

# Material Safety Data Sheet

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

## ACIDUM FUSIDICUM

EN

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

#### 1.1 Product identifier

Product name: Fusidic acid  
Acidum fusidicum  
Fusidinezuur  
Fusidique (acide)  
Fusidinsäure  
N° CAS: 6990-06-3  
N° EC: 230-256-0

#### 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

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

Precautionary statements:

P264 Wash hands and other exposed areas thoroughly after handling.

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

P330 Rinse mouth.

P501 Dispose of contents/container to: Hazardous waste. Comply with applicable regulations.

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Additional applicable label elements: Not applicable.

### 2.3 Other hazards

Other hazards not contributing to the classification: Exposure may produce an allergic reaction.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Fusidic acid
IUPAC name:	2-(16-acetoxy-3,11-dihydroxy-4,8,10,14-tetramethylgonan-17-ylidene)-6-methylhept-5-enoic acid
Synonyms:	Ramycin Fucithalmic
N° CAS:	6990-06-3
N° EC:	230-256-0
Molecular Formula:	$C_{31}H_{48}O_6, \frac{1}{2} H_2O$
Content:	97.5 per cent to 101.0 per cent (anhydrous substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation:	Move to fresh air in case of accidental inhalation. Assure fresh air breathing.
After skin contact:	Rinse skin with water/shower.
After eye contact:	Rinse with water while holding the eyes wide open. Contact lenses should be removed.
After ingestion:	Rinse mouth out with water.

### 4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries: See Heading 2.

### 4.3 Indication of any immediate medical attention and special treatment needed

In all cases of doubt, or when symptoms persist, seek medical attention.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:	Small amounts: Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder. Large amounts: Not applicable.
Unsuitable extinguishing media:	Water may be ineffective in firefighting due to low solubility.

### 5.2 Special hazards arising from the substance/mixture

Not available.

### 5.3 Advice for firefighters

Surrounding fires:	Small amounts: Use normal individual fire protective equipment. Large amounts: Not applicable.
Protection against fire:	Not available.

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Hazardous combustion products: Not available.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

##### For non-emergency personnel

Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Large amounts: Not applicable.

Protective equipment: See Headings 7 and 8.

##### For emergency responders

Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Large amounts: Not applicable.

#### 6.2 Environmental precautions

Not available.

#### 6.3 Methods and material for containment and cleaning up

Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents.

#### 6.4 Reference to other sections

Not available.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:

Small amounts: See Heading 1. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

Handle and open container with care. See Heading 8.

Personal protection:

Not available.

Technical protective measures:

Not available.

Handling:

Hygiene measures: Handle in accordance with good industrial hygiene and safety procedures.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Comply with applicable regulations.

Store at a temperature of 2 °C to 8 °C.

Incompatible products: Strong oxidizing agents.

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

Not available.

##### Individual protection measures

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Eye/face protection:	Not determined.
Skin protection:	Lab coat.
Hand protection:	Gloves.
Respiratory protection:	Quarter mask (DIN EN 140).
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 or almost white, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	4.77 – 4.82
Melting/freezing point:	178 – 180 °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. < 1 mg/l
Partition coefficient (n-octanol/water):	Log Pow: 6.75 at 20°C
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.

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### 10.3 Possibility of hazardous reactions

Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. Large amounts: Not applicable.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Small amounts: None under normal use. Large amounts: Not applicable.

### 10.6 Hazardous decomposition products

When heated to decomposition, emits dangerous fumes. Large amounts: Not applicable.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Harmful if swallowed. LD <sub>50</sub> oral rat: 1500 mg/kg ATE (oral): 500,000 mg/kg
Skin corrosion/irritation:	Not classified. pH: 4.77 – 4.82
Serious eye damage/irritation:	Not classified. pH: 4.77 – 4.82
Respiratory/skin sensitisation:	Not classified.
Germ cell mutagenicity:	Not classified.
Carcinogenicity:	Not classified.
Reproductive toxicity:	Not classified.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not classified.
STOT-repeated exposure:	Not classified.
Aspiration Hazard:	Not classified.
Other:	Potential adverse human health effects and symptoms: Avoid any direct contact with the product. Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. Large amounts: Not applicable.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Ecology – general: Small amounts: See Heading 2. Poorly soluble in water. No data available on ecotoxicity. Large amounts: Not applicable.

### 12.2 Persistence and degradability

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Log Pow: 6.75 at 20°C

Bioaccumulative potential: Strong.

### 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

Regional legislation (waste): 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),  
IATA/ICAO (Air) : No dangerous good in sense of transport regulations.

#### 14.2 UN proper shipping name

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

#### 14.3 Transport hazard class(es)

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

#### 14.4 Packing group

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

#### 14.5 Environmental hazards

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

#### 14.6 Special precautions for user

Not available.

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

Not applicable.

#### 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:

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Irritant

Risk phrases:

R22 Harmful if swallowed.

Safety phrases:

S64 If swallowed, rinse mouth with water (only if the person is conscious).

### 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

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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA

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### 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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