



# SUPRIYA LIFESCIENCE LTD.

Creating true values that bind global health

## Safety Data Sheet

Product: Ketamine Hydrochloride

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Effective Date: 07/11/2017

Review Date: 06/11/2020

Revision : 01

### Section 1: Chemical Product and Company Identification

**Product Name:** : Ketamine Hydrochloride

**Catalog Codes :** NA

**CAS#:** [1867-66-9]

**RTECS:** NA

**TSCA:** TSCA 8(b) inventory:  
Ketamine Hydrochloride

**CI#:** Not available.

**Synonym:** (2RS)-2-(2-Chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride.

**Chemical Formula:** C<sub>13</sub>H<sub>17</sub>Cl<sub>2</sub>NO

**Use** : Anesthetic

#### Contact Information:

Supriya Lifescience Ltd.

A-5/2, Lote Parshuram M.I.D.C.

Industrial Area

Tal. - Khed, Dist. - Ratnagiri.

Tel. No. : 91-2356-272299

Fax No.: 91-2356-272178

**E-mail id:** [supriya@supriyalifescience.com](mailto:supriya@supriyalifescience.com)

### Section 2: Hazards Identification

#### Classification of the Substance or Mixture

#### GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral (Category 4), H302

Skin irritation (Category 2), H315

Eye irritation (Category 2A), H319

Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335

For the full text of the H-Statements mentioned in this Section, see Section 16.

#### Hazard Statement

:  
Hazard statement(s)  
H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.

**Australian Hazard Classification (NOHSC)**

: Hazardous Substance. Non-Dangerous Goods.



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**Factory**


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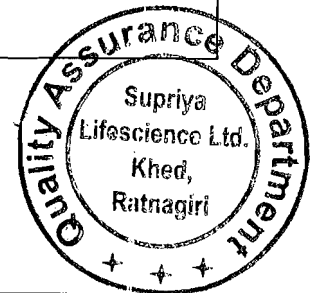
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GOVT. RECOGNISED EXPORT HOUSE



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<b>Pictogram</b>	: 
<b>Signal word</b>	: Warning
<b>Precautionary Statement</b>	:
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.	
P264 Wash skin thoroughly after handling.	
P270 Do not eat, drink or smoke when using this product.	
P271 Use only outdoors or in a well-ventilated area.	
P280 Wear protective gloves/ eye protection/ face protection.	
P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.	
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.	
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.	
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
P312 Call a POISON CENTER or doctor/ physician if you feel unwell.	
P321 Specific treatment (see supplemental first aid instructions on this label).	
P330 Rinse mouth.	
P332 + P313 If skin irritation occurs: Get medical advice/ attention.	
P337 + P313 If eye irritation persists: Get medical advice/ attention.	
P362 Take off contaminated clothing and wash before reuse.	
P403 + P233 Store in a well-ventilated place. Keep container tightly closed.	
P405 Store locked up.	
P501 Dispose of contents/ container to an approved waste disposal plant.	
<b>Hazards not otherwise classified:</b> None	
<b>Ingredients with unknown toxicity</b>	: None
<b>Emergency Overview:</b> Ketamine Hydrochloride Injection is a solution containing Ketamine Hydrochloride, a rapid acting non-barbiturate anesthetic indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation, Ketamine is a general anesthetic that is a Schedule III controlled substance. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Possible target organs include the eyes, respiratory system, cardiovascular system, and central nervous system.	
<b>Occupational Exposure Potential :</b> Information on the absorption of this product via inhalation or skin contact is not available. A void liquid aerosol generation and skin contact	



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**Signs and Symptoms:** None known from occupational exposure. 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. 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 been observed; however, this is not usually severe.

**Section 3: Composition and Information on Ingredients**

Chemical characterization Active pharmaceutical ingredient.

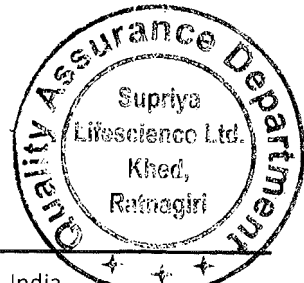
**Composition:**

Components	Percentage	Health hazards	EC-Symbol(s) R-phrase(s)	CAS	REACH No
Ketamine Hydrochloride	100%	--	R-22 R36/37/38	1867-66-9	NA

For the full text of the phrases mentioned in this Section, see Section 16.

**Section 4: First Aid Measures**

**Eye contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation



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persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.  
**Skin contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.  
**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention . If operson is conscious induce vomiting. Never induce vomiting on an unconscious person  
**Ingestion:** If difficulty breathing, administer oxygen. Seek attention of a physician immediately. If necessary, provide artificial respiration

**Section 5: Fire and Explosion Data**

**Extinguishing Media**

**Suitable extinguishing media:**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Special hazards arising from the substance or mixture:**

Carbon oxides, nitrogen oxides (NOx), Hydrogen chloride gas

**Precautions for fire-fighters:**

Wear self contained breathing apparatus for fire fighting if necessary.

**Section 6: Accidental Release Measures**

**Spill Cleanup and Disposal:** Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

**Section 7: Handling and Storage**

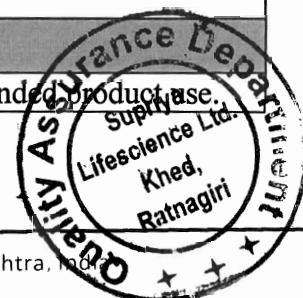
**Handling:** Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

**Storage:** No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert. "Store protected from light"

**Special Precautions:** No special precautions required for hazard control.

**Section 8: Exposure Controls/Personal Protection**

**Respiratory protection :** Respiratory protection is normally not needed during intended product use.



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However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEP A cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirator that offer high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 191 0.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin Protection:** If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye Protection:** Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

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

**Components with workplace control parameters/exposure limits if applicable :**

**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. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective**

**Equipment:**

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**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.

**Section 9: Physical and Chemical Properties**

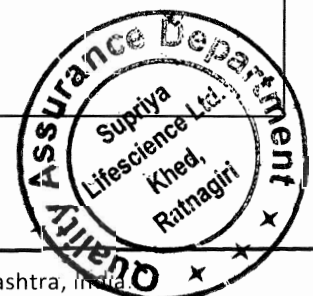
Physical and chemical properties

Form: Solid.

Physical State : Crystalline powder.

Appearance: A white crystalline powder

Odour: Odorless.



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Vapor Pressure: Not available

Melting Point: About 260°C.

Solubility: Water soluble.

Molecular Formula: C<sub>13</sub>H<sub>17</sub>CHNO

Molecular Weight: 274.2

**Section 10: Stability and Reactivity Data**

Chemical Stability: Stable under normal temperatures and pressures.

Incompatibilities with Other Materials : Not available.

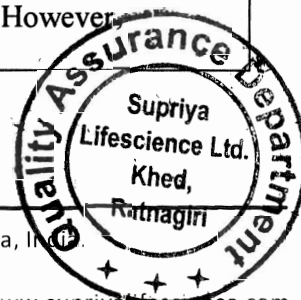
Hazardous Decomposition Products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>) and hydrogen chloride.

Hazardous Polymerization: Not anticipated to occur with this product.

**Section 11: Toxicological Information****Acute Toxicity**

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Ketamine Hydrochloride	100	LD50	Oral	447	Mg/kg	Rat
				617	Mg/kg	Mouse
Ketamine Hydrochloride	100	LD50	Intravenous	58.9	Mg/kg	Rat
				55.9	Mg/kg	Mouse
Ketamine Hydrochloride	100	LD50	Intraperitoneal	224	Mg/kg	Rat
				224	Mg/kg	Mouse
Ketamine Hydrochloride	100	LD50	Intramuscular	356	Mg/kg	Mouse
				361	Mg/kg	Pig

**Aspiration Hazard** : None anticipated from normal handling of this product.**Dermal Irritation/Corrosion** : None anticipated from normal handling of this product.**Ocular Irritation/Corrosion** : None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation

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with redness and tearing.

**Dermal or Respiratory Sensitization:** None anticipated from normal handling of this product.

**Reproductive Effects :** 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 group. To determine the effect of Ketamine on 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.

**Mutagenicity:** Ketamine Hydrochloride was negative in the Ames test for mutagenicity.

**Carcinogenicity :** No data found

**Target Organ Effects:** In the workplace, possible target organs include the eyes, respiratory system, cardiovascular system, and central nervous system.

**Section 12: Ecological Information**

Toxicity : No data available  
Persistence and degradability : No data available  
Bioaccumulative potential : No data available  
Mobility in soil : No data available  
Results of PBT and vPvB assessment : No data available  
Other adverse effects : No data available

**Section 13: Disposal Considerations**

**Waste Disposal :** All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

**Section 14: Transport Information**

**ADR/ADG/DOT STATUS :** Not regulated  
**IMDG STATUS :** Not regulated  
**ICAO/IATA STATUS :** Not regulated  
**Transport Comments :** None



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Ketamine Hydrochloride is not a USDOT hazardous material.  
 Ketamine Hydrochloride is not a Marine pollutant.  
**RCRA Status** : Not listed  
**O.S.OSHA** : Target Organ toxic  
**Classification** : Possible Irritant  
**Hazard Class** : Not Applicable  
 Hazard Category : Not Applicable  
 Signal Word : Not Applicable  
 Symbol : Not Applicable  
 Prevention : P260- Do not breathe dust/fume/gas/mist/vapours/spray.  
 Hazard Statement : Not Applicable  
 GHS Classification : \*In the EU, classification under GH8/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 200 1183/EC, which are in the finished state, intended for the final user.  
 Response : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell.  
 EU Classification : Medicinal products are exempt from the requirements of the EU Dangerous  
 Preparation Directive . Information provided below is for the pure drug substance (S)-Ketamine Hydrochloride.  
**Classification** : Not Applicable  
**Symbol** : Not Applicable  
**Indication of Danger** : Not Applicable  
**Risk Phrases** : Not Applicable  
**Safety Phrases** : S23- Do not breathe vapour.  
 S24-Avoid contact with skin.  
 S25- A void contact with eyes.  
 S37/39- Wear suitable gloves and eye/face protection.

**Section 15: Other Regulatory Information**

**RCRA Status** : Not listed  
**O.S.OSHA** : Target Organ toxic  
**Classification** : Possible Irritant  
**Hazard Class** : Not Applicable  
 Hazard Category : Not Applicable  
 Signal Word : Not Applicable



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**Symbol** : Not Applicable  
**Prevention** : P260- Do not breathe dust/fume/gas/mist/vapours/spray.  
**Hazard Statement** : Not Applicable  
**GHS Classification** : \*In the EU, classification under GH8/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 200 1183/EC, which are in the finished state, intended for the final user.  
**Response** : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell.  
**EU Classification** : Medicinal products are exempt from the requirements of the EU Dangerous Preparation Directive . Information provided below is for the pure drug substance (S)-Ketamine Hydrochloride.  
**Classification** : Not Applicable  
**Symbol** : Not Applicable  
**Indication of Danger** : Not Applicable  
**Risk Phrases** : Not Applicable  
**Safety Phrases** : S23- Do not breathe vapour.  
S24-Avoid contact with skin.  
S25- A void contact with eyes.  
S37/39- Wear suitable gloves and eye/face protection..

**Section 16: Other Information**

**Notes:**  
**ACGIH TLV Value** : American Conference of Governmental Industrial Hygienists- Threshold Limit Value  
**CAS Liability Act** : US EPA law, Comprehensive Environmental Response, Compensation & Liability Act  
**CERCLA DOT** : US Department of Transportation Regulations  
**EEL** : Employee Exposure Limit  
**IATA** : International Air Transport Association  
**LD50** : Dosage producing 50% mortality  
**NA** : Not applicable, Not available  
**NE** : Not established  
**NIOSH** : National Institute for Occupational Safety and Health



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Chemical Abstracts Service Number .

<b>OSHA PEL</b>	: US Occupational Safety and Health Administration - Permissible Exposure Limit
<b>Prop 65</b>	: California Proposition 65
<b>RCRA</b>	: US EPA, Resource Conservation and Recovery Act
<b>RTECS</b>	: Registry of Toxic Effects of Chemical Substances
<b>SARA</b>	: Superfund Amendments and Reauthorization Act
<b>STEL</b>	: 15 minute Short Term Exposure Limit
<b>TSCA</b>	: Toxic Substance Control Act
<b>TWA</b>	: 8-hour Time Weighted Average

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