



Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • Sodium Edecrin®
- Product Code** • NDC 25010-210-27

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

- Recommended use** • Ethacrynic acid is indicated for treatment of edema when an agent with greater diuretic potential than those commonly employed is required.
- 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** • Valeant Pharmaceuticals North America, LLC
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
valeant.com
- Telephone (General)** • 1-800-321-4576

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - US - Infotrac
- Manufacturer** • +1 352-323-3500 - International - Infotrac

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** • Skin Mild Irritation 3
Eye Mild Irritation 2B
Acute Toxicity Oral 4
Specific Target Organ Toxicity Single Exposure 2

Label elements

UN GHS

WARNING



- Hazard statements** • Harmful if swallowed
Causes mild skin irritation

Causes eye irritation
May cause damage to organs - Ears/Otic

Precautionary statements

Prevention • Avoid breathing dust, fume, gas, mist, vapours and/or spray.
Wash thoroughly after handling.

Response • Call a POISON CENTER or doctor/physician if you feel unwell.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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	%
Ethacrynate sodium	CAS:6500-81-8	44%
Mannitol, D-	CAS:69-65-8 EINECS:200-711-8	56%

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- Normal use of this product does not pose an inhalation hazard. However, during bulk handling should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation (redness, rash, blistering) develops, get medical attention.

Eye

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get medical attention immediately if symptoms occur.

Ingestion

- If swallowed, seek medical advice immediately and show this container or label.

Most important symptoms and effects, both acute and delayed

- Ethacrynic acid is a potent diuretic which, if given in excessive amounts, may lead to profound diuresis with water and electrolyte depletion.

Indication of any immediate medical attention and special treatment needed

Notes to Physician

- Overdosage may lead to excessive diuresis with electrolyte depletion and dehydration. In the event of overdosage, symptomatic and supportive measures should be employed. Emesis should be induced or gastric lavage performed. Correct dehydration, electrolyte imbalance, hepatic coma, and hypotension by established procedures. If required, give oxygen or artificial respiration for respiratory impairment.

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

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • No data available

Hazardous Combustion Products • No data available.

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

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 • Keep unauthorized personnel away. Clean up spilled tablets and place in sealed container. Avoid breaking tablets or creating dust during clean up.

Environmental precautions

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

Methods and material for containment and cleaning up

Containment/Clean-up Measures • LARGE SPILLS: Use HEPA vacuum to clean up spill. If HEPA vacuum is not available, dampen spilled material with water prior to cleaning up to prevent dust cloud.

Section 7 - Handling and Storage

Precautions for safe handling

Handling • Minimize dust generation and accumulation. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage • Keep tightly closed. Store at controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.

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**
- For bulk handling, the personal breathing protection should be determined based upon a risk assessment and in accordance with local regulations. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

- Eye/Face**
- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.

- Hands**
- Wear protective gloves when handling bulk product before closed in final packaging.

- Skin/Body**
- Avoid contact with skin.

- General Industrial Hygiene Considerations**
- Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly with soap and water after handling.

- Environmental Exposure Controls**
- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	White powder.
Color	White	Odor	Not relevant
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	Not relevant
Specific Gravity/Relative Density	No data available	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

- Stable under normal temperatures and pressures.

Chemical stability

- Hazardous polymerization will not occur.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Excessive heat or moisture.

Incompatible materials

- Strong oxidizing agents.

Hazardous decomposition products

- When heated to decomposition carbon oxides and halogenated compounds may be released.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Ethacrynate sodium (44%)	6500-81-8	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 627 mg/kg; Intravenous-Mouse LD50 • 175 mg/kg

GHS Properties	Classification
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Mild Irritation 2B
Acute toxicity	UN GHS • Acute Toxicity - Oral 4
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Mild Irritation 3
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Specific Target Organ Toxicity Single Exposure 2
Toxicity for Reproduction	UN GHS • Classification criteria not met

Target Organs

- Ear/Otic

Potential Health Effects

Inhalation

Acute (Immediate)

- May mildly irritate the respiratory tract.

Chronic (Delayed)

- No data available

Skin

Acute (Immediate)

- May cause skin irritation.

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Eye

Acute (Immediate)

- May cause mild eye irritation with direct contact to eye.

Chronic (Delayed)

- No data available

Ingestion

Acute (Immediate)

- Ethacrynic acid is a potent diuretic which, if given in excessive amounts, may lead to profound diuresis with water and electrolyte depletion.

Chronic (Delayed)

- Repeated and prolonged exposure may affect the bones and/or musculoskeletal system.

Other information

- Deafness, tinnitus, and vertigo with a sense of fullness in the ears have occurred, most frequently in patients with severe impairment of renal function. These symptoms have been associated most often with intravenous administration and with doses in excess of those recommended. The deafness has usually been reversible and of short duration (one to 24 hours). However, in some patients the hearing loss has been permanent. A number of these patients were also receiving drugs known to be ototoxic. Ethacrynic acid may increase the ototoxic potential of other drugs.

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 data available

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
Ethacrynate sodium	6500-81-8	Yes	No	No
Mannitol, D-	69-65-8	Yes	Yes	Yes

Canada**Labor****Canada - WHMIS - Classifications of Substances**

• Mannitol, D-	69-65-8	Uncontrolled product according to WHMIS classification criteria
• Ethacrynate sodium	6500-81-8	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Mannitol, D-	69-65-8	Not Listed
• Ethacrynate sodium	6500-81-8	Not Listed

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

• Mannitol, D-	69-65-8	Not Listed
• Ethacrynate sodium	6500-81-8	Not Listed

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

• Mannitol, D-	69-65-8	Not Listed
• Ethacrynate sodium	6500-81-8	Not Listed

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

• Mannitol, D-	69-65-8	Not Listed
• Ethacrynate sodium	6500-81-8	Not Listed

Section 16 - Other Information**Revision Date** • 17/December/2015**Last Revision Date** • 17/December/2015**Preparation Date** • 17/December/2015**Disclaimer/Statement of Liability**

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