SAFETY DATA SHEET

Date of Original Issue: 06JUN2023 **Revision Number**: 2 **Revision Date**: 15MAR2024

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1. Product identifier

Product name: Acetylcysteine Injection

1.2. Relevant identified uses of the substance or mixture

Product Use: Acetylcysteine injection is an antidote for acetaminophen overdose indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen in patients with an acute ingestion or from repeated supratherapeutic ingestion

1.3. Details of the responsible party of the safety data sheet

Manufacturer
Stelis Biopharma Limited
Bengaluru
Karnataka, 561203
India
+91 80678 40444

Distributor
Xellia Pharmaceuticals
2150 East Lake Cook Road
Buffalo Grove, IL 60089
USA
+1 833 657 3519

Email address for the competent person responsible for the safety data sheet: sales@xellia.com

1.4 Emergency telephone number

Poison Control Center (USA):	+1 877 800 5553
CHEMTREC (USA Transportation):	+1 800 424 9300
CANUTREC (Canadian Transportation):	+1 613 996 6666
EU:	http://apps.who.int/poisoncentres/

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Eye Irritation - Category 2

2.2. Label elements

WARNING

H319: Causes serious eye irritation.
P280: Wear protective gloves/eye protection.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
P337+P317: If eye irritation persists: Get medical help.
P501: Dispose of contents/container to approved company.

2.3. Other hazards

The substance is not considered PBT/vPvB, or endocrine disruptive according to the criteria in the CLP regulation.

SECTION 3: Composition/Information on Ingredients

3.2. Mixtures

Active component	CAS #	EC/List #
Acetylcysteine 6 g/30 mL (200 mg/mL)	616-91-1	210-498-3

REACH: not registered, exempted.

SECTION 4: First Aid Measures

4.1. Description of first aid measures

Eye contact: Flush eyes for 15 minutes with plenty of water. Get medical attention immediately.

Skin contact: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation or rash develops.

Ingestion: Do not induce vomiting. Call a physician or poison control center. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

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

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None

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

In case of discomfort or unconsciousness: Show this safety data sheet to a physician or emergency center, treat symptomatically.

SECTION 5: Firefighting Measures

5.1. Extinguishing media

Water, carbon dioxide, dry chemical, foam, or other alternatives. The product is not flammable.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and sulfur dioxide.

Unsuitable extinguishing media: None

Specific methods: Not available

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment, and emergency response
Wear personal protective equipment to avoid exposure – see section 8.

6.2. Environmental precautions
Water spill: Do not empty into drains.
Land spill: Wear appropriate equipment including eye protection, to avoid exposure.
Release notes: If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities.

6.3. Methods and materials for containment and cleaning up
Pump up the spilled product. Smaller spills can be absorbed by sand or other similar materials. Decontamination can be performed by burning.

6.4. References to other sections
See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling
For large quantities: Engineering controls are recommended to ensure adequate ventilation such that exposures do not exceed TWA for an eight-hour exposure. Personal protective equipment may include chemical-resistant gloves and goggles. Adequate eye protection is always required.
Work hygienic practices: Facilities storing or using this material should be equipped with an emergency eyewash and safety shower. Good personal hygiene practices should always be followed.

7.2. Conditions for safe storage, including any incompatibilities
Store securely, inaccessible for unauthorized persons. Store between 20°C - 25°C (68°F - 77°F) in original, unopened or securely sealed package.

7.3. Specific end uses
See section 1.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters
OSHA'S hazardous components (29 CFR 1910.1020) EXPOSURE LIMITS AND GUIDELINES

	OSHA PEL		ACGIH TLV		OTHER OEL (TWA)	
	ppm	mg/ m3	ppm	mg/ m3	ppm	mg/ m3
Acetylcysteine (CAS #: 616-91-1)	N/A	N/A	N/A	N/A		
N/A 0.89						

Other country exposure limits: Not listed.

8.2. Exposure controls
PERSONAL PROTECTIVE EQUIPMENT:

Eyes and face: Wear safety glasses with side shields or goggles as appropriate when handling this material.
Skin: Chemical resistant gloves (nitrile or latex) and body covering.
Respiratory: Use an approved respirator suitable to provide level of protection required.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

(a) Physical state: Liquid. Active ingredient is solid.
(b) Color: Colorless
(c) Odor: Not available. Active ingredient smells like acetic acid
(d) Melting point/freezing point: Injection solution has melting point below 0 ºC. Active ingredient has melting point 110.4 ºC.
(e) Boiling point or initial boiling point and boiling range: Injection solution has boiling point above 100 ºC
(f) Flammability: The injection solution is not flammable.
(g) Lower and upper explosion limit: Not applicable
(h) Flash point: Not applicable
(i) Auto-ignition temperature: Not available
(j) Decomposition temperature: Not available
(k) pH: 7.2 – 7.4
(l) Kinematic viscosity: Not available
(m) Solubility: Miscible with water. Active ingredient has a solubility in water: 179,5 g/L at 20 oC. This solution has a pH of 2.7.
(n) Partition coefficient n-octanol/water (log value): Active ingredient has a Pow: -0.6 at 23ºC
(o) Vapor pressure: Not available
(p) Density and/or relative density: Not available
(q) Relative vapor density: Not available
(r) Particle characteristics: Solution

9.2. Other information:

Not available.

SECTION 10: Stability and Reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization has not been reported.

10.4. Conditions to avoid

Incompatible materials, excess heat, alkaline materials, strong oxidants.

10.5. Incompatible materials

Strong oxidants.

10.6. Hazardous decomposition products
Nitrogen oxides, sulfur oxides, carbon monoxide, and carbon dioxide.

SECTION 11: Toxicological Information

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

Acute dermal LD50:	No information available
Acute oral LD50:	4400 mg/kg (mouse), 5050 mg/kg (rat), >1000 mg/kg (dog)
Acute inhalation LC50:	No information available
Chronic oral:	100, 200, 400 mg/kg/day intravenous doses in dogs. Adverse effects were observed at 200 mg/kg/day dose and higher.
Eye effects:	based on the available data the substance is classified for eye irritation, Cat. 2
Skin effects:	A test according to EU Method B.46 showed the criteria for irritant classification are not met.
Sensitization:	Using Derek Nexus v5.0, the skin sensitising potential of the test item was estimated to be plausible. However, based on the results of an in chemico/in vitro test strategy the test item is not peptide reactive (DPRA, OECD TG 442C, reference 7.4.1 -2) and does not activate keratinocytes (LuSens, OECD TG 422D, reference 7.4.1 -3). Therefore, the active ingredient is not predicted to be a skin sensitizer.
Target organ:	No information available
Carcinogenicity:	1000 mg/kg/day in rats for 12 months followed by 6 months of observation provided no evidence of oncogenic potential for active ingredient.
	Listed by IARC: No Listed by NTP: No Listed by OSHA: No
Mutagenicity:	Negative results in Ames test, in mouse micronucleus test, and in mouse lymphoma assay for active ingredient.
Reproductive effects:	Negative results in rabbits at oral doses of 500 mg/kg/day and in rats up to 2000 mg/kg/day. It gave negative result for embryotoxicity at 800 mg/kg/day in mice for active ingredient.
Teratogenic effects:	Negative Results for active ingredient.

11.2. Information on other hazard
Not available

SECTION 12: Ecological Information

12.1. Toxicity
Aquatic short-term (acute) toxicity of acetyl cysteine
- 48-h EC50 (Daphnia magna): > 100 mg/L
- 72-h ErC50 (Raphidocelis subcapitata): > 100 mg/L

Aquatic long-term (chronic) toxicity of acetyl cysteine
- 72-h ErC10 (Raphidocelis subcapitata): > 100 mg/L.

Based on these results, the active ingredient is neither classified for short term (acute), nor for long-term (chronic) aquatic toxicity.

12.2. Persistence and degradability
Readily biodegradable; 76 % biodegradation of acetyl cysteine after 28 days (OECD TG 301 F).

12.3. Bio-accumulative potential
No applicable information found.

12.4. Mobility in soil
No applicable information found.

12.5. Results of PBT and vPvB assessment
The active ingredient is not considered PBT/vPvB according to criteria in Annex XIII.

12.6. Endocrine disrupting properties
No such properties are known to the active ingredient.

12.7. Other adverse effects
No further information is available.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods: Do not empty into drain. Dispose of any cleanup materials and waste residue according to applicable laws and regulations.

SECTION 14: Transport Information

14.1. UN Number or ID number
Not Regulated.

14.2. UN proper shipping name
Not Regulated.

14.3. Transport hazard class(es)
Not Regulated.

14.4. Packing group
Not Regulated.

14.5. Environmental hazards
Not Regulated.

14.6. Special precautions for user
Not Regulated.

14.7. Maritime transport in bulk according to IMO instruments
Not relevant.
USA DOT (DEPARTMENT OF TRANSPORTATION)
Proper Shipping Name: Not regulated.
CANADA TRANSPORT OF DANGEROUS GOODS
Proper Shipping Name: Not regulated.
AIR (ICAO/IATA)
Proper Shipping Name: Not regulated.
VESSEL (IMO/IMDG)
Proper Shipping Name: Not regulated.
EUROPEAN TRANSPORTATION:

ADR/RID HAZARD CLASSIFICATION: Not Regulated.
U.S. CUSTOMS HARMONIZATION NUMBER: Not Available.

SECTION 15: Regulatory Information

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

EUROPEAN UNION

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work:

Must not be used by persons under 18 years of age.

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:

The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions.

Implementation of directive 2001/82/EC of the European Parliament and of the council of 6 November 2001 in the Community code relating to veterinary medical products:

Denmark: The Danish Medicines Agency (Lægemiddelstyrelsen) must be notified that this substance is produced, imported, exported, stored, sold, delivered, packed, possessed or in other ways handled in Denmark (Bekendtgørelse nr. 1226 af 7 December 2005 om omgang med visse stoffer og produkter hvis indhold kan anvendes som lægemidler til dyr.).

For other countries: Please contact national authorities regarding notification of the substance.

UNITED STATES FEDERAL REGULATIONS

Superfund Amendments and Reauthorization Act (SARA) Title III 311/312 hazard categories:

Fire: No **Pressure generating:** No **Reactivity:** No **Acute:** No **Chronic:** No

313 Reportable Ingredients: Not Listed

Title III notes:

Comprehensive Response, Compensation, and Liability Act (CERCLA)

CERCLA RQ: Not listed

Toxic Substances Control Act (TSCA)

TSCA Regulatory: Exempt

National Response Center: US Coast Guard National Center Response Telephone +1 800 424 8802.

UNITED STATES STATE REGULATIONS

California Proposition 65: This product does not contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

CANADA

Workplace Hazardous Material Information System (WHMIS) hazard symbol and classification

WHMIS Controlled: Not regulated.

Canadian Environmental Protection Act: Not listed

15.2. Chemical safety assessment

No CSR is compiled because the active ingredient is exempted.

SECTION 16: Other Information

Reason for issue: It is an update because of adding data from the REACH registration of acetyl cysteine.
Contact Information: See Section 1.
Revision summary: Second version. Classification is reduced to Eye Irritation Category 2. Measures have been changed because the product is liquid and not solid as well as not classified according to CLP regulation.
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