SAFETY DATA SHEETS

This SDS packet was issued with item:

078913036

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078848709

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078905544

SAFETY DATA SHEET

Product Name: Ketorolac Tromethamine Injection, USP

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
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. HAZARD(S) IDENTIFICATION

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. Based on clinical use, possible target organs include the gastrointestinal system, hematopoietic system, nervous system, cardiovascular system, liver, and kidneys.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Flammable Liquid	3

Health Hazards	**Hazard Class**	**Hazard Category**
	Eye Damage / Irritation	2B
	Toxic to Reproduction	2
	STOT – RE	2

Label Element(s)

Pictogram

Signal Word Warning

Hazard Statement(s)

Flammable liquid and vapor
Causes eye irritation
Suspected of damaging fertility or the unborn child
May cause damage to organs through prolonged or repeated exposure

2. HAZARD(S) IDENTIFICATION: continued

Precautionary Statement(s)

Prevention

Keep away from heat/sparks/open flames/hot surfaces.– No smoking
Keep container tightly closed
Ground/bond container and receiving equipment
Use explosion-proof equipment
Use only non-sparking tools
Take precautionary measures against static discharge

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.

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.

IN CASE OF FIRE: For small fires, use water fog or fire extinguishing media suitable for Class B fires (e.g. dry chemical, carbon dioxide or foam). For large fires, apply water from as far away as possible; use very large quantities of water applied as a mist or spray.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Ketorolac Tromethamine
Chemical Formula $C_{19}H_{24}N_2O_6$

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

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.

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 GHS Flammable Liquid – Category 3. 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 such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting 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 control 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 for hazard control 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	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Ketorolac Tromethamine	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established
Ethyl Alcohol	8 hr TWA: 1000 ppm; 1900 mg/m3	8 hr TWA: 1000 ppm	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average

Respiratory Protection Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols or vapors 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) with an organic vapor cartridge is recommended under conditions where airborne aerosol or vapor 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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION: continued

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	Clear to slightly yellow solution
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
Flash Point	43°C (109°F)
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	LEL: 3.3% based on ethanol UEL: 19% based on ethanol
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Water, ethyl alcohol
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	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 - 11,500	mg/kg	Guinea Pig, Rat, Mouse, Dog
Ethyl Alcohol	100	LC50 (10h)	Inhalation	20,000	ppm	Rat
Ethyl Alcohol	100	LC50 (4h)	Inhalation	39,000	mg/m3	Mouse

LD 50: Dosage that produces 50% mortality.
Product contains between approximately 1.5 to 3.0% ketorolac tromethamine.

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

None anticipated from normal handling of this product. 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.

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

None anticipated from normal handling of this product. 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 has been shown to produce fetotoxicity in the embryo or fetus of laboratory animals. Chronic prenatal exposure to ethanol has been associated with a distinct pattern of congenital malformations that have collectively been termed the "fetal alcohol syndrome".

11. TOXICOLOGICAL INFORMATION: continued

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 ≥ 1590 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.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs include the gastrointestinal system, hematopoietic system, nervous system, cardiovascular system, liver, and kidneys.

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 for ethanol LC50 (24 hr) = 11,200 mg/L in fingerling trout for ethanol LC50(48 hr) = 9,268 - 14,221 mg/L in Daphnia magna for ethanol EC50 = 9310 mg/L in Chlorella pyrenoidosa (green algae) for ethanol
Persistence/Biodegradability	*Ketorolac tromethamine was not inherently biodegradable. Ethanol was reported to be degraded between 45% and 74% in five days in two aqueous biodegradation assays.
Bioaccumulation	Not determined for product. Because of its low octanol:water partition coefficient, ethanol is not anticipated to bioaccumulate.
Mobility in Soil	Not determined.

*Roche MSDS
Notes:
1. LC50: Concentration in water that produces 50% mortality in fish or Daphnia
2. EC50: Concentration in water that produces 50% inhibition of growth in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, 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
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Product classified as D001 hazardous waste based on ignitability.
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP 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	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Keep away from heat/sparks/open flames/hot surfaces.– No smoking
Keep container tightly closed
Ground/bond container and receiving equipment
Use explosion-proof equipment
Use only non-sparking tools
Take precautionary measures against static discharge

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe vapor or spray
Wash hands thoroughly after handling

15. REGULATORY INFORMATION: continued

Response	Get medical attention if you feel unwell. 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. IN CASE OF FIRE: For small fires, use water fog or fire extinguishing media suitable for Class B fires (e.g. dry chemical, carbon dioxide or foam). For large fires, apply water from as far away as possible; use very large quantities of water applied as a mist or spray.
EU Classification*	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S17: Keep away from sources of ignition - No smoking S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with 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
LD_{50}	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

16. OTHER INFORMATION: continued

MSDS Coordinator: Hospira GEHS
Date Prepared: October 18, 2012
Date Revised: June 02, 2014

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