

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Ketamine Hydrochloride Injection, USP

Formula: C₁₃H₁₆CL₂NO

1.2. Intended Use of the Product

General anesthetic indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation, for the induction of anesthesia prior to the administration of other general anesthetic agents, and as a supplement to other anesthetic agents.

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
 (800)255-3924 (North America)
 +1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

| | |
|--|------|
| Reproductive toxicity Category 2 | H361 |
| Specific target organ toxicity – Single exposure, Category 3, Narcosis | H336 |
| Specific target organ toxicity (repeated exposure) Category 2 | H373 |

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA) :



Signal Word (GHS-US/CA) :

Warning

Hazard Statements (GHS-US/CA) :

H336 - May cause drowsiness or dizziness.
 H361 - Suspected of damaging fertility or the unborn child (oral).
 H373 - May cause damage to organs through prolonged or repeated exposure (oral).

Precautionary Statements (GHS-US/CA) :

P201 - Obtain special instructions before use.
 P202 - Do not handle until all safety precautions have been read and understood.
 P260 - Do not breathe vapors, mist, or spray.
 P271 - Use only outdoors or in a well-ventilated area.
 P280 - Wear protective gloves, protective clothing, and eye protection.
 P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P314 - Get medical advice/attention if you feel unwell.
 P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
 P405 - Store locked up.
 P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

Ketamine Hydrochloride Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

| Name | Synonyms | Product Identifier | % * | GHS Ingredient Classification |
|------------------------|---|------------------------|--|--|
| Water | water / AQUA (Water, pyrogen-free, for injection) | (CAS-No.) 7732-18-5 | > 80 | Not classified |
| Ketamine hydrochloride | Cyclohexanone, 2-(2-chlorophenyl)-2-(methylamino)-, hydrochloride, (+.-)- / Cyclohexanone, 2-(2-chlorophenyl)-2-(methylamino)-, hydrochloride / 2-(2-Chlorophenyl)-2-methylaminocyclohexanone hydrochloride / Cyclohexanone, 2-(2-chlorophenyl)-2-(methylamino)-, hydrochloride (1:1) / ketamine hydrochloride | (CAS-No.) 1867-66-9 | 1.15 [^] 5.76 [^] | Acute Tox. 4 (Oral), H302 Repr. 2, H361 STOT SE 3, H336 STOT RE 2, H373 |
| Sodium chloride # | Salt / SEA SALT / Sodium salt of hydrochloric acid / SODIUM CHLORIDE / Sodium chloride (NaCl) / Sea salt | (CAS-No.) 7647-14-5 | 0.1 – 1 | Not classified |
| Benzethonium chloride | Anti-germ 77 / Antiseptol / Benzenemethanaminium, N,N-dimethyl-N-[2-[2-[4-(1,1,3,3-tetramethylbutyl)-phenoxy]ethoxy]ethyl]-, chloride / Benzyltrimethyl(2-(2-(p-(1,1,3,3-tetramethylbutyl)phenoxy)ethoxy)ethyl) ammonium chloride / Benzyltrimethyl[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl] ammonium chloride / p-tert-Octylphenoxyethoxyethyltrimethylbenzylammonium chloride / Phemerol chloride / Benzenemethanaminium, N,N-dimethyl-N-[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]-, chloride (1:1) / BENZETHONIUM CHLORIDE / Ammonium, benzyltrimethyl(2-(2-(p-(1,1,3,3-tetramethylbutyl)phenoxy)ethoxy)ethyl)-, chloride / Ammonium, benzyltrimethyl [2-[2-(p-(1,1,3,3-tetramethylbutyl)phenoxy)ethoxy]ethyl]-, chloride / (Diisobutylphenoxy-ethoxyethyl)dimethylbenzylammonium chloride | (CAS-No.) 121-54-0 | < 0.1 | Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |

[^] to equal 1% (10 mg/mL) or 5% (50 mg/mL) solution.

Not present in 50 mg/mL product.

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%). Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Gently wash with plenty of soap and water followed by rinsing with water for at least 15 minutes. Call a POISON CENTER or doctor/physician if you feel unwell. Wash contaminated clothing before reuse.

Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. Obtain medical attention if irritation persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Suspected of damaging the unborn child. (if swallowed). May cause damage to organs through prolonged or repeated exposure (if swallowed).

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Causes mild skin irritation.

Eye Contact: Mild eye irritation.

Ingestion: Ingestion may cause adverse effects. May cause drowsiness and loss of coordination.

Chronic Symptoms: Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure (if swallowed).

Ketamine Hydrochloride Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand. Naloxone is not effective for treating ketamine intoxication. Activated carbon may be of benefit in treating recent oral exposures. Other treatments should be based on toxidrome severity and specific presentation.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Solutions do not burn. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Prevent fire-fighting water from entering environment. Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen chloride. Sodium oxides. chlorine.

Other Information: No additional information available.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Use only as directed. Avoid all contact with skin, eyes, or clothing. Avoid breathing vapor, mist, or spray. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE) in accordance with Section 8.

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material, then place in suitable container. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13. See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms during use.

Precautions for Safe Handling: Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with accepted protocols. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do NOT breathe (dust, vapor, mist, gas).

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

Ketamine Hydrochloride Injection, USP

Safety Data Sheet

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7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store locked up/in a secure area. Store in a dry, cool and well-ventilated place. Do not freeze. Keep container closed when not in use. Keep/Store away from extremely high or low temperatures and incompatible materials. Protect from light.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 20 – 25 °C (68 – 77 °F). Do not freeze.

7.3. Specific End Use(s)

General anesthetic indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation, for the induction of anesthesia prior to the administration of other general anesthetic agents, and as a supplement to other anesthetic agents.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

8.2. Exposure Controls

Appropriate Engineering Controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear chemically resistant protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

| | |
|--------------------------------|--|
| Physical State | : Liquid |
| Appearance | : Clear, colorless to slightly yellow solution |
| Odor | : Not determined |
| Odor Threshold | : No data available |
| pH | : 3.5 – 5.5 |
| Evaporation Rate | : No data available |
| Melting Point | : No data available |
| Freezing Point | : ≈ 0 °C (32 °F) |
| Boiling Point | : ≈ 100 °C (212 °F) |
| Flash Point | : No data available |
| Auto-ignition Temperature | : No data available |
| Decomposition Temperature | : No data available |
| Flammability (solid, gas) | : Not applicable |
| Lower Flammable Limit | : No data available |
| Upper Flammable Limit | : No data available |
| Vapor Pressure | : No data available |
| Relative Vapor Density at 20°C | : No data available |
| Relative Density | : No data available |
| Specific Gravity | : No data available |
| Solubility | : Water: Miscible. |

Ketamine Hydrochloride Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Partition Coefficient: N-Octanol/Water : No data available
Viscosity : No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Do not freeze. Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen chloride. Chlorine. Sodium oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Dermal, Eye Contact, Inhalation, Oral.

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified

pH: 3.5 – 5.5

Eye Damage/Irritation: Not classified

pH: 3.5 – 5.5

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): May cause damage to organs through prolonged or repeated exposure (oral).

Reproductive Toxicity: Suspected of damaging fertility or the unborn child (oral).

Specific Target Organ Toxicity (Single Exposure): May cause drowsiness or dizziness.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Causes mild skin irritation.

Symptoms/Injuries After Eye Contact: Mild eye irritation.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects. May cause drowsiness and loss of coordination.

Chronic Symptoms: Suspected of damaging fertility or the unborn child (oral). May cause damage to organs through prolonged or repeated exposure (if swallowed).

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

| | |
|--|--|
| Cyclohexanone, 2-(o-chlorophenyl)-2-(methylamino)-, hydrochloride (1867-66-9) | |
| LD50 Oral Rat | 447 mg/kg |
| Sodium chloride (7647-14-5) | |
| LD50 Oral Rat | 3550 mg/kg (Species: Wistar) |
| LD50 Dermal Rabbit | > 10000 mg/kg (Species: New Zealand White) |
| LC50 Inhalation Rat | > 42 mg/l (Exposure time: 1 h) |
| Benzethonium chloride (121-54-0) | |
| LD50 Oral Rat | 295 mg/kg |

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Ketamine Hydrochloride Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

| Sodium chloride (7647-14-5) | |
|----------------------------------|---|
| LC50 Fish 1 | 5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through]) |
| EC50 - Crustacea [1] | 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna) |
| LC50 Fish 2 | 12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static]) |
| EC50 - Crustacea [2] | 340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static]) |
| NOEC Chronic Fish | 252 mg/l (Species: Pimephales promelas) |
| Benzethonium chloride (121-54-0) | |
| LC50 Fish 1 | 1.4 mg/l |
| EC50 - Crustacea [1] | 0.22 mg/l |

12.2. Persistence and Degradability

| Ketamine Hydrochloride Injection, USP | |
|---------------------------------------|--|
| Persistence and Degradability | Not persistent, readily biodegradable. |

12.3. Bioaccumulative Potential

| Ketamine Hydrochloride Injection, USP | |
|---------------------------------------|--------------------------------|
| Bioaccumulative Potential | Not expected to bioaccumulate. |

| Sodium chloride (7647-14-5) | |
|---|------------------------------|
| BCF Fish 1 | (no bioaccumulation) |
| Benzethonium chloride (121-54-0) | |
| Partition coefficient n-octanol/water (Log Pow) | 1.08 (at 20 °C (at pH 6.85)) |

12.4. Mobility in Soil

| Ketamine Hydrochloride Injection, USP | |
|---------------------------------------|------------------------------|
| Ecology - Soil | Leaches if exposed to water. |

12.5. Other Adverse Effects

Other Adverse Effects: None known.

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product. . Can be landfilled, when in compliance with local regulations.

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

| Ketamine Hydrochloride Injection, USP | |
|---------------------------------------|--|
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard Health hazard - Reproductive toxicity Health hazard - Specific target organ toxicity (single or repeated exposure) |

Ketamine Hydrochloride Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Sodium chloride (7647-14-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Benzethonium chloride (121-54-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

15.3. Canadian Regulations

Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List)

Sodium chloride (7647-14-5)

Listed on the Canadian DSL (Domestic Substances List)

Benzethonium chloride (121-54-0)

Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 11/27/2023

Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

| | |
|------|---|
| H301 | Toxic if swallowed |
| H302 | Harmful if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H318 | Causes serious eye damage |
| H336 | May cause drowsiness or dizziness |
| H361 | Suspected of damaging fertility or the unborn child |
| H373 | May cause damage to organs through prolonged or repeated exposure |
| H400 | Very toxic to aquatic life |
| H410 | Very toxic to aquatic life with long lasting effects |

NFPA Health Hazard : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA Fire Hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.

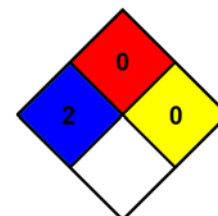
HMIS III Rating

Health : 2 Moderate Hazard - Temporary or minor injury may occur

Flammability : 0 Minimal Hazard

Physical : 0 Minimal Hazard

Personal protection : C



This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)