

ALLOPURINOLUM

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

1.1 Product identifier

Product name: Allopurinol
Allopurinolum
Allopurinol
Allopurinol
Allopurinol

N° CAS: 315-30-0

N° EC: 206-250-9

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

Identified uses: Active Pharmaceutical Ingredient.

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

Acute Tox. 3	H301
Skin Sens. 1	H317

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

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H301	Toxic if swallowed.
H317	May cause an allergic skin reaction.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands [and ...] thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P316	IF SWALLOWED: Get emergency medical help immediately.
P302+P352	IF ON SKIN: wash with plenty of water.
P330	Rinse mouth.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P333+P317	If skin irritation or rash occurs: Get medical help.
P321	Specific treatment (see section 4 on this label).
P362+P364	Take off contaminated clothing and wash it before reuse.
P363	Wash contaminated clothing before reuse.
P405	Store locked up.
P501	Dispose of contents/container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Allopurinol
IUPAC name:	1,5-dihydropyrazolo[3,4-d]pyrimidin-4-one
Synonyms:	1H-pyrazolo[3,4-d]pyrimidin-4-ol Zyloprim Lopurin Zyloric
N° CAS:	315-30-0
N° EC:	206-250-9
Molecular Formula:	C ₅ H ₄ N ₄ O
Content:	97.0 % to 102.0 % (dried substance)

3.2 Mixtures

Not applicable.

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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Assure fresh air breathing. Rest. If you feel unwell, seek medical advice.
After skin contact:	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
After eye contact:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persist.
After ingestion:	Rinse mouth. If swallowed, seek medical advice immediately and show this container or label. In case of reactions described in hazards identification or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.

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 or appropriate form.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Avoid spill into drains, surface, and groundwater and soil. Dust may form explosive mixture in air. Emits toxic fumes under fire conditions.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Hazardous combustion products:	O _x , NO _x and other noxious gases or vapours in case of incomplete combustion.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

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General precautions: Remove ignition sources. Evacuate area.

Personal precautions: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

For emergency responders

General precautions: Remove ignition sources. Evacuate area.

Personal precautions: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

To clean the floor and all objects contaminated by this material, use: water/detergent. Avoid dust production. Ensure adequate ventilation.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Preserve in well-closed containers.
Conditions for safe storage, including any incompatibilities:	Store at room temperature.
Storage – away from:	Protect from heat and direct sunlight. Protect from moisture.

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

Provide local exhaust or general room ventilation.

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Individual protection measures

Eye/face protection:	Chemical goggles or safety glasses.
Skin protection:	Wear suitable protective clothing.
Hand protection:	Wear suitable gloves resistant to chemical penetration.
Respiratory protection:	Wear approved mask (P2). In case of insufficient ventilation, wear suitable respiratory protection.
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 or almost white powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	> 350 °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:	Very slightly soluble in ethanol (96 per cent). It dissolves in dilute solutions of alkali hydroxides.
Solubility in water:	Very slightly soluble in water.
Partition coefficient (n-octanol/water):	-0.55 (20 °C)
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: 136.1

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

When heated to decomposition, emits dangerous fumes.

Hazardous reactions: None under normal conditions.

Hazardous polymerization: Will not occur.

10.4 Conditions to avoid

Light.

10.5 Incompatible materials

Strong oxidisers.

10.6 Hazardous decomposition products

Carbon monoxide. Nitrogen oxides. Carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Rat oral LD ₅₀ : > 7500 mg/kg Rabbit dermal LD ₅₀ : No data available. Rat inhalation LC ₅₀ : No data available. Exposure may produce an allergic reaction.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	May cause sensitization by skin contact.
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.

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Aspiration Hazard: Not available.
Other: RTECS nr: UR0785000 (see actual entry in RTECS for complete information)

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

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
LC50 – 96h – fish: > 100 mg/l
EC50 – 48h – *Daphnia magna*: No data available.
IC50 – 72h- algae: 0.45 mg/l

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 available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

General: Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.
Special precautions: This product contains hazardous components for the environment; Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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ADR/ RID(Land),IMDG(Sea), 3077
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Allopurinol)
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 9
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), Not available.
IATA/ICAO (Air) :

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 available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R43 May cause sensitization by skin contact.

Safety phrases:

S35 This material and its container must be disposed of in a safe way.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S56 Dispose of this material and its container at hazardous or special waste collection point.

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

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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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the Magis-Pharma NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. Magis-Pharma NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Magis-Pharma NV
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MATERIAL SAFETY DATA SHEET

EN

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

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