ETomidate Injection, USP
SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier
Product name: Etomidate Injection, USP, 20 mg/10 ml, 40 mg/20 ml (2 mg/ml)

Intended Use of the Product
Use of the substance/mixture: Pharmaceutical. Intravenous Injection. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, and Telephone of the Responsible Party
Supplier: Mylan Institutional LLC
1718 Northrock Court
Rockford, IL 61103 USA
1-888-258-4199
www.mylan.com

Manufacturer: Agila Specialities Pvt. Ltd.
Opposite IIM, Bilekallii
Bangalore, India

Emergency Telephone Number
Emergency number: +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician’s directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Classification of the Substance or Mixture
Classification (GHS-US)
Not classified

Label Elements
GHS-US labeling
Not applicable

Other Hazards
Aquatic Acute 3

Hazard statements (GHS-US): H402 - Harmful to aquatic life

                                   P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

Unknown acute toxicity (GHS-US): Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>% (w/w)</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2-Propylene glycol</td>
<td>(CAS No) 57-55-6</td>
<td>35 (v/v)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Etomidate</td>
<td>(CAS No) 33125-97-2</td>
<td>0.1 - 1</td>
<td>Acute Tox. 4 (Oral), H302 Aquatic Acute 1, H400</td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

Description of First Aid Measures
General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.
Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

**Most Important Symptoms and Effects Both Acute and Delayed**

**General:** Please refer to the package insert for more detailed information.

**Inhalation:** May cause respiratory irritation.

**Skin Contact:** May cause skin irritation.

**Eye Contact:** May cause eye irritation.

**Ingestion:** Ingestion is likely to be harmful or have adverse effects.

**Injection:** The most frequent adverse reactions associated with use of intravenous etomidate are transient venous pain on injection and transient skeletal muscle movements, including myoclonus.

**Chronic symptoms:** None expected under normal conditions of use.

**Indication of Any Immediate Medical Attention and Special Treatment Needed**

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

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**5. FIREFIGHTING MEASURES**

**Extinguishing Media**

- **Suitable extinguishing media:** Not flammable. Use extinguishing media appropriate for surrounding fire.
- **Unsuitable extinguishing media:** None known.

**Special Hazards Arising From the Substance or Mixture**

- **Fire hazard:** Not flammable.
- **Explosion hazard:** Product is not explosive.
- **Reactivity:** Hazardous reactions will not occur under normal conditions.

**Advice for Firefighters**

- **Precautionary measures fire:** Exercise caution when fighting any chemical fire.
- **Firefighting instructions:** Use water spray or fog for cooling exposed containers.
- **Protection during firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.
- **Hazardous Combustion Products:** Carbon oxides (CO, CO₂).
- **Other information:** Refer to Section 9 for flammability properties.

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**6. ACCIDENTAL RELEASE MEASURES**

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

- **General measures:** Avoid all eye and skin contact and do not breathe vapor and mist.

  **For Non-Emergency Personnel**

  - **Protective equipment:** Use appropriate personal protection equipment (PPE).
  - **Emergency procedures:** Evacuate unnecessary personnel.

  **For Emergency Personnel**

  - **Protective equipment:** Equip cleanup crew with proper protection.

**Environmental Precautions**

Prevent entry to sewers and public waters.

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

- **Methods for cleaning up:** For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

**Reference to Other Sections**

See heading 8, Exposure Controls and Personal Protection.

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**7. HANDLING AND STORAGE**

**Precautions for Safe Handling**

- **Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician’s directions.

- **Hygiene measures:** This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

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

- **Storage conditions:** Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.
Specific End Use(s)
Pharmaceutical. Intravenous Injection. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

<table>
<thead>
<tr>
<th>1,2-Propylene glycol (57-55-6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ontario OEL TWA (mg/m³)</td>
</tr>
<tr>
<td>Ontario OEL TWA (ppm)</td>
</tr>
</tbody>
</table>

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Appearance</td>
<td>Sterile, nonpyrogenic solution</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>6.0 (4.0 - 7.0)</td>
</tr>
<tr>
<td>Relative evaporation rate (butyl acetate=1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting/Freezing point</td>
<td>Not available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not available</td>
</tr>
<tr>
<td>Upper/Lower flammable limit</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not available</td>
</tr>
<tr>
<td>Relative vapor density at 20 ºC</td>
<td>Not available</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>Not available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not available</td>
</tr>
<tr>
<td>Log Pow/ Log Kow</td>
<td>Not available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosion data - sensitivity to mechanical impact</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosion data - sensitivity to static discharge</td>
<td>Not available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.

Chemical Stability Stable under normal conditions.

Possibility of Hazardous Reactions Hazardous polymerization will not occur.

Conditions to Avoid Direct sunlight. Extremely high or low temperatures.


Hazardous Decomposition Products Carbon oxides (CO, CO₂).

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute toxicity: Not classified
LD50 and LC50 Data: Not available
Skin Corrosion/Irritation: Not classified
Serious Eye Damage/Irritation: Not classified
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Not classified
Teratogenicity: Not available
Carcinogenicity: Not classified
Specific Target Organ Toxicity (Repeated Exposure): Not classified
Reproductive Toxicity: Not classified
Specific Target Organ Toxicity (Single Exposure): Not classified
Information on Toxicological Effects - Ingredient(s)
LD50 and LC50 Data:

| LD50 (oral rat) | 20000 mg/kg |
| LD50 (dermal rabbit) | 20800 mg/kg |

12. ECOLOGICAL INFORMATION

Toxicity
Ecology - general: Harmful to aquatic life.

1,2-Propylene glycol (57-55-6)

| LC50 (fish) 1 | 51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |
| EC50 (Daphnia 1) | 10000 mg/l (Exposure time: 24 h - Species: Daphnia magna) |
| LC50 (fish) 2 | 41 (41 - 47) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |
| EC50 (Daphnia 2) | 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static]) |

Persistence and Degradability: Not available

Bioaccumulative Potential

| 1,2-Propylene glycol (57-55-6) | BCF (fish) 1 | < 1 |

13. DISPOSAL CONSIDERATIONS

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.

Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG
UN Number: Not regulated for transport
UN Proper Shipping Name: Not regulated for transport

15. REGULATORY INFORMATION

US Federal Regulations

1,2-Propylene glycol (57-55-6)

- Listed on the United States TSCA (Toxic Substances Control Act) inventory
- EPA TSCA Regulatory Flag: Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

US State Regulations

1,2-Propylene glycol (57-55-6)

- U.S. - Minnesota - Hazardous Substance List
- RTK - U.S. - New Jersey - Right to Know Hazardous Substance List
- RTK - U.S. - Pennsylvania - RTK (Right to Know) List
- U.S. - Texas - Effects Screening Levels - Long Term
- U.S. - Texas - Effects Screening Levels - Short Term

Canadian Regulations

Etomidate Injection, USP, 20 mg/10 ml, 40 mg/20 ml (2 mg/ml)

Uncontrolled product according to WHMIS classification criteria

1,2-Propylene glycol (57-55-6)

- Listed on the Canadian DSL (Domestic Substances List) inventory.
- Listed on the Canadian Ingredient Disclosure List

- WHMIS Classification: Uncontrolled product according to WHMIS classification criteria
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

### 16. OTHER INFORMATION

<table>
<thead>
<tr>
<th>Revision date</th>
<th>06/13/2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data sources</td>
<td>This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.</td>
</tr>
<tr>
<td>Other information</td>
<td>This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.</td>
</tr>
</tbody>
</table>

### GHS Full Text Phrases:

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Acute toxicity (oral) Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute 1</td>
<td>Hazardous to the aquatic environment - Acute Hazard Category 1</td>
</tr>
<tr>
<td>Aquatic Acute 3</td>
<td>Hazardous to the aquatic environment - Acute Hazard Category 3</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life</td>
</tr>
<tr>
<td>H402</td>
<td>Harmful to aquatic life</td>
</tr>
</tbody>
</table>

### Party Responsible For The Preparation Of This Document:

Mylan Global Environmental, Health, and Safety Department  
Phone Number: 304-599-2595  

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer’s directions.  
To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

North America Mylan Pharmaceuticals