Product Name: AMIDATE - Etomidate Injection, Solution

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
224 212-2000

Product Name
AMIDATE - Etomidate Injection, Solution

Synonyms
(R)-(+-)ethyl-1-(1-phenylethyl)-1H-imidazole-5-carboxylate

2. HAZARD(S) IDENTIFICATION

Emergency Overview
AMIDATE - Etomidate Injection, Solution is a solution containing etomidate, an intravenous anesthetic used for the induction of general anesthesia. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the central nervous system, respiratory system, cardiovascular system, and adrenal glands.

U.S. OSHA GHS Classification

Physical Hazards
Hazard Class: Not Classified
Hazard Category: Not Classified

Health Hazards
Hazard Class: Not Classified
Hazard Category: Not Classified

Label Element(s)

Pictogram
NA

Signal Word
NA

Hazard Statement(s)
NA

Precautionary Statement(s)

Prevention
Do not breathe vapor or spray.
Wash hands thoroughly after handling.

Response
Get medical attention 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 eye irritation persists, get medical attention.
Product Name: AMIDATE - Etomidate Injection, Solution

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Active Ingredient Name</th>
<th>Chemical Formula</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etomidate</td>
<td>C$<em>{14}$H$</em>{16}$N$_2$O$_2$</td>
<td>0.2</td>
<td>33125-97-2</td>
<td>NI4021500</td>
</tr>
<tr>
<td>Propylene Glycol, USP</td>
<td>C$_3$H$_8$O$_2$</td>
<td>35</td>
<td>57-55-6</td>
<td>TY2000000</td>
</tr>
</tbody>
</table>

Non-hazardous ingredients include Water for Injection.

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 such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures
No special provisions required beyond normal firefighting 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 control 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>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>AIHA WEEL</th>
<th>Hospira EEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etomidate Hydrochloride</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: 10 mg/m3</td>
<td>8-hr TWA: Not Established</td>
</tr>
</tbody>
</table>

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level.
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

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>Amidate (etomidate injection) is a sterile, nonpyrogenic solution.</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>6.0 (4.0 to 7.0)</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>Flash Point</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 (Air =1)</td>
<td>NA</td>
</tr>
<tr>
<td>Relative Density</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>
<tr>
<td>Viscosity</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: AMIDATE - Etomidate Injection, Solution

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) and nitrogen oxides (NOx).

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>
<tbody>
<tr>
<td>Etomidate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>650</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Etomidate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>20.4, 14.8</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td>Etomidate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>29.5</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>10,400-29,536</td>
<td>mg/kg</td>
<td>Rat, Mouse, Rabbit, Dog, Guinea Pig</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>6423-6800</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>6630-8000</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>20,800</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
</tbody>
</table>

LD 50: Dosage that produces 50% mortality.

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 anticipated from normal handling of this product. In clinical use, adverse effects may include transient venous pain on injection and transient skeletal muscle movements, including myoclonus. Hyperventilation, hypoventilation, apnea of short duration (5 to 90 seconds with spontaneous recovery), laryngospasm, hiccup and snoring have been noted in some patients. Hypertension, hypotension, tachycardia, bradycardia and other arrhythmias have occasionally been noted during induction and maintenance of anesthesia. Hypersensitivity reactions including anaphylaxis have been reported. Etomidate is associated with less hypotension than other drugs commonly used for induction.

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 mild irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. However, in clinical use, immediate widespread cutaneous flushing or urticaria attributed to etomidate has been reported.
### 11. TOXICOLOGICAL INFORMATION: continued

**Reproductive Effects**
None anticipated from normal handling of this product. In reproduction studies, no impairment of fertility in male and female rats when etomidate was given prior to pregnancy at dosages of 0.31, 1.25 and 5 mg/kg. Etomidate has not been shown to be teratogenic in animals. However, etomidate has been shown to have an embryocidal effect in rats when given in doses 1 and 4 times the human dose.

**Mutagenicity**
No mutagenesis studies have been carried out on etomidate.

**Carcinogenicity**
No carcinogenesis studies have been carried out on etomidate.

**Carcinogen Lists**
- **IARC:** Not listed
- **NTP:** Not listed
- **OSHA:** Not listed

**Specific Target Organ Toxicity**
- **Single Exposure**
  - NA

**Specific Target Organ Toxicity**
- **Repeat Exposure**
  - Based on clinical use, possible target organs include the central nervous system, respiratory system, cardiovascular system, and adrenal glands.

### 12. ECOLOGICAL INFORMATION

**Aquatic Toxicity**
- Not determined for product.
  - LC50(96 hr) = 0.48 mg/L in Bluegill (Lepomis macrochirus) for etomidate
  - LC50(96 hr) = 51,600 mg/L in rainbow trout for propylene glycol
  - LC50(48 hr) = 34,400 - 43,500 mg/L in Daphnia magna for propylene glycol
  - EC50(14 day) = 19,000 mg/L in algae for propylene glycol

**Persistence/Biodegradability**
- Not determined for product.
  - Propylene glycol was reported to be 100% biodegradable after 24-hours in activated sludge.

**Bioaccumulation**
- Not determined for product.

**Mobility in Soil**
- Not determined for product.

**Notes:**
1. LC50: Concentration in water that produces 50% mortality in fish.
2. EC50: Concentration in water that produces 50% inhibition of growth in algae.

### 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

<table>
<thead>
<tr>
<th>ADR/ADG/ DOT STATUS</th>
<th>Not regulated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper Shipping Name</td>
<td>NA</td>
</tr>
<tr>
<td>Hazard Class</td>
<td>NA</td>
</tr>
<tr>
<td>UN Number</td>
<td>NA</td>
</tr>
<tr>
<td>Packing Group</td>
<td>NA</td>
</tr>
<tr>
<td>Reportable Quantity</td>
<td>NA</td>
</tr>
<tr>
<td>ICAO/IATA STATUS</td>
<td>Not regulated</td>
</tr>
<tr>
<td>Proper Shipping Name</td>
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<tr>
<td>Hazard Class</td>
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</tr>
<tr>
<td>UN Number</td>
<td>NA</td>
</tr>
<tr>
<td>Packing Group</td>
<td>NA</td>
</tr>
<tr>
<td>Reportable Quantity</td>
<td>NA</td>
</tr>
</tbody>
</table>

IMDG STATUS Not regulated

| Proper Shipping Name | NA |
| Hazard Class        | NA |
| UN Number           | NA |
| Packing Group       | NA |
| Reportable Quantity | NA |

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>US TSCA Status</th>
<th>Exempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>US CERCLA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US SARA 302 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US SARA 313 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US RCRA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US PROP 65 (Calif.)</td>
<td>Not listed</td>
</tr>
</tbody>
</table>


GHS/CLP 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.

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Prevention</td>
<td></td>
<td></td>
<td></td>
<td>Do not breathe vapor or spray.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Wash hands thoroughly after handling.</td>
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<tr>
<td>Response</td>
<td></td>
<td></td>
<td></td>
<td>Get medical attention if you feel unwell.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>
Product Name: AMIDATE - Etomidate Injection, Solution

15. REGULATORY INFORMATION: continued

**EU Classification**
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s) NA
Symbol NA
Indication of Danger NA

**Risk Phrases** NA

**Safety Phrases**
S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with 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
LD$_{50}$ 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
STOT - SE Specific Target Organ Toxicity – Single Exposure
STOT - RE Specific Target Organ Toxicity – Repeated Exposure
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: October 17, 2012
Date Revised: June 02, 2014

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