

# 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: 04/01/2021

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## ACETYL CYSTEINUM

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

#### 1.1 Product identifier

Acetylcysteinum:	Acetylcysteine Acetylcysteinum Acetylcysteïne Acétylcystéine Acetylcyein
N° CAS:	616-91-1
N° EC:	210-498-3

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 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

The product is not classified as hazardous pursuant to the provisions set forth in CE Regulation 1272/2998(CLP)

#### 2.2 Label elements

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

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

#### 2.3 Other hazards

Not available.

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## ACETYL CYSTEINUM

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Product name:	Acetylcysteine
IUPAC name:	2-acetamido-3-sulfanylpropanoic acid
Synonyms:	N-Acetyl-L-cysteine acetylcysteine N-Acetylcysteine mercapturic acid
N° CAS:	616-91-1
N° EC:	210-498-3
Molecular Formula:	C <sub>5</sub> H <sub>9</sub> NO <sub>3</sub> S
Content:	98.0 % to 101.0 % (dried substance)

#### < 3.2 Mixtures

Not applicable.

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

General notes:	Notify the doctor. Show the doctor the security file of this service.
After inhalation:	Go outside (open air). If breathing is irregular, call a doctor immediately. Only apply artificial respiration if respiration is stopped or under medical supervision.
After skin contact:	Wash immediately with soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical advice/attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, clean under the eyelids, for at least minus 15 minutes. Get medical advice/attention if needed.
After ingestion:	If the person is conscious, give the person enough 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

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:	Foam, dry powder, carbon dioxide, sand, water mist.
Unsuitable extinguishing media:	Waterjet stream.

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

Not available.

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### 5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Helmet with visor, fireproof clothing (jacket and trousers with straps around the arms, legs and waist) EN 469, gloves (fireproof and dielectric) EN 659, a face mask covering the entire face of the operator or the car (self-protection) in the case of large quantities 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

Avoid the inhalation of dust. Read section 8.

#### For emergency responders

Avoid the inhalation of dust. Read section 8.

### 6.2 Environmental precautions

The product does not qualify as dangerous for the environment. Avoid the spillage of the product.

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

Clean and shovel. Store in appropriate, closed containers for disposal.

### 6.4 Reference to other sections

For control of exposition and self-protection, read section 8.  
For the elimination of the rest of the product, read section 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Adequate extraction must be available where dust is formed. Have normal preventive fire protection provisions.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

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

Storage:	Conserve the product close in a ventilated area.
Conditions for safe storage, including any incompatibilities:	No more information apart from section 1.
Storage – away from:	No more information apart from section 1.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

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### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Since the use of appropriate technical measures should always take priority over personal protective equipment, ensure good ventilation at the workplace through effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE mark attesting to compliance with the applicable regulations. Arrange an emergency shower with a visco-elastic tray.

#### 8.2 Exposure controls

##### Appropriate engineering control

Not available.

##### Individual protection measures

Eye/face protection: Protection mask and security glasses according to the regulation EN166.

Skin protection: Choose body protection depending on the quantity and concentration of the dangerous substance in the working place.

Hand protection: Use gloves. All the gloves must follow the specifications of the EU Directive 89/686/CEE and the regulation EN 374 belonging to it.

Respiratory protection: When risk assessment shows air-purifying respirators to be appropriate, use type N95 (USA) or type P1 (EN 143) dust mask. Use respirators and components tested and approved under appropriate government standards such as NIOSH (USA) or CEN (EU).

Thermal hazards: Handle with appropriate industrial hygiene precautions and respect safety practices. Wash your hands before breaks and after finishing workday.

##### Environmental exposure control

Not available.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance: Crystalline powder.

Odour: Almost odorless.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: 106-108

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.

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Vapour density:	Not available.
Relative density:	0.730 g/mL
Solubility:	Not available.
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not available.
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

Without special conditions.

### 10.2 Chemical stability

Stable under the conditions mentioned in section 7.

### 10.3 Possibility of hazardous reactions

The product does not show the possibility of dangerous reactions.

### 10.4 Conditions to avoid

Avoid any type of incorrect manipulation: pressures or high temperatures.

### 10.5 Incompatible materials

Heavy metals, salt of heavy metals, rubber, oxygen and anti-oxidant agents.

### 10.6 Hazardous decomposition products

Products of dangerous compositions made in situations of fire: carbon oxides (COx), oxides of nitrogen (NOx) and sulfur oxides (SOx).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	5050 mg/Kg
Skin corrosion/irritation:	Can cause skin irritation.
Serious eye damage/irritation:	Can cause severe eye irritation.
Respiratory/skin sensitisation:	Can irritate the respiratory airways.
Germ cell mutagenicity:	Not available.

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Carcinogenicity:	There is no component in this product identified with higher levels than 0,1% as a carcinogenic agent, possible or confirmed.
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:	NºRTECS: HA1660000

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

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

Consider federal state and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn it in a chemical incinerator equipped with an afterburner and a scrubber.

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### 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) :

##### 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 available.

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

Not available.

##### 14.8 Additional transport information

The Safety Data Sheet complies with the requirements of Regulation (EC) No. 1907/2006 (REACH) and does not with the regulation 1272/2008 (CLP).

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not classified.

Risk phrases: Not classified.

Safety phrases: Not classified.

#### 15.2 Chemical safety assessment

A chemical safety assessment of the product has not been made.

### SECTION 16: OTHER INFORMATION

#### 16.1 Changes since the previous version

Not applicable.

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## ACETYL CYSTEINUM

### 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.

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### 16.8 Department issuing MSDS

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