

# SAFETY DATA SHEET



## Edaravone for Injection

### 1) PRODUCT AND COMPANY IDENTIFICATION

**Product Identifier**

Product Name: Edaravone Injection, 30 mg/100mL (0.3 mg mL)

**Substance Name**

Edaravone

**Product Use**

Edaravone injection is indicated for the treatment of amyotrophic lateral sclerosis (ALS)

**Route of Administration**

Intravenous

**Manufacturer**

Piramal Critical Care, Inc  
 268 Brodhead Road  
 Bethlehem, PA 18017

**Emergency Telephone Number**

Customer Service: 610-974-9760 x510  
 E-Mail: pcccustomerconnect@piramal.com  
 Emergency Number: CHEMTREC 1-800-424-9300

### 2) HAZARDS IDENTIFICATION

Classification according to Regulations (EC) No 1272/2008 (CLP): NA

Classification According to EU-Directive 67/548/EEC or 1999/45/EC: NA

**Classification of the Substance or Mixture**

Skin Irritation	Category 2
Skin Sensitization	Category 1
Hazardous to the aquatic environment, long-term (Chronic)	Category Chronic 2

**GHS Label Elements, Including Precautionary Statements**

Hazard pictograms:



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**Signal Word:**

Warning

**Hazard Statements:**

H315 - Causes skin irritation

H317 – May cause allergic skin reaction

H411- Toxic to aquatic life with long lasting effects

**Precautionary Statements:**

P261 – Avoid breathing dust/fume/gas/mist/vapors/spray.

P264 – Wash thoroughly after handling.

P273 – Avoid release to the environment.

P272 - Contaminated work clothing must not be allowed out of the workplace.

P280 – Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 – IF ON SKIN: Wash with plenty of water.

P333+P317 – If skin irritation or rash occurs: Get medical help.

P391 – Collect spillage.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P332+P317 - If skin irritation occurs: Get medical help

P362+P364 – Take of contaminated clothing and wash it before reuse.

P501: Dispose the contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

### 3) COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS No.	Concentration %	EC Number
Water	7732-18-5	<100	231-791-2
3-methyl-1-phenyl-5-pyrazolone	89-25-8	.03	201 – 891 - 0
L-Cysteine Hydrochloride hydrate	7048-04-6	N/A	N/A
Sodium Chloride	7647-14-5	N/A	N/A
Sodium Bisulfite	7631-90-5	N/A	N/A
Sodium Hydroxide	1310-73-2	N/A	N/A
Phosphoric Acid	7664-38-2	N/A	N/A

### 4) FIRST AID MEASURES

Description of First Aid Measures

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First-aid measures after inhalation :

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

First-aid measures after skin contact:

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

First-aid measures after eye contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

First-aid measures after ingestion :

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention or call Poison Control Center immediately.

### **Most important symptoms and effects, both acute and delayed**

**SYMPTOMS:** Symptoms of exposure to this compound may include irritation of the skin, eyes, and mucous membranes. **ACUTE/CHRONIC HAZARDS:** This compound may cause skin and eye irritation. It is moderately toxic by ingestion. When heated to decomposition it emits toxic fumes.

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

No additional information available

## **5) FIRE FIGHTING MEASURES**

### **Suitable extinguishing media :**

Fires involving this material can be controlled with a dry chemical, carbon dioxide, or Halon extinguisher.

### **Special Hazards arising from the chemical:**

Flash point data for this chemical are not available. Treat as combustible

### **Advice for Firefighters:**

Wear self-contained breathing apparatus for firefighting if necessary.

## **6) ACCIDENTAL RELEASE MEASURES**

### **Personal Precautions, Protective Equipment and Emergency Procedures**

Avoid dust formation. Avoid breathing mist, gas, or vapors. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

### **Environmental Precautions**

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into environment must be avoided.

### **Methods and Material for Containment and Cleaning Up**

Collect and arrange disposal. Keep the chemical in suitable and closed containers for disposal. Remove all sources of ignition. Use spark-proof tools and explosion proof equipment. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

**7) HANDLING AND STORAGE****Precautions for Safe Handling**

Handling in a well-ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

**Conditions for Safe Storage, Including Any Incompatibilities**

Store the container tightly closed in a dry, cool, and well-ventilated place. Store apart from foodstuff containers or incompatible materials.

**8) EXPOSURE CONTROLS/PERSONAL PROTECTION****Control Parameters**

**Occupational Exposure Limit Values:** No data available

**Biologic Limit Values:** No data available

**Exposure Controls**

Appropriate engineering controls : Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice.

**Individual Protection Measures (PPE)**

Thermal Hazards: No data available  
 Eye/Face protection: Wear tightly fitting safety goggles with side-shields.  
 Skin protection: Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands.  
 Respiratory protection: If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

**9) PHYSICAL AND CHEMICAL PROPERTIES**

<b>Appearance</b>	Liquid (aqueous solution)
<b>Color</b>	Clear/Colorless
<b>Odor</b>	No data available
<b>pH</b>	No data available
<b>Melting Point / Freezing Point</b>	127.7 C
<b>Boiling point or initial boiling point and boiling range</b>	287 C / Atm. Press. : 105mm Hg 191 C / Atm. Press.: 17 mm Hg
<b>Flash Point</b>	55 C (lit)
<b>Flammability</b>	No data available
<b>Lower and Upper explosion limit/flammability limit</b>	No data available
<b>Partition coefficient n-octanol/water</b>	Log Pow = 1.71 Temperature 20 C / Remarks: pH not provided.
<b>Vapor Pressure</b>	< 0.01 mm Hg Temperature 20 C
<b>Kinematic viscosity</b>	No data available
<b>Auto-ignition temperature</b>	Remarks: No self-ignition observed up to the melting point
<b>Decomposition temperature</b>	No data available
<b>Density and / or relative density</b>	1.267 g/cm <sup>3</sup> Temperature: 20 C 1.266 g/cc Temperature 20 C
<b>Relative vapor density</b>	No data available
<b>Particle characteristics</b>	No data available

**10) STABILITY AND REACTIVITY**

<b>Reactivity</b>	No data available
<b>Chemical Stability</b>	Amines are chemical bases. They neutralize acids to form salts plus water. These acid-base reactions are exothermic. The amount of heat that is evolved per mole of amine in a neutralization is largely independent of the strength of the amine as a base. Amines may be incompatible with isocyanates, halogenated organics, peroxides, phenols (acidic), epoxides, anhydrides, and acid halides. Flammable gaseous hydrogen is generated by amines in combination with strong reducing agents, such as hydrides.
<b>Possibility of Hazardous Reactions</b>	No data available
<b>Conditions to avoid</b>	No data available
<b>Incompatible materials</b>	No data available
<b>Hazardous decomposition products</b>	No data available

**11) TOXICOLOGICAL INFORMATION**

<b>Acute Toxicity</b>	<b>Oral: LD0 – rat (male /female) - &gt; 2 000 mg/kg bw</b> <b>Inhalation:</b> No data available <b>Dermal:</b> No data available
<b>Skin corrosion /irritation</b>	No data available
<b>Serious eye damage / eye irritation</b>	No data available
<b>Respiratory or skin sensitization</b>	No data available
<b>Germ cell mutagenicity</b>	No data available
<b>Carcinogenicity</b>	No data available
<b>Specific Target Organ Toxicity (Repeated Exposure)</b>	No data available
<b>Reproductive Toxicity</b>	No data available
<b>Aspiration Hazard</b>	No data available

**12) ECOLOGICAL INFORMATION**

<b>Toxicity</b>	<b>Toxicity to fish:</b> No data available <b>Toxicity to daphnia and other aquatic invertebrates:</b> EC50 – Daphnia magna – 4.81 mg/L – 48 h <b>Toxicity to algae:</b> EC50 – Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) – ca. 9.15 mg/L – 72 h <b>Toxicity to microorganisms:</b> No data available
<b>Persistence and degradability</b>	No data available
<b>Bio-accumulative potential</b>	No data available
<b>Mobility in soil</b>	No data available
<b>Other adverse effects</b>	No data available

**13) DISPOSAL CONSIDERATIONS**

**Disposal Methods**

**Product:** The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed, or seed by storage or disposal. Do not discharge to sewer systems.

**Contaminated Packaging:** Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

**14) TRANSPORT INFORMATION****In Accordance with ICAO/IATA/DOT/TDG****UN Number:**

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

**UN Proper Shipping Name:**

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

**Transport Hazard Class(es):**

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

**Packaging Group, if applicable:**

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

**Environmental Hazards:**

ADR/RID: Yes

IMDG: Yes

IATA: Yes

**Special Precautions for User:** No data available**Transport in bulk according to IMO instruments:** No data available**15) REGULATORY INFORMATION****Safety, health, and environmental regulations specific for the product in question:**

<b>European Inventory of Existing Commercial Chemical substances (EINECS)</b>	Listed
<b>EC Inventory</b>	Listed
<b>United States Toxic Substances Control Act (TSCA) Inventory</b>	Listed
<b>China Catalog of Hazardous chemicals 2015</b>	Not Listed
<b>New Zealand Inventory of Chemicals (NZIoC)</b>	Listed
<b>Philippines Inventory of Chemicals and Chemical Substances (PICCS)</b>	Listed
<b>Vietnam National Chemical Inventory</b>	Listed
<b>Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)</b>	Listed
<b>Korea Existing Chemicals List (KECL)</b>	Listed

**16) OTHER INFORMATION**

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SDS Updates:

6-03-2024 – New Doc

7-15-2024 – Updated Section 3 concentration for aqueous solution and Section 9 Color and Physical State

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