



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Nov-2008

Version: 1.0

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

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### Material Name: (S)-(+)-Ketamine Hydrochloride Solution

<b>Trade Name:</b>	KETANEST-S, S-KETAMIN
<b>Synonyms:</b>	S-(+)-Ketamine hydrochloride , Esketamine hydrochloride
<b>Chemical Family:</b>	Not determined
<b>Intended Use:</b>	Pharmaceutical product used as anesthetic agent

## 2. HAZARDS IDENTIFICATION

**Appearance:** Aqueous solution

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

**Additional Hazard Information:**  
**Short Term:**

Anesthetic drug; may cause central nervous system and cardiovascular system. May be harmful if absorbed through the skin. May be harmful if swallowed. (based on components) . 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.

**Known Clinical Effects:**

**EU Indication of danger:**

Not classified

**Australian Hazard Classification (NOHSC):**

Hazardous Substance. Non-Dangerous Goods.

**Note:**

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
S-(+)-Ketamine Hydrochloride	33795-24-3	Not listed	Xn;R22	2.5-5.0
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*

#### Additional Information:

\* Proprietary

\*\* to adjust pH

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

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire Fighting Procedures:</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

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### 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.

## 7. HANDLING AND STORAGE

### General Handling:

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

### Storage Conditions:

Store as directed by product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

### S-(+)-Ketamine Hydrochloride

Pfizer OEL TWA-8 Hr: 100µg/m<sup>3</sup>, Skin

### Sodium chloride

Latvia OEL - TWA Listed

Lithuania OEL - TWA Listed

### Hydrochloric Acid

ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling

Australia PEAK = 5 ppm Peak

= 7.5 mg/m<sup>3</sup> Peak

Austria OEL - MAKs Listed

Belgium OEL - TWA Listed

Bulgaria OEL - TWA Listed

Cyprus OEL - TWA Listed

Czech Republic OEL - TWA Listed

Estonia OEL - TWA Listed

Germany - TRGS 900 - TWAs = 2 ppm TWA

= 3 mg/m<sup>3</sup> TWA

Germany (DFG) - MAK = 2 ppm MAK

= 3.0 mg/m<sup>3</sup> MAK

Greece OEL - TWA Listed

Hungary OEL - TWA Listed

Ireland OEL - TWAs = 5 ppm TWA

= 7 mg/m<sup>3</sup> TWA

Italy OEL - TWA Listed

Japan - OELs - Ceilings = 5 ppm Ceiling

= 7.5 mg/m<sup>3</sup> Ceiling

Latvia OEL - TWA Listed

Lithuania OEL - TWA Listed

Luxembourg OEL - TWA Listed

Malta OEL - TWA Listed

Netherlands OEL - TWA Listed

Poland OEL - TWA Listed

Romania OEL - TWA Listed

Slovenia OEL - TWA Listed

Spain OEL - TWA Listed

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Analytical Method:</b>	Analytical method available for (S)-(+)-Ketamine Hydrochloride. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	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.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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:

<b>Physical State:</b>	Aqueous solution	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers

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### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

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

##### **Ketamine hydrochloride**

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

##### **Sodium chloride**

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD50 4000mg/kg

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

##### **Hydrochloric Acid**

Skin Irritation Severe  
Eye Irritation Severe

##### **Sodium chloride**

Eye Irritation Rabbit Moderate  
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

#### Reproduction & Development Toxicity: (Duration, 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.

#### Hydrochloric Acid

##### **IARC:**

Group 3 (Not Classifiable)

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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material 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. 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

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

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## 15. REGULATORY INFORMATION

EU Indication of danger: Not classified

### OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

Class D, Division 1, Subdivision B



### Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

### Water for Injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

### Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 500 lb TPQ gas only
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	Schedule 6 231-595-7

### 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

#### Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R23 - Toxic by inhalation.

R35 - Causes severe burns.

#### **Data Sources:**

Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

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**