

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	: C5H9NO3S
Synonyms	: N-Acetyl-L-Cysteine ; n-Acetyl-Cysteine; L-alpha acetamido betamercaptopropionic acid
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use

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**Supplier**

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 - 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 - 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

May ignite spontaneously if exposed to 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 heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P261 - Avoid breathing dust, mist.
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P262 - Do not get in eyes, on skin, or on clothing.
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 ignite spontaneously if exposed to 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 : 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 Heading 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 away from ignition sources. Keep container closed when not in use. Store in original container. Store in a well-ventilated place.

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/m3)

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

No additional information available

8.2.2.2. Skin protection

Hand protection

Type	Material	Standard
Disposable gloves	Butyl rubber, Natural rubber, Polyvinylchloride (PVC), Latex, Vinyl	EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection

Device	Filter type	Standard
Dust mask	Type P3	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
Molecular mass	: 163,13 g/mol
Colour	: white.
Odour	: characteristic.
Odour threshold	: No data available
pH	: 2 – 2,8 [1 % aq. Sol.]
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 109 – 110 °C
Freezing point	: No data available
Boiling point	: 371 °C

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Flash point	: ≈ 200 °C Predicted by ACDLAB
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 0,7 g/cm ³
Solubility	: Water: 20 g/l
Partition coefficient n-octanol/water (Log Pow)	: - 0,03 [Predicted by ALOPS]
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

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 ³ . 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.

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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]

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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

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)

Partition coefficient n-octanol/water (Log Koc)	1 [PCKOCWIN v1.66]
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12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information	: Avoid release to the environment.
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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.

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SECTION 14: Transport information

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

14.1. UN 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

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

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Rail transport

Not applicable

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

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

No REACH Annex XVII restrictions

ACETYLCYSTEINE is not on the REACH Candidate List

ACETYLCYSTEINE is not on the REACH Annex XIV List

ACETYLCYSTEINE is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

ACETYLCYSTEINE is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

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

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

Denmark

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

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

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Abbreviations and acronyms

REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
PBT	Persistent Bioaccumulative Toxic
SDS	Safety Data Sheet

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.