

# SAFETY DATA SHEET

## 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Ketaved<sup>®</sup> Injection  
**Product No.:** VINV-KETA-0VED  
**GHS Product Identifier:** Not applicable  
**Synonyms:** Ketamine hydrochloride for injection

Molecular Formula: Mixture, not applicable  
Molecular Weight: Mixture, not applicable  
CAS Number: Mixture, not applicable  
Chemical Family: Anesthetic

**Manufacturer:**  
Boehringer Ingelheim Vetmedica, Inc.  
5<sup>th</sup> Street NW  
PO Box 518  
Fort Dodge, IA 50501  
Telephone: (515) 955-4600

**Transportation Emergency:** For Chemical  
Emergency Spill, Leak, Fire, Exposure, or 800  
Accident Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300  
Outside USA and Canada: +1 703-527-3887  
(collect calls accepted)

**Medical Emergency (24HR):** (866) 638-2226  
**Non-Emergency Telephone:** (800) 821-7467

**Intended Use:** Indicated as an anesthetic  
for cats and for restraint in subhuman primates.

## 2. HAZARDS IDENTIFICATION

### Emergency Overview

**Physical State:** Liquid  
**Color:** Yellowish  
**Odor:** Slight



**WARNING! Harmful if swallowed.**  
**For use in felines and subhuman primates only.**

**Not for human use.**

**Allergic reactions can occur.**

**Precautionary Statements:**

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Keep only in original container.

Keep at a temperature not exceeding 30°C (86° F).

Store out of direct sunlight.

Fire-fighting: Use foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Wear suitable gloves and eye/face protection.

Spills: Cover with absorbent or contain. Collect and incinerate.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed, seek medical advice immediately and show this container or label.

In case of contact with eyes, flush with gently flowing fresh water thoroughly.

Dispose of contents and container in accordance with applicable local authority requirements.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

**Potential Health Effects**

**Inhalation:** Not expected to be an inhalation hazard with prescribed use.

**Eye Contact:** Not expected to be a hazard to the eye with prescribed use. May cause eye irritation if exposed. Exposure may cause eye tearing, redness and discomfort.

**Skin Contact:** Not expected to be a hazard to the skin with prescribed use. Prolonged or repeated contact may cause itching, redness, and rash in some individuals or animals.

**Ingestion:** Harmful if swallowed. Exposure may cause vomiting, nausea or other systemic effects. Anesthetics can cause respiratory depression which if not monitored, can cause death.

**Chronic Health Effects:** Prolonged and repeated exposure may cause hypersensitization in sensitive animals. Prolonged and repeated exposure may cause adverse effects to the gastrointestinal tract and kidneys. Possible reproductive hazard – may cause adverse effects on the embryo, fetus or newborn.

**Injection:** Swelling at injection site may occur.

**Target Organ(s):** Central nervous system

**OSHA Regulatory Status:** Hazardous (exempt)

**Environment:** No data available

Components not listed are not hazardous or are below reportable limits.

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Ketamine hydrochloride	217-484-6	1867-66-9	< 15%	Xn; R22	----

The full texts for all R-Phrases are displayed in Section 16.

#### 4. FIRST AID MEASURES

**General:** Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

**Inhalation:** Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

**Eye Contact:** Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

**Skin Contact:** Wash with soap and water. Get medical attention if symptoms occur.

**Ingestion:** Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

**Injection:** In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

**Note to Physician:** For use in felines and subhuman primates only. Not for human use.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish with water spray, alcohol foam, dry chemical, carbon dioxide

**Unsuitable Extinguishing Media:** None known

**Special Fire Fighting Procedures:** Wear self-contained breathing apparatus and protective clothing.

**Unusual Fire & Explosion Hazards:** None known.

**Hazardous Combustion Products:** Carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Wear appropriate personal protective equipment (See Section 8).

**Spill Cleanup Methods:** STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Absorb or cover with dry earth, sand or other non-combustible

material. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

**Environmental Precautions:** Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

## 7. HANDLING AND STORAGE

**Handling:** HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Avoid accidental injection. Wash hand thoroughly after handling.

**Storage:** Keep only in the original container. Store at 20°-25° C (68°-77° F). Store out of direct sunlight. Store away from foodstuffs.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Limits:** None Established.

**Engineering Controls:** Not generally required when handling vials or containers. Good ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

**Respiratory Protection:** Not generally required when handling vials or containers. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

**Europe:** Wear appropriate personal protective equipment according to the Council Directive 89/686/EEC (4) and the appropriate CEN standards.

**PERSONAL PROTECTIVE EQUIPMENT:** Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely wear:

**Eye Protection:** Wear safety glasses with side shields (or goggles).

**Hand Protection:** Wear suitable gloves.

**Skin Protection:** Wear lab coat, apron or appropriate clothing to prevent skin contact.

**Hygiene Measures:** Eye bath, washing facilities

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Color:** Yellowish

**Odor:** Not applicable

**Odor Threshold:** No data available

**Physical State:** Liquid

**pH:** 3.5 to 5.5 (acidic)

**Melting Point:** 0°C (32°F) based on data for: Water for injection

**Freezing Point:** Not applicable

**Boiling Point:** 100°C (212°F)

**Flash Point:** Not flammable

**Flammability Limit – Upper (%):** No data available  
**Flammability Limit – Lower (%):** No data available  
**Evaporation rate:** Not applicable  
**Vapor Pressure:** 18 mm of Hg (@ 20°C) (Water for injection)  
**Vapor Density (Air=1):** No data available  
**Viscosity:** Not applicable  
**Specific Gravity:** 1 (water = 1) (Water for injection)  
**Solubility:** Soluble in cold and hot water  
**Partition Coefficient (n-Octanol/water):** No data available  
**Autoignition Temperature:** Not applicable  
**Decomposition Temperature:** Not applicable

## 10. STABILITY AND REACTIVITY

**Stability:** Stable.

**Conditions to Avoid:** High temperatures

**Incompatible Materials:** Strong oxidizing agents, reducing agents

**Hazardous Decomposition Products:** Carbon dioxide, carbon monoxide, nitrogen oxides, hydrogen chloride

**Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

## 11. TOXICOLOGICAL INFORMATION

### Specified Substances

#### Acute Toxicity

Chemical Name	Test Results
Ketamine hydrochloride	Oral LD50 (rat): 447 mg/kg Oral LD50 (mouse): 617 mg/kg

**Listed Carcinogens:** None listed.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity:** No data available  
**Persistence and degradability:** No data available  
**Mobility in soil:** No data available  
**Other adverse effects:** No data available

Germany WGK: Ketamine hydrochloride: ID 3231: WGK 3 (severely water-endangering)

### 13. DISPOSAL CONSIDERATIONS

**General Information:** Dispose of in accordance with local, state, federal, national or international regulations.

**Disposal Methods:** Drug Enforcement Administration controlled substances must be destroyed following DEA Guidelines for witnessed destruction of the reclamation. Disposal by incineration is recommended. Do not empty into drains. Dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by disposal.

**III** is a DEA Schedule III controlled substance.

**RCRA Information:** Not applicable

### 14. TRANSPORT INFORMATION

**DOT:** Not Regulated

**TDG:** Not Regulated

**ADR/RID:** Not Regulated

**IATA:** Not Regulated

**IMDG:** Not Regulated

### 15. REGULATORY INFORMATION

**Canadian Controlled Products Regulations:** This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

**WHMIS Classification:** D1B

**Inventory Status** This material is listed on the following inventories: AICS, EINECS, PICCS and NZIoC.

This material is **not** listed on the following inventories: TSCA, DSL, IECSC, ENCS and KECI. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

#### US Regulations

**FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.**

**CERCLA Hazardous Substance List (40 CFR 302.4):** None listed.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):** None listed.

**Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):** None listed.

**Drug Enforcement Administration (DEA):** Ketamine Hydrochloride is a DEA Schedule III controlled substance.

**SARA Title III**

**Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):** None listed.

**Section 311/312 (40 CFR 370):**

Acute (Immediate)     Chronic (Delayed)     Fire  
 Reactive     Pressure Generating

**Section 313 Toxic Release Inventory (40 CFR 372):** None listed.

**State Regulations**

**California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):** None listed.

**Massachusetts Right-To-Know List:** None listed.

**Minnesota Hazardous Substances List:** None listed.

**New Jersey Right-To-Know List:** None listed.

**Pennsylvania Right-To-Know List:** None listed.

**Rhode Island Right-To-Know List:** None listed.

**European Regulations**

**Austria MAK List (Annex I):** None listed.

**Denmark (Annex 3.6):** None listed.

**Germany (Dangerous Substances Ordinance 2004, Annex III):** None listed.

**Norway (List of Dangerous Substance):** None listed.

**Sweden (Annex 3):** None listed.

**Switzerland (Toxins List 1):** None listed.

**16. OTHER INFORMATION**

**Hazard Ratings**

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	2*	1	0

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Ketamine hydrochloride	217-484-6	1867-66-9	< 15%	Xn; R22	----

\* – Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

**EU Symbol and R Phrase Definitions**

Xn – Harmful

R22 – Harmful if swallowed.

**ABBREVIATIONS:**

BIV – Boehringer Ingelheim Vetmedica, Inc.

AIHA – American Industrial Hygiene Association mppcf – million particles/cubic foot

N/A – Not applicable.

N/E – Not established.

**References:**

- 1 Ketaved<sup>®</sup> Injection MSDS and Package Insert.
- 2 Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
- 3 GHS Manual

**Revision Information:** New SDS

**Prepared by:** Boehringer Ingelheim Vetmedica, Inc.

**Issue Date:** 06/01/2015

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