



SAFETY DATA SHEET

Revision date 17-Mar-2022

Version 3

Page 1 / 10

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name AMIDATE (Etomidate) Injection, Solution (Hospira, Inc.)
Product Code(s) PZ03406
Trade Name: AMIDATE
Chemical Family: Imidazole

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as sedative-hypnotic

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Reproductive toxicity

Category 1B
Effects on or via lactation

2.2. Label elements

Signal word

Danger

Hazard statements

H360D - May damage the unborn child
H362 - May cause harm to breast-fed children

Precautionary Statements

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

SAFETY DATA SHEET

Product Name AMIDATE (Etomidate) Injection, Solution (Hospira, Inc.)
Revision date 17-Mar-2022

Page 2 / 10
Version 3



2.3. Other hazards

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 require the inclusion of all known hazards of the product or its ingredients 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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Propylene glycol (CAS #: 57-55-6)	*		200-338-0	Not classified as hazardous	Not Listed	No data available	No data available
Etomidate (CAS #: 33125-97-2)	0.2		251-385-9	Repr. 1B (H360D) Lact. (H362) Acute Tox. 4 (H302)	Not Listed	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm

SAFETY DATA SHEET

Product Name AMIDATE (Etomidate) Injection, Solution (Hospira, Inc.)
Revision date 17-Mar-2022

Page 3 / 10
Version 3

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Propylene glycol 57-55-6	20000	20800	No data available	No data available	No data available

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. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
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	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, carbon dioxide, water spray or alcohol-resistant foam.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous combustion products	May include oxides of carbon.

5.3. Advice for firefighters

Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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Section 6: ACCIDENTAL RELEASE MEASURES

SAFETY DATA SHEET

Product Name AMIDATE (Etomidate) Injection, Solution (Hospira, Inc.)
Revision date 17-Mar-2022

Page 4 / 10
Version 3

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment Keep away from incompatible materials.

Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on 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 thoroughly after handling. 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.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Etomidate

Pfizer OEL TWA-8 Hr: 4 µg/m³

Propylene glycol

Ireland

10 mg/m³
150 ppm
470 mg/m³
STEL: 1410 mg/m³
STEL: 30 mg/m³
STEL: 450 ppm
7 mg/m³

Latvia

SAFETY DATA SHEET

Product Name AMIDATE (Etomidate) Injection, Solution (Hospira, Inc.)
Revision date 17-Mar-2022

Page 5 / 10
Version 3

Poland	100 mg/m ³
Russia	MAC: 7 mg/m ³
United Kingdom	TWA: 150 ppm
	TWA: 474 mg/m ³
	TWA: 10 mg/m ³
	STEL: 450 ppm
	STEL: 1422 mg/m ³
	STEL: 30 mg/m ³

8.2. 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.
Environmental exposure controls	No information available.
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).
Eye/face protection	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.).
Hand protection	Impervious gloves (e.g. Nitrile, etc.) are 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.).
Skin and body protection	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.).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solution
Color	No information available
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture
Property	Values
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available

SAFETY DATA SHEET

Product Name AMIDATE (Etomidate) Injection, Solution (Hospira, Inc.)
Revision date 17-Mar-2022

Page 6 / 10
Version 3

Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

SAFETY DATA SHEET

Product Name AMIDATE (Etomidate) Injection, Solution (Hospira, Inc.)
Revision date 17-Mar-2022

Page 7 / 10
Version 3

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.
Acute toxicity Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation Based on available data, the classification criteria are not met.
Skin corrosion/irritation Based on available data, the classification criteria are not met.
Respiratory or skin sensitization Based on available data, the classification criteria are not met.
STOT - single exposure Based on available data, the classification criteria are not met.
STOT - repeated exposure Based on available data, the classification criteria are not met.
Reproductive toxicity Based on available data, the classification criteria are not met.
Germ cell mutagenicity Based on available data, the classification criteria are not met.
Carcinogenicity Based on available data, the classification criteria are not met.
Aspiration hazard Based on available data, the classification criteria are not met.

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

Propylene glycol

Rat Oral LD 50 22,000 mg/kg
Mouse Oral LD 50 24,900 mg/kg
Rabbit Dermal LD 50 20,800 mg/kg

Etomidate

Mouse Oral LD50 650 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Propylene glycol	= 20 g/kg (Rat)	= 20800 mg/kg (Rabbit)	-

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

Propylene glycol

Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

Reproduction & Development Toxicity: (Duration, 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

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

SAFETY DATA SHEET

Product Name AMIDATE (Etomidate) Injection, Solution (Hospira, Inc.)
Revision date 17-Mar-2022

Page 8 / 10
Version 3

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

12.1. Toxicity

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
Propylene glycol	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. 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 wastewater 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.

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.

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

SAFETY DATA SHEET

Product Name AMIDATE (Etomidate) Injection, Solution (Hospira, Inc.)
Revision date 17-Mar-2022

Page 9 / 10
Version 3

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

Propylene glycol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-338-0
AICS	Present

Etomidate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	251-385-9
AICS	Present

Chemical name	French RG number	Title
Propylene glycol 57-55-6	RG 84	-

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

SAFETY DATA SHEET

Product Name AMIDATE (Etomidate) Injection, Solution (Hospira, Inc.)
Revision date 17-Mar-2022

Page 10 / 10
Version 3

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under 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.
Reason for revision	Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.
Revision date	17-Mar-2022
Prepared By	Pfizer Global Environment, Health, and Safety

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