1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ketamine (5%) Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Skin corrosion/irritation: Category 3
Reproductive toxicity: Category 2

GHS label elements
Hazard pictograms: 

Signal word: Warning
Hazard statements: H316 Causes mild skin irritation.
H361d Suspected of damaging the unborn child.

Precautionary statements: 
Prevention:
P203 Obtain, read and follow all safety instructions before use.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P318 IF exposed or concerned, get medical advice.
P332 + P317 If skin irritation occurs: Get medical help.

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

### Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 5 %

**Other hazards which do not result in classification**

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketamine hydrochloride</td>
<td>1867-66-9</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

### 4. FIRST AID MEASURES

**General advice**

In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

**If inhaled**

If inhaled, remove to fresh air.
Get medical attention.

**In case of skin contact**

In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

**In case of eye contact**

Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

**If swallowed**

If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed**

Causes mild skin irritation.
Suspected of damaging the unborn child.

**Protection of first-aiders**

First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

**Notes to physician**

Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES
**SAFETY DATA SHEET**

**Ketamine (5%) Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Chlorine compounds
- Nitrogen oxides (NOx)

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**: Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions**: Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up**: Soak up with inert absorbent material.
For large spills, provide dyeing or other appropriate containment to keep material from spreading. If dyed material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 7. HANDLING AND STORAGE

**Technical measures**: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

**Local/Total ventilation**: Use only with adequate ventilation.

**Advice on safe handling**: Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketamine hydrochloride</td>
<td>1867-66-9</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
- Minimize open handling.

Personal protective equipment

Respiratory protection:
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - Filter type: Particulates type

Hand protection:
- Material: Chemical-resistant gloves

Eye protection:
- Remarks: Consider double gloving.
  - Wear safety glasses with side shields or goggles.
  - If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
  - Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection:
- Work uniform or laboratory coat.
- Additional body garments should be used based upon the task.
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
</tbody>
</table>
Water solubility : soluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
  Method: Calculation method

Components:
Ketamine hydrochloride:
Acute oral toxicity : LD50 (Rat): 447 mg/kg
  LD50 (Mouse): 617 mg/kg
Acute toxicity (other routes of administration) : LD50 (Rat): 59 mg/kg
  Application Route: Intravenous
LD50 (Mouse): 59 mg/kg  
Application Route: Intramuscular  
LD50 (Mouse): 356 mg/kg  
Application Route: Intramuscular  
LD50 (Guinea pig): 361 mg/kg  
Application Route: Intramuscular  
LD50 (Rat): 224 mg/kg  
Application Route: Intraperitoneal  

Skin corrosion/irritation  
Causes mild skin irritation.  

**Components:**  
Ketamine hydrochloride:  
Species: Rabbit  
Result: irritating  

Serious eye damage/eye irritation  
Not classified based on available information.  

**Components:**  
Ketamine hydrochloride:  
Species: Rabbit  
Result: irritating  

Respiratory or skin sensitisation  

Skin sensitisation  
Not classified based on available information.  

**Respiratory sensitisation**  
Not classified based on available information.  

**Germ cell mutagenicity**  
Not classified based on available information.  

**Carcinogenicity**  
Not classified based on available information.  

**Reproductive toxicity**  
Suspected of damaging the unborn child.  

**Components:**  
Ketamine hydrochloride:  
Effects on foetal development: Test Type: Development  
Species: Rat  
Application Route: Intramuscular  
Developmental Toxicity: NOAEL: 120 mg/kg body weight
Target Organs: Kidney, Liver, Heart
Result: No teratogenic effects

Test Type: Development
Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 20 mg/kg body weight
Symptoms: Skeletal and visceral variations
Result: Effects on prenatal and postnatal growth.

Test Type: Development
Species: Rat
Application Route: Intramuscular
Symptoms: Skeletal and visceral variations
Result: Effects on prenatal and postnatal growth.

Test Type: Development
Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 60 mg/kg body weight
Symptoms: Skeletal and visceral variations
Result: Effects on prenatal and postnatal growth.

Test Type: Development
Species: Monkey
Application Route: Intramuscular
Target Organs: Brain
Result: Effects on prenatal and postnatal growth.

Reproductive toxicity - Assessment

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

Ketamine hydrochloride:

Exposure routes: Skin contact
Target Organs: Kidney, Liver, Brain
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Ketamine hydrochloride:

Species: Mouse
LOAEL: 30 mg/kg
Application Route: Intraperitoneal
Exposure time: 3 Months
Target Organs: Kidney, Liver, Bladder
## Remarks

Significant toxicity observed in testing.

### Species
- **Mouse**

### LOAEL
- 30 mg/kg

### Application Route
- Intraperitoneal

### Exposure time
- 6 Months

### Target Organs
- Kidney, Liver, Bladder

### Remarks
- Significant toxicity observed in testing.

---

### Species
- **Mouse**

### LOAEL
- 30 mg/kg

### Application Route
- Intraperitoneal

### Exposure time
- 28 Weeks

### Target Organs
- Kidney

### Remarks
- Significant toxicity observed in testing.

---

### Species
- **Mouse**

### LOAEL
- 30 mg/kg

### Application Route
- Intraperitoneal

### Exposure time
- 30 Days

### Target Organs
- Brain, Liver

### Remarks
- Significant toxicity observed in testing.

---

### Species
- **Monkey**

### LOAEL
- 1 mg/kg

### Application Route
- Intraperitoneal

### Exposure time
- 6 Months

### Target Organs
- Brain

### Remarks
- Significant toxicity observed in testing.

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

**Components:**

**Ketamine hydrochloride:**

**Ingestion**

Symptoms: The most common side effects are:, central nervous system effects, hypertension, Dizziness, Headache, Nausea, Drowsiness.

---

### Ecotoxicity

**Components:**

**Ketamine hydrochloride:**

**Ecotoxicology Assessment**

**Acute aquatic toxicity**

Toxic effects cannot be excluded.

**Chronic aquatic toxicity**

Toxic effects cannot be excluded.
Persistence and degradability
No data available

Bioaccumulative potential

Components:

Ketamine hydrochloride:
Partition coefficient: n-octanol/water: log Pow: 2.18

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

The components of this product are reported in the following inventories:

AICS: not determined

DSL: not determined

IECSC: not determined
SAFETY DATA SHEET

Ketamine (5%) Formulation

Version 1.2  Revision Date: 10.10.2020  SDS Number: 3976741-00003  Date of last issue: 13.09.2019

Date of first issue: 14.02.2019

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet:

Date format: dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxictology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

IN / EN