MATERIAL SAFETY DATA SHEET

Product Name: Edetate Disodium Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name and Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA 60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency 224-212-2000

Product Name
Edetate Disodium Injection

Synonyms
Endrate®; disodium (ethylenedinitrilo) tetraacetate dihydrate; disodium salt of ethylenediamine tetraacetic acid (EDTA).

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Edetate Disodium

Chemical Formula
C_{10}H_{14}N_{2}O_{8} \cdot Na_{2}

Preparation
Non-hazardous ingredients include Water for Injection. Sodium hydroxide is added to adjust the pH.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edetate Disodium</td>
<td>15</td>
<td>139-33-3</td>
<td>AH4375000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edetate Disodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Endrate (Edetate Disodium Injection) is a solution containing edetate disodium, a chelating agent that binds cations such as sodium and calcium. Clinically, it is indicated for emergency treatment of hypercalcemia and for the control of ventricular arrhythmias associated with digitalis toxicity. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs may include the gastrointestinal system, cardiovascular system, kidneys and blood.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposures. In clinical use, gastrointestinal symptoms such as nausea, vomiting and diarrhea occur commonly following administration of this drug. Transient symptoms such as circulatory paresthesia, numbness and headache and a transient drop in systolic and diastolic blood pressure may also occur. Thrombophlebitis, febrile reactions, hyperuricemia, anemia, exfoliative dermatitis and other toxic skin and mucous membrane
Product Name: Edetate Disodium Injection

reactions have been reported. Nephrotoxicity and damage to the reticuloendothelial system with hemorrhagic tendencies have been reported with excessive dosages.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to this material; pre-existing gastrointestinal, cardiovascular, or renal ailments; pre-existing hypocalcemia.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this aqueous product.

Fire & Explosion Hazard
None anticipated for this aqueous product.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling
No special handling required under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions
No special precautions required for hazard control.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not Applicable</td>
<td>mg/m3</td>
</tr>
<tr>
<td>Edetate Disodium</td>
<td></td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Respiratory protection**

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Sterile, nonpyrogenic, concentrated solution in water</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>7.0 (6.5 to 7.5)</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>NA</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Not determined.

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and oxides of sodium.

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
</table>
| Edetate Disodium  | 100     | LD50      | Oral                    | 2000, 3700  
                           |         |           | 40  
                           |         | mg/kg    | Rat     |
                           |         |           | 2300                   | mg/kg   |        | Mouse   |
| Edetate Disodium  | 100     | LD50      | Intravenous             | 56       | mg/kg  | Rabbit  |
                           |         |           |                         | 47       |        |         |

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
Long term animal studies have not been conducted with edetate disodium to evaluate its effect on fertility.

Mutagenicity
Long term animal studies have not been conducted with edetate disodium to evaluate its mutagenic potential.

Carcinogenicity
Long term animal studies have not been conducted with edetate disodium to evaluate its carcinogenic potential.

Target Organ Effects
Based on clinical use, possible target organs may include the gastrointestinal system, cardiovascular system, kidneys and blood.
12. ECOLOGICAL INFORMATION

Aquatic Toxicity  
Not determined for product. For edetate disodium: LC50(96 hr, semi-static) = 320 mg/L in Poecilia reticulata (freshwater fish) EC50(3 hr) = 403 mg/L in activated sludge

Persistence/Biodegradability  
Not determined for product.

Bioaccumulation  
Not determined for product.

Mobility in Soil  
Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal  
All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal  
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/DOT STATUS:  
Not regulated

IMDG STATUS:  
Not regulated

ICAO/IATA STATUS:  
Not regulated

Transport Comments:  
None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
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<tbody>
<tr>
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</tr>
</tbody>
</table>

RCRA Status  
Not Listed

U.S. OSHA Classification  
Target Organ Toxin

Possible Irritant

GHS Classification  
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class  
Not Applicable

Hazard Category  
Not Applicable

Signal Word  
Not Applicable
Product Name: Edetate Disodium Injection

Symbol: Not Applicable


Hazard Statement: Not Applicable

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 attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification:
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Edetate Disodium.

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases:
- S23 - Do not breathe vapor.
- S24/25 - Avoid contact with skin and eyes.
- S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:
- ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value
- CAS: Chemical Abstracts Service Number
- CERCLA: US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
- DOT: US Department of Transportation Regulations
- EEL: Employee Exposure Limit
- IATA: International Air Transport Association
- LD50: Dosage producing 50% mortality
- NA: Not applicable/Not available
- NE: Not established
- NIOSH: National Institute for Occupational Safety and Health
- OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
- Prop 65: California Proposition 65
- RCRA: US EPA, Resource Conservation and Recovery Act
- RTECS: Registry of Toxic Effects of Chemical Substances
- SARA: Superfund Amendments and Reauthorization Act
- STEL: 15-minute Short Term Exposure Limit
- TSCA: Toxic Substance Control Act
- TWA: 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/19/2011
Obsolete Date: 10/21/2008
Product Name: Edetate Disodium Injection

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