



**MATERIAL SAFETY DATA SHEET**

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**SECTION 1 MATERIAL IDENTIFICATION**

**PRODUCT NAME:** Ketalar<sup>®</sup> CIII **DATE OF ISSUE:** 10/29/2008

**FORMULA:** Mixture **SUPERCEDES:** 03/07/2009 **REVISION:** 3.0

**SYNONYMS:** Ketamine Hydrochloride Injection, USP

**NDC #:** 42023-113-10 Ketalar<sup>®</sup> CIII (*ketamine hydrochloride injection, USP*) 10 mg/mL, 20mL MDV  
42023-114-10 Ketalar<sup>®</sup> CIII (*ketamine hydrochloride injection, USP*) 50 mg/mL, 10mL MDV  
42023-115-10 Ketalar<sup>®</sup> CIII (*ketamine hydrochloride injection, USP*) 100mg/mL, 5mL MDV

**MANUFACTURING DIVISION:** JHP Pharmaceuticals, LLC. **ADDRESS:** 870 Parkdale Road **PHONE:** Emergency: 248-656-5400  
Rochester, MI 48307 **Medical Affairs:** 866-923-2474

**SECTION 2 INGREDIENT (S)**

**CAS #:** 1867-66-9 **INGREDIENT NAME:** Ketamine Hydrochloride

**EXPOSURE LIMITS/ GUIDELINES:** No occupational exposure limits established.

**OSHA PEL:** NA

**ACGIH TLV:** NA

**OTHER:** NA

**LISTED AS CARCINOGEN:** No

**SECTION 3 HAZARD IDENTIFICATION**

**HMIS Hazard Ratings:**

**Health Hazard = 2**

**Flammability = 1**

**Reactivity = 0**

**Other: None**

**Key:** 4 = Severe  
3 = Serious  
2 = Moderate  
1 = Slight  
0 = Minimal

**MAJOR HEALTH HAZARDS:**

**POTENTIAL HEALTH EFFECTS:** Harmful if swallowed. Central Nervous System effects.

**SECTION 3**

**HAZARD IDENTIFICATION cont.**

**INHALATION:**

**SHORT TERM EXPOSURE:** Rash, changes in blood pressure, tearing, nausea, vomiting, loss of appetite, difficulty breathing, irregular heartbeat, hallucinations, lack of pain sensation, loss of coordination, visual disturbances.

**LONG TERM EXPOSURE:** ND

**SKIN CONTACT:**

**SHORT TERM EXPOSURE:** Irritation

**LONG TERM EXPOSURE:** ND

**EYE CONTACT:**

**SHORT TERM EXPOSURE:** Irritation.

**LONG TERM EXPOSURE:** ND

**INGESTION:**

**SHORT TERM EXPOSURE:** Changes in blood pressure, tearing, nausea, vomiting, loss of appetite, difficulty breathing, irregular heartbeat, hallucinations, lack of pain sensation, loss of coordination, visual disturbances, unconsciousness and death.

**LONG TERM EXPOSURE:** ND

**SECTION 4**

**FIRST AID INFORMATION**

**THERAPEUTIC CLASS:** General anesthetic

**EYES:** Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

**SKIN:** Wash with soap and water for at least 15 minutes. Remove contaminated clothing and shoes. Get medical attention if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

**INHALATION:** If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

**INGESTION:** If swallowed, drink plenty of water, do NOT induce vomiting. Get immediate medical attention. Induce vomiting only at the instructions of a physician. Do not give anything by mouth to unconscious or convulsive person.

**NOTE TO PHYSICIAN:** For ingestion, consider gastric lavage.

**SECTION 5**

**FIRE AND EXPLOSION DATA**

**FLASH POINT AND METHOD:** Aqueous solution

**EXTINGUISHING MEDIUM:** Carbon dioxide, regular dry chemical, regular foam, water.

**SPECIAL FIRE PROCEDURES:** Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

**HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS:** Thermal decomposition products or combustion: oxides of carbon, oxides of nitrogen, hydrogen chloride.

**FIRE HAZARDS:** Slight

**EXPLOSION HAZARDS:** Slight

**SECTION 6****ACCIDENTAL RELEASE MEASURES****ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:**

Stop leak if possible without personal risk. Small Spills: Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal.

**SECTION 7****HANDLING AND STORAGE**

**STORAGE:** Store and handle in accordance with all current regulations and standards. Store between 15°C and 30°C. Keep in the dark. See original container for storage recommendations. Keep separated from incompatible substances.

**SECTION 8****SPECIAL PROTECTION INFORMATION**

**VENTILATION:** Provide local exhaust or process enclosure ventilation system. Ensure compliance with applicable exposure limits.

**EYE PROTECTION:** Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

**CLOTHING:** Wear appropriate chemical resistant clothing.

**GLOVES:** Wear appropriate chemical resistant gloves.

**RESPIRATOR:** Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.

Any powered, air-purifying respirator with a full face piece and organic vapor and acid gas cartridge(s).

Any chemical cartridge respirator with a full face piece and organic vapor and acid gas cartridge(s).

**For Unknown Concentrations or Immediately Dangerous to Life or Health-**

Any supplied-air respirator with full face piece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply.

Any self-contained breathing apparatus with a full face piece.

**SECTION 9****PHYSICAL AND CHEMICAL DATA**

**PHYSICAL STATE:** Liquid

**APPEARANCE:** Colorless solution

**CHARACTERISTIC ODOR:** NA

**SPECIFIC GRAVITY:** 1.014

**SOLUBILITY:**

**pH:** 3.5 - 5.5

**WATER:** Soluble

**OTHER:** ND

**SECTION 10****STABILITY AND REACTIVITY**

**REACTIVITY:** Stable at normal conditions.

**CONDITIONS TO AVOID:** Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

**INCOMPATIBLES:** Oxidizing materials.

**POLYMERIZATION:** Will not polymerize.

**SECTION 11**

**TOXICOLOGY**

**TOXICITY INFORMATION:**

**KETAMINE HYDROCHLORIDE:**

447 mg/kg oral-rat LD<sub>50</sub>

**ACUTE TOXICITY LEVEL:** Toxic: ingestion

**TARGET ORGANS:** Central nervous system

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** High blood pressure.

**MUTAGENIC DATA:** Available

**REPRODUCTIVE EFFECTS DATA:** Available

**ADDITIONAL DATA:** Interactions with drugs may occur. May impair performance of tasks requiring alertness. The toxicity and health effects are presumed to be essentially the same as the intravenous route of administration. This product may be administered by intravenous or intramuscular routes. May cause fetal harm.

**(Refer to package insert for further information)**

**SECTION 12**

**ECOLOGICAL INFORMATION**

Not available

**SECTION 13**

**DISPOSAL**

Dispose in accordance with all applicable local, state and federal regulations or the authority having jurisdiction.

**SECTION 14**

**TRANSPORTATION**

**SHIPPING REQUIREMENTS AND LIMITATIONS**

**PROPER SHIPPING NAME:** NA      **ID/UN NUMBER:** NA      **CONTAINER SPECIFICATION:** NA

**HAZARD CLASS:** NA      **LABEL:** NA      **PACKAGING GROUP:** NA

**SHIPPING LIMITATIONS:** NA      **MARKING:** NA      **OTHER COMMENTS:** NA

**U.S REGULATIONS:****CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.**SARA TITLE III SECTIONS 302/304 EXTREMELY HAZARDOUS SUBSTANCES:** Not regulated.**SARA TITLE III SECTIONS 311/312 HAZARDOUS CATEGORIES:** Not regulated.

ACUTE: Yes

CHRONIC: No

FIRE: No

REACTIVE: No

SUDDEN RELEASE: No

**SARA TITLE II SECTION 313:** Not regulated.**OSHA PROCESS SAFETY:** Not regulated.**STATE REGULATIONS:****California Proposition 65:** Not regulated**NATIONAL INVENTORY STATUS:****U.S. INVENTORY (TSCA):** This product is exempt.**TSCA 12(b) EXPORT NOTIFICATION:** Not listed.**DEA:** Schedule III

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**NA – NOT APPLICABLE****ND – NO DATA FOUND**

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company to make sure the sheet is the latest one issued.