



300 Northfield Road
 Bedford, OH 44146
 Telephone: (440) 232-3320
 -or- (800) 562-4797

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Ketamine Hydrochloride Injection, USP (10mL; 50mg/mL)
Chemical Names: (®)-2-(0-Chlorophenyl)-2-(methylamino)cyclohexanone hydrochloride
Synonyms: Ketalar®; Ketamine Hydrochloride, Calipsol, CI 581, Vetalar
Manufacturer's Name: BEN VENUE LABORATORIES, INC.
Address: 300 NORTHFIELD ROAD
 BEDFORD, OH 44146
Emergency Telephone Number: Chemtrec: 1(800)424-9300
Telephone Number for Info.: (440)232-3320 or (800)562-4797
Medical Emergency: Professional Services: 1(800)521-5169
Date Prepared: June 19, 1996
Date Revised: December 18, 2001

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Ketamine Hydrochloride	5.77	1867-66-9	NONE	NONE	25 mcg/m3 0.2 mg/m3 (SKIN)
Benzethonium Chloride	0.01	121-54-0	NONE	NONE	NONE
Water for Injection	94.22	7732-18-5	NONE	NONE	NONE

Ketamine is a general anesthetic that is a Schedule III controlled substance. Ketamine is a sterile injectable liquid drug provided in a vial.

Section III - HEALTH HAZARD DATA

Routes of Entry: Product may be absorbed via inhalation or skin or eye absorption.
Health Hazard (Acute & Chronic): Ketamine is a general anesthetic for diagnostic and surgical procedures. Product affects the central nervous and circulatory systems. Exposure may elevate blood pressure and increase pulse rate. May cause allergic reaction.
Carcinogenicity: NTP? NO IARC Monographs? NONE
 OSHA Regulated? NO
Signs & Symptoms of Exposure: Nausea, vomiting, tingling, numbness, tiredness, and muscle movements may be observed. May irritate eyes, skin, and respiratory tract. Allergic reactions are possible.
Medical Conditions Generally Aggravated by Exposure: Exposure may elevate blood pressure.
BVL Hazard Category: 3

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 minutes.

Skin Exposure: Wash skin with cool, soapy water.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately.

If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately.

If necessary, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not Applicable **LEL:** NA **UEL:** NA

Flammable Limits: Not Applicable

Extinguishing Media: Use water or an ABC multi-purpose extinguisher

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Absorb Ketamine Hydrochloride with absorbent materials and dispose according to local, state, and federal guidelines.

Release to Air: If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation.

Release to Water: Refer to local water authority. Drain disposal is not recommended; however, refer to local state and federal disposal guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above. Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

Waste Disposal Method: Incineration in an approved incinerator is recommended.

Precautions to be taken in handling and storing: Refer to local, state, and federal rules.

Other Precautions: None

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Ventilation: Handle product in a well-ventilated area.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses or goggles

Other Protective Clothing or Equipment: Lab coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking while handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Liquid

Specific Gravity: 1.014

Appearance and Odor: Clear, colorless to slightly yellowish liquid with no odor

Melting Point: Not Applicable

Boiling Point: Not available

Evaporation Rate: Not available

Vapor Pressure: Not available

Solubility in Water: Water soluble

Vapor Density: Not available

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable materials

Incompatibility (Materials to Avoid): Strong oxidizers and water reactive materials

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include carbon monoxide, carbon dioxide, and sulfur oxides.

Hazardous Polymerization: Will not occur

Conditions to Avoid: Storage with oxidizers or water-reactive materials

Section XI - TOXICOLOGICAL INFORMATION

For Ketamine Hydrochloride

LD₅₀ rat, oral = 447 mg/kg

LD₅₀ rat, intraperitoneal = 224 mg/kg

LD₅₀ mouse, oral = 617 mg/kg

LD₅₀ mouse, intraperitoneal = 224 mg/kg

LD₅₀ rat, intravenous = 59 mg/kg

LD₅₀ mouse, intramuscular = 356 mg/kg

LD₅₀ mouse, intravenous = 56 mg/kg

LD₅₀ guinea pig, intramuscular = 361 mg/kg

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Ketamine. Handle in a manner to prevent spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted incinerator. Ketamine is a Schedule III controlled substance and requires documentation of disposal.

Review local, state, and federal regulations for your regulatory area.

Section XIV - TRANSPORTATION INFORMATION

Ketamine Hydrochloride Injection is not a D.O.T. hazardous material.

Ketamine Hydrochloride Injection is not a Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed?: NO
RCRA listed?: NO
Ketamine is a Schedule III Controlled Substance

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician.
This MSDS does not address the therapeutic use of this material.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.