

Ketamine (10%) Formulation

Version 1.8 Revision Date: 30.09.2023 SDS Number: 3976787-00009 Date of last issue: 04.04.2023
Date of first issue: 14.02.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ketamine (10%) Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

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

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification in accordance with ABNT NBR 14725 Standard**

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 in accordance with ABNT NBR 14725 Standard

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.

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Precautionary Statements : **Prevention:**
 P201 Obtain special instructions before use.
 P264 Wash skin thoroughly after handling.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
 P312 Call a POISON CENTER/ doctor if you feel unwell.
 P332 + P313 If skin irritation occurs: Get medical advice/ attention.
 P337 + P313 If eye irritation persists: Get medical advice/ attention.

Additional Labeling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 10 %

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Ketamine hydrochloride	1867-66-9	Acute toxicity (Oral), Category 4 Skin irritation, Category 2 Eye irritation, Category 2B Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Dermal) (Kidney, Liver, Brain), Category 2	>= 10 -< 20

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.

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| In case of eye contact | : | <p>Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.</p> <p>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.</p> |
| If swallowed | : | <p>Get medical attention.</p> <p>If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.</p> |
| Most important symptoms and effects, both acute and delayed | : | <p>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.</p> |
| Protection of first-aiders | : | <p>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).</p> |
| Notes to physician | : | <p>Treat symptomatically and supportively.</p> |
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SECTION 5. FIRE-FIGHTING MEASURES

- | | | |
|--|---|---|
| Suitable extinguishing media | : | <p>Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical</p> |
| Unsuitable extinguishing media | : | <p>None known.</p> |
| Specific hazards during fire fighting | : | <p>Exposure to combustion products may be a hazard to health.</p> |
| Hazardous combustion products | : | <p>Carbon oxides
Chlorine compounds
Nitrogen oxides (NO_x)</p> |
| Specific extinguishing methods | : | <p>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.</p> |
| Special protective equipment for fire-fighters | : | <p>In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.</p> |
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SECTION 6. ACCIDENTAL RELEASE MEASURES

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|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | <p>Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</p> |
| Environmental precautions | : | <p>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</p> |

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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.
 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 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
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis
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SAFETY DATA SHEET



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		exposure)	concentration	
Ketamine hydrochloride	1867-66-9	TWA	10 µg/m ³ (OEB 3)	Internal
Further information: Skin				
		Wipe limit	100 µg/100 cm ²	Internal

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

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 : No data available

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range

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

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

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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.

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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

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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

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

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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 : Do not dispose of waste into sewer.
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.

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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**ANTT**

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**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATIONRevision Date : 30.09.2023
Date format : dd.mm.yyyy**Further information**Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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Full text of other abbreviations

AllC - 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; 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; 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.

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