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

1.1 Product identifier

Product name: Salicylic acid

Acidum salicylicum

Salicylzuur

Salicylique (acide)

Salicylsäure

N° CAS: 69-72-7 N° EC: 200-712-3

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 toxicity, oral (category 4) H302 Serious eye damage/eye irritation H318

(Category 1)

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):







Signal word(s): Danger

Hazard statements:

H302 Harmful if swallowed
H318 Causes serious eye damage

H361d Suspected of damaging the unborn child

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Precautionary statements:

P264 Wash hands, forearms and face thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

P330 Rinse mouth.

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

present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P501 Dispose of contents/container to an approved waste disposal plant.

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

Slightly irritating to the skin. Divided solid. Dust explosion possible when mixed with air

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Salicylic acid

IUPAC name: 2-Hydroxybenzoic acid

Synonyms: 2-Hydroxybenzenecarboxylic acid

N° CAS: 69-72-7 N° EC: 200-712-3 Molecular Formula: $C_7H_6O_3$

Content: 99.0 – 100.5 % (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Do not attempt to take action without suitable protective equipment

After inhalation: Move the affected person to the fresh air

After skin contact: Immediately remove contaminated clothing or footwear. Wash off with soap and

plenty of water. If irritation persists, consult a doctor.

After eye contact: Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15

minutes minimum). Consult an eye specialist immediately.

After ingestion: Do not induce vomiting. Give nothing to drink. If necessary, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries after eye contact: Serious damage to eyes.

Symptoms/injuries after ingestion: Ingestion may cause nausea and vomiting. Abdominal pain.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray. Foam. Powder.

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance/mixture

Fire hazard: Combustible.

Explosion hazard: Risk of dust explosion.

Hazardous decomposition products in case of fire: On combustion or on thermal decomposition (pyrolysis) releases:

Toxic vapours. Carbon oxides (CO, CO2). Phenol.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Do not attempt to take action without suitable protective equipment.

Self-contained breathing apparatus. Complete 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 contact with skin and eyes. Do not breathe dust. Mark out the contaminated area with signs and prevent access to unauthorized personnel.

For emergency responders

Concerning personal protective equipment to use, see section 8.

6.2 Environmental precautions

Stop leak if safe to do so. Do not allow uncontrolled discharge of product into the environment.

6.3 Methods and material for containment and cleaning up

For containment: Shovel into suitable and closed containers for disposal.

Methods for cleaning up: Decontaminate and wash the floor with: Sodium hydroxide (2 - 5%). Wash off with plenty of water. Recover the cleaning water for subsequent disposal.

Other information: Avoid creating or spreading dust. Concerning disposal elimination after cleaning, see section 13.

6.4 Reference to other sections

Concerning disposal elimination after cleaning, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Earth the equipment. Handle under inert gas. Protect from moisture.

Provide adequate ventilation. Avoid contact with skin and eyes.

Personal protection: Always wash hands after handling the product. Do not eat, drink or

smoke during use.

Technical protective measures: The floor of the depot should be impermeable and designed to form

a water-tight basin

Handling: Not available.

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7.2 Conditions for safe storage, including any incompatibilities

Storage: Store in a well-ventilated place. Protect from light. Keep away from

open flames, hot surfaces and sources of ignition. Keep the container

Recommended packaging materials: Stainless steel. Plastic materials.

tightly closed. Protect from moisture.

Conditions for safe storage, including any

incompatibilities:

Polyethylene. Polypropylene.

Packaging material to avoid: Some plastics. Steel.

Alkalis and caustic products. Oxidizing materials.

7.3 Specific end use(s)

Storage – away from:

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

DNEL/DMEL (Workers)

Long-term - systemic effects, dermal: 2 mg/kg bodyweight/day

Long-term - systemic effects, inhalation: 12 mg/m³ 5 mg/m³ Long-term - local effects, inhalation:

DNEL/DMEL (General population)

Acute - systemic effects, oral: 4 mg/kg bodyweight/day Long-term - systemic effects, oral: 1 mg/kg bodyweight/day

Long-term - systemic effects, inhalation: 4 mg/m³

Long-term - systemic effects, dermal: 1 mg/kg bodyweight/day

PNEC (Water)

PNEC aqua (freshwater): 0.2 mg/l PNEC aqua (marine water): 0.02 mg/l

PNEC (Sediment)

PNEC sediment (freshwater): 1.42 mg/kg dwt PNEC sediment (marine water): 0.14 mg/kg dwt

PNEC (Soil)

PNEC soil: 0.17 mg/kg dwt

PNEC (STP)

PNEC sewage treatment plant: 162 mg/l

8.2 Exposure controls

Appropriate engineering control

Extraction to remove dust at its source. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure

Individual protection measures

Eye/face protection: Safety spectacles with side shields

Skin protection: Protective clothing

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Hand protection: Wear suitable gloves. The protective gloves to be used must comply with the

specifications of EC directive 89/686/EEC and the resultant standard EN 374.

Breakthrough time: refer to the recommendations of the supplier

Respiratory protection: Breathing apparatus with filter. Handling product in bulk: Particle filter. (EN 143)

Thermal hazards: Not determined.

Environmental exposure control

Do not allow uncontrolled discharge of product into the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White crystalline powder. Needles.

Odour: odourless.

Odour threshold: Not available.

pH: 2.4 (2 % (m/v)) (Aqueous solution)

Melting/freezing point: 157 - 160 °C

Initial boiling point: $256 \, ^{\circ}\text{C} \, (1013 \, \text{hPa})$ Boiling range: Not available.

Flash point: 157 °C (closed cup)

Evaporation rate: Not available.

Flammability (solid/gas): The product is not flammable.

Upper/lower flammability or

explosive limits:

Not available.

Vapour pressure: 0.0002 hPa (25 °C) Vapour density: Not available.

density: 1.44 g/cm³ (20 °C)

Solubility: Soluble in : Ether. Acetone. Ethanol. Chloroform.

Solubility in water: Slightly: 2 g/l (20 °C)

Partition coefficient Not available.

(n-octanol/water):

Auto-ignition temperature: 549 °C

Decomposition temperature: 230 °C (2 K/min) Viscosity: Not available.

Explosive properties: Dust may form explosive mixture in air.

Oxidising properties: Non oxidizing

9.2 Other information

Not available.

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

To our knowledge, the product does not present any particular risk.

10.2 Chemical stability

Stable at ambient temperature and under normal conditions of use.

10.3 Possibility of hazardous reactions

Risk of dust explosion.

10.4 Conditions to avoid

High temperature.

10.5 Incompatible materials

Alkalis and caustic products. Oxidizing materials.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Harmful if swallowed.

Skin corrosion/irritation: Not classified (Based on available data, the classification criteria are not met)

pH: 2.4 (2 % (m/v)) (Aqueous solution)

Not irritating to rabbits on cutaneous application

May cause slight temporary irritation

Serious eye damage/irritation: Causes serious eye damage.

pH: 2.4 (2 % (m/v)) (Aqueous solution)

Extremely irritating to rabbits on ocular application

Respiratory/skin sensitisation: Not classified (Based on available data, the classification criteria are not met)

Did not cause sensitisation

mouse (LLNA)

human (Diluted product)

Germ cell mutagenicity: Not classified (Based on available data, the classification criteria are not met)

In vitro and in vivo tests did not reveal any genotoxic potential

Carcinogenicity: Not classified (Based on available data, the classification criteria are not met)

Reproductive toxicity: Not classified (Based on available data, the classification criteria are not met)

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: Not classified (Based on available data, the classification criteria are not met)

Dust from this product may cause irritation to the respiratory tract

STOT-repeated exposure: Not classified (Based on available data, the classification criteria are not met)

Aspiration Hazard: Not classified (Technical impossibility to obtain the data)

Other: Dust from this product may cause irritation to the respiratory tract.

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11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Causes serious eye damage.

Skin contact: Not available. Inhalation: Not available. Ingestion: Not available. Not available. Aspiration:

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

12.2 Persistence and degradability

Readily biodegradable. 100 % biodegradation (14 days).

12.3 Bioaccumulative potential

Not potentially bioaccumulable.

12.4 Mobility in soil

Mobile.

12.5 Results of PBT and vPvB assessment

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with relevant local regulations. Incinerate at a licensed installation.

Completely empty the packaging prior to decontamination.

Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

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

Not classified.

IATA/ICAO (Air):

14.2 UN proper shipping name

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

Not classified.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

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

Not classified.

IATA/ICAO (Air):

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14.4 Packing group

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

Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

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

Not classified.

IATA/ICAO (Air):

14.6 Special precautions for user

Not classified.

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

Not classified.

14.8 Additional transport information

Not classified.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not available. Not available. Risk phrases: Safety phrases: Not available.

15.2 Chemical safety assessment

A chemical safety assessment has 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

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 United Nations (number) UN (number):

vPvB: very Persistent and very Bioaccumalative

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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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