

Material Safety Data Sheet

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

GLUTAMINUM

EN

FORM-06-14-01 (V00)

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Publication: 18/09/2022

Revision: XX/XX/XXXX

Version: 00



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

1.1 Product identifier

Product name: Glutamine
Glutaminum
Glutamine
Glutamine
Glutamin

N° CAS: 56-85-9

N° EC: 200-292-1

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

Not classified.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable.

Signal word(s): Not applicable.

Hazard statements: Not applicable.

Precautionary statements: Not applicable.

Additional applicable label elements: Not applicable.

2.3 Other hazards

May cause eye and skin irritation. It will increase the biological oxygen demand (BOD) of water.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Glutamine
IUPAC name:	(2S)-2,5-diamino-5-oxopentanoic acid
Synonyms:	L-glutamine Levoglutamide
N° CAS:	56-85-9
N° EC:	200-292-1
Molecular Formula:	$C_5H_{10}N_2O_3$
Content:	Glutamine contains NLT 98.5% and NMT 101.5% of L-glutamine ($C_5H_{10}N_2O_3$), calculated on the dried basis.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Immediately relocate to a fresh air environment. Rinse mouth with water. If not breathing, give artificial respiration. If breathing becomes difficult, give oxygen and seek medical attention.
After skin contact:	Wash with soap and copious amounts of water. If irritation persists, seek medical attention.
After eye contact:	Immediately flush eyes with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. If contact lenses are being worn, remove lenses and continue rinsing. Seek medical attention.
After ingestion:	Rinse mouth with water and seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray, carbon dioxide, dry chemical powder/foam.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source, is a potential dust explosion hazard. Upon combustion will result in carbon monoxide, carbon dioxide and nitrogen oxide being released.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Not available.

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Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use personal protection.

Make spills wet to prevent the generation of dust and then, sweep up into a closed container.

For emergency responders

Use personal protection.

6.2 Environmental precautions

Do not discharge into sewer, river, underground water, etc.

6.3 Methods and material for containment and cleaning up

After recovering, wash away spilled area with plenty of water.

6.4 Reference to other sections

Personal protection: see section 8.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Follow good industrial practice in housekeeping and personal hygiene.

Personal protection:

Wear personal protective equipment as outlines in section 8.

Technical protective measures:

Not available.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Store in a well-closed container.

Conditions for safe storage, including any incompatibilities:

Store at a controlled room temperature.

Store in a dry area.

Storage – away from:

Avoid humidity, sunlight and high temperature.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substance with occupational exposure limit value.

8.2 Exposure controls

Appropriate engineering control

Local exhaust ventilation.

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Individual protection measures

Eye/face protection:	Chemical safety goggles.
Skin protection:	Wear appropriate laboratory apparel, protect exposed skin.
Hand protection:	Protective gloves: rubber.
Respiratory protection:	Dust mask or appropriate respirator. Utilize local exhaust ventilation.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White crystals or crystalline powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	4.5 – 6.0 (1.0g in 50 ml of H ₂ O)
Melting/freezing point:	185 – 186 °C (decomposes)
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:	Practically insoluble in alcohol and in ether.
Solubility in water:	Soluble in water: 3.73 g/100g H ₂ O (20 °C)
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.

9.2 Other information

Not available.

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: In correspondingly fine distribution, when whirled up, a dust explosion potential may generally be assumed.

10.2 Chemical stability

Stable under normal temperature and pressures.

10.3 Possibility of hazardous reactions

Nitrogen oxides (combustion).

10.4 Conditions to avoid

Humidity and high temperature.

In presence of moisture, will oxidise and darken.

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

Nitrogen oxides (combustion).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 7.5 g/kg
Skin corrosion/irritation:	May cause skin irritation. No specific data available.
Serious eye damage/irritation:	May cause eye irritation. No specific data available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause eye irritation. No specific data available.
Skin contact:	May cause skin irritation. No specific data available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

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SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

BOD = 0.70 g/g

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

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

12.6 Other adverse effects

WGK class (Europe): 1 (group classification according to VwVwS / 17 May 1999, Germany)

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of the material as you would with a non-hazardous material in accordance with all applicable national, state and local 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

Avoid humidity and high temperature.

Prevent damage of the container.

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

Not available.

14.8 Additional transport information

Not classified as dangerous in meaning of transport regulations.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

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.

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.

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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

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