



MATERIAL SAFETY DATA SHEET

Revision date: 29-Jan-2007

Version: 1.2

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Ketamine Hydrochloride Injection, U.S.P

Trade Name: Ketalar
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as anesthetic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ketamine hydrochloride	1867-66-9	217-484-6	< 100 mg/mL
Benzethonium chloride	121-54-0	204-479-9	<1.0

Ingredient	CAS Number	EU EINECS List	%
Water for injection	7732-18-5	231-791-2	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
May be harmful if absorbed through the skin
Anesthetic drug: may cause central nervous system and cardiovascular system

Additional Hazard Information:
Short Term: May cause eye irritation (based on components) . May be harmful if absorbed through the skin.
Harmful if swallowed (based on animal data) .

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.

EU Indication of danger: Harmful

EU Hazard Symbols:

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EU Risk Phrases:

R22 - Harmful if swallowed.

Additional Information:

Ketamine has been reported being used as a drug of abuse, it is a DEA Schedule III Controlled Drug Substance.

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.

4. FIRST AID MEASURES

Eye Contact:

Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin Contact:

Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion:

Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media:

Water, carbon dioxide, dry chemical or foam

Hazardous Combustion Products:

May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

Fire Fighting Procedures:

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance. Dike and collect water used to fight fire.

Fire / Explosion Hazards:

Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

Measures for Environmental Protections:

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

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.

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7. HANDLING AND STORAGE

General Handling: Use only in a well-ventilated area. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

Storage Temperature: 15-30°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ketamine hydrochloride
Pfizer OEL TWA-8 Hr:
Pfizer STEL

0.2 mg/m³, Skin
0.5 mg/m³, Skin

Analytical Method: Analytical method available for ketamine. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Rubber gloves
Eyes: Safety glasses or goggles
Skin: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.

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:

Physical State:	Liquid solution	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	Soluble: Water		
pH:	3.5-5.5		
Specific Gravity:	1.008 - 1.028		
Flash Point (Liquid) (°C):			>93

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

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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

Skin Irritation / Sensitization Ketamine May be absorbed through the skin in harmful amounts.

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

Reproduction & 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.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

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14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful

EU Risk Phrases:
R22 - Harmful if swallowed.

EU Safety Phrases:
S24 - Avoid contact with skin.
S46 - If swallowed, seek medical advice immediately and show this container or label.

OSHA Label:
WARNING
Harmful if swallowed.
May be harmful if absorbed through the skin
Anesthetic drug: may cause central nervous system and cardiovascular system

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 1, Subdivision B



Ketamine hydrochloride

Australia (AICS):	Present
EU EINECS List	217-484-6

Benzethonium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-479-9

Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule III. As per 21 CFR 1302, Labeling and packaging requirements for controlled substances, the label should include the symbol "CIII".

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16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet