SAFETY DATA SHEET



1. Identification

Product identifier Ketamine Hydrochloride Injection

Other means of identification

Synonyms Ketaset® * KETASET * Rogarsetic * Vetalar * Ketaset Injectable

Recommended use Veterinary product used as anesthetic agent

Recommended restrictions Not for human use Manufacturer/Importer/Supplier/Distributor information

Company Name (USA) Zoetis Inc.

10 Sylvan Way

Parsippany, New Jersey 07054 (USA)

Rocky Mountain Poison &

Drug Safety

1-866-531-8896

Product Support/Technical

Services

1-888-963-8471

Emergency telephone

numbers

CHEMTREC (24 hours): 1-800-424-9300

International CHEMTREC (24 hours): +1-703-527-3887

Company Name (CA) Zoetis Canada Inc.

> 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7

Emergency telephone

number

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail productsupport@zoetis.com

1-800-461-0917 **Product Support**

All Safety Data Sheets are available via our Zoetis Canada website at

https://www.zoetis.ca/sds/sds.aspx

Not available. **Supplier**

2. Hazard identification

Physical hazards Not classified. **Health hazards** Not classified. **Environmental hazards** Not classified.

Label elements

Hazard symbol None. Signal word None.

The mixture does not meet the criteria for classification. **Hazard statement**

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Supplemental information Anesthetic drug: may cause central nervous system and cardiovascular system effects. May be

absorbed through the skin and cause systemic effects.

Other hazards None known.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Water for Injection		7732-18-5	90
Ketamine Hydrochloride		1867-66-9	10
Benzethonium chloride		121-54-0	0.01

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation For breathing difficulties, oxygen may be necessary.

Skin contact

Wash off immediately with soap and plenty of water. Get medical advice/attention if you feel unwell. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing

before reuse. May be absorbed through the skin and cause systemic effects. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water.

Get medical attention immediately.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove

contact lenses, if present and easy to do.

Ingestion Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the

instruction of medical personnel. Never give anything by mouth to an unconsious person.

Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. 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.

Indication of immediate medical attention and special treatment needed

Monitor respiratory, cardiac and central nervous system. Anesthetic drug: may cause central nervous system and cardiovascular system effects.

General informationIF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS.

5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

Move containers from fire area if you can do so without risk.

equipment/instructions
Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazardsNo unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapour. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. Avoid contact with eyes, skin, and clothing. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Avoid release to the environment. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Ensure adequate ventilation. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Environmental precautions

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

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7. Handling and storage

Precautions for safe handling Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged

exposure. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Wash contaminated clothing before reuse. Observe good industrial hygiene practices. Use with adequate

ventilation. Avoid accidental injection.

Conditions for safe storage, including any incompatibilities

Store locked up. Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Keep container tightly closed. Store in a well-ventilated place. Do not allow material to freeze. Keep out of the reach of children. Store away from incompatible materials (see Section 10 of the SDS). Protect from light. Storage Temperature: 15-30°C (59-86°F).

8. Exposure controls/personal protection

Occupational exposure limits

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Components	Туре	Value	
Ketamine Hydrochloride (CAS 1867-66-9)	TWA	0.2 mg/m³	

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Ketamine hydrochloride STEL: 0.5 mg/m3; Skin (May be absorbed through the skin and cause

systemic effects.)

Control banding approach

Appropriate engineering

controls

Not available.

Good general 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. Ensure adequate ventilation, especially in confined areas. Engineering controls should be used as the

primary means to control exposures.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Wear impervious gloves if skin contact is possible.

Other Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and

laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation,

wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. 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.

Thermal hazards None known.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective

equipment to remove contaminants.

9. Physical and chemical properties

Appearance Liquid solution.

Physical state Liquid. Form Liquid.

Colorless - Pale yellow.

Odour Not available.
Odour threshold Not available.
pH > 3.5 - < 5.5
Melting point/freezing point Not available.
Initial boiling point and boiling Not available.

range

Flash point >93.3 °C (>200.0 °F)

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

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Upper/lower flammability or explosive limits

Explosive limit - lower (%) Not available. Explosive limit - upper Not available.

(%)

Vapour pressure Not available. Not available. Vapour density Not available. Relative density

Solubility(ies)

Soluble Solubility (water)

Partition coefficient (n-octanol/water)

Not available.

Not available. **Auto-ignition temperature** Not available. **Decomposition temperature Viscosity** Not available.

Other information

Explosive properties Not explosive.

Combustible IIIB estimated Flammability class

Oxidising properties Not oxidising. > 1.01 - < 1.03 Specific gravity

10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

Material is stable under normal conditions. Chemical stability

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Sunlight. Exposure to light. Heat, flames and sparks. Avoid temperatures exceeding the flash

point. Contact with incompatible materials.

Incompatible materials

Hazardous decomposition

products

Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Carbon

oxides. Nitrogen oxides (NOx). May include hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

May be harmful if inhaled. May cause drowsiness and dizziness. Inhalation

Skin contact Prolonged skin contact may cause temporary irritation. May be absorbed through the

skin and cause systemic effects.

Benzethonium chloride Severity: Mild - Severe

Strong oxidising agents.

Eve contact Direct contact with eyes may cause temporary irritation.

Benzethonium chloride

Species: Rabbit Severity: Severe

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of

occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. 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.

Information on toxicological effects

Acute toxicity May be harmful if inhaled. May be harmful in contact with skin. May be harmful if

swallowed.

Product Species Test Results

Ketamine Hydrochloride Injection

Acute Oral

ATE 4545 mg/kg

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Components Species Test Results

Benzethonium chloride (CAS 121-54-0)

Acute

Intravenous

LD50 Rat 19 mg/kg

Oral

LD50 Rat 368 mg/kg

295 mg/kg

Subcutaneous

LD50 Rat 119 mg/kg

Chronic

Dermal

Mouse 2 years Not carcinogenic

Rat 2 years Not carcinogenic

Ketamine Hydrochloride (CAS 1867-66-9)

Acute

Intravenous

LD50 Mouse 55.9 mg/kg

Rat 58.9 mg/kg

Oral

LD50 Mouse 617 mg/kg

Rat 447 mg/kg

Subacute

Intramuscular

NOAEL Dog 40 mg/kg/day, 6 weeks No effects at

maximum dose

Intravenous

NOAEL Rat 10 mg/kg/day, 6 weeks No effects at

maximum dose

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Benzethonium chloride Severity: Mild - Severe

Serious eye damage/eye

irritation

Direct contact with eyes may cause temporary irritation.

Eye contact

Benzethonium chloride

Species: Rabbit

Severity: Severe

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitiser.

Skin sensitisation This product is not expected to cause skin sensitisation.

Germ cell mutagenicityNo data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Mutagenicity

Benzethonium chloride Ames (Salmonella)

Result: Negative

Ketamine Hydrochloride Bacterial Mutagenicity (Ames)

Result: Negative

Species: Salmonella, E. coli

Benzethonium chloride In vitro chromosomal aberration

Result: Negative

Mutagenicity

Ketamine Hydrochloride In Vitro Sister Chromatid Exchange

Result: positive

Species: Chinese Hamster Ovary (CHO) cells

Benzethonium chloride Sister Chromatid Exchange (SCE)

Result: Negative

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Developmental effects Ketamine Hydrochloride

120 mg/kg/day Embryo / Fetal Development, Not Teratogenic

Result: NOAEL Species: Rat

Organ: Intramuscular

24 mg/kg/day Embryo / Fetal Development, Not Teratogenic

Result: NOAEL Species: Rabbit Organ: Intramuscular

300 mg/kg/day Embryo / Fetal Development, Not Teratogenic

Result: NOAEL Species: Mouse Organ: Intravenous

Reproductivity

Ketamine Hydrochloride 60 Reproductive & Fertility, No effects at maximum dose

> Result: NOAEL Species: Rat Organ: Intravenous

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

CAUTION! Anesthetic drug: may cause central nervous system and cardiovascular **Further information**

system effects. Individuals sensitive to this material or other materials in its chemical

class may develop allergic reactions.

12. Ecological information

Avoid release to the environment. Based on available data, the classification criteria are not met **Ecotoxicity**

for hazardous to the aquatic environment.

Components **Species Test Results** Benzethonium chloride (CAS 121-54-0) Aquatic Algae ErC50 Algae 0.3 mg/l, 72 hours Crustacea EC50 Daphnia magna (Water Flea) 0.22 mg/l, 48 hours Acute Fish LC50 Bluegill (Lepomis macrochirus) 1.4 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product. The following information is available for

the individual ingredients.

Biodegradability

Mobility in soil

Percent Degradation (Aerobic Biodegradation)

Benzethonium chloride 0 % OECD 301B Test Duration: 29 days

Bioaccumulative potential No data available.

No data available.

Material name: Ketamine Hydrochloride Injection

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Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions

Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and Not established.

the IBC Code

15. Regulatory information

Canadian regulations

This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Ketamine Hydrochloride (CAS 1867-66-9)

14(1)

Export Control List (CEPA 1999, Schedule 3)

Not listed

Greenhouse Gases

Not listed.

Narcotic Control Regulations (C.R.C., c. 1041) Controlled Drugs and Substances Act, as amended

Ketamine Hydrochloride (CAS 1867-66-9)

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Not applicable.

Material name: Ketamine Hydrochloride Injection

International Inventories

Basel Convention

Country(s) or region Inventory name On inventory (yes/no)*

Australia Australian Inventory of Industrial Chemicals (AICIS)

No

Canada Domestic Substances List (DSL) No

Country(s) or regionInventory nameOn inventory (yes/no)*CanadaNon-Domestic Substances List (NDSL)NoChinaInventory of Existing Chemical Substances in China (IECSC)NoEuropeEuropean Inventory of Existing Commercial ChemicalYes

Substances (EINECS)

EuropeEuropean List of Notified Chemical Substances (ELINCS)NoJapanInventory of Existing and New Chemical Substances (ENCS)NoKoreaExisting Chemicals List (ECL)NoNew ZealandNew Zealand InventoryYes

Philippine Inventory of Chemicals and Chemical Substances

(PICCS)

Taiwan Chemical Substance Inventory (TCSI)

United States & Puerto Rico

Toxic Substances Control Act (TSCA) Inventory

No

16. Other information

Philippines

Issue date23-May-2017Revision date21-August-2023

Version No. 02

List of abbreviations ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).

Disclaimer Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while

it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently

available.

Revision information Identification: Recommended restrictions

First-aid measures: Skin contact

Accidental release measures: Personal precautions, protective equipment and emergency

procedures

Accidental release measures: Methods and materials for containment and cleaning up Handling and storage: Conditions for safe storage, including any incompatibilities

Exposure controls/personal protection: Appropriate engineering controls

Exposure controls/personal protection: Hand protection

Exposure controls/personal protection: Other Physical & Chemical Properties: Multiple Properties

Stability and reactivity: Conditions to avoid Toxicological Information: Toxicological Data

Ecological information: Ecotoxicity

Ecological information: Persistence and degradability

GHS: Classification

Material name: Ketamine Hydrochloride Injection

Version #: 02 Revision date: 21-August-2023 Issue date: 23-May-2017

Yes

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).