Material Safety Data Sheet

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

ALLANTOINUM

Publication: 26/08/2022
Revision: XX/XX/XXXX
Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Allantoin Allantoinum Allantoïne Allantoïne Allantoin
N° CAS:	97-59-6
N° EC:	202-592-8

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 Tox. 4	H302

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): Attention

Hazard statements:

H302	Harmful if swallowed.

Precautionary statements:

P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/… if you feel unwell.

P330	Rinse mouth.
P501	Dispose of contents/container in accordance with national and local environmental regulation.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Allantoin
IUPAC name:	1-(2,5-dioxoimidazolidin-4-yl)urea
Synonyms:	Glyoxyldiureide 5-ureidohydantoin Cordianine Allantol
N° CAS:	97-59-6
N° EC:	202-592-8
Molecular Formula:	$C_4H_6N_4O_3$
Content:	Allantoin contains not less than 98.5 per cent and not more than the equivalent of 101.0 per cent of (RS)-(2,5-dioxoimidazolidin-4-yl)urea.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Ensure that eyewash stations and safety showers are close to the workstation location.
After inhalation:	Move exposed person to fresh air.
After skin contact:	Wash with soap and water. Remove contaminated clothing and shoes. Obtain medical attention if symptoms occur.
After eye contact:	Rinse with plenty of running water during several minutes. Obtain medical attention if symptoms occur.
After ingestion:	If swallowed, rinse mouth with water (only if the person is conscious). Obtain medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

No symptoms known currently.

4.3 Indication of any immediate medical attention and special treatment needed

Obtain medical attention if symptoms occur.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use water spray, foam, dry chemical powder or CO_2.
Unsuitable extinguishing media:	Water jet.

5.2 Special hazards arising from the substance/mixture

Carbon monoxide, carbon dioxide, nitrogen oxides (NO, NO_2), ammonia (NH_3), amines.

5.3 Advice for firefighters

Surrounding fires:	No special measures required.
Protection against fire:	Wear suitable protective clothing. Self-contained breathing apparatus.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use suitable protective equipment (see section 8).

For emergency responders

Use suitable protective equipment (see section 8).

6.2 Environmental precautions

No special measures required.

6.3 Methods and material for containment and cleaning up

Vacuum aspiration or sweep-up of the material and storing in a properly labelled waste container. Recycle if possible. Clean-up affected area with a large amount of water.

6.4 Reference to other sections

See section 8 for personal protective equipment and section 13 for waste disposal.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Use with adequate ventilation.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Suitable packaging materials: primary packaging polyethylene liner; secondary packaging cardbox.
Conditions for safe storage, including any incompatibilities:	Store in a fireproof location.

Storage – away from:	Keep away from incompatible materials and avoid specific conditions (see section 10). Keep the container tightly closed and dry.

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

Use only with adequate ventilation.

General protective and hygiene measures: When using do not eat, drink or smoke. Wash hands after handling the product and before eating, smoking, using lavatory and at the end of the working day.

Individual protection measures

Eye/face protection:	Safety glasses with side shields.
Skin protection:	Working clothes.
Hand protection:	Wear suitable gloves. Recommended material(s): > 8 hours (breakthrough time): Nitrile rubber, butyl rubber, neoprene, Viton, PVC. Replace damaged gloves.
Respiratory protection:	No special protection is required. In case of insufficient ventilation, wear suitable respiratory equipment.
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:	A white or almost white, crystalline powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	4 to 6 (concentration 0.5%)
Melting/freezing point:	229 °C ± 3 °C (decomposition)
Initial boiling point:	Not relevant.
Boiling range:	Not available.
Flash point:	Not relevant.
Evaporation rate:	Not available.
Flammability (solid/gas):	Non flammable.

Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	< 0.001 Pa (20 °C)
Vapour density:	Not available.
Relative density:	1.71 g/cm^3 ± 0.01 g/cm^3 (22 °C)
Solubility:	Very slightly soluble in alcohol.
Solubility in water:	Slightly soluble in water. 4.9 g/l (20 °C)
Partition coefficient (n-octanol/water):	LogKow: -2.26 (20 °C)
Auto-ignition temperature:	Non auto-flammable.
Decomposition temperature:	~ 230 °C
Viscosity:	Not available.
Explosive properties:	Non dust-explosive.
Oxidising properties:	No oxidising properties.

9.2 Other information

Bulk density:	800 kg/m^3
Surface tension:	Not surface active.
Thermal stability:	Decomposes at ~ 230 °C.
pKa:	8.96 (25 °C)
Molecular weight:	158.1154 g/mole

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Keep away from heat, sparks and flame.

10.5 Incompatible materials

No special recommendations.

10.6 Hazardous decomposition products

In case of fire: see section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

Oral toxicity

Value	Test species	Remarks
LD_{50} > 5000 mg/kg bw	Rat	No adverse effect observed.

Dermal toxicity

Value	Test species	Remarks
LD_{50} > 5000 mg/kg bw	Rat	No adverse effect observed.

Inhalative toxicity: No study available

Skin corrosion/irritation: Rabbit (OECD 404; EU Method B.4): No adverse effect observed. Not irritating.

Serious eye damage/irritation: Rabbit (OECD 405): No adverse effect observed. Not irritating.

Respiratory/skin sensitisation: Mouse (OECD 429): No adverse effect observed. Not sensitizing.

Germ cell mutagenicity:

In vitro genotoxicity

Ingredient name	Test	Route	Result
Allantoin	Ames test OECD 471	*S. Typhimurium*	No adverse effect observed (negative)

Carcinogenicity:

Ingredient name	Test	Species	Route	Result
Allantoin	0.2% in feed 106 weeks	Fischer 344 Rat (male/female)	Oral	No adverse effect observed (negative)
Allantoin			Dermal	No study available
Allantoin			Inhalation	No study 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: Not available.

Skin contact: Not available.

Inhalation: Not available.

Ingestion: Not available.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish

Value	Duration of exposure	Remarks
LC_{50}: > 5000 mg/l	96 h	Test substance: Allantoin Species: Danio rerio Method: OECD 203 No toxicity

Toxicity to daphnia

Value	Duration of exposure	Remarks
EC_{50}: > 100 mg/l	48 h	Test substance: Allantoin Species: *Daphnia magna* Method: OECD Test Guideline 202 No toxicity

Toxicity to algae

Value	Duration of exposure	Remarks
EC_{50}: > 100 mg/l	72 h	Test substance: Allantoin Species: *Desmodesmus subspicatus* Method: OECD Test Guideline 201 No toxicity

Toxicity to aquatic micro-organisms

Value	Duration of exposure	Remarks
EC_{10}/LC_{10}: > 1000 mg/l	72 h	Test substance: Allantoin Method: OECD Test Guideline 209 No toxicity

12.2 Persistence and degradability

Biodegradability: Readily biodegradable.
Testing period: 28 days
Method: OECD Test Guideline 301 B (CO_2 evolution test)

12.3 Bioaccumulative potential

Based on the n-octanol/water partition coefficient, accumulation in organisms is not expected.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Substance readily biodegradable, with an octanol water partition coefficient (Log Kow) or -2.26 at 25 °C and a NOEC for Algae of 100 mg/l. Substance not classified as CMR or STOT. Therefore, based on screening criteria and Annes XIII of REACH, the substance is not PBT or vPvB.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste must be disposed of in accordance with national and local environmental regulation (Spain: Ley 11/1997 – Europe: Directives 94/62/EC).

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

No dangerous good in sense of this transport regulation.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Risk phrases: R22 Harmful if swallowed.

Safety phrases: S20/21 When using do not eat, drink or smoke.
S64 If swallowed, rinse mouth with water (only if the person is conscious).

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 Bioaccumalative

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

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