gases if possible during heating or in case of fire.

Can be released in case of fire: Nitrogen oxides, Carbon monoxide, carbon dioxide, Hydrogen chloride

### 5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear self-contained breathing apparatus. Do not inhale explosion gases or combustion gases. Wear full protective suit.

Hazardous combustion products: Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### For non-emergency personnel

Avoid causing dust

#### For emergency responders

Wear protective clothing

### 6.2 Environmental precautions

Do not allow to enter drainage system, surface of ground water.

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

Collect mechanically. Dispose of contaminated material as waste.

### 6.4 Reference to other sections

See section 7 for information on safe handling.

See section 8 for information in personal protection equipment.

See section 13 for information on disposal.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Store in cool, dry place in tightly closed containers. Prevent formation of dust.
Personal protection:	Not available
Technical protective measures:	Not available.
Handling:	Not available.

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

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Not available.
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

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Not available.

#### Individual protection measures

Eye/face protection:	Safety glasses.
Skin protection:	Not determined.
Hand protection:	Protective gloves
Respiratory protection:	In case of brief exposure of low pollution use breathing filter apparatus. In case of intensive or longer exposure use breathing apparatus that is independent of circulating air.
Thermal hazards:	Not determined.

#### Environmental exposure control

Do not allow to release of the product to the ground waters, sewage, sewerage system or soil.

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### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

Appearance:	Solid material. White.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	6.5
Melting/freezing point:	206 – 208 °C
Initial boiling point:	Not determined.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Product is not inflammable. Product is not explosive.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	320 kg/m <sup>3</sup>
Solubility:	Not available.
Solubility in water:	Not available.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Product is not explosive.
Oxidising properties:	Not available.

#### 9.2 Other information

Not available.

### SECTION 10: STABILITY AND REACTIVITY

#### 10.1 Reactivity

Not available.

#### 10.2 Chemical stability

No decomposition if used according to specifications. Over 50 °C: formation of lactam.

#### 10.3 Possibility of hazardous reactions

No dangerous reactions known.

#### 10.4 Conditions to avoid

Not available.

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### 10.5 Incompatible materials

Strong oxidizing materials.

### 10.6 Hazardous decomposition products

No dangerous decomposition products known.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Toxic if swallowed.
Skin corrosion/irritation:	May cause irritation by longer exposition. Causes skin irritation.
Serious eye damage/irritation:	Minimal irritant effect. Causes serious eye irritation.
Respiratory/skin sensitisation:	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May causes an allergic skin reaction.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	May cause respiratory irritation
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	Not available.

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

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
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.

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### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Must not be disposed of together with household garbage. Do not allow product to reach sewage system

## SECTION 14: TRANSPORT INFORMATION

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

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), UN2811  
IATA/ICAO (Air) :

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), 28100 toxic solid, organic, N.O.S  
IATA/ICAO (Air) :

#### 14.3 Transport hazard class(es)

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

#### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III  
IATA/ICAO (Air) :

#### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Marine pollutant  
IATA/ICAO (Air) :

#### 14.6 Special precautions for user

Warning: Toxic substances. Kemler number 60; EMS number F-A, S-A; Stowage category A

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

Not available.

#### 14.8 Additional transport information

Not available.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not available.

Risk phrases: Not available.

Safety phrases: Not available.

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### 15.2 Chemical safety assessment

Not available.

## 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.

### 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

FAC SECUNDUM ARTEM NV

info@magis-pharma.be