



A Pfizer Company

SAFETY DATA SHEET

Revision date: 19-Sep-2016

Version: 1.0

Page 1 of 7

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

Product Identifier

Material Name: Ketamine Hydrochloride Injection (Hospira, Inc.)

Trade Name: Not established

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

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not required

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

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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 (Hospira, Inc.)

Page 2 of 7

Revision date: 19-Sep-2016

Version: 1.0

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ketamine hydrochloride	1867-66-9	217-484-6	Acute Tox.4 (H302)	5.7
Benzethonium chloride	121-54-0	204-479-9	Not Listed	*

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

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 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.

SAFETY DATA SHEET

Material Name: Ketamine Hydrochloride Injection (Hospira, Inc.)

Page 3 of 7

Revision date: 19-Sep-2016

Version: 1.0

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

SAFETY DATA SHEET

Material Name: Ketamine Hydrochloride Injection (Hospira, Inc.)

Page 4 of 7

Revision date: 19-Sep-2016

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid solution	Color:	Colorless
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
Solubility:	Soluble: Water
pH:	3.5-5.5
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Water for injection

No data available

Ketamine hydrochloride

No data available

Benzethonium chloride

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Specific Gravity: 1.008 - 1.028

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): >93

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

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

SAFETY DATA SHEET

Material Name: Ketamine Hydrochloride Injection (Hospira, Inc.)

Page 5 of 7

Revision date: 19-Sep-2016

Version: 1.0

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)

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

Benzethonium chloride

Rat Oral LD50 368mg/kg
Rat Subcutaneous LD50 119mg/kg
Rat IV LD50 19mg/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

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.

SAFETY DATA SHEET

Material Name: Ketamine Hydrochloride Injection (Hospira, Inc.)

Page 6 of 7

Revision date: 19-Sep-2016

Version: 1.0

11. TOXICOLOGICAL INFORMATION

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
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.
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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

Ketamine hydrochloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
U.S. Drug Enforcement Administration:	III

SAFETY DATA SHEET

Material Name: Ketamine Hydrochloride Injection (Hospira, Inc.)

Page 7 of 7

Revision date: 19-Sep-2016

Version: 1.0

15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	217-484-6
Benzethonium chloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-479-9
Water for injection	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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

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

Revision date: 19-Sep-2016
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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