

Material Safety Data Sheet

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

EN

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SACCHARINUM NATRICUM

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

1.1 Product identifier

Product name:	Saccharin sodium Saccharinum natricum Natriumsaccharine Saccharine sodique Saccharin-Natrium
N° CAS:	128-44-9
N° EC:	204-886-1

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:	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

None known.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Saccharin sodium
IUPAC name:	Sodium;1,1-dioxo-1,2-benzothiazol-2-id-3-one
Synonyms:	Sodium saccharinate 1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt
N° CAS:	128-44-9
N° EC:	204-886-1
Molecular Formula:	$C_7H_4NNaO_3S \cdot xH_2O$
Content:	99.0 per cent to 101.0 per cent (anhydrous substance) It may be anhydrous or contain a variable quantity of water.

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. Remove contact lenses.
After ingestion:	Make victim drink water (two glasses at most). Consult doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed

We have no description of any symptoms of toxicity.

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, foam, carbon dioxide (CO ₂), dry powder.
Unsuitable extinguishing media:	For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance/mixture

Combustible.
Forms explosive mixtures with air on intense heating.
Vapours are heavier than air and may spread along floors.
Development of hazardous combustion gases or vapours possible in the event of fire.
Fire may cause evolution of: Sulphur oxides, nitrogen oxides.

5.3 Advice for firefighters

Surrounding fires:	Suppress (knock down) gases/vapours/mists with a water spray jet.
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Protection against fire:

Stay in danger area only with self-contained breathing apparatus.
Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

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.

Evacuate the danger area, observe emergency procedures, consult an expert.

For emergency responders

Protective equipment: see section 8.

6.2 Environmental precautions

No special precautionary measures necessary.

6.3 Methods and material for containment and cleaning up

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

For instructions on waste treatment, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Observe label precautions.

Personal protection:

Not available.

Technical protective measures:

Not available.

Handling:

Hygiene measures: Change contaminated clothing. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

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

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values.

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 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:	Glove material:	Nitrile rubber
		Glove thickness:	0.11 mm
		Break through time:	> 480 min
	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 (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Respiratory protection: Required when dusts are generated.
Recommended Filter type: Filter P 1 (acc. to DIN 3181) for solid particles of inert 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

No special precautionary measures necessary.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder or colourless crystals, efflorescent in dry air.

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Odour:	Odourless.
Odour threshold:	Not applicable.
pH:	6.0 - 7.5 at 100 g/l (20 °C)
Melting/freezing point:	226 °C to 230 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	> 200 °C Method: open cup
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:	Sparingly soluble in ethanol (96 per cent).
Solubility in water:	Freely soluble in water. 1 000 g/l at 20 °C
Partition coefficient (n-octanol/water):	log Pow: 0.45 (calculated) (Lit.) Bioaccumulation is not expected.
Auto-ignition temperature:	Not available.
Decomposition temperature:	230 - 235 °C
Viscosity:	Not available.
Explosive properties:	Not applicable.
Oxidising properties:	None.

9.2 Other information

Bulk density: 600 - 800 kg/m³

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Forms explosive mixtures with air on intense heating.

A range from approx. 15 Kelvin below the flash point is to be rated as critical.

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up, a dust explosion potential may generally be assumed.

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: Strong oxidising agents.

10.4 Conditions to avoid

Strong heating (decomposition).

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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 LD ₅₀ (rat): 14 200 mg/kg (anhydrous substance) (RTECS)
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Genotoxicity in vitro: Ames test, Result: negative (anhydrous substance) (Lit.)
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:	Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately. Handle in accordance with good industrial hygiene and safety practice.

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

Partition coefficient: n-octanol/water: log Pow: 0.45 (calculated)
(Lit.) Bioaccumulation is not expected.

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12.4 Mobility in soil

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Discharge into the environment must be avoided.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Notice Directive on waste 2008/98/EC.

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle contaminated containers like the product itself.

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

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.

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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

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 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

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(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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