

HYDROXYCARBAMIDUM

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

1.1 Product identifier

Product name:	Hydroxycarbamide Hydroxycarbamidum Hydroxycarbamide Hydroxycarbamide Hydroxycarbamid
N° CAS:	127-07-1
N° EC:	204-821-7

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

Muta. 1B	H340
Repr. 2	H361

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H340	May cause genetic defects.
H361	Suspected of damaging fertility or the unborn child.

HYDROXYCARBAMIDUM

Precautionary statements:

P203	Obtain, read and follow all safety instructions before use.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P318	If exposed or concerned, get medical advice.
P405	Store locked up.
P501	Dispose of contents/container to local/regional/national/international regulations.

Additional applicable label elements: Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Hydroxycarbamide
IUPAC name:	Hydroxyurea
Synonyms:	N-Hydroxyurea Hydroxyurea Hydrea
N° CAS:	127-07-1
N° EC:	204-821-7
Molecular Formula:	CH ₄ N ₂ O ₂
Content:	97.5 per cent to 102.0 per cent (anhydrous substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take outdoors. If breathing is irregular, call a doctor immediately. Only apply artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

HYDROXYCARBAMIDUM

The most important known symptoms and effects are described on the label (see section 2.2) and/or in heading 11.

4.3 Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water mist. Neighboring fires (containers exposed to fire): Atomized or nebulized water.
Unsuitable extinguishing media:	For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance/mixture

Carbon oxides (CO, CO₂). Nitrogen oxides (NO_x).
In the event of fire, fumes that are harmful to health may be produced.

5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent product decomposition and development of potential health hazards. Always use full fire protection. Collect the water that should not enter the sewer. Eliminate the contaminated water used to extinguish and the remains of the second current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and trousers with braces around the arms, legs and waist, EN 469), gloves (fire and dielectric proof, EN 659), a mask with a full-face mask. operator's face or car (protective car) in the case of large amounts of smoke, a self-contained breathing apparatus (EN 137).
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8.

For emergency responders

Not available.

6.2 Environmental precautions

Avoid getting into sewers and water pipes. If the product reaches drains or public water pipes, notify the authorities.

6.3 Methods and material for containment and cleaning up

Ensure waste is collected and contained. Clean thoroughly.
Wash the non-recoverable remainder with: Sodium hypochlorite solution.

HYDROXYCARBAMIDUM

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking, and leaving work.
Personal protection:	Not available.
Technical protective measures:	Provide good ventilation of the processing area to prevent vapor formation.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Tightly closed. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorized persons.
Storage – away from:	Protected from light.

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

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation in the workplace by means of effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE marking that certifies compliance with the applicable regulations. Arrange an emergency shower with a visco-elastic tray.

Hygiene measures: Handle with adequate industrial hygiene precautions, and respect safety practices. Wash your hands before breaks and after finishing the workday.

Individual protection measures

Eye/face protection:	Protection masks and safety glasses according to EN 165, EN 166, EN 167, EN 168.
Skin protection:	Choose body protection based on the amount and concentration of the dangerous substance in the workplace.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of the EU Directive 89/686/EEC and the standards EN 374-1, EN 374-2, EN 374-3, EN 420 derived from it.

HYDROXYCARBAMIDUM

Respiratory protection:	Where risk assessment shows that air purifying respirators are appropriate, use type N95 (USA) or type P1 (EN 149) dust mask. Use respirators and components tested and approved under the appropriate government standards such as NIOSH (USA) or CEN (EU).
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, crystalline powder, hygroscopic.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	135 °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:	Practically insoluble in ethanol (96 per cent).
Solubility in water:	Freely 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.

9.2 Other information

Molecular weight (g/mol): 76.1

HYDROXYCARBAMIDUM

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity (LD ₅₀ , rat): 5760 mg/kg
Skin corrosion/irritation:	No additional information available (Lack of data).
Serious eye damage/irritation:	No additional information available (Lack of data).
Respiratory/skin sensitisation:	No additional information available (Lack of data).
Germ cell mutagenicity:	In vivo tests showed mutagenic effects (test type: Hamster). The experimental fibroblast system was used and chromatid exchanges have been observed.
Carcinogenicity:	This product is or contains a component that is not classifiable as to its carcinogenicity based on its IARC, ACGIH, NTP, or EPA classification.
Reproductive toxicity:	Suspected human reproductive toxicant. Overexposure may cause reproductive disorder(s) based on tests with laboratory animals.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	No additional information available (Lack of data).
STOT-repeated exposure:	No additional information available (Lack of data).
Aspiration Hazard:	No additional information available (Lack of data).
Other:	RTECS: YT4900000

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	No additional information available (Lack of data).
Skin contact:	No additional information available (Lack of data).
Inhalation:	No additional information available (Lack of data).

HYDROXYCARBAMIDUM

Ingestion: Toxic if swallowed.
Aspiration: No additional information available (Lack of data).

SECTION 12: ECOLOGICAL INFORMATION

Use in accordance with good work practices, avoiding dispersing the product in the environment. Notify the competent authorities if the product has reached water courses or if it has contaminated the soil or vegetation.

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 available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

HYDROXYCARBAMIDUM

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

The product is not classified by the conventions of dangerous substances.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R46 May cause inheritable genetic damage.

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

Safety phrases:

S53 Avoid exposure - obtain special instructions before use.

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

HYDROXYCARBAMIDUM

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
 info@magis-pharma.be