

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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Publication: 19/02/2022

Revision: 19/02/2022

Version: 00



ACIDUM FLUFENAMICUM

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

1.1 Product identifier

| | |
|---------------|--|
| Product name: | Flufenamic acid Acidum flufenamicum Flufenaminezuur Flufénamique (acide) Flufenaminsäure |
| N° CAS: | 530-78-9 |
| N° EC: | 208-494-1 |

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 Tox. 3 | H301 |
| Skin Mild Irrit. 3 | H316 |

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H301 Toxic if swallowed.

H316 Causes mild skin irritation.

Precautionary statements:

P264 Wash skin thoroughly after handling.

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

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/...

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| | |
|---------------------------------------|--|
| P332+P313 | If skin irritation occurs: Get medical advice/attention. |
| P405 | Store locked up. |
| P501 | Dispose of contents/container to local regulations. |
| Additional applicable label elements: | Not applicable. |

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

| | |
|--------------------|--|
| Product name: | Flufenamic acid |
| IUPAC name: | 2-[[3-(trifluoromethyl)phenyl]amino]benzoic acid |
| Synonyms: | N-(3-Trifluoromethylphenyl)anthranilic acid Arlef |
| N° CAS: | 530-78-9 |
| N° EC: | 208-494-1 |
| Molecular Formula: | C ₁₄ H ₁₀ F ₃ NO ₂ |
| Content: | 99.0 per cent to 101.0 per cent (dried substance) |

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

| | |
|---------------------|---|
| After inhalation: | Remove person to fresh air. If respiratory irritation, dizziness, nausea or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, give artificial respiration. |
| After skin contact: | Wash exposed skin with soap and water in abundance. Remove contaminated clothing and wash before reuse. If you feel unwell, call a poison centre or doctor/physician. |
| After eye contact: | Flush immediately with plenty of cold water for 15 minutes, while holding eyelids apart. If you feel unwell, call a poison centre or doctor/physician. |
| After ingestion: | If swallowed, do NOT induce vomiting. Call a poison centre or doctor/physician immediately. |

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: | Use dry chemical, carbon dioxide, foam or water fog. In case of fire, cool endangered containers with water fog. |
| Unsuitable extinguishing media: | Not available. |

5.2 Special hazards arising from the substance/mixture

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Not available.

5.3 Advice for firefighters

| | |
|--------------------------------|---|
| Surrounding fires: | In case of fire, cool endangered containers with water fog. Do not flush down sewers or other drainage systems. |
| Protection against fire: | Wear self contained breathing apparatus for fire fighting if necessary. For fires in enclosed areas, wear full protective clothing and self-contained breathing apparatus to fight fires. |
| Hazardous combustion products: | Carbon oxides. |

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Not available.

For emergency responders

Not available.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Containment procedures: Absorb with inert absorbent such as dry clay, sand or diatomaceous earth, commercial sorbents. Scoop up used absorbent into drums or other appropriate container.

Clean-up procedures: Wear appropriate protective equipment and clothing during clean-up. Stop source of leak if without risk. Eliminate all ignition sources. Do not use metal tools or equipment. Prevent entry into sewers, basements or confined areas; dike if needed. Dispose of used absorbent in an approved industrial landfill.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

| | |
|--------------------------------|--|
| Precautions for safe handling: | Use clean plastic or stainless steel scoops only. Wash all exposed areas with soap and water before eating and after handling material. In case of fire or decomposition, deluge with plenty of water to control decomposition. |
| Personal protection: | Wear respiratory protection if ventilation is inadequate or not available. Use respiratory, eye and skin protection when contact is expected. |
| Technical protective measures: | Use adequate ventilation when transferring product. |
| Handling: | Not available. |

7.2 Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| Storage: | Not available. |
| Conditions for safe storage, including any incompatibilities: | Keep container tightly closed and dry. Store in a cool, clean, dry and well-ventilated area. Flammable materials should be stored in a separate safety storage cabinet or room. Ground all equipment containing material. |
| Storage – away from: | Store protected from light. |

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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

Not available.

8.2 Exposure controls

Appropriate engineering control

Use exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Individual protection measures

Eye/face protection: Chemical goggles.

Skin protection: Not determined.

Hand protection: Nitrile or neoprene gloves.

Respiratory protection: In case of brief exposure or low pollution, use respiratory filter device.
In case of intensive or longer exposure, use self-contained respiratory protective device.

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-yellow to grey-green crystalline powder or needles. Many different polymorphs are known.

Odour: N/A.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: 132 – 135 °C

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: Not available.

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

Solubility in water: Practically insoluble 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: 281.23

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable under normal temperatures and pressures.

10.3 Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4 Conditions to avoid

Heat, flames, sparks and other sources of ignition.

10.5 Incompatible materials

Strong acids, oxidants, reducing agents, organic materials and alkalis.

10.6 Hazardous decomposition products

Carbon monoxide and dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral LD₅₀ (rat): 249 mg/kg

Skin corrosion/irritation: Very hazardous (irritant).

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.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Not available.

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| | |
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| Skin contact: | Causes mild skin irritation. |
| Inhalation: | Not available. |
| Ingestion: | Toxic if swallowed. |
| 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

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal: Dispose of in a manner consistent with federal, state, and local regulations, preferably by dissolution or mixture with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 2811
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), TOXIC SOLID, ORGANIC, N.O.S. (FLUFENAMIC ACID)
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), Division 6.1
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not available.
IATA/ICAO (Air) :

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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:



Risk phrases:

Toxic

R25 Toxic if swallowed.

Safety phrases:

S1 Keep locked up.

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

S46 If swallowed, seek medical advice immediately and show this container or label.

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 |
| 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

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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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