SDS: VetaKet® CIII
(ketamine hydrochloride injection, USP)

SAFETY DATA SHEET

1. Identification

Product Identifier:	VetaKet® CIII (ketamine hydrochloride injection, USP)
Synonyms:	(±)-2-(o-Chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride
National Drug Code (NDC):	59399-114-10
Recommended Use:	For Intramuscular use in Cats and Subhuman Primates Only
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:

Eye Damage / Irritation	Category 2A
Skin Irritation	Category 2
STOT – RE	Category 2

Symbol(s):

Signal Word: Warning.

Hazard Statement(s):

H319	Causes serious eye irritation.
H315	Causes skin irritation.
H373	May cause damage to organs through prolonged or repeated exposure.

Precautionary Statement(s):

P260	Do not breathe dust/fume/gas/mist/vapours/ spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P264	Wash hands thoroughly after handling.

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

Hazards Not Otherwise Classified: None.
Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Ketamine Hydrochloride	1867-66-9	(±)-2-(o-Chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride	$C_{13}H_{16}ClNO•HCl$	274.21	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.

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:	None anticipated from normal handling of this product. 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:	Not determined.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Not determined.

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

Special Protective Equipment/ 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: Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area 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: Handle in accordance with product label and/or product insert information. Ketamine is a general anesthetic that is a Schedule III controlled substance. Additional training may be required for proper handling of controlled substances. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Ketamine Hydrochloride	0.5 mg/m^3 STEL 0.2 mg/m^3 TWA

Engineering Controls: Engineering controls are normally not needed during the normal use of this product.

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:	Not required for the normal use of this product. Safety glasses with side shields are recommended. 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:	Not required for the normal use of this product. Chemically compatible gloves are recommended. For handling solutions, 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:	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Clear colorless liquid solution.
Odor:	None.
Odor Threshold:	No data available.
pH:	3.7.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
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):	No data available.
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: No data available.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.

Incompatible Materials: Oxidizers, acids, bases.

Hazardous Decomposition Products: Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: This product may be absorbed after inhalation.

Ingestion: This product may be absorbed after oral consumption.

Skin Contact: This product may be absorbed dermally.

Eye Contact: This product may be absorbed through the conjunctiva.

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: No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Ketamine Hydrochloride	Rat	Oral	LD_{50}	447 mg/kg
Ketamine Hydrochloride	Mouse	Oral	LD_{50}	617 mg/kg
Ketamine Hydrochloride	Rat	Intravenous	LD_{50}	58.9 mg/kg
Ketamine Hydrochloride	Mouse	Intravenous	LD_{50}	55.9 mg/kg

LD_{50}: Dosage that produces 50% mortality.

Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.
Dermal Irritation: No data available.

Eye Irritation:	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Specific Target Effects:	Based on clinical use, possible target organs include the respiratory system, cardiovascular system, and nervous system.
Reproductive Effects:	None anticipated from normal handling of this product. Male and female rats given five times the average human intravenous dose of ketamine for three consecutive days about one week before mating had a reproductive performance equivalent to that of controls. When given to pregnant rats and rabbits intramuscularly at twice the average human intramuscular dose during the respective periods of organogenesis, the litter characteristics were equivalent to those of controls. A small group of rabbits was given a single large dose (six times the average human dose) of ketamine on Day 6 of pregnancy. The outcome of pregnancy was equivalent in control and treated groups. To determine the effect of ketamine on the perinatal and postnatal period, pregnant rats were given twice the average human intramuscular dose during Days 18 to 21 of pregnancy. Litter characteristics at birth and through the weaning period were equivalent to those of the control animals. There was a slight increase in incidence of delayed parturition by one day in treated dams of this group. Three groups each of mated beagle females were given 2.5 times the average human intramuscular dose twice weekly for the three weeks of the first, second, and third trimesters of pregnancy, respectively, without the development of adverse effects in the pups.
Carcinogenicity:	No data available.
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.
Mutagenicity:	Ketamine hydrochloride was negative in the Ames test for mutagenicity.
Aspiration Hazard:	None anticipated from normal handling of this product.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	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

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	Exempt.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Not listed.
Pennsylvania:	Not listed.
California Proposition 65:	Not listed.

16. Other Information

Revision Date: 07/23/2015

Revision Number: 0

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