Material Safety Data Sheet

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

AMMONII HYDROGENOCARBONAS

Publication: 30/11/2024
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:	Ammonium hydrogen carbonate Ammonii hydrogenocarbonas Ammoniumwaterstofcarbonaat Ammonium (bicarbonate d') Ammoniumhydrogencarbonat
N° CAS:	1066-33-7
N° EC:	213-911-5

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:	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. 4	H302
Aquatic Chronic 3	H412

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): Attention
Warning

Hazard statements:

H302	Harmful if swallowed.
H412	Harmful to aquatic life with long lasting effects.
Precautionary statements:	
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P301+P317	IF SWALLOWED: Get medical help.
P330	Rinse mouth.
P501	Dispose of contents/container to in accordance with local/regional/national/international regulation.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Ammonium hydrogen carbonate
IUPAC name:	Azanium;hydrogen carbonate
Synonyms:	Ammonium bicarbonate Monoammonium carbonate
N° CAS:	1066-33-7
N° EC:	213-911-5
Molecular Formula:	NH_4HCO_3
Content:	98.0 per cent to 101.0 per cent.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Fresh air.
After skin contact:	Take off immediately all contaminated clothing. Rinse skin with water/shower.
After eye contact:	Rinse out with plenty of water.
After ingestion:	Immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

Irritant effects, nausea, vomiting.

The following applies to ammonium salts in general: after swallowing: local irritation symptoms, nausea, vomiting, diarrhoea. Systemic effect: after the uptake of very large quantities: drop in blood pressure, collapse, CNS disorders, spasms, narcotic conditions, respiratory paralysis, haemolysis.

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:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media:	For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance/mixture

Not combustible.

Ambient fire may liberate hazardous vapours.

Fire may cause evolution of: nitrogen oxides

5.3 Advice for firefighters

Surrounding fires:	Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.
Protection against fire:	In the event of fire, wear 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

Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

For emergency responders

Protective equipment: see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and material for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

Indications for waste treatment: see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Observe label precautions. Change contaminated clothing. Wash hands after working with substance.
Personal protection:	Preventive skin protection recommended.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in an airtight container.
Conditions for safe storage, including any incompatibilities:	Tightly closed. Dry.
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

Derived No Effect Level (DNEL):

Worker DNEL, acute, systemic effects, inhalation: 160.7 mg/m^3

Worker DNEL, acute, local effects, inhalation: 160.7 mg/m^3

Worker DNEL, long-term, systemic effects, inhalation: 62.5 mg/m^3

Worker DNEL, long-term, local effects, inhalation: 62.5 mg/m^3

Worker DNEL, long-term, systemic effects, dermal: 57 mg/kg Body weight

Consumer DNEL, acute, systemic effects, inhalation: 143.91 mg/m^3

Consumer DNEL, acute, systemic effects, oral: 34.05 mg/kg Body weight

Consumer DNEL, acute, local effects, inhalation: 143.91 mg/m^3

Consumer DNEL, long-term, systemic effects, dermal: 34.2 mg/kg Body weight

Consumer DNEL, long-term, systemic effects, inhalation: 13.33 mg/m^3

Consumer DNEL, long-term, systemic effects, oral: 17.1 mg/kg Body weight

Consumer DNEL, long-term, local effects, inhalation: 13.33 mg/m^3

Predicted No Effect Concentration (PNEC) :

PNEC Fresh water: 0.37 mg/l

PNEC Fresh water sediment: 0.1332 mg/kg

PNEC Marine water: 0.037 mg/l

PNEC Marine sediment: 0.01332 mg/kg

PNEC Aquatic intermittent release: 0.63 mg/l

PNEC Soil: 74.9 mg/kg

PNEC Sewage treatment plant: 1347 mg/l

8.2 Exposure controls

Appropriate engineering control

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See section 7.1.

Individual protection measures

Eye/face protection:	Safety glasses.
Skin protection:	Protective clothing. Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.
Hand protection:	Full contact/splash contact: Glove material: Nitrile rubber Glove thickness: 0.11 mm Break through time: > 480 min The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 741 Dermatril® L (full contact), KCL 741 Dermatril® L (splash contact). The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types. This recommendation applies only to the product stated in the safety data sheet supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves.
Respiratory protection:	Required when dusts are generated. Recommended Filter type: Filter P 2 (acc. to DIN 3181) for solid and liquid particles of harmful substances. The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.
Thermal hazards:	Not determined.

Environmental exposure control

Do not let product enter drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Fine, white or almost white, crystalline powder or white or almost white crystals, slightly hygroscopic.
Odour:	Ammoniacal.
Odour threshold:	Not available.

pH:	Ca. 8 at 50 g/l (20 °C)
Melting/freezing point:	Not available.
Initial boiling point:	Not applicable.
Boiling range:	Not applicable.
Flash point:	Does not flash.
Evaporation rate:	Not available.
Flammability (solid/gas):	The product is not flammable.
Upper/lower flammability or explosive limits:	Not applicable.
Vapour pressure:	67 hPa (20 °C)
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Practically insoluble in ethanol (96 per cent).
Solubility in water:	Freely soluble in water: 220 g/l (20 °C)
Partition coefficient (n-octanol/water):	log Pow: -2,4 (25 °C) OECD Test Guideline 107 Bioaccumulation is not expected. (IUCLID)
Auto-ignition temperature:	Not available.
Decomposition temperature:	Ca. 60 °C
Viscosity:	Not available.
Explosive properties:	Not classified as explosive.
Oxidising properties:	None.

9.2 Other information

Ignition temperature: not applicable.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Violent reactions possible with: nitrates, nitrites, acids, alkalines.

10.4 Conditions to avoid

Heating (decomposition).

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

In the event of fire: See section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 1 576 mg/kg (OECD Test Guideline 401) Symptoms: Nausea, vomiting absorption
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Possible damages: slight irritation.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Genotoxicity in vitro: Ames test, Salmonella typhimurium, Result: negative (OECD Test Guideline 471). Mutagenicity (mammal cell test): Result: negative.
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:	The following applies to ammonium salts in general: after swallowing: local irritation symptoms, nausea, vomiting, diarrhoea. Systemic effect: after the uptake of very large quantities: drop in blood pressure, collapse, CNS disorders, spasms, narcotic conditions, respiratory paralysis, haemolysis. Other dangerous properties can not be excluded. Handle in accordance with good industrial hygiene and safety practice.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Slight irritation.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish: LC50 *Oncorhynchus mykiss* (rainbow trout): 173 mg/l; 96 h (ECOTOX Database)

Toxicity to bacteria: EC50 *Pseudomonas putida*: 1 895 mg/l; 16 h (OECD Test Guideline 209)

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

log Pow: -2,4 (25 °C) (OECD Test Guideline 107)

Bioaccumulation is not expected. (IUCLID)

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

12.6 Other adverse effects

Additional ecological information: Discharge into the environment must be avoided.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Must not be disposed of with household waste. Do not allow product to reach sewage system.

Uncleaned packaging: Recommendation: Disposal must be made according to official 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

Not available.

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

Not relevant.

14.8 Additional transport information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Irritant

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

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 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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