SAFETY DATA SHEET

Ketamine (5%) Formulation

Version 1.3  Revision Date: 10/10/2020  SDS Number: 3976747-00004  Date of last issue: 03/23/2020  Date of first issue: 02/14/2019

SECTION 1. IDENTIFICATION

Product name: Ketamine (5%) Formulation

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
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: 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 and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and 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;= 5 - &lt; 10</td>
<td></td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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: 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 firefighting: 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 (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.

Conditions for safe storage: Keep in properly labeled containers. Store locked up.
SAFETY DATA SHEET

Ketamine (5%) Formulation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents

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 Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketamine hydrochloride</td>
<td>1867-66-9</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3) Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm² 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:
General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.
Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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.

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.

**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>
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</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
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</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>
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<tr>
<td>Relative vapor density</td>
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</tr>
<tr>
<td>Relative density</td>
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</tr>
<tr>
<td>Density</td>
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</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td></td>
<td>soluble</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
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
SAFETY DATA SHEET

Ketamine (5%) Formulation

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
Not classified based on available information.

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.

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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.
SAFETY DATA SHEET

Ketamine (5%) Formulation

Version 1.3  Revision Date: 10/10/2020  SDS Number: 3976747-00004  Date of last issue: 03/23/2020  Date of first issue: 02/14/2019

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
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
SAFETY DATA SHEET

Ketamine (5%) Formulation

Version     Revision Date:      SDS Number:      Date of last issue: 03/23/2020
1.3         10/10/2020          3976747-00004      Date of first issue: 02/14/2019

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations
Pennsylvania Right To Know
Water 7732-18-5
Ketamine hydrochloride 1867-66-9

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Ketamine (5%) Formulation

Version 1.3
Revision Date: 10/10/2020
SDS Number: 3976747-00004
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NFPA 704:

- Flammability: 1 (Concern)
- Health: 1 (Concern)
- Special hazard: 
- Instability: 0 (None)

HMIS® IV:

- HEALTH: 2 (Critical, Immediate Risk)
- FLAMMABILITY: 1 (Moderate)
- PHYSICAL HAZARD: 0 (None)

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The '*' represents a chronic hazard, while the '/' represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RO - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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
Sources of key data used to compile the Material Safety Data Sheet:


Revision Date: 10/10/2020

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.

US / Z8