

72323



## 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 60045  
USA

**Note:** Hospira, formerly the Hospital Products Division of Abbott Laboratories, was created as an independent company in May 2004.

**Emergency Telephone Hospira, Inc.** CHEMTREC: 800 424-9300  
224 212-2055

**Product Name** Ketorolac Tromethamine Injection, USP

**Synonyms** None

### 2. 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	1.5 - 3	74103-07-4	N/A
Ethyl Alcohol	10	64-17-5	KQ6300000
Water	87	7732-18-5	ZC0110000

### 3. HAZARD INFORMATION

**Emergency Overview** In clinical use, this material is used for the management of pain. The active ingredient is a potent drug and is toxic by ingestion. Possible target organs include the gastrointestinal tract, hematopoietic system, nervous system, reproductive system, liver, kidneys, skin and possibly the eyes.

**Occupational Exposure Potential** Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

**Signs and Symptoms** No signs or symptoms from occupational exposure are known. Clinical data suggest the following: nausea, headaches, dizziness, insomnia, constipation, sleep, gastrointestinal upset, abdominal pain. May cause abnormal kidney function or rash. Direct contact with the eyes could result in eye irritation and stinging.

**Medical Conditions Aggravated by Exposure** Hypersensitivity to the material and/or similar materials. Pre-existing ailments in the following organs: kidney, liver, hematopoietic system, gastrointestinal tract.

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#### **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

**Fire & Explosion Hazard:** None

**Extinguishing Media:** 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** Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

#### **7. HANDLING AND STORAGE**

**Handling** No special handling required.

**Storage** No special storage required for hazard control. For product protection store at controlled room temperature of 15-30°C (59-86°F). Protect from light, retain in carton until time of use.

**Special Precautions** Protect from freezing and extreme heat.

#### **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

##### **Exposure Guidelines**

<b>Component</b>	<b>Exposure limits</b>		
	<b>OSHA-PEL</b>	<b>ACGIH-TLV</b>	<b>Hospira EEL</b>
Ketorolac Tromethamine	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 40 mcg/m3 STEL: Not Established
Ethyl Alcohol	8 hr TWA: 1900 mg/m3	8 hr TWA: 1900 mg/m3	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.  
EEL: Employee Exposure Limit.  
TWA: 8 hour Time Weighted Average.  
STEL: 15-minute Short Term Exposure Limit.

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**Respiratory Protection**                      Respiratory protection is not needed during normal product use.

**Skin Protection**                              If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.

**Eye Protection**                              Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.

**Engineering Controls**                      Engineering controls are not needed during normal product use conditions.

**9. PHYSICAL/CHEMICAL PROPERTIES**

**Appearance/Physical State**                      Clear, slightly yellow solution.

**Odor**    Not Determined.

**Boiling Point**                                  91°C at 760 mm Hg

**Freezing Point**                                Not Determined

**Vapor Pressure**                                Not Determined

**Vapor Density (Air=1)**                        Not Determined

**Evaporation Rate**                            Not Applicable

**Bulk Density**                                  0.991 g/mL

**Specific Gravity**                              Not Determined

**Solubility**                                      Water, ethyl alcohol

**pH**    6.9-7.9

**10. STABILITY AND REACTIVITY**

**Chemical Stability**                            Stable under standard use and storage conditions.

**Incompatibilities**                            Not Determined

**Hazardous Decomposition Products**                            Oxides of carbon

**Hazardous Polymerization**                            Not Determined.

**11. TOXICOLOGICAL INFORMATION:**

**Acute Toxicity: Oral**

<b>Ingredient(s)</b>	<b>Percent</b>	<b>Test Type</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
Ketorolac Tromethamine	100	LD50	202-505	mg/kg	Rats
Ethyl Alcohol	100	LD50	5560-13,700	mg/kg	Guinea Pigs, Rats, Mice, Rabbits

LD 50: Dosage that produces 50% mortality.  
Product contains between approximately 1.5-3.0% Ketorolac Tromethamine.

**Mutagenicity**                                  Not Determined

**Target Organ Effects**                        In clinical use target organ effects include the gastrointestinal tract, hematopoietic system, nervous system, reproductive system, liver, kidneys, skin and possibly the eyes.

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**12. ECOLOGICAL INFORMATION:**

**Aquatic Toxicity**                      Not Available

**13. DISPOSAL CONSIDERATIONS:**

**Waste Disposal**                      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**

**DOT Proper Shipping Name:**      Ethanol Solutions

**UN Number:**                              UN 1170

**Hazard Class:**                            3

**Packing Group:**                         III

Notes:      DOT - US Department of Transportation Regulations

**15. REGULATORY INFORMATION**

**TSCA Status**                              Not Regulated

**CERCLA Status**                          Not Regulated

**SARA Status**                              Not Regulated

**RCRA Status**                              Not Regulated

**PROP 65 (Calif.)**                        Not Regulated

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

**16. OTHER INFORMATION:**

**MSDS Coordinator**                      T. Straits MPH, CIH

**Date Prepared**                            September 15, 2005

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