SAFETY DATA SHEET

Ketamine (5%) Formulation

Version 1.1  Revision Date: 13.09.2019  SDS Number: 3976743-00002  Date of last issue: 14.02.2019
Date of first issue

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ketamine (5%) Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Skin irritation: Category 3
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure (Dermal): Category 2 (Kidney, Liver, Brain)

GHS label elements
Hazard pictograms:

Signal Word: Warning

Hazard Statements:
H316 Causes mild skin irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Kidney, Liver, Brain) through prolonged or repeated exposure in contact with skin.

Precautionary Statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P332 + P313 IF skin irritation occurs: Get medical advice/ attention.
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Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

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

SECTION 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.
May cause damage to organs through prolonged or repeated exposure in contact with skin.

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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing
None known.
SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- 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 diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 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.
- Avoid inhalation of vapor or mist.
- 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.

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.

Conditions for safe storage:
Keep in properly labeled 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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.
Eye protection: 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 being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance:** liquid
- **Color:** No data available
- **Odor:** No data available
- **Odor Threshold:** No data available
- **pH:** No data available
- **Melting point/freezing point:** No data available
- **Initial boiling point and boiling range:** No data available
- **Flash point:** No data available
- **Evaporation rate:** No data available
- **Flammability (solid, gas):** Not applicable
- **Flammability (liquids):** No data available
- **Upper explosion limit / Upper flammability limit:** No data available
- **Lower explosion limit / Lower flammability limit:** No data available
- **Vapor pressure:** No data available
- **Relative vapor density:** No data available
- **Relative density:** No data available
- **Density:** No data available
- **Solubility(ies):**
  - **Water solubility:** soluble
- **Partition coefficient: n-octanol/water:** Not applicable
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</thead>
</table>

- **Autoignition 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

### SECTION 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.

### SECTION 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 sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
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 fetal 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: Suspected of damaging the unborn child.

**STOT-single exposure**  
Not classified based on available information.

**STOT-repeated exposure**  
May cause damage to organs (Kidney, Liver, Brain) through prolonged or repeated exposure in contact with skin.

**Components:**

**Ketamine hydrochloride:**  
Routes of exposure: 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
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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

SECTION 12. ECOLOGICAL INFORMATION

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

SECTION 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.

SECTION 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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable
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版次 | 修订日期 | SDS编号 | 最后更新日期 | 首次发布日期
--- | --- | --- | --- | ---

产品成分如下表所列：

- AICS: 未确定
- DSL: 未确定
- IECSC: 未确定

SECTION 16. OTHER INFORMATION

全文字词缩写的含义

AICS - 澳大利亚化学品库存; ANTT - 巴西联邦航空运输局; ASTM - 美国材料与试验协会; bw - 体重; CMR - 肿瘤、致突变或生殖毒性物质; DIN - 德国标准研究院; DSL - 加拿大国内物质列表; ECx - 浓度相关x%响应; ELx - 负载率相关x%响应; EmS - 紧急预案; ENCS - 新兴和新化学品（日本）; ErCx - 浓度相关x%生长率响应; ERG - 紧急响应指南; GHS - 全球协调制; GLP - 良好实验室实践; IARC - 国际癌症研究机构; IATA - 国际航空运输协会; IBC - 国际船舶和设备标准; IC50 - 半最大抑制浓度; ICAO - 国际民用航空组织; IECSC - 中国现有化学品库存; IMDG - 国际海运危险货物; IMO - 国际海事组织; IC50 - 半最大抑制浓度; IC50 - 中位致死剂量（中位致死剂量）; MARPOL - 国际防止油污公约; n.o.s. - 另外未指定; Nch - 智利规范; NO(A)EC - 未观察到（不良）效应浓度; NO(A)EL - 未观察到（不良）效应水平; NOELR - 未观察到效应的负载率; NOM - 官方墨西哥规范; NTP - 国家毒理学计划; NZIoC - 新西兰化学品注册; OECD - 经济合作与发展组织; OPPTS - 美国化学品安全与污染预防办公室; PBT - 持久性、生物累积性和毒性物质; PICCS - 菲律宾化学品和化学物质库存; (Q)SAR - 结构-活动关系; REACH - 欧盟化学法规; SADT - 自加速分解温度; SDS - 安全数据表; TCSI - 台湾化学物质库存; TDG - 危险货物运输; TSCA - 美国化学品控制法; UN - 国际公约; UNRTDG - 国际海事组织关于危险货物的推荐; vPvB - 非常持久和非常生物累积; WHMIS - 工作场所危险材料信息


最后修订日期：13.09.2019
The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8