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

1.1 Product identifier

Product name: Sodium salicylate

Natrii salicylas Natriumsalicylaat Sodium (salicylate de) Natriumsalicylat

N° CAS: 54-21-7 N° EC: 200-198-0

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

Acute Tox. 4 H302 Eye Irrit. 2 H319 Repr. 2 H361

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):





Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

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H319 Causes serious eye irritation.

H361 Suspected of damaging fertility or the unborn child.

Precautionary statements:

P201 Obtain special instructions before use

P202 Do not handle until all safety precautions have been read and understood.

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, clothing, goggles and face shield.

P281 Use personal protective equipment as required.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if

present and easy to do - continue rinsing.

P308+P313 If exposed: Call a POISON CENTER or doctor/physician.

P330 Rinse mouth.

P337+P313 If eye irritation persists, get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container to an appropriate waste disposal site in accordance

with current legislation.

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Sodium salicylate

IUPAC name: Sodium 2-hydroxybenzoate

Synonyms: Salsonin

Sodium 2-hydroxybenzenecarboxylate

Enterosalicyl

N° CAS: 54-21-7N° EC: 200-198-0Molecular Formula: C_7H_5 NaO $_3$

Content: 99.0 per cent to 101.0 per cent (dried substance).

3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

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.

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After inhalation: Take to fresh air. If breathing is irregular, call a doctor immediately. Only give 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. Remove 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, including under

the eyelids, for at least 15 minutes. Get medical attention.

After ingestion: If conscious, give the 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

Product irritant, repeated or prolonged contact with skin or mucous membranes may cause redness, blistering or dermatitis, inhalation of spray mist or airborne particles may cause respiratory tract irritation, some symptoms may not be immediate. Harmful product, prolonged exposure by inhalation may cause anaesthetic effects and the need for immediate medical attention.

4.3 Indication of any immediate medical attention and special treatment needed

Do not administer anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water fog.

Neighbouring fires (fire-exposed containers): Water spray or water

fog.

Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

In case of fire, fumes harmful to health may be produced.

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to prevent decomposition of product and

development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues

in accordance with current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with

straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in 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

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For exposure control and personal protective measures, see section 8. Equip clean-up personnel with appropriate means of protection. Ventilate the area.

For emergency responders

For exposure control and personal protective measures, see section 8. Ventilate the area.

6.2 Environmental precautions

Prevent release to the environment. Prevent entry into sewers and watercourses. If product enters drains or public waterways, notify authorities.

6.3 Methods and material for containment and cleaning up

Store away from other materials. If on the ground, sweep or scoop (shovel or similar) into suitable containers. Limit dust production.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Wash thoroughly after handling.

Do not eat, drink or smoke while handling this product.

Ask for special instructions before use.

Personal protection: Not available.

Technical protective measures: Ensure good ventilation of the processing area to avoid formation of

vapours.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: In an airtight container.

Conditions for safe storage, including any

Keep only in the original container in a cool, well-ventilated place.

incompatibilities: Keep container closed when not in use.

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

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 at the workplace by effective local suction. When choosing personal protective equipment, ask

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your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

Skin protection: Choose body protection according to the quantity and concentration of the

hazardous substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the

specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust

> mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN

(EU).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

Odour:

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

White or almost white, crystalline powder or small, colourless crystals or shiny Appearance:

flakes.

Not available.

Odour threshold: Not available. Not available. Melting/freezing point: Not available. Initial boiling point: Not available. Not available. Boiling range: Flash point: Not available. Not available. Evaporation rate: Flammability (solid/gas): Not available. Upper/lower flammability or

explosive limits:

Not available.

Not available. Vapour pressure: Vapour density: Not available. Relative density: Not available.

Solubility: Sparingly soluble in ethanol (96 per cent).

Solubility in water: Freely soluble in water.

Partition coefficient

(n-octanol/water):

Not available.

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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): 160.10

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

Stable under recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Not established.

10.4 Conditions to avoid

Avoid any type of incorrect handling: high pressures and/or temperatures. Direct sunlight.

10.5 Incompatible materials

Strong oxidising agents and strong bases.

10.6 Hazardous decomposition products

Fumes. Carbon monoxide. Carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral LD₅₀ (rat): 500 mg/Kg

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Causes serious eye irritation.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: No component of this product is identified as a probable, possible or confirmed

human carcinogen at levels greater than or equal to 0.1%.

Reproductive toxicity: Not available.

Summary of evaluation of the Not available.

CMR properties:

Niet er elleble

STOT-single exposure: Not available. STOT-repeated exposure: Not available.

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Aspiration Hazard: Not available.

Other: Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Causes serious eye irritation.

Skin contact: Not available.

Inhalation: Not available.

Ingestion: Harmful if swallowed.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Harmful to aquatic organisms, with long lasting harmful effects.

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 for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: 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),

It is not dangerous in transport.

IATA/ICAO (Air):

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

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14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

14.4 Packing group

ADR/RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

14.6 Special precautions for user

It is not dangerous in transport.

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 to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

×

Irritant Harmful

Risk phrases: R22 Harmful if swallowed.

R36 Irritating to eyes.

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

Safety phrases: S1 Keep locked up.

S20/21 When using, do not eat, drink or smoke.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S53 Avoid exposure - obtain special instructions before use.

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

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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

Quality Department FAC SECUNDUM ARTEM NV info@magis-pharma.be

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