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

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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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Identifiers</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethacrynate sodium</td>
<td>CAS:6500-81-8</td>
<td>44%</td>
</tr>
<tr>
<td>Mannitol, D-</td>
<td>CAS:69-65-8</td>
<td>56%</td>
</tr>
<tr>
<td></td>
<td>EINECS:200-711-8</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material Description</th>
<th>Physical Form</th>
<th>Appearance/Description</th>
<th>General Properties</th>
<th>Volatility</th>
<th>Flammability</th>
<th>Environmental</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Solid</td>
<td>White powder.</td>
<td>Boiling Point</td>
<td>No data available</td>
<td>Flash Point</td>
<td>Octanol/Water Partition coefficient</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Decomposition Temperature</td>
<td>No data available</td>
<td>LEL</td>
<td>No data available</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Specific Gravity/Relative Density</td>
<td>No data available</td>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Viscosity</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Water Solubility</td>
<td>Soluble</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>pH</td>
<td>Not relevant</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Melting Point/Freezing Point</td>
<td>No data available</td>
<td></td>
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</tbody>
</table>

Section 10: Stability and Reactivity

Reactivity

• Stable under normal temperatures and pressures.

Chemical stability

• Hazardous polymerization will not occur.

Possibility of hazardous reactions
### 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

<table>
<thead>
<tr>
<th>Ethacrynate sodium (44%)</th>
<th>6500-81-8</th>
<th>Acute Toxicity: Ingestion/Oral-Mouse LD50 • 627 mg/kg; Intravenous-Mouse LD50 • 175 mg/kg</th>
</tr>
</thead>
</table>

### GHS Properties

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

### 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.

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### 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

<table>
<thead>
<tr>
<th></th>
<th>UN number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class(es)</th>
<th>Packing group</th>
<th>Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>TDG</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>IMO/IMDG</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

**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

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### Section 15 - Regulatory Information

Preparation Date: 17/December/2015
Revision Date: 17/December/2015
Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications

- No data available

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS</th>
<th>Canada DSL</th>
<th>EU EINECS</th>
<th>TSCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethacrynate sodium</td>
<td>6500-81-8</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Mannitol, D-</td>
<td>69-65-8</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Canada

Labor - WHMIS - Classifications of Substances

- Mannitol, D- 69-65-8
- Ethacrynate sodium 6500-81-8

Uncontrolled product according to WHMIS classification criteria

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
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