



## Acetadote®, Acetylcysteine, 6g in 30mL, Injection

Phebra Pty Ltd

Chemwatch Hazard Alert Code: 1

Chemwatch: 24-8797

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Material Safety Data Sheet according to NOHSC and ADG requirements

S.Local.AUS.EN

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

#### Product Identifier

Product name	Acetadote®, Acetylcysteine, 6g in 30mL, Injection
Synonyms	Not Available
Other means of identification	Not Available

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

Relevant identified uses	Acetadote® Injection is an antidote for paracetamol poisoning; Acetadote Injection is indicated in the treatment of paracetamol overdose to protect against hepatotoxicity.
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#### Details of the supplier of the safety data sheet

Registered company name	Phebra
Address	19 Orion Road Lane Cove West NSW 2066 Australia
Telephone	+61 2 9420 9199 1800 720 020
Fax	+61 2 9420 9177
Website	www.phebra.com
Email	info@phebra.com

#### Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	+61 401 264 004
Other emergency telephone numbers	N/A

### SECTION 2 HAZARDS IDENTIFICATION

#### Classification of the substance or mixture

**NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS. According to NOHSC Criteria, and ADG Code.**

#### CHEMWATCH HAZARD RATINGS

	Min	Max	
Flammability	0		
Toxicity	1		
Body Contact	0		
Reactivity	0		
Chronic	0		

0 = Minimum  
 1 = Low  
 2 = Moderate  
 3 = High  
 4 = Extreme

Poisons Schedule	S4
Risk Phrases [1]	Not Applicable
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

Not Applicable

Relevant risk statements are found in section 2

Indication(s) of danger	Not Applicable
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#### SAFETY ADVICE

Not Applicable

#### Other hazards

Ingestion may produce health damage\*.

Cumulative effects may result following exposure\*.

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## SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

### Substances

See section below for composition of Mixtures

### Mixtures

CAS No	%[weight]	Name
63664-54-0	15-25	<u>acetylcysteine sodium</u>
139-33-3	0-1	<u>EDTA disodium salt</u>
7732-18-5	>60	<u>water</u>
		nitrogen as vial overlay

## SECTION 4 FIRST AID MEASURES

### Description of first aid measures

<b>Eye Contact</b>	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> <li>▶ Wash out immediately with fresh running water.</li> <li>▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.</li> <li>▶ Seek medical attention without delay; if pain persists or recurs seek medical attention.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▶ Other measures are usually unnecessary.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ <b>If swallowed do NOT induce vomiting.</b></li> <li>▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>▶ Observe the patient carefully.</li> <li>▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.</li> <li>▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.</li> <li>▶ Seek medical advice.</li> </ul>

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

Treat symptomatically.

## SECTION 5 FIREFIGHTING MEASURES

### Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.

Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.

In such an event consider:

- ▶ foam.
- ▶ dry chemical powder.
- ▶ carbon dioxide.

### Special hazards arising from the substrate or mixture

<b>Fire Incompatibility</b>	None known.
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### Advice for firefighters

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use fire fighting procedures suitable for surrounding area.</li> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ The material is not readily combustible under normal conditions.</li> <li>▶ However, it will break down under fire conditions and the organic component may burn.</li> <li>▶ Not considered to be a significant fire risk.</li> <li>▶ Heat may cause expansion or decomposition with violent rupture of containers.</li> <li>▶ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO).</li> <li>▶ May emit acid smoke.</li> </ul> <p>Decomposes on heating and produces toxic fumes of:</p> <ul style="list-style-type: none"> <li>, carbon dioxide (CO<sub>2</sub>)</li> <li>, nitrogen oxides (NO<sub>x</sub>)</li> <li>, sulfur oxides (SO<sub>x</sub>)</li> <li>, other pyrolysis products typical of burning organic material.</li> </ul> <p>May emit poisonous fumes.</p>

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HAZCHEM | Not Applicable

## SECTION 6 ACCIDENTAL RELEASE MEASURES

## Personal precautions, protective equipment and emergency procedures

Minor Spills	<ul style="list-style-type: none"> <li>▶ Clean up waste regularly and abnormal spills immediately.</li> <li>▶ Avoid breathing dust and contact with skin and eyes.</li> <li>▶ Wear protective clothing, gloves, safety glasses and dust respirator.</li> <li>▶ Use dry clean up procedures and avoid generating dust.</li> <li>▶ Vacuum up or sweep up. <b>NOTE:</b> Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).</li> <li>▶ Dampen with water to prevent dusting before sweeping.</li> <li>▶ Place in suitable containers for disposal.</li> </ul>
Major Spills	<p>Moderate hazard.</p> <ul style="list-style-type: none"> <li>▶ Clear area of personnel and move upwind.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water course.</li> <li>▶ Stop leak if safe to do so.</li> <li>▶ Contain spill with sand, earth or vermiculite.</li> <li>▶ Collect recoverable product into labelled containers for recycling.</li> </ul>

Personal Protective Equipment advice is contained in Section 8 of the SDS.

## SECTION 7 HANDLING AND STORAGE

## Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> <li>▶ Limit all unnecessary personal contact.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ When handling, <b>DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> </ul>
Other information	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ Store in a cool, dry, well-ventilated area.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> <li>▶ Protect containers against physical damage and check regularly for leaks.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>

## Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> <li>▶ Glass container is suitable for laboratory quantities</li> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Packing as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul> <p>glass vial</p>
Storage incompatibility	<ul style="list-style-type: none"> <li>▶ Store away from incompatible materials.</li> </ul>

## SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

## Control parameters

## OCCUPATIONAL EXPOSURE LIMITS (OEL)

## INGREDIENT DATA

Not Available

## EMERGENCY LIMITS


Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
EDTA disodium salt	Ethylenediaminetetraacetic acid, disodium salt	11 mg/m <sup>3</sup>	120 mg/m <sup>3</sup>	730 mg/m <sup>3</sup>
Ingredient	Original IDLH	Revised IDLH		
acetylcysteine sodium	Not Available	Not Available		
EDTA disodium salt	Not Available	Not Available		
water	Not Available	Not Available		

## Exposure controls

Appropriate engineering controls	<p>Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.</p> <p>HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.</p> <p>Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.</p> <p>A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.</p>
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	<p>When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology.</p> <p>Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.</p>
<b>Personal protection</b>	
<b>Eye and face protection</b>	<p>When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:</p> <ul style="list-style-type: none"> <li>▶ Chemical goggles.</li> <li>▶ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.</li> <li>▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses 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.</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	<p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturizer is recommended.</p> <p>Suitability and durability of glove type is dependent on usage.</p> <ul style="list-style-type: none"> <li>▶ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.</li> <li>▶ Double gloving should be considered.</li> <li>▶ PVC gloves.</li> <li>▶ Change gloves frequently and when contaminated, punctured or torn.</li> <li>▶ Wash hands immediately after removing gloves.</li> <li>▶ Protective shoe covers. [AS/NZS 2210]</li> <li>▶ Head covering.</li> </ul>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▶ For quantities up to 500 grams a laboratory coat may be suitable.</li> <li>▶ For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.</li> <li>▶ For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.</li> <li>▶ For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.</li> <li>▶ Eye wash unit.</li> <li>▶ Ensure there is ready access to an emergency shower.</li> <li>▶ For Emergencies: Vinyl suit</li> </ul>
<b>Thermal hazards</b>	Not Available

**Recommended material(s)****GLOVE SELECTION INDEX**

Glove selection is based on a modified presentation of the:

**"Forsberg Clothing Performance Index"**.

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

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Material	CPI
BUTYL	C
NATURAL RUBBER	C
NEOPRENE	C
PVA	C
VITON	C

\* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

**NOTE:** As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

\* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

**Respiratory protection**

Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content. The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.

**SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES****Information on basic physical and chemical properties**

<b>Appearance</b>	Clear colourless liquid; mixes with water. Acetadote® Injection is a clear, colourless solution.		
<b>Physical state</b>	Liquid	<b>Relative density (Water = 1)</b>	Not Available

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## Acetadote®, Acetylcysteine, 6g in 30mL, Injection

Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	6.0-7.5	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water (g/L)	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

## SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> <li>▶ Unstable in the presence of incompatible materials.</li> <li>▶ Product is considered stable.</li> <li>▶ Hazardous polymerisation will not occur.</li> </ul>
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

## SECTION 11 TOXICOLOGICAL INFORMATION

## Information on toxicological effects

Inhaled	The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and 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
Ingestion	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.
Skin Contact	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. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye	Although the liquid 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).
Chronic	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

Acetadote®, Acetylcysteine, 6g in 30mL, Injection	TOXICITY	IRRITATION
	Not Available	Not Available
acetylcysteine sodium	TOXICITY	IRRITATION
	Not Available	Not Available
EDTA disodium salt	TOXICITY	IRRITATION
	Oral (rat) LD50: 2000 mg/kg <sup>[2]</sup>	Not Available
water	TOXICITY	IRRITATION
	Not Available	Not Available

**Legend:** 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. \* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

ACETYLCYSTEINE SODIUM	Adverse effects associated with acetylcysteine have included stomatitis, nausea, vomiting, fever, rhinorrhea, drowsiness, clamminess, chest tightness, and bronchoconstriction. Clinically overt acetylcysteine induced bronchospasm occurs infrequently and unpredictably even in patients with asthmatic bronchitis or bronchitis complicating bronchial asthma. Acquired sensitisation to acetylcysteine has been reported rarely. Reports of sensitisation in patients have not been confirmed by patch testing. Sensitisation has been confirmed in several inhalation therapists who reported a history of dermal eruptions after frequent
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## Acetadote®, Acetylcysteine, 6g in 30mL, Injection

	and extended exposure to acetylcysteine. Reports of irritation to the tracheal and bronchial tracts have been received and although haemoptysis has occurred in patients receiving acetylcysteine such findings are not uncommon in patients with bronchopulmonary disease and a causal relationship has not been established
<b>EDTA DISODIUM SALT</b>	For ethylenediaminetetraacetic acid (EDTA) and its salts: EDTA is a strong organic acid, with a high affinity for alkaline-earth ions (for example, calcium and magnesium) and heavy-metal ions (such as lead and mercury), resulting in highly stable chelate complexes. The ability of EDTA to complex is used commercially to either promote or inhibit chemical reactions, depending on application. EDTA and its salts are expected to be absorbed by the lungs and the gastrointestinal tract; absorption through skin is unlikely. They cause mild skin irritation, and severe eye irritation. The greatest risk in the human body will occur when the EDTA attempts to scavenge the trace metals used and required by the body. The binding of divalent and trivalent cations by EDTA can cause mineral deficiencies, such as zinc deficiency. These appear to be responsible for all of the known pharmacological effects. EDTA and its salts are mostly eliminated through the urine, with 5% eliminated via the bile, along with the metal ions which are bound to it.
<b>Acetadote®, Acetylcysteine, 6g in 30mL, Injection &amp; WATER</b>	No significant acute toxicological data identified in literature search.
<b>Acetadote®, Acetylcysteine, 6g in 30mL, Injection &amp; ACETYLCYSTEINE SODIUM &amp; EDTA DISODIUM SALT</b>	The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.
<b>Acetadote®, Acetylcysteine, 6g in 30mL, Injection &amp; EDTA DISODIUM SALT</b>	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.
<b>Acute Toxicity</b>	☉
<b>Skin Irritation/Corrosion</b>	☉
<b>Serious Eye Damage/Irritation</b>	☉
<b>Respiratory or Skin sensitisation</b>	☉
<b>Mutagenicity</b>	☉
<b>Carcinogenicity</b>	☉
<b>Reproductivity</b>	☉
<b>STOT - Single Exposure</b>	☉
<b>STOT - Repeated Exposure</b>	☉
<b>Aspiration Hazard</b>	☉

**Legend:** ✘ – Data available but does not fill the criteria for classification  
✔ – Data available to make classification  
☉ – Data Not Available to make classification

## SECTION 12 ECOLOGICAL INFORMATION

## Toxicity

Acetadote®, Acetylcysteine, 6g in 30mL, Injection	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
acetylcysteine sodium	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
EDTA disodium salt	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	=180mg/L	1
	EC50	72	Algae or other aquatic plants	>60mg/L	2
	NOEC	840	Fish	>=25.7mg/L	2
water	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available

**Legend:** *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

**DO NOT** discharge into sewer or waterways.

## Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
EDTA disodium salt	LOW	LOW
water	LOW	LOW

## Bioaccumulative potential

Continued...

Ingredient	Bioaccumulation
EDTA disodium salt	LOW (LogKOW = -3.8573)
water	LOW (LogKOW = -1.38)

**Mobility in soil**

Ingredient	Mobility
EDTA disodium salt	LOW (KOC = 1046)
water	LOW (KOC = 14.3)

**SECTION 13 DISPOSAL CONSIDERATIONS****Waste treatment methods**

<b>Product / Packaging disposal</b>	<p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> <li>▶ Reduction</li> <li>▶ Reuse</li> <li>▶ Recycling</li> <li>▶ Disposal (if all else fails)</li> </ul> <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.</p> <ul style="list-style-type: none"> <li>▶ <b>DO NOT allow wash water from cleaning or process equipment to enter drains.</b></li> <li>▶ It may be necessary to collect all wash water for treatment before disposal.</li> <li>▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.</li> <li>▶ Where in doubt contact the responsible authority.</li> <li>▶ Recycle wherever possible.</li> <li>▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.</li> <li>▶ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material).</li> <li>▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.</li> </ul>
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**SECTION 14 TRANSPORT INFORMATION****Labels Required**

<b>Marine Pollutant</b>	NO
<b>HAZCHEM</b>	Not Applicable

**Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Transport in bulk according to Annex II of MARPOL and the IBC code**

Not Applicable

**SECTION 15 REGULATORY INFORMATION****Safety, health and environmental regulations / legislation specific for the substance or mixture****ACETYLCYSTEINE SODIUM(63664-54-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS**

Not Applicable

**EDTA DISODIUM SALT(139-33-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS**

Australia Inventory of Chemical Substances (AICS)

**WATER(7732-18-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS**

Australia Inventory of Chemical Substances (AICS)

National Inventory	Status
Australia - AICS	N (acetylcysteine sodium)
Canada - DSL	N (acetylcysteine sodium)
Canada - NDSL	N (EDTA disodium salt; water; acetylcysteine sodium)
China - IECSC	N (acetylcysteine sodium)
Europe - EINEC / ELINCS / NLP	N (acetylcysteine sodium)
Japan - ENCS	N (acetylcysteine sodium)
Korea - KECI	N (acetylcysteine sodium)
New Zealand - NZIoC	N (acetylcysteine sodium)
Philippines - PICCS	N (acetylcysteine sodium)

## Acetadote®, Acetylcysteine, 6g in 30mL, Injection

USA - TSCA	N (acetylcysteine sodium)
<b>Legend:</b>	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

### SECTION 16 OTHER INFORMATION

#### Other information

#### Ingredients with multiple cas numbers

Name	CAS No
EDTA disodium salt	139-33-3, 69772-70-9

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

#### Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average  
 PC – STEL: Permissible Concentration-Short Term Exposure Limit  
 IARC: International Agency for Research on Cancer  
 ACGIH: American Conference of Governmental Industrial Hygienists  
 STEL: Short Term Exposure Limit  
 TEEL: Temporary Emergency Exposure Limit,  
 IDLH: Immediately Dangerous to Life or Health Concentrations  
 OSF: Odour Safety Factor  
 NOAEL :No Observed Adverse Effect Level  
 LOAEL: Lowest Observed Adverse Effect Level  
 TLV: Threshold Limit Value  
 LOD: Limit Of Detection  
 OTV: Odour Threshold Value  
 BCF: BioConcentration Factors  
 BEI: Biological Exposure Index

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