SAFETY DATA SHEET

Ketamine (10%) Formulation

Version 1.1   Revision Date: 13.09.2019   SDS Number: 3976793-00002   Date of last issue: 14.02.2019

Date of first issue: 14.02.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ketamine (10%) 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
Acute toxicity (Oral): Category 5
Skin irritation: Category 2
Eye irritation: Category 2B
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:
H303 May be harmful if swallowed.
H315 + H320 Causes skin and eye 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.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
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.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

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>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Ketamine hydrochloride</td>
<td>1867-66-9</td>
<td>&gt;= 10 -&lt; 20</td>
<td></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 for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention.
SAFETY DATA SHEET

Ketamine (10%) Formulation

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

Most important symptoms and effects, both acute and delayed:
- Rinse mouth thoroughly with water.
- May be harmful if swallowed.
- Causes skin and eye 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 media:
- None known.

Specific hazards during fire fighting:
- 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 fire-fighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

### 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.
Do not get in 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., dripless 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: Chemical-resistant gloves

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: No data available
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor 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>Water solubility</td>
<td>Soluble</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
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<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**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
May be harmful if swallowed.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 4,470 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 skin irritation.

**Components:**

**Ketamine hydrochloride:**

Species : Rabbit  
Result : irritating

**Serious eye damage/eye irritation**
Causes eye irritation.

**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:

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Kidney, Liver, Brain</td>
</tr>
<tr>
<td>Assessment</td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

Repeated dose toxicity

Components:

Ketamine hydrochloride:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>30 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intraperitoneal</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney, Liver, Bladder</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>30 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intraperitoneal</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney, Liver, Bladder</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>30 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intraperitoneal</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>30 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intraperitoneal</td>
</tr>
<tr>
<td>Exposure time</td>
<td>30 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Brain, Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intraperitoneal</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Brain</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

### SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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 Chemical Substances 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 Toxicology 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

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


Revision Date: 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