

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product form	: Substance
Trade name	: ACETYLCYSTEINE
Chemical name	: (2R)-2 acetamido-3-Sulfanylpropionic Acid
IUPAC name	: (2R)-2 acetamido-3-Sulfanylpropionic Acid
EC-No.	: 210-498-3
CAS-No.	: 616-91-1
Product code	: 70250
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C <sub>5</sub> H <sub>9</sub> NO <sub>3</sub> S
Synonyms	: N-Acetyl-L-Cysteine ; n-Acetyl-Cysteine; L-alpha acetamido betamercaptopropionic acid
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	: SMILES:CC(=O)NC(CS)C(=O)O

**1.2. Relevant identified uses of the substance or mixture and uses advised against****1.2.1. Relevant identified uses**

Main use category	: API, Industrial use
Use of the substance/mixture	: Mucolytic. It is used as a mucolytic agent to reduce the viscosity of mucous secretions. It has also been shown to have antiviral effects in patients with HIV due to inhibition of viral stimulation by reactive oxygen intermediates.
Function or use category	: Pharmaceuticals

**1.2.2. Uses advised against**

No additional information available

**1.3. Details of the supplier of the safety data sheet****Head office**

MOEHS IBÉRICA, S.L.  
Roma, 8 - P.I. Cova Solera  
08191 Rubi  
Spain  
T +34 93 586 05 20 - F +34 93 699 8350  
[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**Manufacturer**

MOEHS CATALANA, S.L.  
Cesar Martinell i Brunet, 12 A P.I. Rubi Sud  
08191 Rubi  
Spain  
T +34 93 586 05 20 - F +34 93 699 8350  
[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**1.4. Emergency telephone number**

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
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**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

**Adverse physicochemical, human health and environmental effects**

Dust may form explosive mixture in air.

**2.2. Label elements****Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Precautionary statements (CLP)	: P202 - Do not handle until all safety precautions have been read and understood. P210 - Keep away from sparks, heat, open flames, hot surfaces. No smoking. P261 - Avoid breathing dust, mist. P262 - Do not get in eyes, on skin, or on clothing.
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P264 - Wash hands, forearms and face thoroughly after handling.  
P273 - Avoid release to the environment.

### 2.3. Other hazards

Other hazards which do not result in classification : Dust may form explosive mixture in air.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
ACETYLCYSTEINE	CAS-No.: 616-91-1 EC-No.: 210-498-3	100

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow affected person to breathe fresh air. If you feel unwell, seek medical advice.

First-aid measures after skin contact : Wash with plenty of water/... If skin irritation occurs: Get medical advice/attention.

First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Call a physician immediately.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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

Never give anything by mouth to an unconscious person.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Sand. Water spray.

Unsuitable extinguishing media : Do not use a heavy water stream.

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

Fire hazard : May form combustible dust concentrations in air.

Hazardous decomposition products in case of fire : Carbon dioxide. fume. Carbon monoxide. Nitrogen oxides.

### 5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

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### SECTION 6: Accidental release measures

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

General measures : Remove ignition sources.

##### 6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

Measures in case of dust release : Dust formation: dust mask.

##### 6.1.2. For emergency responders

Protective equipment : Wear recommended personal protective equipment. Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

#### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

For containment : Collect spillage.

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.

Other information : Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

See Section 8.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Separate working clothes from town clothes. Launder separately.

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

Technical measures : Provide local exhaust or general room ventilation. Comply with applicable regulations.

Storage conditions : Store at room temperature. Keep container closed when not in use. Keep only in the original container in a cool, well ventilated place away from : Heat sources, Direct sunlight.

Incompatible products : Oxidizing agent. Strong acids. Strong bases.

Incompatible materials : Sources of ignition. Direct sunlight.

#### 7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use. Pharmaceutical Precursor Chemicals.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

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### 8.1.4. DNEL and PNEC

No additional information available

### 8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 1 (> 1 mg/m<sup>3</sup>)

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Dust extraction (suction).

### 8.2.2. Personal protection equipment

#### Personal protective equipment:

Gloves. Dust production: dust mask with filter type P3. Safety glasses. Avoid all unnecessary exposure.

#### Personal protective equipment symbol(s):



#### 8.2.2.1. Eye and face protection

Eye protection		
Type	Field of application	Standard
Safety glasses	Dust	EN 166

#### 8.2.2.2. Skin protection

Hand protection		
Type	Material	Standard
Disposable gloves	Butyl rubber, Natural rubber, Polyvinylchloride (PVC), Latex, Vinyl, Nitrile rubber (NBR), Fluoroelastomer (FKM), Neoprene rubber (HNBR)	EN 374-2

#### 8.2.2.3. Respiratory protection

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask, Full face mask	Type P3	Dust protection	EN 143

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

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

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: white.
Molecular mass	: 163.13 g/mol
Odour	: characteristic.
Odour threshold	: Not available

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Melting point	: 109 – 110 °C
Freezing point	: Not available
Boiling point	: 371 °C
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: ≈ 200 °C Predicted by ACDLAB
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 2 – 2.8 [1 % aq. Sol.]
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 20 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: - 0.03 [Predicted by ALOPS]
Vapour pressure	: ≈ 0.0±2.0 mmHg at 25°C [Predicted by ACD/Labs]
Vapour pressure at 50°C	: Not available
Density	: 0.7 g/cm <sup>3</sup>
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

## 9.2. Other information

### 9.2.1. Information with regard to physical hazard classes

No additional information available

### 9.2.2. Other safety characteristics

Minimum ignition energy	: > 1000 mJ
Additional information	: Layer Minimum flammability Temperature : Melt. Dust Cloud minimum Flammability Temperature : 380°C. Explosion Class : St1. Minimum Explosive Concentration : 20 g/m <sup>3</sup> . Explosivity Pmax : 5.8 bar.g. Explosion Severity Factor Kmax (bar.m/s) : 82 bar.m/s

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under use and storage conditions as recommended in section 7.

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Strong bases.

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### 10.6. Hazardous decomposition products

fume. Carbon dioxide. Carbon monoxide. Sulphur oxides. Nitrogen oxides.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified  
Acute toxicity (dermal) : Not classified  
Acute toxicity (inhalation) : Not classified

#### ACETYLCYSTEINE (616-91-1)

LD50 oral rat	5050 mg/kg
LD50 oral	1140 mg/kg [mouse]

Skin corrosion/irritation : Slightly irritant but not relevant for classification  
pH: 2 – 2.8 [1 % aq. Sol.]  
Additional information : Based on available data, the classification criteria are not met  
Serious eye damage/irritation : Not classified  
pH: 2 – 2.8 [1 % aq. Sol.]  
Respiratory or skin sensitisation : Not classified  
Germ cell mutagenicity : Not classified  
Carcinogenicity : Not classified  
Reproductive toxicity : Not classified  
STOT-single exposure : Not classified  
STOT-repeated exposure : Not classified  
Aspiration hazard : Not classified

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

#### 11.2.2. Other information

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.  
Ecology - water : WGK Class (German Water Hazard Classes): 1  
Hazardous to the aquatic environment, short-term (acute) : Not classified  
Hazardous to the aquatic environment, long-term (chronic) : Not classified

### 12.2. Persistence and degradability

#### ACETYLCYSTEINE (616-91-1)

Persistence and degradability	Biodegradable.
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### 12.3. Bioaccumulative potential

#### ACETYLCYSTEINE (616-91-1)

BCF - Fish [1]	3.162 [BCFWIN v2.17]
Partition coefficient n-octanol/water (Log Pow)	- 0.03 [Predicted by ALOPS]

### 12.4. Mobility in soil

#### ACETYLCYSTEINE (616-91-1)

Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1 [PCKOCWIN v1.66]
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### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

### 12.7. Other adverse effects

Additional information : Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.  
Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.  
Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.  
Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

In accordance with / ADR / IMDG / IATA / ADN / RID

### 14.1. UN number or ID number

UN-No. (ADR) : Not applicable  
UN-No. (IMDG) : Not applicable  
UN-No. (IATA) : Not applicable  
UN-No. (ADN) : Not applicable  
UN-No. (RID) : Not applicable

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable  
Proper Shipping Name (IMDG) : Not applicable  
Proper Shipping Name (IATA) : Not applicable  
Proper Shipping Name (ADN) : Not applicable  
Proper Shipping Name (RID) : Not applicable

### 14.3. Transport hazard class(es)

**ADR**  
Transport hazard class(es) (ADR) : Not applicable

**IMDG**  
Transport hazard class(es) (IMDG) : Not applicable

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### IATA

Transport hazard class(es) (IATA) : Not applicable

### ADN

Transport hazard class(es) (ADN) : Not applicable

### RID

Transport hazard class(es) (RID) : Not applicable

## 14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

## 14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

## 14.6. Special precautions for user

### Overland transport

Not applicable

### Transport by sea

Not applicable

### Air transport

Not applicable

### Inland waterway transport

Not applicable

### Rail transport

Not applicable

## 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

##### POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)



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### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.1.2. National regulations

#### Germany

Water hazard class (WGK) : WGK 2, Significantly hazardous to water (Classification according to AwSV; ID No. 3411).  
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

#### Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed  
SZW-lijst van mutagene stoffen : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

#### Denmark

Classification remarks : Emergency management guidelines for the storage of flammable liquids must be followed

#### Switzerland

Storage class (LK) : NG - Non-hazardous

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
PBT	Persistent Bioaccumulative Toxic
SDS	Safety Data Sheet

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Data sources

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.