



# MATERIAL SAFETY DATA SHEET

Revision date: 18-Nov-2011

Version: 2.0

Page 1 of 6

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
Emergency telephone number:  
International CHEMTREC (24 hours): +1-703-527-3887

### Material Name: Etomidate Injection

Trade Name:	Not applicable
Chemical Family:	Imidazole
Intended Use:	Pharmaceutical product used as sedative-hypnotic

## 2. HAZARDS IDENTIFICATION

**Appearance:** Aqueous sterile solution

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

### Additional Hazard Information:

Short Term:	Active ingredient may be harmful if swallowed.
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

**Known Clinical Effects:** Common adverse effects include respiratory depression, changes in blood pressure, headache, lightheadedness, dry mouth, dizziness and drowsiness. This compound can cross the placenta in pregnant women. Secreted in human breast milk.

**EU Indication of danger:** Not classified

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## MATERIAL SAFETY DATA SHEET

Material Name: Etomidate Injection  
Revision date: 18-Nov-2011

Page 2 of 6  
Version: 2.0

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Etomidate	33125-97-2	251-385-9	R64 Repr. Cat.2;R61 Xn;R22	0.2
Propylene glycol	57-55-6	200-338-0	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Water, purified	7732-18-5	231-791-2	Not Listed	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Dry chemical, carbon dioxide, water spray or alcohol-resistant foam

**Hazardous Combustion Products:** May include oxides of carbon.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** May generate flammable vapors. Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

## MATERIAL SAFETY DATA SHEET

Material Name: Etomidate Injection  
Revision date: 18-Nov-2011

Page 3 of 6  
Version: 2.0

**Measures for Environmental Protections:**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:**

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

**General Handling:**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Storage Conditions:**

Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

**Propylene glycol**

**Australia TWA**

150 ppm  
474 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>

**Ireland OEL - TWAs**

150 ppm  
470 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>

**Latvia OEL - TWA**

7 mg/m<sup>3</sup>

**Lithuania OEL - TWA**

7 mg/m<sup>3</sup>

**Etomidate**

**Pfizer Occupational Exposure Band (OEB):**

OEB 4 (control exposure to the range of >1ug/m<sup>3</sup> to <10ug/m<sup>3</sup>)

**Engineering Controls:**

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Environmental Exposure Controls:**

Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:**

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:**

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:**

Wear safety glasses or goggles if eye contact is possible.

**Skin:**

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:**

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

## MATERIAL SAFETY DATA SHEET

Material Name: Etomidate Injection  
Revision date: 18-Nov-2011

Page 4 of 6  
Version: 2.0

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

### 10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
----------------------	---

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Etomidate**

Mouse	Oral	LD50	650 mg/kg
-------	------	------	-----------

##### **Propylene glycol**

Mouse	Oral	LD50	22,000 mg/kg
Rat	Oral	LD50	20,000 mg/kg
Rabbit	Dermal	LD50	20,800 mg/kg

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Propylene glycol**

Skin Irritation	Rabbit	Mild
Eye Irritation	Rabbit	Mild

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Etomidate**

Reproductive & Fertility	Rat	No route specified	5 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rat	No route specified	0.3 mg/kg/day	LOAEL	Fetal mortality
Embryo / Fetal Development	Rabbit	No route specified	1.5 mg/kg/day	LOAEL	Fetal mortality

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

### 12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been investigated. Releases to the environment should be avoided.
-------------------------	---

## MATERIAL SAFETY DATA SHEET

Material Name: Etomidate Injection  
Revision date: 18-Nov-2011

Page 5 of 6  
Version: 2.0

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

**EU Safety Phrases:**

**OSHA Label:**

Non-hazardous in accordance with international standards for workplace safety.

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

**Etomidate**

Australia (AICS):	Present
EU EINECS/ELINCS List	251-385-9

**Water, purified**

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

## MATERIAL SAFETY DATA SHEET

Material Name: Etomidate Injection  
Revision date: 18-Nov-2011

Page 6 of 6  
Version: 2.0

### 15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

#### Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R64 - May cause harm to breastfed babies.

R61 - May cause harm to the unborn child.

R22 - Harmful if swallowed.

**Data Sources:** Publicly available toxicity information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 8 - Exposure Controls / Personal Protection.

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**