Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **Calcium Disodium Versenate (edetate calcium disodium) injection**

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

Recommended use • Edetate calcium disodium is indicated for the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy, in both pediatric populations and adults.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Maiva Pharma Pvt Ltd

32, Sipcot industrial Complex,
Phase I, Hosur-635 126
India

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS •Eye Mild Irritation 2B
Skin Mild Irritation 3

Label elements

UN GHS

WARNING

Hazard statements • Causes mild skin irritation
Causes eye irritation

Precautionary statements

Prevention • Wash thoroughly after handling.

Response • 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.
If skin irritation occurs: Get medical advice/attention.

Storage/Disposal • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

UN GHS • No data available

Section 3 - Composition/Information on Ingredients

Substances

• Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition		
Chemical Name	**Identifiers**	**%**
Calcium disodium edetate	**CAS:**62-33-9 **EINECS:**200-529-9	20%
Water	**CAS:**7732-18-5 **EINECS:**231-791-2	80%

Section 4: First-Aid Measures

Description of first aid measures

Inhalation • No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention if cough or other symptoms develop.

Skin • After contact with skin, take off immediately all contaminated clothing and wash immediately with plenty of (to be specified by manufacturer)

Eye • 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.

Ingestion • If swallowed, get medical help or contact a Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

• Stop use and ask a doctor if: you experience eye pain, changes in vision, continued redness, irritation of the eye, or if condition worsens or persists for more than 72 hours.

Indication of any immediate medical attention and special treatment needed Other information

• Additional details are provided on the product packaging and/or the product insert.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder, or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available.

Firefighting Procedures • As in any fire, wear self-contained breathing apparatus and full protective gear.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known.

Hazardous Combustion Products • None known.

Advice for firefighters

• Refer to Section 5 Firefighting Procedures.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures • No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

• No data available on the environmental impact of this product.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Prohibited Materials • None known.

Reference to other sections

• Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling • When using this product: do not touch tip of container to any surface to avoid contamination, remove contact lenses before using, and always replace the cap after use. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage • Keep tightly closed. Store at controlled room temperature 25ºC/77ºF (excursions permitted to 15-30ºC/59-86ºF), to maintain product integrity. Use before date marked on carton and/or container.

Special Packaging Materials • Maintain product in original container only.

Incompatible Materials or Ignition Sources • None specified.

Specific end use(s)

• Refer to Section 1.2 - Relevant identified uses.

Other Information

• Refer to product literature.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines •Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls •No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory • No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face • No special personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands • No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

Skin/Body • No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Thermal hazards • None known.

General Industrial Hygiene Considerations • Wash thoroughly with soap and water after handling.

Environmental Exposure Controls • No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Not relevant
Color	Colorless to slightly yellow.	Odor	Not relevant
General Properties			

Boiling Point	100 °C(212 °F)	Melting Point/Freezing Point	0 °C(32 °F)
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	= 1 Water=1	Water Solubility	Soluble
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No data available

Chemical stability

- No data available

Possibility of hazardous reactions • No data available

Conditions to avoid • No data available **Incompatible materials**

- No data available

Hazardous decomposition products

• No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Calcium disodium edetate (20%)	62-33-9	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 10 g/kg

GHS Properties	Classification
Acute toxicity	**UN GHS•** Classification criteria not met

Skin corrosion/Irritation	**UN GHS•** Skin Mild Irritation 3
Serious eye damage/Irritation	**UN GHS•** Eye Mild Irritation 2B
Skin sensitization	**UN GHS•** Classification criteria not met
Respiratory sensitization	**UN GHS•** Classification criteria not met
Aspiration Hazard	**UN GHS•** Classification criteria not met
Carcinogenicity	**UN GHS•** Classification criteria not met
Germ Cell Mutagenicity	**UN GHS•** Classification criteria not met
Toxicity for Reproduction	**UN GHS•** Classification criteria not met
STOT-SE	**UN GHS•** Classification criteria not met
STOT-RE	**UN GHS•** Classification criteria not met

Potential Health Effects

Inhalation

Acute (Immediate) • No hazard when used as directed. **Chronic (Delayed)** • No data available

Skin

Acute (Immediate) • May cause mild irritation.

Chronic (Delayed) • No data available

Eye

Acute (Immediate) • May cause mild irritation.

Chronic (Delayed) • No data available

Ingestion

Acute (Immediate) • No data available

Chronic (Delayed) • No data available

Other information

- Calcium Disodium Versenate is capable of producing toxic effects which can be fatal. Patients with lead encephalopathy and cerebral edema may experience a lethal increase in intracranial pressure following intravenous infusion. Renal toxicity during chelation therapy.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability • No data available. **Bioaccumulative potential**

- No data available. **Mobility in Soil**
- No data available.

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste
- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user • No special precautions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications • No data available

Inventory				
Component	**CAS**	**Canada DSL**	**EU EINECS**	**TSCA**
Calcium disodium edetate	62-33-9	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Calcium disodium edetate	62-33-9	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Calcium disodium edetate	62-33-9	0.1 %

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Calcium disodium edetate	62-33-9	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Calcium disodium edetate	62-33-9	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Calcium disodium edetate	62-33-9	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Calcium disodium edetate	62-33-9	Not Listed

Section 16 - Other Information

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Preparation Date • 11/March/2016

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