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 - 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. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Ketorolac Tromethamine

Chemical Formula C_{19}H_{24}N_{2}O_{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.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>10</td>
<td>64-17-5</td>
<td>KQ6300000</td>
</tr>
<tr>
<td>Ketorolac Tromethamine</td>
<td>≤ 3</td>
<td>74103-07-4</td>
<td>UY7759900</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Ketorolac Tromethamine</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

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
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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 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 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Guidelines</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>Component Type</td>
<td>mg/m3</td>
</tr>
<tr>
<td>ACGIH 8 Hr TLV</td>
<td>N/A</td>
<td>1000</td>
</tr>
<tr>
<td>US OSHA 8 Hr PEL</td>
<td>N/A</td>
<td>1000</td>
</tr>
<tr>
<td>Australia NOHSC</td>
<td>N/A</td>
<td>1000</td>
</tr>
<tr>
<td>Ketorolac Tromethamine</td>
<td>Not Applicable</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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
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:

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

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.
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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 ≥ 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.

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>Listed</td>
<td>Not Listed</td>
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**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
Product Name: Ketorolac Tromethamine Injection, USP

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: 10/18/2012
Obsolete Date: 10/12/2011

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