

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

## 94467-ACETYL CYSTEINE



Version 1 Date of compilation: 25/04/2016

Version 3 (replaces version 2)

Revision date: 02/08/2022

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

#### 1.1 Product identifier.

Product Name: ACETYLCYSTEINE  
Product Code: 94467

Chemical Name: acetylcysteine  
CAS No: 616-91-1  
EC No: 210-498-3

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

Active pharmaceutical ingredient

#### Uses advised against:

Uses other than those recommended.

#### 1.3 Details of the supplier of the safety data sheet.

Company: **GUINAMA**  
Address: C/ Praga, s/n. P.I. Gutenberg  
City: 46185 La Pobla de Vallbona  
Province: Valencia  
Telephone: +34961869090 / 902119816  
Fax: +34961850352  
E-mail: ventas@guinama.com  
Web: www.guinama.com

**1.4 Emergency telephone number:** +34961869090 / 902119816 (Only available during office hours; Monday-Friday; 08:00-18:00)

### SECTION 2: HAZARDS IDENTIFICATION.

#### 2.1 Classification of the substance or mixture.

In accordance with Regulation (EU) No 1272/2008:

Eye Dam. 1 : Causes serious eye damage.

Skin Corr. 1 : Causes severe skin burns and eye damage.

#### 2.2 Label elements.

##### Labelling in accordance with Regulation (EU) No 1272/2008:

Pictograms:



Signal Word:

**Danger**

H statements:

H314 Causes severe skin burns and eye damage.

P statements:

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash ... thoroughly after handling.

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

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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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/doctor/...  
P501 Dispose of contents/container to ...

### 2.3 Other hazards.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

### 3.1 Substances.

#### Mono-constituent.

Chemical Name: acetylcysteine  
CAS No: 616-91-1  
EC No: 210-498-3

### 3.2 Mixtures.

Not Applicable.

## SECTION 4: FIRST AID MEASURES.

### 4.1 Description of first aid measures.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

#### Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

#### Eye contact.

Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Don't let the person to rub the affected eye.

#### Skin contact.

Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

#### Ingestion.

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

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

Corrosive Product, contact with eyes or skin can cause burns; ingestion or inhalation can cause internal damage, if this occurs immediate medical assistance is required.

Contact with eyes may cause irreversible damage.

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

Request immediate medical attention. Never administer anything orally to persons who are unconscious. Do not induce vomiting. If the person vomits, clear the respiratory tract. Cover the affected area with a dry sterile bandage. Protect the affected area from pressure or friction.

## SECTION 5: FIREFIGHTING MEASURES.

The product does not present any particular risk in case of fire.

### 5.1 Extinguishing media.

#### Suitable extinguishing media:

Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

#### Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

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### 5.2 Special hazards arising from the substance or mixture.

#### Special risks.

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

### 5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

#### Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

## SECTION 6: ACCIDENTAL RELEASE MEASURES.

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

For exposure control and individual protection measures, see section 8.

### 6.2 Environmental precautions.

Prevent the contamination of drains, surface or subterranean waters, and the ground.

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

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations

### 6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

## SECTION 7: HANDLING AND STORAGE.

### 7.1 Precautions for safe handling.

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

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

Store according to local legislation. Observe indications on the label. Store the containers between 5 and 25 ° C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

### 7.3 Specific end use(s).

Not available.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

### 8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

### 8.2 Exposure controls.

#### Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

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<b>Concentration:</b>	<b>100 %</b>		
<b>Uses:</b>	<b>Active pharmaceutical ingredient</b>		
<b>Breathing protection:</b>			
PPE:	Particle filter mask		
Characteristics:	«CE» marking, category III. Made of filtering material, it covers nose, mouth and chin.		
CEN standards:	EN 149		
Maintenance:	Check for any tears, defects, etc. before use. Since it is disposable individual protection equipment, it should be replaced after use.		
Observations:	Does not protect worker unless properly adjusted. Follow the manufacturer's instructions regarding suitable use of the equipment.		
Filter Type needed:	P2		
<b>Hand protection:</b>			
PPE:	Non-disposable protective gloves against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals for which the glove has been tested.		
CEN standards:	EN 374-1, EN 374-2, EN 374-3, EN 420		
Maintenance:	A schedule for the periodical replacement of gloves should be established in order to guarantee their replacement before pollutants permeate them. The use of contaminated gloves could be more dangerous than not using gloves, since the pollutant can gradually accumulate in the glove's material.		
Observations:	They are to be replaced whenever tears, cracks or deformations are observed or when exterior dirt could reduce their strength.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
<b>Eye protection:</b>			
PPE:	Protective goggles against particle impacts.		
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
<b>Skin protection:</b>			
PPE:	Chemical protective clothing		
Characteristics:	«CE» marking, category III. Clothing should fit properly. The level of protection must be set according to a test parameter called BT (Breakthrough Time), which indicates how long it takes for the chemical to pass through the material.		
CEN standards:	EN 464, EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing's design should facilitate correct positioning, staying in place without moving for the period of use expected, bearing in mind environmental factors as well as any movement or position the user might adopt while carrying out the activity.		
PPE:	Anti-static safety footwear against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals against which the footwear is resistant.		
CEN standards:	EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345		
Maintenance:	For correct maintenance of this kind of safety footwear, it is necessary to observe the instructions specified by the manufacturer. The footwear should be replaced as soon as any sign of damage is observed.		
Observations:	The footwear should be cleaned regularly and dried when damp, although it should not be placed too close to a source of heat in order to avoid any sharp changes in temperature.		

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

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

Appearance: Crystal powder

Colour: white

Odour: característico

Odour threshold: N.A./N.A.

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pH: 2,0-2,8 (1%)  
Melting point: 109-110 °C  
Boiling Point: 371 °C  
Flash point: > 60 °C  
Evaporation rate: N.A./N.A.  
Inflammability (solid, gas): N.A./N.A.  
Lower Explosive Limit: N.A./N.A.  
Upper Explosive Limit: N.A./N.A.  
Vapour pressure: N.A./N.A.  
Vapour density: N.A./N.A.  
Relative density: N.A./N.A.  
Solubility: N.A./N.A.  
Liposolubility: N.A./N.A.  
Hydrosolubility: soluble in water  
Partition coefficient (n-octanol/water): N.A./N.A.  
Auto-ignition temperature: N.A./N.A.  
Decomposition temperature: N.A./N.A.  
Viscosity: N.A./N.A.  
Explosive properties: N.A./N.A.  
Oxidizing properties: N.A./N.A.  
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

### 9.2 Other information.

Dropping point: N.A./N.A.  
Blink: N.A./N.A.  
Kinematic viscosity: N.A./N.A.  
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

## SECTION 10: STABILITY AND REACTIVITY.

### 10.1 Reactivity.

The product does not present hazards by their reactivity.

### 10.2 Chemical stability.

Unstable in contact with:  
- Bases.

### 10.3 Possibility of hazardous reactions.

Neutralization can occur on contact with bases.

### 10.4 Conditions to avoid.

- Avoid contact with bases.

### 10.5 Incompatible materials.

Avoid the following materials:  
- Bases.

### 10.6 Hazardous decomposition products.

Depending on conditions of use, can be generated the following products:  
- Corrosive vapors or gases.

## SECTION 11: TOXICOLOGICAL INFORMATION.

### 11.1 Information on toxicological effects.

There are no tested data available on the product.  
Splatters in the eyes can cause irritation and reversible damage.

a) acute toxicity;  
Not conclusive data for classification.

b) skin corrosion/irritation;  
Product classified:  
Skin Corrosive, Category 1: Causes severe skin burns and eye damage.

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c) serious eye damage/irritation;

Product classified:

Serious eye damage, Category 1: Causes serious eye damage.

d) respiratory or skin sensitisation;

Not conclusive data for classification.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) reproductive toxicity;

Not conclusive data for classification.

h) STOT-single exposure;

Not conclusive data for classification.

i) STOT-repeated exposure;

Not conclusive data for classification.

j) aspiration hazard;

Not conclusive data for classification.

### SECTION 12: ECOLOGICAL INFORMATION.

#### 12.1 Toxicity.

No information is available regarding the ecotoxicity.

#### 12.2 Persistence and degradability.

No information is available regarding the biodegradability.

No information is available on the degradability. No information is available about persistence and degradability of the product.

#### 12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation.

#### 12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

#### 12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

#### 12.6 Other adverse effects.

No information is available about other adverse effects for the environment.

### SECTION 13: DISPOSAL CONSIDERATIONS.

#### 13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

### SECTION 14: TRANSPORT INFORMATION.

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Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

### 14.1 UN number.

Transportation is not dangerous.

### 14.2 UN proper shipping name.

Description:

ADR: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

### 14.3 Transport hazard class(es).

Transportation is not dangerous.

### 14.4 Packing group.

Transportation is not dangerous.

### 14.5 Environmental hazards.

Transportation is not dangerous.

### 14.6 Special precautions for user.

Transportation is not dangerous.

### 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code.

Transportation is not dangerous.

## SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

The product is not affected by Directive 2012/18/EU (SEVESO III).

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

### 15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

## SECTION 16: OTHER INFORMATION.

Classification codes:

Eye Dam. 1 : Serious eye damage, Category 1

Skin Corr. 1 : Skin Corrosive, Category 1

Changes regarding to the previous version:

- Change in the hazard classification (SECTION 2.1).
- Removal of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Addition of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Modifications in the first aid measures (SECTION 4.1).
- Modifications in the accidental release measures (SECTION 6.3).
- Modifications in the handling and storage precautions (SECTION 7.1).
- Modifications in the handling and storage precautions (SECTION 7.2).
- Addition of personal protective equipment (SECTION 8.2).
- Modifications of the personal protective equipment (SECTION 8.2).
- Modification in the values of the physical and chemical properties (SECTION 9).

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- Change in the hazard classification (SECTION 11.1).
- Modification of the classification ADR/IMDG/ICAO/IATA/RID (SECTION 14).

### Classification and procedure used to derive the classification for mixtures according to Regulation (EC)

#### 1272/2008 [CLP]:

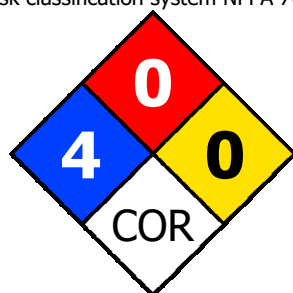
Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

### Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
616-91-1	acetylcysteine	Registered

Risk classification system NFPA 704:



Health hazard: 4 (Deadly)  
Flammability: 0 (Will not burn)  
Reactivity: 0 (Stable)  
Specific hazard: COR (Corrosive)

Abbreviations and acronyms used:

CEN: European Committee for Standardization.

PPE: Personal protection equipment.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2015/830.

Regulation (EC) No 1907/2006.

Regulation (EU) No 1272/2008.

The information given in this Safety Data Sheet has been drafted 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, Authorisation and Restriction of Chemicals (REACH), establishing a 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 Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.