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

1.1 Product identifier

Product name: Acetylsalicylic acid

Acidum acetylsalicylicum

Acetylsalicylzuur

Acétylsalicylique acide

Acetylsalicylsäure

N° CAS: 50-78-2 N° EC: 200-064-1

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

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Warning

Hazard statements:

H302 Harmful if swallowed

Precautionary statements:

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

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

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P330 Rinse mouth.

P501 Dispose of contents/container to...

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Acetylsalicylic acid

IUPAC name: 2-(Acetyloxy)benzoic acid.

Synonyms: O-Acetylsalicylic acid

N° CAS: 50-78-2 $\label{eq:case2} \mbox{N° EC:} 200-064-1$ $\mbox{Molecular Formula:} \mbox{C}_9\mbox{H}_8\mbox{O}_4$

Content: 99.5% - 101.0% (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Remove from exposure. Remove contaminated clothing. Persons developing serious

hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give

oxygen. Obtain medical attention.

After inhalation: Assure fresh air breathing. Rest. If you feel unwell, seek medical advice

After skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water,

followed by warm water rinse.

After eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking,

tears or redness persist.

After ingestion: Rinse mouth. If swallowed, seek medical advice immediately and show this container

or label.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

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 spray. Carbon dioxide. Dry powder

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Unsuitable extinguishing media: Do not use a heavy water stream

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires: Use water spray or fog for cooling exposed containers

Protection against fire: Do not enter fire area without proper protective equipment, including

respiratory

Hazardous combustion products: Incomplete combustion will generate poisonous carbon monoxide,

carbon dioxide and other toxic gases.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove ignition sources. Evacuate area.

For emergency responders

Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Clean spills promptly. To clean the floor and all objects contaminated by this material, use: sodium hypochlorite solution. Ensure adequate ventilation.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Not available.

Personal protection: Avoid all unnecessary exposure. Ensure prompt removal from eyes,

skin and clothing.

Technical protective measures: Keep away from open flame, sources of ignition and sparks.

Handling: As a general rule, when handling Acetylsalicylic Acid avoid all contact

and inhalation of dust, mists, and/or vapors associated with the

material. Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Preserve in an airtight container.

Conditions for safe storage, including any

incompatibilities:

Not available.

Storage – away from: All heat sources, including direct sunlight. Open flame. Sources of

ignition. Sparks. Incompatible materials.

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7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

ACGIH: 5 mg/m3 NIOSH: 5 mg/m3

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: Chemical goggles or safety glasses
Skin protection: Wear suitable protective clothing.

Hand protection: Wear suitable gloves resistant to chemical penetration.

Respiratory protection: Wear approved mask. (P3) In case of insufficient ventilation, wear suitable respiratory

equipment.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White crystalline powder

Odour: Odorless or has a faint odor.

Odour threshold: Not available. pH: 3.5 at 2.5 g/L

Melting/freezing point: MP about 143 °C (instantaneous method)

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: 250°C

Evaporation rate: Not available. Flammability (solid/gas): Not available. Upper/lower flammability or Not available.

explosive limits:

NOL available.

Vapour pressure: 2.52 x 10-5 mm Hg
Vapour density: Not available.
Relative density: Not available.

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

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Solubility in water: Slightly soluble in water

Partition coefficient Not available.

(n-octanol/water):

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Not available.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Moisture.

10.5 Incompatible materials

Avoid strong bases. Strong oxidizers. Strong acids

10.6 Hazardous decomposition products

When heated to decomposition, emits dangerous fumes. Carbon monoxide. Carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Blood and lymphatic system disorders. Reduced blood clotting. Hemorrhage. Changes

in blood pressure. Gastrointestinal disorders. May produce ulcers. Nausea. Respiratory, thoracic and mediastinal disorders. Oedema. Nervous system disorders.

Numbness.

Skin corrosion/irritation:

Serious eye damage/irritation:

Respiratory/skin sensitisation:

Germ cell mutagenicity:

Carcinogenicity:

Reproductive toxicity:

Not available.

Not available.

Not available.

Not available.

Not available.

Not available.

CMR properties:

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STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: Chronic toxicity: Can affect cell formation. This material or its emissions may cause

damage to kidney and liver and/or aggravate existing disorders.

11.2 Additional information on potential adverse human health effects and symptoms

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

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Biodegradation.

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

Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

Not dangerous goods

IATA/ICAO (Air):

14.2 UN proper shipping name

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

Not dangerous goods

IATA/ICAO (Air):

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14.3 Transport hazard class(es)

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

Not dangerous goods

IATA/ICAO (Air):

14.4 Packing group

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

Not dangerous goods

IATA/ICAO (Air):

14.5 Environmental hazards

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

Not dangerous goods

IATA/ICAO (Air):

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:

R22- Harmful if swallowed Risk phrases:

Not available. Safety phrases:

15.2 Chemical safety assessment

Not available.

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 International Union of Pure and Applied Chemistry **IUPAC:** PBT: Persistent, Bioaccumulative and Toxic substance

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

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STOT: Specific Target Organ Toxicity

UN (number): United Nations (number)

very Persistent and very Bioaccumalative vPvB:

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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