

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

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CARBOXYMETHYLAMYLUM NATRICUM A

Publication: 13/08/2024

Revision: XX/XX/XXXX

Version: 00



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

1.1 Product identifier

Product name:	Sodium starch glycolate (type A) Carboxymethylamylum natricum A Carboxymethylzetmeel-natrium (type A) Carboxymétylamidon sodique (type A) Carboxymethylstärke-Natrium (Typ A)
N° CAS:	9063-38-1
N° EC:	618-597-7

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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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

The product has not been classified as dangerous according to the legislation in force: CLP 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.

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Additional applicable label elements:

Not applicable.

2.3 Other hazards

May form explosible dust-air mixture if dispersed in the air.

Not fulfilling PBT (persistent/bioaccumulative/toxic) criteria.

Not fulfilling vPvB (very persistent/very bioaccumulative) criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Sodium starch glycolate (type A)

IUPAC name: Sodium carboxyl methylstarch

Synonyms: Carboxymethyl starch

Natrium Stärke Glycolat

N° CAS: 9063-38-1

N° EC: 618-597-7

Molecular Formula: Not applicable.

Content: 2.8 % to 4.2 % of Na (A, 22.99) (substance washed with ethanol (80 % V/V) and dried).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Not applicable.

After inhalation: Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.

After skin contact: Wash with soap and water.

After eye contact: Flush thoroughly with water for at least 15 minutes. Get medical assistance.

After ingestion: Get medical attention if symptoms occur.

Self-protection of the first aider: Not applicable.

4.2 Most important symptoms and effects, both acute and delayed

Dust may irritate the eyes and the respiratory system.

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May cause eye irritation.

May cause skin irritation/eczema.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:

Water spray.

Unsuitable extinguishing media:

Dry chemicals or foams.

Straight streams of water.

5.2 Special hazards arising from the substance/mixture

Fire or excessive heat may produce hazardous decomposition products. See section 10. Combustible dusts: may form an explosible mixture in the air.

5.3 Advice for firefighters

Surrounding fires:

Prevent dust cloud. Do not use water jet as an extinguisher, as this will spread the fire.

Protection against fire:

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

See section 8 of the SDS for Personal Protective Equipment.

For emergency responders

See section 8 of the SDS for Personal Protective Equipment.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Remove material, as much as possible, using mechanical equipment. Prevent dust cloud. Collect and dispose of spillage as indicated in section 13 of the SDS.

6.4 Reference to other sections

For waste disposal, see section 13 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

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Precautions for safe handling:

Avoid generation and spreading of dust. See section 8 of the SDS for Personal Protective Equipment.

Personal protection:

Not available.

Technical protective measures:

Not available.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

In an airtight container.

Conditions for safe storage, including any incompatibilities:

Preserve in well-closed original packing, preferably protected from large temperature and humidity variations, which may cause caking.

Storage – away from:

Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits:

This product does not contain any components >1% with specific occupational exposure limits.

Chemical name	Type	Exposure Limit Values	Source
Dust - Inhalable fraction.	TWA	10 mg/m ³	Belgium. Exposure Limit Values. (01 2020)
Dust - Respirable fraction.	TWA	3 mg/m ³	Belgium. Exposure Limit Values. (01 2020)

8.2 Exposure controls

Appropriate engineering control

Ventilate as needed to control airborne dust. Use explosion-proof ventilation equipment if airborne dust levels are high.

Individual protection measures

Eye/face protection: Wear dust-proof safety goggles where there is a risk of eyes contact. (EN 166)

Skin protection: Wear appropriate clothing to prevent any possibility of skin contact.

Hand protection: Wear gloves are recommended for prolonged use.

Respiratory protection: In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P1). (EN 143)

Thermal hazards: Not determined.

Environmental exposure control

Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white, fine, free-flowing powder, very hygroscopic.

Odour: Odourless.

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Odour threshold:	Not available.
pH:	~ 4.4 at 3 % w/w in water
Melting/freezing point:	Not available.
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:	~ 0.55
Solubility:	Practically insoluble in methylene chloride. It gives a translucent suspension in water.
Solubility in water:	~ 50 g/l at 20 °C
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

9.2.1 Information with regard to physical hazard classes:

Not available.

9.2.2 Other safety characteristics:

Formation of explosible dust/air mixtures: - INERIS - Data from similar product.

MIT (Minimum ignition temperature): MITc (cloud): ~ 380 °C (EN 50281-2-1 / ASTM E1491) TDA (Differential Thermal Analysis), Δt : ~ 251 °C (EN 50281-2-1 / ASTM E1491)

MIE (Minimum Ignition Energy): 1 200 mJ (Hartmann) Very insensitive to the risk of inflammation by an electrostatic discharge.

(dp/dt)max (Maximum Rate of explosion Pressure rise): ~ 220 bar/s (EN 14034-2 / ASTM E1226)

Pmax (Maximum Explosion OverPressure) ±10%: ~ 7.2 bar (EN 14034-1 / ASTM E1226)

Kst value (±20%): ~ 59 barm/s (EN 14034-2 / ASTM E1226)

Dust Explosion Class: st 1 (VDI 3673)

Volume resistivity: >10⁹ Ω.m (IEC 61241-2-2 / Group IIIB non-conductive dust.)

Moisture: ~ 3.85 % (ISO 589)

Mv (Median value): ~ 48.24 μm (ISO 13320)

Other Data: MEC (Minimum Explosible Concentration): 30-60 g/m³ (EN 14034-3 / ASTM E1515)

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Oxidizing properties NC: Not applicable.

Evaporation Rate: Not applicable.

The data reported in this section does not take the place of specifications.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Oxidizing agents.

10.2 Chemical stability

Material is stable under normal conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions under ordinary conditions of use and storage.

10.4 Conditions to avoid

Prevent dust cloud. Dust clouds may be explosive under certain conditions. Avoid dust close to ignition sources.

10.5 Incompatible materials

Strong oxidizing substances.

10.6 Hazardous decomposition products

Carbon Dioxide. Carbon Monoxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

Test/substance	Species	Type/Result	Exposure	Remarks
Carboxymethyl starch	Rat	LD ₅₀ - oral: > 2000 mg/kg Not classified		- Literature Reference -

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Not available.

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.

Aspiration Hazard: Not available.

Other: Not available.

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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

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

Exempted.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Dispose of waste in an appropriate authorized treatment facility in accordance with regulations in force and product characteristics at time of disposal.

Packaging material: Single use packaging. Collect for salvage or disposal.

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.

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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

Not available.

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

Exempted.

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

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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.

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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