SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ketamine (5%) Formulation

Version 1.4  Revision Date: 09.04.2021  SDS Number: 3983600-00005  Date of last issue: 10.10.2020
Date of first issue: 14.02.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Ketamine (5%) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Kilsheelan
Clonmel Tipperary, IE
Telephone: 353-51-601000
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Reproductive toxicity, Category 2  H361d: Suspected of damaging the unborn child.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms:

Signal word: Warning
Hazard statements: H361d  Suspected of damaging the unborn child.
Precautionary statements:
Prevention: P201  Obtain special instructions before use.  P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response: P308 + P313  IF exposed or concerned: Get medical advice/ attention.
**Storage:**
P405  Store locked up.

**Hazardous components which must be listed on the label:**
Ketamine hydrochloride

**Additional Labelling**
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 5 %

**2.3 Other hazards**
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**SECTION 3: Composition/information on ingredients**

**3.2 Mixtures**

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketamine hydrochloride</td>
<td>1867-66-9 217-484-6</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 2; H373 (Kidney, Liver, Brain)</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

**SECTION 4: First aid measures**

**4.1 Description of 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.

**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).

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.

4.2 Most important symptoms and effects, both acute and delayed
Risks : Suspected of damaging the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
                           Chlorine compounds
                           Nitrogen oxides (NOx)

5.3 Advice for firefighters
Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-
Hygiene measures:
- Take care to prevent spills, waste and minimize release to the environment.
- 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>

8.2 Exposure controls

**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**

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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Physical state</th>
<th>liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</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>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>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Ketamine (5%) Formulation

Solubility(ies)
   Water solubility : soluble

Partition coefficient: n-octanol/water
   : Not applicable

Vapour pressure
   : No data available

Relative density
   : No data available

Density
   : No data available

Relative vapour density
   : No data available

Particle characteristics
   Particle size : Not applicable

9.2 Other information

Explosives
   : Not explosive

Oxidizing properties
   : The substance or mixture is not classified as oxidizing.

Evaporation rate
   : No data available

Molecular weight
   : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
   Not classified as a reactivity hazard.

10.2 Chemical stability
   Stable under normal conditions.

10.3 Possibility of hazardous reactions
   Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
   Conditions to avoid : None known.

10.5 Incompatible materials
   Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
   No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
   Information on likely routes of : Inhalation
Ketamine (5%) Formulation

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
</tr>
</tbody>
</table>

**Acute toxicity**
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**
Not classified based on available information.

**Components:**

**Ketamine hydrochloride:**
Species: Rabbit
Result: irritant

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Ketamine hydrochloride:**
Species: Rabbit
Result: irritant
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
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 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
Not classified based on available information.

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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

12.1 Toxicity

Components:
Ketamine hydrochloride:
Ecotoxicology Assessment
Acute aquatic toxicity : Toxic effects cannot be excluded
Chronic aquatic toxicity : Toxic effects cannot be excluded

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

Components:
Ketamine hydrochloride:
Partition coefficient: n-octanol/water : log Pow: 2.18

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or
very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:**
Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

14.1 UN number or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
Remarks: Not applicable for product as supplied.
SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered:

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable

REACH - List of substances subject to authorisation (Annex XIV): Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable


Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

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

AICS: not determined

DSL: not determined

IECSC: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H302: Harmful if swallowed.

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H361d: Suspected of damaging the unborn child.

H373: May cause damage to organs through prolonged or repeated exposure in contact with skin.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Ketamine (5%) Formulation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information


Classification of the mixture: Classification procedure:

Repr. 2 H361d Calculation method

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.

IE / EN