

**SAFETY DATA SHEET**  
**Etomidate Injection, USP**



**Caplin Steriles Limited**

**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

**Product Name** : Etomidate Injection, USP (Caplin Steriles Ltd.)

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

**Manufacturer or Supplier's Details** : Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.

**Details of the Supplier of the Safety Data Sheet**

**Emergency Telephone Number** : +91-4467901901/02/03

**SECTION 2: HAZARDS IDENTIFICATION**

**Classification of the substance or mixture**

**GHS Classification** : Not Classified as hazardous

**Label Elements**

**Signal Word** : Not Classified.

**Hazard Statements** : Not classified in accordance with international standards for workplace safety.

**Other Hazards** : An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

**SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS**

**Hazardous**

<b>Ingredient</b>	<b>CAS Number</b>	<b>EU EINECS/ELINCS List</b>	<b>GHS Classification</b>	<b>%</b>
Etomidate	33125-97-2	251-385-9	Repr. 1B (H360D) Lact. (H362) Acute Tox. 4 (H302)	0.2
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*

**SAFETY DATA SHEET**  
**Etomidate Injection, USP**



**Caplin Steriles Limited**

**Additional Information** : \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16**

**SECTION 4: FIRST AID MEASURES**

**Description of 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.

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

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

**Most important symptoms/effects, acute and delayed**

**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.

**Medical Conditions Aggravated by Exposure** : None known

**Indication of immediate medical attention and special treatment needed,**

**Notes to Physician** : None

**SECTION 5: FIRE FIGHTING MEASURES**

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

**Specific hazards arising from the Substance or Mixture**

**Hazardous combustion products** : May include oxides of carbon.

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

**Advice for fire-fighters** : During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**SAFETY DATA SHEET**  
**Etomidate Injection, USP**



**Caplin Steriles Limited**

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**Personal precautions, protective equipment and emergency procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

**Methods and materials for containment and cleaning up**

**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.

**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.

**SECTION 7: HANDLING AND STORAGE**

**Precautions for safe 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.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** : Store as directed by product packaging.

**Specific end use(s)** : Pharmaceutical drug product

**SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION**

**Control Parameters**

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 Injection, USP**  
**Revision date: March 01, 2024**

**SAFETY DATA SHEET**  
**Etomidate Injection, USP**



**Caplin Steriles Limited**

**Exposure Controls**

**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.

**Personal Protective Equipment**

: Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands**

: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes**

: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin**

: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory Protection**

: Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**Physical State**

: Solution

**Color**

: No data available.

**Odor**

: No data available.

**Odor Threshold**

: No data available.

**Molecular Formula**

: Mixture

**Molecular Weight**

: Mixture

**Solvent Solubility**

: No data available.

**Water Solubility**

: No data available.

**pH**

: No data available.

**Melting/Freezing Point (°C)**

: No data available.

**Boiling Point (°C)**

: No data available.

**Etomidate Injection, USP**

**Revision date: March 01, 2024**

**SAFETY DATA SHEET**  
**Etomidate Injection, USP**



Caplin Steriles Limited

**Partition Coefficient: (Method, pH, Endpoint, Value)**

<b>Etomidate</b>	: No data available.
<b>Propylene glycol</b>	: No data available.
<b>Water, purified</b>	: No data available.
<b>Decomposition Temperature (°C)</b>	: No data available.
<b>Evaporation Rate (Gram/s)</b>	: No data available.
<b>Vapour Pressure</b>	: No data available.
<b>Vapor Density</b>	: No data available.
<b>Relative Density</b>	: No data available.
<b>Viscosity</b>	: No data available.

**Flammability**

<b>Auto ignition Temperature (Solid) (°C)</b>	: No data available.
<b>Flammability (Solids)</b>	: No data available.
<b>Flash Point (Liquid) (°C)</b>	: No data available.
<b>Upper Explosive Limits (Liquid) (% by Vol.)</b>	: No data available.
<b>Lower Explosive Limits (Liquid) (% by Vol.)</b>	: No data available.

**SECTION 10: STABILITY AND REACTIVITY**

<b>Reactivity</b>	: No data available.
<b>Chemical Stability</b>	: Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties</b>	: No data available.
<b>Conditions to Avoid</b>	: Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials</b>	: As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products</b>	: No data available

**SECTION 11: TOXICOLOGICAL INFORMATION**

**Information on toxicological effects**

<b>General Information</b>	: The information included in this section describes the potential hazards of the individual ingredients.
<b>Short Term</b>	: Active ingredient may be harmful if swallowed.
<b>Long Term</b>	: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.
<b>Known Clinical Effects</b>	: Common adverse effects include respiratory depression, changes in blood pressure, headache, lightheadedness, dry mouth, dizziness and

**SAFETY DATA SHEET**  
**Etomidate Injection, USP**



**Caplin Steriles Limited**

drowsiness. This compound can cross the placenta in pregnant women.  
Secreted in human breast milk.

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

**Etomidate** : Mouse Oral LD50 650 mg/kg  
Rat Oral LD 50 22,000 mg/kg  
**Propylene glycol** : Mouse Oral LD 50 24,900mg/kg  
Rabbit DermalLD 50 20,800mg/kg

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

**Propylene glycol** : Skin Irritation Rabbit Mild  
: Eye Irritation Rabbit Mild

**Mutagenicity** : There is no data available.

**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

**SECTION 12: ECOLOGICAL INFORMATION**

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

**Toxicity** : No data available.

**Persistence and Degradability** : No data available.

**Bio-accumulative Potential** : Not available.

**Mobility in Soil** : No data available.

**SAFETY DATA SHEET**  
**Etomidate Injection, USP**



Caplin Steriles Limited

**SECTION 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 waste water.

**SECTION 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.

**SECTION 15: REGULATORY INFORMATION**

**Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

**Etomidate**

**CERCLA/SARA 313 Emission reporting** : Not Listed  
**California Proposition 65** : Not Listed  
**Australia (AICS)** : Present  
**EU EINECS/ELINCS List** : 251-385-9

**Propylene glycol**

**CERCLA/SARA 313 Emission reporting** : Not Listed  
**California Proposition 65** : Not Listed  
**Inventory - United States TSCA - Sect. 8(b)** : Present  
**Australia (AICS)** : Present  
**EU EINECS/ELINCS List** : 200-338-0

**Water, purified**

:  
**CERCLA/SARA 313 Emission reporting** : Not listed.  
**California Proposition 65** : Not listed.  
**Inventory - United States TSCA - Sect. 8(b)** : Present  
**Australia (AICS)** : Present  
**REACH - Annex IV - Exemptions from the obligations of Register:** : Present  
**EU EINECS/ELINCS List** : 231-791-2

**Etomidate Injection, USP**  
**Revision date: March 01, 2024**

**SAFETY DATA SHEET**  
**Etomidate Injection, USP**



**Caplin Steriles Limited**

**SECTION 16: ADDITIONAL INFORMATION**

**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

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

**SDS Creation Date** : February 09, 2021

**SDS Revision Date** : March 01, 2024

**Version** : 01

**Prepared by** : Caplin Steriles Limited

**Disclaimer** : The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Caplin Steriles assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

. ----End of Safety Data Sheet---