# SAFETY DATA SHEET



## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

**Product Identifier**

**Material Name: Ketamine Hydrochloride Injection**

**Trade Name:** KETASET; Rogarsetic; Vetalar
**Synonyms:** Ketaset Injectable
**Chemical Family:** Mixture

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against**

**Intended Use:** Veterinary product used as anesthetic agent.

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

**Zoetis Inc.**
**100 Campus Drive, P.O. Box 651**
**Florham Park, New Jersey 07932 (USA)**
**Rocky Mountain Poison Control Center Phone: 1-866-531-8896**
**Product Support/Technical Services Phone: 1-800-366-5288**

**Zoetis Belgium S.A.**
**Mercuriusstraat 20**
**1930 Zaventem**
**Belgium**

**Emergency telephone number:**
**CHEMTREC (24 hours): 1-800-424-9300**
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

**Appearance:** Colorless to pale yellow solution

**Classification of the Substance or Mixture**

**GHS - Classification**

Acute Oral Toxicity: Category 5

**EU Classification:**

EU Indication of danger: Not classified

**Label Elements**

**Signal Word:** Warning
**Hazard Statements:** H303 - May be harmful if swallowed

**Precautionary Statements:** P312 - Call a POISON CENTRE/doctor/physician if you feel unwell

**Other Hazards**

**Short Term:** Anesthetic drug: may cause central nervous system and cardiovascular system May cause eye irritation. May be harmful if absorbed through the skin. (based on components) .

**Known Clinical Effects:** Ketamine is an anesthetic agent which is known to cause double vision, motor incoordination, delirium, hallucinations, irrational behavior, and temporary elevation of blood pressure and pulse rate.

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---|---|---|---|---|---|
| Ketamine hydrochloride | 1867-66-9 | 217-484-6 | Xn,R22 | Acute Tox. 4,H302 | 10 |
| Benzethonium chloride | 121-54-0 | 204-479-9 | Not Listed | Not Listed | 0.01 |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---|---|---|---|---|---|
| Water for Injection | 7732-18-5 | 231-791-2 | Not Listed | Not Listed | 90 |

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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

## 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**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.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both 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 the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

## 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

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

**Advice for Fire-Fighters**

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 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 Material 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.

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling**

Minimize generating airborne mists and vapors. Avoid breathing mist or aerosols. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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. Keep away from heat, sparks, and flame. Avoid accidental injection.

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Specific end use(s):** No data available

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

**Ketamine hydrochloride**

**Zoetis OEL TWA 8-hr** 0.2 mg/m³, Skin

**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.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Wear impervious gloves if skin contact is possible.

**Eyes:** Safety glasses or goggles

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

**Respiratory protection:** 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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Liquid solution
**Color:** Colorless to Pale yellow
**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
**Solubility:** Soluble: Water
**pH:** 3.5-5.5
**Melting/Freezing Point (°C):** No data available
**Boiling Point (°C):** No data available.
**Partition Coefficient: (Method, pH, Endpoint, Value)**
No data available
**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available
**Vapor Pressure (kPa):** No data available
**Vapor Density (g/ml):** No data available
**Relative Density:** No data available
**Specific Gravity:** 1.008 - 1.028
**Viscosity:** No data available

**Flammablity:**
**Autoignition Temperature (Solid) (°C):** No data available
**Flammability (Solids):** No data available
**Flash Point (Liquid) (°C):** >93
**Upper Explosive Limits (Liquid) (% by Vol.):** No data available
**Lower Explosive Limits (Liquid) (% by Vol.):** No data available
**Polymerization:** Will not occur

## 10. STABILITY AND REACTIVITY

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

## 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**
**General Information:** The information included in this section describes the potential hazards of the individual ingredients. Toxicological properties of the formulation have not been investigated.

# 11. TOXICOLOGICAL INFORMATION

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

**Ketamine hydrochloride**
Rat Oral LD50 447 mg/kg
Mouse Oral LD50 617mg/kg
Rat IV LD50 58.9mg/kg
Mouse IV LD50 55.9mg/kg

**Benzethonium chloride**
Rat Oral LD50 368mg/kg
Rat Subcutaneous LD50 119mg/kg
Rat IV LD50 19mg/kg

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

**Benzethonium chloride**
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Ketamine hydrochloride**
6 Week(s) Rat Intravenous 10 mg/kg/day NOAEL No effects at maximum dose
6 Week(s) Dog Intramuscular 40 mg/kg/day NOAEL No effects at maximum dose

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Ketamine hydrochloride**
Reproductive & Fertility Rat Intravenous 60 NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Intramuscular 120 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Mouse Intravenous 300 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rabbit Intramuscular 24 mg/kg/day NOAEL Not Teratogenic

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Ketamine hydrochloride**
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
*In Vitro* Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

## 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 wastewater.

## 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.

## 15. REGULATORY INFORMATION

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

**Canada - WHMIS: Classifications**
**WHMIS hazard class:**
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

**Water for Injection**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |

## 15. REGULATORY INFORMATION

| | |
|---|---|
| **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 |

**Ketamine hydrochloride**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **U.S. Drug Enforcement Administration:** | III |
| **Australia (AICS):** | Present |
| **EU EINECS/ELINCS List** | 217-484-6 |

**Benzethonium chloride**

| | |
|---|---|
| **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** | 204-479-9 |

**Additional Information:** U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule III. As per 21 CFR 1302, Labeling and packaging requirements for controlled substances, the label should include the symbol "CIII".

## 16. OTHER INFORMATION

**Text of R phrases and GHS Classification abbreviations mentioned in Section 3**

H302 - Harmful if swallowed

Xn - Harmful

R22 - Harmful if swallowed.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication
Zoetis Global Risk Management

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**End of Safety Data Sheet**