



MATERIAL SAFETY DATA SHEET

Product Name: Ketamine Hydrochloride Injection, USP **CIII**

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Responsible Party
Name and Address: Putney, Inc.
400 Congress Street, Suite 200
Portland, ME 04101
USA

Emergency Telephone: Putney, Inc.
1-866-683-0660

Product Name: Ketamine Hydrochloride Injection, USP

Synonyms: None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name: Ketamine Hydrochloride

Chemical Formula: $C_{13}H_{16}Cl_2NO$

Component	Approximate Quantity	CAS Number	RTECS Number
Ketamine Hydrochloride	101 mg/mL	1867-66-9	GW I400000
Benzethonium Chloride	0.10 mg/mL	121-54-0	204-479-9
Water	q.s. to 1.0 mL	7732-18-5	ZC0110000

3. HAZARD INFORMATION

Emergency Overview: In clinical use, this material is used as a non-barbiturate anesthetic. Possible target organs include the central nervous system, skin, eyes, respiratory tract, gastrointestinal tract and possible fetus.

Occupational Exposure: Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

NOTE: The U. S. Department of Labor, Occupational Safety & Health Administration published a Hazard Information Bulletin dated

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January 12, 1989 in which they stated that the Food and Drug Administration notified OSHA of a reported human exposure and adverse drug reaction to Vetalar (ketamine hydrochloride). Approximately 75 mg of Vetalar was accidentally squirted in the eye of a veterinary assistant and within a few minutes the individual became unconscious which lasted about 10 minutes. She was treated and fully recovered after two and one-half hours, but was still lethargic.

Signs and Symptoms: No signs or symptoms from occupational exposure are known. Clinical data suggests the following: incoordination, increased blood pressure, confusion, psychiatric changes, fast heart rate, gastrointestinal upset.

Medical Conditions Aggravated by Exposure: Hypersensitivity to the material and/or similar materials. Pre-existing ailments in the following organs: eyes, skin, gastrointestinal system, cardiovascular system, respiratory system.

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.

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5. FIRE FIGHTING MEASURES

Flammability: Non-flammable

Fire & Explosion Hazard: None

Extinguishing Media: 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: Absorb with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling: Protect from light by retaining in carton until contents have been used.

Storage: No special storage required for hazard control. For product protection, store at controlled room temperature of 68-77°F (20-25°C).

Special Precautions: Protect from freezing, light and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines:

Component	Exposure Limits	
	OSHA-PEL	ACGIH-TLV
Ketamine Hydrochloride	8 Hour TWA: Not Established	8 Hour TWA: Not Established

NOTES:

OSHA-PEL: US Occupational Safety and Health Administration - Permissible Exposure Limit

ACGIH-TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value

TWA: 8 Hour Time Weight Average

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Respiratory Protection: Respiratory protection is not needed during normal product use.

Skin Protection: If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.

Eye Protection: Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.

Accidental Needle Sticks: Care should be taken to avoid accidental needle penetrations. Contact a physician immediately should such an incident occur.

Engineering Controls: Engineering Controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State: Clear, colorless to slightly yellow solution

Odor: Not Determined

Boiling Point: Approximately that of water (100°C, 212°F)

Freezing Point: Approximately that of water (0°C, 32°F)

Vapor Pressure: Approximately that of water (17.5mm Hg at 20°C)

Vapor Density (Air=1): Not Applicable

Evaporation Rate: Not Applicable

Bulk Density: Not Determined

Specific Gravity: Approximately that of water (1.0)

Solubility: Water

pH: 3.5 to 5.5

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under standard use and storage conditions.

Incompatibilities: Not Determined

Hazardous
Decomposition Products: Toxic fumes of Cl⁻, HCl, and nitrogen oxides

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Hazardous Polymerization: Not Determined

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral:

Ingredient	Percent	Test Type	Value	Units	Species
Ketamine Hydrochloride	100	LD50	447 - 670	Mg/kg	Rats

LD50 is the dosage producing 50% mortality.

Product contains between approximately 5 - 10% Ketamine Hydrochloride

Mutagenicity: Not Determined

Target Organ Effects: In clinical use target organ effects include the central nervous system, cardiovascular system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not Available

13. DISPOSAL CONSIDERATIONS

Waste Disposal: 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

DOT: Not Regulated

ICAO/IATA:
(Air Transport) Not Controlled

IMDG: Not Regulated

Note: DOT = U. S. Department of Transportation
IMDG = International Maritime Dangerous Goods

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15. REGULATORY INFORMATION

TSCA Status: Not Regulated

CERCLA Status: Not Regulated

SARA Status: Not Regulated

RCRA Status: Not Regulated

PROP 65 (California): Not Regulated

Notes: TSCA = Toxic Substance Control Act

CERCLA = U. S. EPA Law Comprehensive Environmental Response,
Compensation and Liability Act

SARA = Superfund Amendments and Reauthorization Act

RCRA = U. S. EPA, Resource Conservation and Recovery Act

Prop 65 = California Proposition 65

16. OTHER INFORMATION

Date Prepared: April 15, 2010

Disclaimer:

The above information is based on information available at the time of preparation and not the result of actual tests or testing conducted by the license holder. Putney does not assume responsibility for injury or damages resulting from its use and it does not constitute an express or implied warranty for the product. The product should be used in accordance with the product labeling.

Version 1: 26 Aug 2010

Version 2: 31 July 2012

Version 3: 11 February 2013

Version 4: 10 April 2013