


SAFETY DATA SHEET

VetaKet® (ketamine hydrochloride injection, USP) 

1. IDENTIFICATION

Product Identifier: VetaKet® (ketamine hydrochloride injection, USP) 

Synonyms: DL2-(o-Chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride.

National Drug Code (NDC): 59399-114-10

Recommended Use: For Animal Use Only. VetaKet® Injection may be used in cats and subhuman primates for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards: Not classifiable.

Health Hazards:

Acute Toxicity, Oral	Category 5
Serious Eye Damage/Eye Irritation	Category 2A
Skin Corrosion/Irritation	Category 2



Symbol(s):

Signal Word: Warning.

Hazard Statement(s):

H303	May be harmful if swallowed.
H319	Causes serious eye irritation.
H315	Causes skin irritation.

Precautionary Statement(s):

P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

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- P314 Get medical advice/attention if you feel unwell.
- P302 IF ON SKIN: Wash with plenty of water.
+
P352
- P332 If skin irritation occurs: Get medical advice/
+
attention.
P313
- P305 IF IN EYES: Rinse cautiously with water for
+
several minutes. Remove contact lenses, if
P351 present and easy to do. Continue rinsing.
+
P338
- P337 If eye irritation persists: Get medical advice/
+
attention.
P313
- P362 Take off contaminated clothing and wash it
+
before reuse.
P364
- P501 Dispose of contents/container in accordance
with local/regional/national/international
regulations.

Hazards Not Otherwise Classified:
Supplementary Information:

None.
None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Chemical Name	CAS Number	Chemical Formula	Molecular Weight	Percentage
Ketamine Hydrochloride	DL-2-(o-Chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride	1867-66-9	C ₁₃ H ₁₆ ClNO•HCl	274.19	10%

The formula also contains Benzethonium Chloride, 0.1 mg as a preservative; and Water for Injection.

4. FIRST AID MEASURES

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

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Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

As a drug of abuse, reports suggest that ketamine produces a variety of symptoms including anxiety, dysphoria, disorientation, insomnia, flashbacks, hallucinations, and psychotic episodes. Ketamine dependence and tolerance are possible following prolonged administration. In clinical use, blood pressure and pulse rate may be elevated following administration of ketamine alone. However, hypotension and bradycardia have been observed. Arrhythmia has also occurred. Although respiration is frequently stimulated, severe depression of respiration or apnea may occur following rapid intravenous administration of high doses of ketamine. Laryngospasms and other forms of airway obstruction have occurred during ketamine anesthesia. Diplopia and nystagmus have also been noted, as well as a slight elevation in intraocular pressure. In some patients, enhanced skeletal muscle tone may be manifested by tonic and clonic movements sometimes resembling seizures. Anorexia, nausea and vomiting have also been observed.

Medical Conditions Aggravated by Exposure:

Note determined.

Notes to Physician:

Treat supportively and symptomatically.

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5. FIREFIGHTING MEASURES

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or water spray.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: No data available.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment and Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations. Wipe working area surfaces to dryness, and then wash with soap and water.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

Precautions for Safe Handling: In the US, Ketamine is Schedule III controlled substance. Appropriate training and procedures may be required during the routine handling of this product. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light and heat. Store away from oxidizing agents and acids.

Specific End Use: Pharmaceutical drug product.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Ketamine Hydrochloride	TWA	0.2 mg/m ³
	STEL	0.5 mg/m ³

TWA: Time Weighted Average; STEL: Short Term Exposure Limit

Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

Respiratory Protection:

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection:

Avoid contact with eyes. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection:

Wear chemically compatible gloves for handling solutions and ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

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

Physical State/Color:

Clear, colorless to slightly yellow solution.

Odor:

No data available.

Odor Threshold:

No data available.

pH:

3.5 to 5.5.

Melting Point:

No data available.

Freezing Point:

No data available.

Boiling Point:

100°C.

Flash Point:

No data available.

Evaporation Rate:

No data available.

Flammability (solid, gas):

No data available.

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Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No dangerous reaction known under conditions of normal use.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Contact with incompatible materials.
Incompatible Materials:	Strong oxidizing agents.
Hazardous Decomposition Products:	No hazardous decomposition products are known. May include products of carbon, nitrogen and hydrogen chloride.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation:	No data available.
Ingestion:	May be harmful if swallowed.
Skin Contact:	Causes skin irritation.
Eye Contact:	Causes serious eye irritation.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	Tolerance, dependence, respiratory failure, cardiac arrest, seizures, high blood pressure.

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Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Ketamine Hydrochloride	Rat	Oral	LD ₅₀	447 mg/kg
	Mouse	Oral	LD ₅₀	617 mg/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
Ketamine Hydrochloride	Developmental Study	Dog	Intramuscular	2.5 x human dose	Not specified	No adverse effects

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

Aspiration Hazard:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

Narcotic effects.

Systemic Effects:

No data available.

Reproductive Effects:

Studies in animals have not shown that ketamine causes birth defects.

Carcinogenicity:

No data available.

Mutagenicity:

Ketamine hydrochloride was negative in the Ames test for mutagenicity.

National Toxicology Program (NTP):

Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC):

Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA):

Not considered to be a carcinogen.

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12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

Terrestrial Toxicity: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Ketamine Hydrochloride	No

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

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EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Ketamine Hydrochloride	Listed	Listed	Not listed

California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

The vial stopper is not made with natural rubber latex.

See footer of this document for Revision Date and Revision Number.

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