



## ETOMIDATE INJECTION, USP

### SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

#### 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](http://www.mylan.com)

###### **Manufacturer:**

Agila Specialities Pvt. Ltd.  
A Mylan Company  
Opposite IIM, Bilekahalli  
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

**Precautionary statements (GHS-US)** :P273 - Avoid release to the environment.

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**

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

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.

### **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, CO<sub>2</sub>).

**Other information:** Refer to Section 9 for flammability properties.

### **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.

### **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.

**Special rules on packaging:** Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

**Specific End Use(s)**

Pharmaceutical. Intravenous Injection. Refer to product insert for usage instructions and product information.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Control Parameters**

1,2-Propylene glycol (57-55-6)		
Ontario	OEL TWA (mg/m <sup>3</sup> )	155 mg/m <sup>3</sup>
Ontario	OEL TWA (ppm)	50 ppm

**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**

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

**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.

**Incompatible Materials** Strong oxidizers. Strong bases. Strong acids.

**Hazardous Decomposition Products** Carbon oxides (CO, CO<sub>2</sub>).

**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  
**Aspiration Hazard:** Not classified  
**Information on Toxicological Effects - Ingredient(s)**  
**LD50 and LC50 Data:**

<b>1,2-Propylene glycol (57-55-6)</b>	
LD50 oral rat	20000 mg/kg
LD50 dermal rabbit	20800 mg/kg

## 12. ECOLOGICAL INFORMATION

### Toxicity

**Ecology - general:** Harmful to aquatic life.

<b>1,2-Propylene glycol (57-55-6)</b>	
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

<b>1,2-Propylene glycol (57-55-6)</b>	
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

<b>1,2-Propylene glycol (57-55-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>EPA TSCA Regulatory Flag</b>	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

<b>1,2-Propylene glycol (57-55-6)</b>	
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

<b>Etomidate Injection, USP, 20 mg/10 ml, 40 mg/20 ml (2 mg/ml)</b>	
Uncontrolled product according to WHMIS classification criteria	
<b>1,2-Propylene glycol (57-55-6)</b>	
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.

<b>16.</b>	<b>OTHER INFORMATION</b>
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<b>Revision date</b>	: 06/13/2014
<b>Data sources</b>	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
<b>Other information</b>	: 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.

**GHS Full Text Phrases:**

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
H302	Harmful if swallowed
H400	Very toxic to aquatic life
H402	Harmful to aquatic life

**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