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 : ![Hazard Pictogram]

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.
SAFETY DATA SHEET

Ketamine (5%) Formulation

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>Ketamine hydrochloride</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.
SAFETY DATA SHEET

Ketamine (5%) Formulation

Version 1.2
Revision Date: 10.10.2020
SDS Number: 3976743-00003
Date of last issue: 13.09.2019
Date of first issue: 14.02.2019

media

Specific hazards during fire fighting
Hazardous combustion products
- Exposure to combustion products may be a hazard to health.
- 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 (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 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.
- Do not breathe mist or vapors.
- 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., 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:

Material: 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. 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor 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>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>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Ketamine (5%) Formulation

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
### Section 1.1. Chemical Identification

**Chemical Name:** Ketamine (5%) Formulation

**CAS Number:** 3976743-00003

### Section 1.2. Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>None</td>
</tr>
<tr>
<td>Appearance</td>
<td>Colorless liquid</td>
</tr>
<tr>
<td>Melting Point</td>
<td>33°C</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>240°C</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.02 g/mL</td>
</tr>
<tr>
<td>Density</td>
<td>0.99 g/cm³</td>
</tr>
</tbody>
</table>

### Section 1.3. Hazard Classification

- **Class:** Anesthetic
- **Category:** Sedative
- **Substance:** Ketamine hydrochloride

### Section 1.4. First Aid Measures

- **Inhalation:** Remove to fresh air. If breathing is difficult, supply oxygen.
- **Skin Contact:** Wash with soap and water. If irritation persists, consult a doctor.
- **Eye Contact:** Flush with plenty of water for 15 minutes. Seek medical attention.
- **Ingestion:** If swallowed, do not induce vomiting. Give 2-4 glasses of water. Consult a doctor.

### Section 1.5. Fire and Explosion Data

- **Extinguishing Media:** Water, foam, carbon dioxide, dry chemical.
- **Special Fire Fighting Procedures:** None specified.
- **Hazardous Combustion Products:** Carbon monoxide, carbon dioxide.
- **Special Hazards:** Reacts with strong oxidizing agents.

### Section 1.6. Accidental Release Measures

- **Precautions:** Wear appropriate personal protective equipment.
- **Environmental Measures:** Do not release into the environment.
- **Disposal:** Disposal must be in accordance with local regulations.

### Section 1.7. Handling and Storage

- **Handling:** Keep away from heat, sparks, and flame.
- **Storage:** Store in a cool, dry place, away from incompatible materials.

### Section 1.8. Exposure Control and Personal Protection

- **Exposure Controls:** Local exhaust ventilation.
- **Personal Protective Equipment:** Respiratory protection, eye protection, and protective clothing.

### Section 1.9. Physical and Chemical Stability

- **Stability:** Stable under normal conditions.
- **Hazardous Decomposition Products:** May form hazardous decomposition products.

### Section 1.10. Reactivity and Incompatibilities

- **Reactivity:** Reacts with strong oxidizing agents.
- **Incompatibilities:** AVOID contact with strong oxidizing agents.

### Section 1.11. Toxicological Information

- **Route of Entry:** Inhalation, ingestion, skin contact, eye contact.
- **Toxicological Effects:** Central nervous system depression, hypotension, tachycardia.
- **Exposure Limits:** STEL: 50 mg/m³.
- **Toxicological Studies:** See Section 20.1.

### Section 1.12. Ecological Information

- **Ecotoxicology Assessment:** Acute aquatic toxicity: Toxic effects cannot be excluded.
- **Chronic aquatic toxicity:** Toxic effects cannot be excluded.

### Section 1.13. Disposal Considerations

- **Disposal Method:** Disposal must be in accordance with local regulations.

### Section 1.14. Transport Information

- **UN Number:** Not applicable.
- **Risk Phrases:** R22, R36/37/39.
- **Safety Phrases:** P201, P202, P204.

### Section 1.15. Regulatory Information

- **Regulatory Agency:** Local health authorities.
- **Regulatory Status:** None specified.

### Section 1.16. Other Information

- **References:** MSD MSDS 3976743-00003.
- **Preparation:** Ketamine hydrochloride solution.

---

**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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<thead>
<tr>
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<th>Date of first issue</th>
</tr>
</thead>
</table>

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

**SECTION 16. OTHER INFORMATION**

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 Chemical Substances in China
- **IDLH**: Immediately Dangerous to Life and Health
- **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
- **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: 10.10.2020
# 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>

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