Material Safety Data Sheet

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

NATRII HYDROGENOCARBONAS

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MAGIS PHARMA

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

1.1 Product identifier

Product name:	Sodium hydrogen carbonate Natrii hydrogenocarbonas Natriumwaterstofcarbonaat Sodium (bicarbonate de) Natriumhydrogencarbonat
N° CAS:	144-55-8
N° EC:	205-633-8

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

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Sodium hydrogen carbonate
IUPAC name:	Sodium;hydrogen carbonate
Synonyms:	Sodium bicarbonate Baking soda E500
N° CAS:	144-55-8
N° EC:	205-633-8
Molecular Formula:	$NaHCO_3$
Content:	99.0 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:	Move to fresh air. If symptoms persist, consult a doctor.
After skin contact:	Wash with soap and water.
After eye contact:	Rinse thoroughly with plenty of water, including under the eyelids. If eye irritation persists, consult a specialist.
After ingestion:	Rinse mouth with water. If symptoms persist, call a doctor or poison control centre immediately.

4.2 Most important symptoms and effects, both acute and delayed

By inhalation

Effects: no specific hazard to be mentioned. At high concentrations: slightly irritating.

In contact with skin

Effects: No specific hazard to be mentioned.

Repeated or prolonged exposure: Contact with dust may cause mechanical irritation or drying of the skin.

In contact with eyes

Effects: Contact of the eyes with dust may cause mechanical irritation.

If swallowed

Effects: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.

4.3 Indication of any immediate medical attention and special treatment needed

Note for the doctor: If symptoms persist and in all cases of doubt seek medical advice.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use extinguishing agents that are suitable for the local conditions and environment.
Unsuitable extinguishing media:	None.

5.2 Special hazards arising from the substance/mixture

Not flammable.

Dust may form an explosive mixture in air.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	In case of fire, wear a compressed air mask. Use personal protective equipment.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Evacuate personnel to a safe area. Avoid dust formation.

For emergency responders

Use personal protective equipment. Sweep up to prevent slipping. Prevent further leaks and spills.

6.2 Environmental precautions

Do not allow to enter surface water or the sewage system. Avoid any mixing with acid in the sewer (gas formation).

6.3 Methods and material for containment and cleaning up

Pick up and transfer to properly labelled containers. Keep in suitable closed containers for disposal.

6.4 Reference to other sections

See protective measures in sections 7 and 8.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Ensure minimum formation of dust and dust deposits. Avoid contact with eyes and skin. Keep away from incompatible products.
Personal protection:	Not available.
Technical protective measures:	Ensure adequate ventilation
Handling:	Do not eat, drink or smoke when using. Wash hands before every break in work and at the end of the working day. Use according to accepted rules and practices for industrial hygiene and safety.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Suitable material: paper, polyethylene.
Conditions for safe storage, including any incompatibilities:	Store in original container. Store in a dry place. Store in labelled containers. Keep containers closed. Incompatibilities: Reacts with acids, acidic salts and many alkaloidal salts, with the evolution of CO_2.
Storage – away from:	Incompatible substances.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

This product is not suitable for peritoneal or parenteral use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

TWA: 10 mg/m^3 (Basis: Solvay Acceptable Exposure Limit)

8.2 Exposure controls

Appropriate engineering control

Provide appropriate exhaust ventilation at dust generation sites. Apply engineering measures to comply with MAC conditions.

Hygiene measures: Do not eat, drink or smoke during use. Wash hands before breaks and at the end of the working day. Use according to established rules and practices for industrial hygiene and safety.

Individual protection measures

Eye/face protection:	Safety goggles.
Skin protection:	Dustproof protective suit.
Hand protection:	Impervious gloves.
Respiratory protection:	Use only respiratory protection in accordance with international/national standards. Respiratory protection with a dust filter. Recommended filter type: P2 filter.
Thermal hazards:	Not determined.

Environmental exposure control

Dispose of rinse water according to local and national regulations.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Between 8,0 and 8,6 (1 % solution)

Melting/freezing point:	Melting point/range: Decomposition: Yes
Initial boiling point:	Not available.
Boiling range:	Thermal decomposition: yes
Flash point:	Not applicable (inorganic).
Evaporation rate:	Not available.
Flammability (solid/gas):	Not applicable. The product is not flammable.
Upper/lower flammability or explosive limits:	Explosivity: not expected.
Vapour pressure:	Thermal decomposition.
Vapour density:	Not applicable.
Relative density:	2.21 – 2.23 (20 °C)
Solubility:	Practically insoluble in ethanol (96%).
Solubility in water:	Soluble in water. 69 g/l (0 °C) 93 g/l (20 °C) 165 g/l (60 °C)
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not applicable.
Decomposition temperature:	> 50 °C
Viscosity:	Dynamic: Not applicable.
Explosive properties:	Not available.
Oxidising properties:	Not expected.

9.2 Other information

Specific gravity: 2.21 kg/dm^3

Bulk density: 0.5 - 1.3 kg/dm^3

pKa: 6,3

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Incompatible with acids. Decomposes slowly when exposed to water.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

None.

10.4 Conditions to avoid

Exposure to moisture. Do not overheat to avoid thermal decomposition.

10.5 Incompatible materials

Acids.

10.6 Hazardous decomposition products

None.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

Acute oral toxicity

LD_{50}: > 4 000 mg/kg - rat, male and female

Method: according to a standardised method

The product has a low acute toxicity.

Unpublished research.

Acute toxicity by inhalation

LC_{50} - 4.5 h (dust particles): > 4,74 mg/l - rat, male and female

Method: according to a standardised method

Not classified as dangerous due to acute inhalation toxicity according to GHS.

Non-published study.

Skin corrosion/irritation:

Rabbit: Slight irritation

Method: Guideline test OECD 404

Non-published study

Serious eye damage/irritation:

Rabbit: Slightly irritant

Method: Guideline test OECD 405

Non-published study

Respiratory/skin sensitisation:

Not available.

Germ cell mutagenicity:

Genotoxicity in vitro

Tribe: *Escherichia coli*

with and without metabolic activation

negative

Method: according to a standardised method

literature data

Ames-test

with metabolic activation

negative

Method: mutagenicity (*Salmonella typhimurium* - reverse mutation test)

Literature data

Genotoxicity in vivo

No data available.

Carcinogenicity:	Not available.
Reproductive toxicity:	<u>Developmental toxicity/Teratogenicity</u> Rat, female Method of application: oral NOAEL teratogenicity: > 340 mg/kg Method: according to a standardized method Highest dose tested The product is not considered to be embryotoxic/foetotoxic. Non-published research Rabbit, female Method of application: oral NOAEL teratogenicity: > 330 mg/kg Method: according to a standardised method Highest dose tested The product is not considered to be embryotoxic/foetotoxic. Non-published research
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Route of exposure: oral, inhalation The substance or mixture is not classified as toxic for any specific target organ, single exposure according to GHS criteria. Internal assessment
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

<u>Acute toxicity to fish</u>

LC_{50} - 96h: 7 100 mg/l - *Lepomis macrochirus* (Sunfish)

flow-through test

Analytical tracking: yes
Method: according to a standardised method
Internal study not published
Not harmful to fish (LC_{50} > 100 mg/l)
Acute toxicity to water fleas and other aquatic invertebrates
EC_{50} - 48h: 4 100 mg/l - *Daphnia magna* (large water flea)
flow-through test
Analytical tracking: yes
Method: according to a standardised method
Internal study not published
Not harmful to aquatic invertebrates (EC_{50} > 100 mg/l)
Chronic toxicity to water fleas and other aquatic invertebrates
NOEC: > 576 mg/l - 21 days - *Daphnia magna* (large water flea)
Semi-static test
Analytical tracking: no
Method: OECD Test Guideline 211
Highest concentration tested
Literature data
No adverse chronic effect observed up to threshold value of 1 mg/l.

12.2 Persistence and degradability

Abiotic degradation

Stability in water:	Product rapidly disintegrates into its ions on contact with water.
Photo degradation:	Hydrolyses Test substance: water Carbonic acid/bicarbonate/carbonate Acid/base balance as a function of pH.

Biodegradability
Not applicable (inorganic substance).

12.3 Bioaccumulative potential

Partition coefficient n-octanol/water: Not applicable (inorganic substance).
Bioconcentration factor (BCF): Not potentially bioaccumulative. Expert judgement.

12.4 Mobility in soil

Adsorption potential (Koc): According to the data on voters, no significant adsorption, internal evaluation.

12.5 Results of PBT and vPvB assessment

Not applicable (inorganic substance).

12.6 Other adverse effects

Ecotoxicity assessment

Acute aquatic toxicity: Not harmful to aquatic organisms (LD/EC_{50} > 100 mg/l)

Chronic aquatic toxicity: No adverse chronic effect observed up to threshold value of 1 mg/l.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Destruction/disposal

Contact waste disposal service. If recycling is not possible, dispose of in accordance with local regulations. Dilute with plenty of water. Neutralise with acid. In accordance with local and national regulations.

Advice on cleaning and disposal of packaging

Reuse where possible is preferable to disposal or incineration. Clean container with water. Dispose of spill water in accordance with local and national regulations. Must be incinerated in an appropriate incinerator licensed by the competent authority.

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

Note: The above mentioned regulations are the regulations valid at the time of publishing this safety data sheet. However, due to possible changes in transport regulations for the transport of hazardous materials, we recommend that you check the validity of these with the sales office.

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

Not applicable.

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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