MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT & COMPANY IDENTIFICATION

1501 East Woodfield Road
Suite 300 East
Schaumburg, IL 60173
(847) 969-2700

Emergency Telephone **(800) 551-7176**

Product Identifier: Ketorolac Tromethamine Injection, USP

Chemical Name: Ketorolac Tromethamine

Category: Anti-Inflammatory

SECTION 2 - COMPOSITION

Ingredient	CAS Number	Amount
Ketorolac Tromethamine	74103-06-3	15 mg/mL, 30 mg/mL, or 60 mg/2mL
Citric Acid, Anhydrous	77-92-9	0.1%
Ethyl Alcohol	64-17-5	10% (w/v)
Sodium Chloride	7647-14-5	see package insert
Water for Injection	7732-18-5	QS

SECTION 3 - HAZARDS IDENTIFICATION

Route of Entry: Inhalation, eye/skin contact, or ingestion

Chemical Listing as Carcinogen

NTP: No

IARC: No

OSHA: No

Note: NA

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Seek medical attention.

Skin: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention if pain, redness, or swelling persists.

SECTION 4 - EMERGENCY & FIRST AID MEASURES…continued

Inhalation:	Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.
Ingestion:	Flush mouth out with water immediately. Seek medical attention.
Contact Info:	For Adverse Event Information, please call (800) 551-7176 or (847) 969-2700.

SECTION 5 - FIRE FIGHTING MEASURES

Fire and Explosion Data

Closed Cup Flash Point:	NE
Open Cup Flash Point:	NE
Fire Point:	NE
Autoignition:	NE
Lower Explosion Limit:	3.3%
Upper Explosion Limit:	19% based on ethanol
General Hazard:	When heated to decomposition, it emits toxic fumes.
Fire Fighting Instructions:	Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
Fire Fighting Equipment:	Wear self-containing breathing apparatus and protective clothing.
Hazardous Combustion Products:	Smoke and NO_X fumes.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Clean-Up:	Wear recommended personal protective equipment (See Section 8 - Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.

SECTION 7 - HANDLING AND STORAGE

General Handling:	When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.
Storage Conditions:	Store at 15° to 30°C (59° to 86°F), with protection from light.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.

Personal Protective Equipment

Eye Protection: Safety glasses or goggles recommended.

Hand Protection: Disposable latex gloves recommended.

Respiratory Protection: With satisfactory ventilation, respiratory protection is usually not required.

Skin Protection: Disposable garments if direct skin contact is anticipated.

Exposure Limits:

Compound	Issuer	Type	OEL
Ketorolac Tromethamine	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Citric Acid, Anhydrous	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Ethyl Alcohol	OSHA	PEL	1900 mg/m³
	ACGIH	TLV	1880 mg/m³
	---	STEL	NE
Sodium Chloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical Form/ Appearance: Clear to slight yellow solution

Boiling Point/Boiling Range: NA

Melting Point/Melting Range: 153°-155°C

Freezing Point: NA

Vapor Pressure: NA

Relative Vapor Density: NA

Percent Volatiles: NA

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES…continued

pH: 7.2 - 7.6

Molecular Weight: 376.41

Solvent Solubility: NA

Note: NA

SECTION 10 - STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Storage with oxidizers or water-reactive materials.

Hazardous Polymerization: Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Signs & Symptoms of Exposure & Overexposure: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Adverse reactions from therapeutic doses include: edema, hypertension, pruritus, rash, nausea, dyspepsia, gastrointestinal pain, diarrhea, constipation, flatulence, gastrointestinal fullness, vomiting, stomatitis, purpura, headache, drowsiness, dizziness, and sweating. Occupational exposure has not been fully investigated.

Medical Conditions Aggravated by Accidental Exposure: Individuals with active peptic ulcer disease, gastrointestinal bleeding or perforation, history of peptic ulcer diseases, gastrointestinal bleeding, advanced renal impairment or at risk for renal failure due to volume depletion, hypersensitivity to ketorolac tromethamine, allergic manifestations to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs), and those with medical conditions that are at high risk for bleeding.

Acute Toxicity:

Compound	Type	Route	Species	Dosage
Ketorolac Tromethamine	LD_{50}	Oral	Rat	189 mg/kg
	LD_{50}	Oral	Mouse	293 mg/kg
	LD_{50}	IP	Mouse	225 mg/kg

Other: NA

SECTION 12 - TRANSPORTATION INFORMATION

UN/NA Number: UN 1170

U.S. DOT Hazard Class: Hazard Class 3 - Flammable Liquid

SECTION 12 - TRANSPORTATION INFORMATION…continued

Proper Shipping Name: Medicines, flammable liquid, n.o.s., (Ketorolac Solution)

Shipping Label: Flammable liquid

SECTION 13 - DISPOSAL INFORMATION

Disposal Procedure: Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state, and local regulations.

SECTION 14 - OTHER

Key to Abbreviations:

ACGIH - American Conference of Governmental Industrial Hygienists
HEPA - High Efficiency Particulate Air
IARC - International Agency for Research on Cancer
NA - Not Applicable
NE - Not Established
NG - Not Given
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OEL - Occupational Exposure Limit
OSHA - Occupational Safety and Health Administration
PEL - Permissible Exposure Limit
PPM - Parts Per Million
QS - Quantity Sufficient
RCRA - Resource Conservation and Recovery Act
STEL - Short Term Exposure Limit
TLV - Threshold Limit Value
USP - United States Pharmacopeia

Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Abraxis BioScience, Inc. assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.