SAFETY DATA SHEET

Ketamine (10%) Formulation

Section 1: Identification

Product name : Ketamine (10%) Formulation

Manufacturer or supplier's details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +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: Hazard identification

GHS Classification

Skin corrosion/irritation : Category 2
Serious eye damage/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 : ![Warning]
Signal word : Warning
Hazard statements : 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 vapours.
                          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.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P332 + P313 If skin irritation occurs: Get medical advice/ attention.
- P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketamine hydrochloride</td>
<td>Chemical name</td>
</tr>
<tr>
<td></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 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.
Rinse mouth thoroughly with water.

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.

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).

Treat symptomatically and supportively.

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

None known.

Exposure to combustion products may be a hazard to health.

Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)

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.

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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.

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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 vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
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 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

Section 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., 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**

<table>
<thead>
<tr>
<th>Respiratory protection</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</td>
<td>: Chemical-resistant gloves</td>
</tr>
<tr>
<td>Filter type</td>
<td>Particulates type</td>
</tr>
<tr>
<td>Hand protection</td>
<td></td>
</tr>
</tbody>
</table>

**Eye protection**

<table>
<thead>
<tr>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>: Consider double gloving.</td>
</tr>
<tr>
<td>: Wear safety glasses with side shields or goggles.</td>
</tr>
<tr>
<td>: If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</td>
</tr>
<tr>
<td>: Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
</tr>
</tbody>
</table>

**Skin and body protection**

<table>
<thead>
<tr>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>: Work uniform or laboratory coat.</td>
</tr>
<tr>
<td>: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.</td>
</tr>
<tr>
<td>: Use appropriate degowning techniques to remove potentially contaminated clothing.</td>
</tr>
</tbody>
</table>

**Section 9: Physical and chemical properties**

<table>
<thead>
<tr>
<th>Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>: liquid</td>
</tr>
<tr>
<td>Colour</td>
</tr>
<tr>
<td>: No data available</td>
</tr>
<tr>
<td>Odour</td>
</tr>
<tr>
<td>: No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
</tr>
<tr>
<td>: No data available</td>
</tr>
<tr>
<td>pH</td>
</tr>
<tr>
<td>: No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
</tr>
<tr>
<td>: No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
</tr>
<tr>
<td>: No data available</td>
</tr>
<tr>
<td>Flash point</td>
</tr>
<tr>
<td>: No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
</tr>
<tr>
<td>: No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
</tr>
<tr>
<td>: Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
</tr>
<tr>
<td>: No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
</tr>
<tr>
<td>: No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Ketamine (10%) Formulation

Version: 2.0  Revision Date: 27.08.2021  SDS Number: 3976795-00004  Date of last issue: 10.10.2020

Date of first issue: 14.02.2019

Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour 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
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  Viscosity, kinematic: Not applicable
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

Exposure routes: Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity:
II Not classified based on available information.

Product:
Acute oral toxicity
Acute toxicity estimate: > 2,000 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 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 sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.
Chronic toxicity

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
- 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.
# SAFETY DATA SHEET

## Ketamine (10%) Formulation

### 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

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
UN number: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
SAFETY DATA SHEET

Ketamine (10%) Formulation

Version 2.0  Revision Date: 27.08.2021  SDS Number: 3976795-00004  Date of last issue: 10.10.2020  Date of first issue: 14.02.2019

Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR
UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code
UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433
UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

Special precautions for user
Not applicable

Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.
The components of this product are reported in the following inventories:

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

Section 16: Other information

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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
- 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
- KECl - Korea Existing Chemicals Inventory
- LC50 - Lethal Concentration
- LD50 - 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
- SADT - Self-Accelerating Decomposition Temperature
- SDS - Safety Data Sheet
- TCSI - Taiwan Chemical Substance Inventory
- TDG - Transportation of Dangerous Goods
- TECI - Thailand Existing Chemicals Inventory
- 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.

NZ / EN