

MATERIAL SAFETY DATA SHEET

Product Name: AMIDATE - Etomidate Injection, Solution

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 AMIDATE - Etomidate Injection, Solution

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Etomidate

Chemical Formula C₁₄H₁₆N₂O₂

Preparation Non-hazardous ingredients include Water for Injection.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Etomidate	0.2	33125-97-2	NI4021500
Propylene Glycol	35	57-55-6	TY2000000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Etomidate	Not Listed	Not Listed	Not Listed
Propylene Glycol	Not Listed	Not Listed	Not Listed

Emergency Overview AMIDATE - Etomidate Injection, Solution contains 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.

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, 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

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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.

Medical Conditions Aggravated by Exposure Pre-existing central nervous system or respiratory ailments or impaired adrenocortical function.

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.
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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

Exposure Guidelines

Component	Type	Exposure limits			
		mg/m ³	ppm	µg/m ³	Note
Propylene Glycol	AIHA WEEL	10	N/A	N/A	8hr TWA
Etomidate	Not Applicable	N/A	N/A	N/A	None Established

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 (N99 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

Appearance/Physical State	Liquid
Color	Sterile, nonpyrogenic solution
Odor	NA
Odor Threshold:	NA
pH:	6.0 (4.0 to 7.0)
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	NA
Solubility:	NA
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	NA

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:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Etomidate	100	LD50	Oral	650	mg/kg	Mouse
Etomidate	100	LD50	Intravenous	20.4, 14.8 29.5	mg/kg mg/kg	Rat Mouse
Propylene Glycol	100	LD50	Oral	10,400 - 29,536	mg/kg	Rat, Mouse, Rabbit, Dog, Guinea Pig
Propylene Glycol	100	LD50	Intravenous Intravenous	6423-6800 6630-8000	mg/kg mg/kg	Rat Mouse
Propylene Glycol	100	LD50	Dermal	20,800	mg/kg	Rabbit

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. In clinical use, immediate widespread cutaneous flushing or urticaria attributed to etomidate have been reported.
Reproductive Effects	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.

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Mutagenicity No mutagenesis studies have been carried out on etomidate.

Carcinogenicity No carcinogenesis studies have been carried out on etomidate.

Target Organ Effects 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.

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

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Etomidate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Propylene Glycol	Listed	Not Listed	Not Listed	Not Listed	Not Listed

RCRA Status Not Listed
U.S. OSHA Target Organ Toxin

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Classification 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

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

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 Etomidate
Propylene Glycol

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24 - Avoid contact with 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
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health



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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

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