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Section 1 - Identification


- (a) **Product Identifier:** Etomidate Injection, USP
- (b) **Product Code:** 70860-652
- Common/Trade Name:** Etomidate
- Chemical Name:** (R)-(+)-ethyl-1-(1-phenylethyl)-1H-imidazole-5-carboxylate
- Chemical Family:** Imidazole
- (c) **Product Use:** Pharmaceutical, Injectable, Sedative-hypnotic
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Not Classified

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	
GHS Signal Word:	N/A
GHS Hazard Statement:	H402 – Harmful to aquatic life
GHS Symbols:	N/A
GHS Precautionary Statements:	P273 - Avoid release to the environment. P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.
Other Hazards	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.

- (d) **Unknown Acute Toxicity:** N/A

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Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(R)-(+)-ethyl-1-(1-phenylethyl)-1H-imidazole-5-carboxylate	Etomidate*	2.0 mg/mL	33125-97-2	N/A
Propylene glycol	Propylene glycol	0.35 mL	57-55-6	N/A
Water for Injection	Water	q.s. to 1 mL	7732-18-5	N/A
Nitrogen	Nitrogen**	As required	7727-37-9	N/A


*Assay compensation to be done on as is basis.

**Nitrogen is used during compounding and to transfer the product through filtration train during filtration and filling.

q.s. = quantity sufficient

Section 4 – First Aid Measures

Emergency Overview	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
Eye Exposure:	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.
Skin Exposure:	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.
Ingestion:	Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.
Injection:	In cases of accidental injection, wash and disinfect area, seek emergency medical attention.
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.


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Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Not flammable. Use extinguishing media appropriate for surrounding fire.
- (b) **Hazardous Combustion Products:** Carbon oxides (CO, CO₂).
- (c) **Special Protective Equipment / Precautions:** Do not enter fire area without proper protective equipment, including respiratory protection.

Section 6 - Accidental Release Measures

- Spill:** 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.
- Release to Air:** Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Release to Water:** Refer to the local water authority; drain disposal is not recommended. Refer to local, state and federal guidelines.

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Section 7 - Handling and Storage

General Handling: Avoid all eye and skin contact and do not breathe vapor and mist.

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.

Storage Conditions: Store at 20 to 25°C (68 to 77°F).

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits


Compound	Issuer	Type	Exposure Limit
Etomidate	OSHA	PEL	NE
	ACGIH	TWA	NE

(b) 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.

(c) Individual Protection Measures

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.
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Eye Protection:	Wear safety glasses or goggles if eye contact is possible.
Skin Protection:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Other Protective Equipment:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Additional Exposure Precautions:	None

Section 9 - Physical and Chemical Properties

(a)	Appearance	Solution
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	6.0 (4.0 – 7.0)
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Not available
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Hazardous reactions will not occur under normal conditions.
(b)	Chemical Stability	Stable at normal temperature and pressures.

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(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur.
(d)	Conditions to Avoid	Direct sunlight. Extremely high or low temperatures.
(e)	Incompatible Materials	Strong oxidizers. Strong bases. Strong acids.
(f)	Hazardous Decomposition Products	Carbon oxides (CO, CO ₂).

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation, ingestion, skin contact or eye contact.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Not available.
(c)	Delayed and immediate effects and chronic effects from short and long term exposure	<p>General: Please refer to the package insert for more detailed information.</p> <p>Inhalation: May cause respiratory irritation.</p> <p>Skin Contact: May cause skin irritation.</p> <p>Eye Contact: May cause eye irritation.</p> <p>Ingestion: Ingestion is likely to be harmful or have adverse effects.</p> <p>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.</p> <p>Chronic symptoms: None expected under normal conditions of use.</p>

(d) Acute Toxicity

Based on available data, the classification criteria are not met.

Component	Type	Route	Species	Dosage
Etomidate	LD ₅₀	Oral	Mouse	650 mg/kg
Propylene glycol	LD ₅₀	Oral	Rat	20,000 mg/kg
	LD ₅₀	Dermal	Rabbit	20,800 mg/kg
	LD ₅₀	Oral	Mouse	22,000 mg/kg

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(e) Hazardous Chemical Listings

NTP: Not Listed **IARC:** Not Listed **OSHA:** Not Listed **ACGIH:** Not Listed

Section 12 - Ecological Information

(a) Ecotoxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
(b) Persistence and degradability	Not Available
(c) Bioaccumulative potential	Not Available
(d) Mobility in soil	Not available
(e) Other Adverse Effects	Not Available


Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(a) UN Number	N/A
(b) UN Proper Shipping Name	N/A
(c) Transport Hazard Class(es)	N/A
(d) Packing Group	N/A
(e) Environmental Hazards	N/A
(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g) Special Precautions	N/A

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA – Not regulated
 CERCLA - Not on this list
 SARA 302 - Not on this list
 SARA 311/312: Not on this list
 SARA 313 - Not on this list
 OSHA – Not on this list

Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division
 10 N. Martingale Road, Suite 230
 Schaumburg, IL 60173
 847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency

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EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS019
Title: Etomidate Injection, USP

Revision: 01

All dates and times are in Eastern Standard Time.

SDS019

Change Request

Name/Signature	Title	Date	Meaning/Reason
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Quality	01 Sep 2017, 09:09:50 AM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	12 Sep 2017, 12:05:49 PM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	14 Sep 2017, 10:14:37 AM	Approved