SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Ketamine Hydrochloride Injection, U.S.P
Trade Name: Ketalar, Ketolar, Ketanest
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anesthetic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous
EU Classification:
EU Indication of danger: Not classified

Label Elements

Signal Word: Not required
Hazard Statements: Non-hazardous in accordance with international standards for workplace safety.

Other Hazards

No data available

Australian Hazard Classification (NOHSC):


Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous
SAFETY DATA SHEET

Material Name: Ketamine Hydrochloride Injection, U.S.P
Revision date: 14-Apr-2015
Version: 3.0

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Ketamine hydrochloride</td>
<td>1867-66-9</td>
<td>217-484-6</td>
<td>Xn.R22</td>
<td>Acute Tox.4 (H302)</td>
<td>5.7</td>
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<tr>
<td>Benzethonium chloride</td>
<td>121-54-0</td>
<td>204-479-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures
Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed
Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

| Measures for Cleaning / Collecting: | Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. |
| Additional Consideration for Large Spills: | Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. |

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
| Storage Conditions: | Store as directed by product packaging. |
| Specific end use(s): | Pharmaceutical drug product |

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

| Ketamine hydrochloride Pfizer OEL TWA-8 Hr: | 200µg/m³, Skin |

Exposure Controls

| Engineering Controls: | Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section. |
| Personal Protective Equipment: | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). |

| Hands: | Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations. |
| Eyes: | Wear safety glasses or goggles if eye contact is possible. |
| Skin: | Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. |
| Respiratory protection: | If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. |
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid solution</td>
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<td>(Method, pH, Endpoint, Value)</td>
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<td>Water for injection</td>
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<td>Ketamine hydrochloride</td>
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<tr>
<td>Benzethonium chloride</td>
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<tr>
<td>Polymerization</td>
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</table>

10. STABILITY AND REACTIVITY

Reactivity:  No data available
Chemical Stability:  Stable under normal conditions of use.
Possibility of Hazardous Reactions:
  Oxidizing Properties:  No data available
  Conditions to Avoid:  Fine particles (such as dust and mists) may fuel fires/explosions.
  Incompatible Materials:  As a precautionary measure, keep away from strong oxidizers
  Hazardous Decomposition Products:  No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information:  The information included in this section describes the potential hazards of the individual ingredients.
Short Term:  Anesthetic drug: may cause central nervous system and cardiovascular system effects. May be harmful if absorbed through the skin. Harmful if swallowed (based on components).
11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: Ketamine is an anesthetic agent which is known to cause double vision, motor incoordination, delirium, hallucinations, irrational behavior, and temporary elevation of blood pressure and pulse rate.

Acute Toxicity: (Species, Route, End Point, Dose)

Ketamine hydrochloride
- Rat Oral LD50 447 mg/kg
- Mouse Oral LD50 617 mg/kg
- Rat IV LD50 58.9 mg/kg
- Mouse IV LD50 55.9 mg/kg

Benzethonium chloride
- Rat Oral LD50 368 mg/kg
- Rat Subcutaneous LD50 119 mg/kg
- Rat IV LD50 19 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Benzethonium chloride
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Ketamine hydrochloride
- 6 Week(s) Rat Intravenous 10 mg/kg/day NOAEL No effects at maximum dose
- 6 Week(s) Dog Intramuscular 40 mg/kg/day NOAEL No effects at maximum dose

Reproductive & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Ketamine hydrochloride
- Reproductive & Fertility Rat Intravenous 60 NOAEL No effects at maximum dose
- Embryo / Fetal Development Rat Intramuscular 120 mg/kg/day NOAEL Not Teratogenic
- Embryo / Fetal Development Mouse Intravenous 300 mg/kg/day NOAEL Not Teratogenic
- Embryo / Fetal Development Rabbit Intramuscular 24 mg/kg/day NOAEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Ketamine hydrochloride
- Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
- In Vitro Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available
SAFETY DATA SHEET

Persistence and Degradability: No data available
Bio-accumulative Potential: No data available
Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 1, Subdivision B

Ketamine hydrochloride
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
U.S. Drug Enforcement Administration: III
Australia (AICS): Present
EU EINECS/ELINCS List: 217-484-6
15. REGULATORY INFORMATION

Benzethonium chloride

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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<tr>
<td>California Proposition 65</td>
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<td>EU EINECS/ELINCS List</td>
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Water for injection

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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<tr>
<td>California Proposition 65</td>
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<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<td>EU EINECS/ELINCS List</td>
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</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Xn - Harmful

R22 - Harmful if swallowed.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 14-Apr-2015

Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet