

N-ACETYL-L-CYSTEINE

GHS Safety Data Sheet

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

N-ACETYL-L-CYSTEINE

OTHER NAMES

C5-H9-N-O3-S, C5-H9-N-O3-S, CH₃CONHCH₂CH₂SH,
"L-alpha-aceamido-beta-mercaptpropionic acid", acetylcysteine, N-acetylcysteine,
N-acetyl-N-cysteine, N-acetyl-3-mercaptoalanine, "mercapturic acid, (R)-",
Acetein, Airbron, Broncholsin, Fluimucetin, Fluimucil, Mucomyst, Mucosolvin

PRODUCT USE

Mucolytic; antidote to acetaminophen (paracetamol) intoxication; corneal vulnerary. Reduces the viscosity of pulmonary secretions in cystic fibrosis of the pancreas. Given by instillation, nebuliser or mouth. Facilitates nitric oxide generation by platelets; increases cellular pools of free radical scavengers; prevents apoptotic death in neuronal cells but induces apoptosis in human and rats smooth cell lines from sputum inhibitor of HIV replication in cell lines and in peripheral blood mononuclear cells.

SUPPLIER

Company: S D FINE- CHEM LIMITED

Address:

315- 317, T.V. INDUSTRIAL ESTATE,
248, WORLI,

MUMBAI- 400030.INDIA.

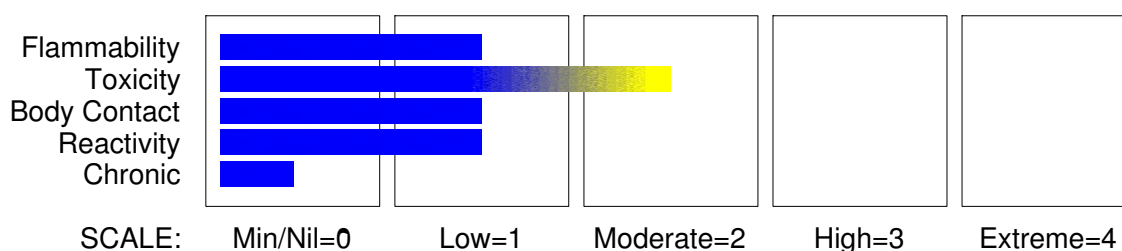
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Telephone: 91- 22- 24959898

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HAZARD RATINGS



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Section 2 - HAZARDS IDENTIFICATION

GHS Classification

Acute Toxicity (Oral) Category 5

EMERGENCY OVERVIEW

HAZARD

WARNING

Determined by using GHS criteria:

H303

May be harmful if swallowed

PRECAUTIONARY STATEMENTS

Response

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
N- acetyl- L- cysteine	616-91-1	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

- Immediately give a glass of water.
- First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

EYE

If this product comes in contact with eyes:

- Wash out immediately with water.
- If irritation continues, seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If dust is inhaled, remove from contaminated area.
- Encourage patient to blow nose to ensure clear passage of breathing.
- If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN

Treat symptomatically.

Bronchospasm may usually be relieved by the administration of a sympathomimetic agent in aerosol form.

Acetylcysteine should be used with caution in elderly patients with severe respiratory insufficiency or in asthmatic patients.

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Section 4 - FIRST AID MEASURES

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

FIRE/EXPLOSION HAZARD

- Combustible.
 - Slight fire hazard when exposed to heat or flame.
 - Heating may cause expansion or decomposition leading to violent rupture of containers.
 - On combustion, may emit toxic fumes of carbon monoxide (CO).
 - May emit acrid smoke.
 - Mists containing combustible materials may be explosive.
- Other combustion products include: carbon dioxide (CO₂), sulfur oxides (SO_x), ammonia and nitrogen oxides (NO_x).

FIRE INCOMPATIBILITY

Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Section 6 - ACCIDENTAL RELEASE MEASURES

EMERGENCY PROCEDURES

MINOR SPILLS

- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Sweep up or
- Vacuum up (consider explosion-proof machines designed to be grounded during storage and use).
- Place in clean drum then flush area with water.

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Control personal contact by using protective equipment and dust respirator.
- Prevent spillage from entering drains, sewers or water courses.
- Avoid generating dust.
- Sweep, shovel up. Recover product wherever possible.

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Section 6 - ACCIDENTAL RELEASE MEASURES

- Put residues in labelled plastic bags or other containers for disposal.
 - If contamination of drains or waterways occurs, advise emergency services.
- Personal Protective Equipment advice is contained in Section 8 of the MSDS.**

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid generating and breathing dust.
- Limit all unnecessary personal contact.
 - Wear protective clothing when risk of exposure occurs.
 - Use in a well-ventilated area.
 - Avoid contact with incompatible materials.
 - When handling, DO NOT eat, drink or smoke.
 - Keep containers securely sealed when not in use.
 - Avoid physical damage to containers.
 - Always wash hands with soap and water after handling.
 - Work clothes should be laundered separately.
 - Use good occupational work practice.
 - Observe manufacturer's storing and handling recommendations.
 - Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

SUITABLE CONTAINER

Glass container.

Plastic container.

Multi-ply woven plastic or paper bag with sealed plastic liner

NOTE: Bags should be stacked, blocked, interlocked, and limited in height so that they are stable and secure against sliding or collapse.

- Check that containers are clearly labelled.

Packaging as recommended by manufacturer.

STORAGE INCOMPATIBILITY

Avoid reaction with oxidising agents.

Incompatible with most metals, rubber, erythromycin, lactobionate, oleandomycin phosphate, oxytetracycline hydrochloride and tetracycline hydrochloride. Some antibiotics may be inactivated if nebulised with acetylsteine.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- No smoking, naked lights or ignition sources.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



+



+



+



+



+



+

+: May be stored together

O: May be stored together with specific preventions

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Section 7 - HANDLING AND STORAGE

X: *Must not be stored together*

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- N- acetyl- L- cysteine: CAS:616- 91- 1

MATERIAL DATA

These "dusts" have little adverse effect on the lungs and do not produce toxic effects or organic disease. Although there is no dust which does not evoke some cellular response at sufficiently high concentrations, the cellular response caused by P.N.O.C.s has the following characteristics:

- the architecture of the air spaces remain intact,
- scar tissue (collagen) is not synthesised to any degree,
- tissue reaction is potentially reversible.

Extensive concentrations of P.N.O.C.s may:

- seriously reduce visibility,
- cause unpleasant deposits in the eyes, ears and nasal passages,
- contribute to skin or mucous membrane injury by chemical or mechanical action, per se, or by the rigorous skin cleansing procedures necessary for their removal. [ACGIH]

This limit does not apply:

- to brief exposures to higher concentrations
- nor does it apply to those substances that may cause physiological impairment at lower concentrations but for which a TLV has as yet to be determined.

This exposure standard applies to particles which

- are insoluble or poorly soluble* in water or, preferably, in aqueous lung fluid (if data is available) and
- have a low toxicity (i.e.. are not cytotoxic, genotoxic, or otherwise chemically reactive with lung tissue, and do not emit ionizing radiation, cause immune sensitization, or cause toxic effects other than by inflammation or by a mechanism of lung overload).

PERSONAL PROTECTION



EYE

- Safety glasses with side shields
- Chemical goggles.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

Wear general protective gloves: i.e. Disposable polythene gloves or Cotton gloves or Light weight rubber gloves, with Barrier cream preferably Safety footwear.

OTHER

- Overalls.
- Barrier cream
- Eyewash unit.

RESPIRATOR

Protection Factor	Half- Face Respirator	Full- Face Respirator	Powered Air Respirator
10 x ES	P1 Air- line*	- -	PAPR- P1 -
50 x ES	Air- line**	P2	PAPR- P2
100 x ES	-	P3	-
		Air- line*	-
100+ x ES	-	Air- line**	PAPR- P3

* - Negative pressure demand ** - Continuous flow.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.

For further information consult your Occupational Health and Safety Advisor.

ENGINEERING CONTROLS

Use in a well-ventilated area.

- Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction.
- Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.
- If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered. Such protection might consist of:
 - (a): particle dust respirators, if necessary, combined with an absorption cartridge;
 - (b): filter respirators with absorption cartridge or canister of the right type;
 - (c): fresh-air hoods or masks
- Build-up of electrostatic charge on the dust particle, may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to efficiently remove the contaminant.

Type of Contaminant:
direct spray, spray painting in shallow booths,
drum filling, conveyer loading, crusher dusts,
gas discharge (active generation into zone of
rapid air motion)
grinding, abrasive blasting, tumbling, high
speed wheel generated dusts (released at high
initial velocity into zone of very high rapid
air motion).

Air Speed:
1- 2.5 m/s (200- 500 f/min.)

2.5- 10 m/s (500- 2000 f/min.)

Within each range the appropriate value depends on:

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Lower end of the range

- 1: Room air currents minimal or favourable to capture
- 2: Contaminants of low toxicity or of nuisance value only
- 3: Intermittent, low production.
- 4: Large hood or large air mass in motion

Upper end of the range

- 1: Disturbing room air currents
- 2: Contaminants of high toxicity
- 3: High production, heavy use
- 4: Small hood- local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 4-10 m/s (800-2000 f/min) for extraction of crusher dusts generated 2 metres distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

White, deliquescent, crystalline powder with slight acetic acid odour; mixes with water.

PHYSICAL PROPERTIES

Solid.
Mixes with water.

Molecular Weight: 163.20
Melting Range (°C): 109- 111
Solubility in water (g/L): Miscible
pH (1% solution): 2.0- 2.8
Volatile Component (%vol): Negligible
Relative Vapour Density (air=1): >1
Lower Explosive Limit (%): Not available
Autoignition Temp (°C): Not available
State: Divided solid

Boiling Range (°C): Not available
Specific Gravity (water=1): Not available
pH (as supplied): Not applicable
Vapour Pressure (kPa): Negligible
Evaporation Rate: Not applicable
Flash Point (°C): Not available
Upper Explosive Limit (%): Not available.
Decomposition Temp (°C): Not available.

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

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Section 11 - TOXICOLOGICAL INFORMATION

ACUTE HEALTH EFFECTS

SWALLOWED

Although ingestion is not thought to produce harmful effects (as classified under EC Directives), the material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.

Considered an unlikely route of entry in commercial/industrial environments.

The material may bind to the N-methyl-D-aspartate (NMDA) neuroreceptor. The NMDA receptor is an ionotropic glutamate receptor found on post-synaptic neurons and is a membrane channel that regulates the flow of sodium and calcium ions, flowing into the neuron, while potassium ions flow out. The NMDA receptor, therefore, tightly regulates "ion channel conductance". NMDA agonists (receptor activators), such as the glutamates, can, however, be highly toxic to the neuron. Excessive amounts of glutamate or its congeners, can be highly toxic to neurons and may contribute to neuron damage/death in stroke, epilepsy and neurodegenerative diseases. The decreased supply of oxygen (hypoxia) in stroke has been shown to result in excess glutamate release.

Overactivation by glutamates, other excitatory amino-acids (EAAs) such as the cysteines and homocysteines, and its congeners (excitotoxins), causes an excessive influx of calcium, into neurons, triggering nervous tissue damage. Glutamate is the major excitatory neurotransmitter in the central nervous system. When concentrations of glutamate and excitotoxins rise above a certain level, in the extracellular fluid, the neuron begins to fire abnormally. At higher concentrations, the cells of the neuron undergo a specialised process of delayed cell death known as excitotoxicity. Although the effects of excitotoxins are generally not dramatic, certain individuals may be especially sensitive and may develop severe symptoms as a result of cardiac irritability. Excess calcium can activate pathways that are potentially harmful to the cell. For example, kinases, phospholipase A2, calpains, NO synthase, endonucleases and other enzymes can be activated. Phospholipase A2 stimulates arachidonic acid production while NO synthase produces nitric oxide. The production of both species ultimately results in free radical damage. Calpain activation may cause breakdown of the cytoskeleton and also contributes to free radical production and lipid peroxidation. Endonucleases damage neuronal DNA, as do free radicals. In addition, high internal calcium ion concentrations create large osmotic forces that drive water into the cell causing swelling and possibly, rupture. Rupture, in turn, causes the release of even more glutamate, inducing excitotoxicity in neighbouring cells. When brain cells are injured, they also release large amounts of glutamate from surrounding astrocytes and this glutamate can produce further damage in adjacent normal neuronal cells. This appears to be the case in strokes, seizures and brain trauma.

Activation of calcium-dependent enzymes is thought to produce changes in neuronal function that are long-lasting, persisting for weeks or months; it has been suggested that such activation is responsible for memory. Blockade (antagonism) of the receptor by several chemical agents produces amnesia in laboratory animals.

NMDA antagonists have been used as neuroprotective agents counteracting the effects of overactivation of the receptor; however such antagonists may also be harmful, at high doses, as the neuron also needs calcium for normal function. Very high doses may produce irreversible damage (including the psychomimetic effects caused by PCP -"angel dust"-abuse). Certain NMDA antagonists (notably those used to produce anaesthesia) induce arousal and even seizures. This class of drug has also produced a model psychosis indistinguishable from schizophrenia.

Large doses of calcium channel blocking agents may produce nausea, weakness, dizziness, drowsiness, confusion and slurred speech. Marked and prolonged hypotension and bradycardia may result from second or third degree atrioventricular block, decreased cardiac output and junctional rhythms; death may ensue.

Certain NMDA receptor antagonists may produce lightheadedness, ataxia, mood elevation and

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Section 11 - TOXICOLOGICAL INFORMATION

muscle incoordination. Side-effects of uptake of these antagonists (such as the isoxazole derivative, ibotenic acid, isolated from hallucinogenic mushrooms), by neurones, include dizziness, ataxia, euphoria, muscle twitches, and initial psychic stimulations followed by dream-filled sleep. More severe ingestions may produce visual disturbances, fever, confusion, myoclonus, mydriasis, seizures and coma. Residual headache may persist for several days. Ibotenic acid binds to NMDA neurotransmitter and inhibits (antagonises) its action. The congener muscimol (also isolated from mushrooms) which is structurally related to ibotenic acid and glutamic acid, by contrast, binds to another neuroreceptor, the so-called GABA receptor. This receptor, when activated inhibits the firing of some central neurones by causing influx of anions (e.g. chloride) into the cell. Muscimol is a GABA receptor agonist and produces a similar effect and almost identical clinical outcome to that of ibotenic acid. Systemic administration of ibotenic acid and muscimol to laboratory animals produces central inhibition of motor activity with little change to peripheral autonomic activity. Both compounds induce EEG changes in cats, rabbits and rats and thus within the central nervous system both compounds behave as false inhibitory neurotransmitters.

There are at least five different NMDA receptor sites that determine whether or not the channel opens. Two important ligands, glutamate and glycine (both amino-acids), are required to bind their respective NMDA sites for the channel to open. At low micromolar concentrations, polyamines, such as dopamine or cholinergic agents (binding to polyamine sites), increase the probability that glutamate and glycine will open the channel; high concentrations of polyamine, in contrast, produce the reverse effect. Two other regulatory ions, magnesium and zinc inhibit the action of amino- acids by binding to sites in the inner pore region of the NMDA channel.

EYE

Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).

The dust may produce eye discomfort causing transient smarting, blinking.

SKIN

The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

INHALED

The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Not normally a hazard due to non-volatile nature of product.

CHRONIC HEALTH EFFECTS

Principal routes of exposure are usually by skin contact and inhalation of generated dust.

No human exposure data available. For this reason health effects described are based on experience with chemically related materials.

As with any chemical product, contact with unprotected bare skin; inhalation of vapour, mist or dust in work place atmosphere; or ingestion in any form, should be avoided by observing good occupational work practice.

TOXICITY AND IRRITATION

unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY

Oral (rat) LD50: 5050 mg/kg

Intravenous (rat) LD50: 1140 mg/kg

Oral (mouse) LD50: 7888 mg/kg

IRRITATION

Nil Reported

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Section 11 - TOXICOLOGICAL INFORMATION

Intraperitoneal (mouse) LD50: 400 mg/kg
Oral (dog) LD50: >1000 mg/kg
Intraperitoneal (dog) LD50: 700 mg/kg
Intravenous (dog) LD50: 700 mg/kg
Gastrointestinal changes recorded.

Section 12 - ECOLOGICAL INFORMATION

No data for N-acetyl-L-cysteine.

Section 13 - DISPOSAL CONSIDERATIONS

- Consult manufacturer for recycling options and recycle where possible .
- Consult State Land Waste Management Authority for disposal.
- Incinerate residue at an approved site.
- Recycle containers if possible, or dispose of in an authorised landfill.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM: None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS:UN, IATA,
IMDG

Section 15 - REGULATORY INFORMATION

REGULATIONS

No regulations applicable

No data available for N-acetyl-L-cysteine as CAS: 616-91-1.

Section 16 - OTHER INFORMATION

The above information is believed to be accurate and represent the best information currently available to us, but does not represent any warranty expressed or implied of the properties of the product. User should make their own investigation to determine the suitability of the information for their particular purpose.

Issue Date: 30-Mar-2018