Hospira

MATERIAL SAFETY DATA SHEET

Product Name: Ketorolac Tromethamine Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira Inc. 275 North Field Drive Lake Forest, Illinois USA 60045
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880
Hospira, Inc., Non-Emergency	224-212-2000
Product Name	Ketorolac Tromethamine Injection, USP
Synonyms	Ketorolac trometamol; (±)-5-benzoyl-2, 3-dihydro-1H-pyrrolizine-1-carboxylic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name	Ketorolac Tromethamine
Chemical Formula	$C_{19}H_{24}N_2O_6$
Preparation	Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride; sodium hydroxide and/or hydrochloric acid are used to adjust the pH.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Ethyl Alcohol	10	64-17-5	KQ6300000
Ketorolac Tromethamine	≤ 3	74103-07-4	UY7759900

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Ethyl Alcohol	Not Listed	Not Listed	Not Listed
Ketorolac Tromethamine	Not Listed	Not Listed	Not Listed

Emergency Overview

Ketorolac Tromethamine Injection, USP, is a solution containing ketorolac tromethamine, a non-steroidal anti-inflammatory agent. Clinically, this product is used for the management of pain. In the workplace, ketorolac tromethamine should be considered a combustible liquid, a potent drug, and potentially irritating to the eyes and respiratory tract. Possible target organs include the gastrointestinal system, hematopoietic system, central nervous system, cardiovascular system, kidneys, liver, and possibly the eyes.

Occupational Exposure Potential

Information on the absorption of this product via inhalation or skin contact is not available. Published reports have indicated that ketorolac acid has some potential to be absorbed through intact skin. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms

During occupational use, this material should be considered potentially irritating to the eyes and

respiratory tract. In clinical use, adverse effects have included edema and hypertension, nausea, gastrointestinal pain, heartburn and headache. More severe side effects may include gastrointestinal ulceration. Exacerbation of existing renal ailments, leading to hematuria, proteinuria, polyuria, glomerular nephritis, interstitial nephritis, renal papillary necrosis, acute renal failure, and nephrotic syndrome may also occur. This drug affects platelet aggregation and clinical use has produced prolonged bleeding times and hemorrhages. Hypersensitivity reactions such as anaphylaxis, rash, bronchospasm, laryngeal edema, and hypotension have also occurred. Rarely, use of ketorolac can cause elevations in liver enzymes. Direct contact of this product with the eyes could result in eye irritation and stinging.

Medical Conditions Aggravated by Exposure

Pre-existing hypersensitivity to ketorolac, other non-steroidal anti-inflammatory agents, or aspirin. Pre-existing gastrointestinal, hematopoietic system, central nervous system, cardiovascular system, liver, or kidney ailments.

4. FIRST AID MEASURES

Eye contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability

Flash Point: 43°C (109°F)

Fire & Explosion Hazard

Combustible liquid. Keep away from flames, sparks, or other sources of ignition. When heated, product may produce combustible vapors due to the alcohol content.

Extinguishing media

As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures

No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal

Isolate area around spill. Remove potential sources of ignition. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required under conditions of normal product use.

Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits				
Component	**Type**	**mg/m3**	**ppm**	**µg/m3**	**Note**
Ethyl Alcohol	ACGIH 8 Hr TLV	N/A	1000	N/A	
Ethyl Alcohol	US OSHA 8 Hr PEL	N/A	1000	1900	
Ethyl Alcohol	Australia NOHSC	N/A	1000	N/A	
Ketorolac Tromethamine	Not Applicable	N/A	N/A	N/A	None Established

Respiratory protection Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection If skin contact with the product solution is likely, the use of latex or nitrile gloves is recommended.

Eye protection Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Liquid
Color	Clear to slightly yellow
Odor	NA
Odor Threshold:	NA
pH:	7.4 (6.9 - 7.9)
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	91°C at 760 mm Hg
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or	LEL: 3.3% UEL 19% based upon ethanol

Explosive Limits:	
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	0.991
Solubility:	Water, ethyl alcohol
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined.
Conditions to avoid	Not determined.
Incompatibilities	Not determined.
Hazardous decomposition products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Ketorolac Tromethamine	100	LD50	Oral	189	mg/kg	Rat
Ketorolac Tromethamine	100	LD50	Oral	293	mg/kg	Mouse
Ketorolac Tromethamine	100	LD50	Intraperitoneal	225	mg/kg	Mouse
Ethyl Alcohol	100	LD50	Oral	3450 to 11,500	mg/kg	Guinea Pig, Rat, Mouse, Dog

Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/Corrosion	None anticipated from normal handling of this product. Skin contact with ethanol may produce mild irritation with redness and dryness.
Ocular Irritation/Corrosion	None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. In clinical use, hypersensitivity reactions such as anaphylaxis, rash, bronchospasm, laryngeal edema, and hypotension have been reported.

Reproductive Effects	In studies in rodents, impairment of fertility did not occur in male or female rats given oral dosages of 9 mg/kg and 16 mg/kg of ketorolac tromethamine, respectively. Reproduction studies were conducted during organogenesis using ketorolac tromethamine at daily oral dosages of 3.6 mg/kg in rabbits and 10 mg/kg in rats; no adverse developmental effects on the fetus were noted in these studies. Dosages of ketorolac tromethamine tablets at 1.5 mg/kg administered after gestation day 17, caused dystocia and higher pup mortality in rats. Ethanol, an ingredient in this product, is a known human developmental toxicant. Ingestion of large amounts of ethanol during pregnancy is generally contra-indicated.
Mutagenicity	Ketorolac tromethamine was not mutagenic in the Ames test, unscheduled DNA synthesis and repair, and in forward mutation assays. Ketorolac tromethamine did not cause chromosome breakage in the in vivo mouse micronucleus assay. At concentrations [redacted]590 mcg/ml, ketorolac tromethamine increased the incidence of chromosomal aberrations in Chinese hamster ovarian cells.
Carcinogenicity	An 18-month oral-dose study in mice with ketorolac tromethamine at dosages of 2 mg/kg/day, and a 24-month oral-dose study in rats at dosages of 5 mg/kg/day, produced no evidence of tumorigenicity.
Target Organ Effects	Based on clinical use, possible target organs include the gastrointestinal system, hematopoietic system, central nervous system, cardiovascular system, liver, kidneys, and possibly the eyes.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product. Information for ingredients is listed below: *LC50(96h) = 1480 mg/L in bluegill sunfish for ketorolac tromethamine LC50(24 hr) = 12,900-15,300 mg/L in rainbow trout LC50 (24 hr) = 11,200 mg/L in fingerling trout LC50(48-hr) = 9,268 – 14,221 mg/L in Daphnia magna EC50 = 9310 mg/L in Chlorella pyrenoidosa *Roche MSDS
Persistence/Biodegradability	*Ketorolac tromethamine was not inherently biodegradable. Ethanol, an ingredient in this product, was reported to be degraded between 45% and 74% in five days in two aqueous biodegradation assays. *Roche MSDS
Bioaccumulation	Not determined for product. Because of its low octanol:water partition coefficient, ethanol is not anticipated to bioaccumulate.
Mobility in Soil	Not determined.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All wastes must be properly characterized by the waste generator. Disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Ethyl Alcohol	Listed	Not Listed	Not Listed	Not Listed	Listed
Ketorolac Tromethamine	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

RCRA Status Not Listed

U.S. OSHA Classification Target Organ Toxin
Possible Irritant
Combustible Liquid

GHS Classification *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class Not Applicable

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not Applicable

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Ketorolac Tromethamine

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/12/2011
Obsolete Date: 05/26/2009

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