



SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE PRODUCT & THE COMPANY

a) Product Name	: Ketorolac Tromethamine Injection, USP
b) Common/ trade Name	: Ketorolac Tromethamine Injection
Chemical Name	: \pm -5-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, Compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)
Chemical Family	: Non-steroidal anti-inflammatory drug (NSAID)
a) Product Use	: Pharmaceutical, injectable
Product type	: Regulated prescription drug
Container Information	: Vial
b) Manufacture Name	: Gland pharma Limited
Address	: Survey No.: 143-148, 150 & 151 Near Gandimaisamma Cross Roads, D.P.Pally, Quthbullapur Mandal Ranga Reddy District Hyderabad- 500043 Telagana, India
c) Telephone Number for Info	: +91-40-30510999

SECTION 2: HAZARDS IDENTIFICATION

Primary Physical and Health Hazards:	In the workplace, ketorolac tromethamine should be considered a potent drug, and possibly irritating to the eyes. Possible target organs include the gastrointestinal system, hematopoietic system, central nervous system, cardiovascular system, kidneys, liver, and possibly the eyes. Ketorolac affects the central nervous system and has relatively low acute toxicity. Chronic toxicity will result only on excessive repetitive exposure. Chronic Toxicity effects may be seen at the digestive system.
Routes of Entry:	Skin and eye absorption, ingestion, inhalation
Signs & Symptoms of Exposure:	Common adverse effects to excessive exposure include nausea, vomiting, gastrointestinal irritation, diarrhea, fatigue, insomnia, headache and dizziness.
Chemical Listed as Carcinogen:	NTP: No IARC: No OSHA: No
Medical Conditions Generally Aggravated by Exposure:	Allergies to non-steroidal, anti-inflammatory drugs such as aspirin.



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SECTION 3 – COMPOSITION AND INGREDIENTS

3.1. Drug Substances

No data found

3.2. Drug mixture

Name	Product Identifier	%
Ketorolac Tromethamine	74103-07-4	1.5
Ethanol	64-17-5	10.0
Sodium Chloride	7647-14-5	0.7
Water for Injection	7732-18-5	87.8

SECTION 4 - FIRST AID MEASURES

4.1 Description of First Aid Measures:

EYE EXPOSURE : In case of contact with eyes rinse thoroughly with plenty of water and get medical advice

Skin Exposure : Remove immediately contaminated clothes, wash affected skin with plenty of water

Ingestion : Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician or poison center

Injection : Under normal use with supervise on of a physician.

Inhalation : In case of inhalation remove to fresh air and seek medical aid.

Notes to Physician : Treat symptoms and eliminate over exposure. See patient package insert in shipping carton for complete information.

4.2. Most important symptoms and effect, both acute and delayed

Symptoms/Injuries after inhalation: May cause skin irritation.

Symptoms/Injuries after skin contact: May cause skin irritation

SECTION 5: FIRE-FIGHTING MEASURES

Flash Point:	106°F
Auto-ignition Temperature:	Not established
Flammable Limits:	Lower %: 3.3% Upper %: 19% based on Ethanol



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Extinguishing Media:	Use a multi-purpose extinguisher, or water spray
Special Fire Fighting Procedures:	During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus. As with all fires, evacuate personnel to a safe area.
Unusual Fire/Explosion Hazards:	None.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- Spill:** Absorb Ketorolac with absorbent materials and dispose according to local, state, and federal guidelines.
- Release to Air:** If aerosolized, reduce exposures by ventilating the area; clean up spill immediately to prevent evaporation.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

SECTION 7: HANDLING AND STORAGE

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use appropriate personal protective equipment(PPE) while handling (see section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. A dust/mist respirator (N95) with organic vapor cartridges may be necessary if excess volatiles are generated.

Waste Disposal Method: Dispose of according to local, state, and federal guidelines. Incineration is recommended.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection: Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) with organic vapor cartridges may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Eye Protection: Wear safety glasses or goggles if eye contact is possible.

Ventilation: General room ventilation is adequate unless the process generates dust, mist or fumes.

Skin Protection: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations; use latex or nitrile gloves.

Other Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).



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Additional Exposure Not applicable

Precautions:

Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Ketorolac Tromethamine	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Ethanol	OSHA	PEL	1000ppm
	ACGIH	TLV	1000ppm
	----	STEL	NE
Sodium Chloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

Exposure controls:

Personal Protective Equipment : Protective goggles. Gloves. Protective clothing.



Materials for Protective Clothing : Chemically resistant materials and fabrics.

Hand Protection : Wear chemically resistant protective gloves.

Eye Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing.

Respiratory Protection : In case of insufficient ventilation, wear suitable respiratory equipment.

Environmental Exposure Controls : Do not allow the product to be released into the environment.

Consumer Exposure Controls : Do not eat, drink or smoke during use.

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Property	Ketorolac Tromethamine injection
Physical state	Liquid
Appearance:	Colorless to slightly yellow liquid
odor	No odor
pH:	6.9 to 7.9



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Water Solubility:	Water, ethyl alcohol
Molecular weight	376.40
Specific Gravity (g/ml):	Approximately to water 1.0
Boiling Point (°C):	91°C
Melting Point (°C):	No data available
Flash Point (°C):	No data available
Ignition Temperature (°C):	No data available
Density	No data available
Evaporation rate	No data available

SECTION 10: STABILITY AND REACTIVITY

Property	Ketorolac Tromethamine injection
Reactivity	Hazardous reactions will not occur normal conditions
Chemical stability	Highly flammable liquid and vapor. May form flammable or explosive vapor –air mixture.
Conditions to avoid:	Extreme heat, any conditions that are incompatibility with water, mixing this product with incompatible chemicals
Materials to avoid:	Strong oxidizing agents
Hazardous decomposition products:	Carbon oxides, toxic fumes
Possibility of Hazardous Reactions	Hazardous polymerization will not occur

SECTION 11: TOXICOLOGICAL INFORMATION

Signs & Symptoms of Exposure:	Common adverse effects to excessive exposure include nausea, vomiting, gastrointestinal irritation, diarrhea, fatigue, insomnia, headache and dizziness.
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Acute Toxicity:

Component	Type	Route	Species	Dosage
Ketorolac Tromethamine	LD ₅₀	Oral	Rat	189 mg/kg
Ketorolac Tromethamine	LD ₅₀	Oral	Mouse	293 mg/kg
Ketorolac Tromethamine	LD ₅₀	Intraperitoneal	Mouse	225 mg/kg



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SECTION 12: ECOLOGICAL CONSIDERATIONS

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
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.
Bioaccumulation:	Not determined for product. Because of its low octanol:water partition coefficient, ethanol is not anticipated to bioaccumulate.
Mobility in Soil:	Not determined.

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.

SECTION 13: DISPOSAL CONSIDERATIONS

Product: Observe all federal, state, and local environmental regulations.

Waste Disposal: - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use take back programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a take back program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

SECTION 14: TRANSPORT INFORMATION

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



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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

SECTION 15: REGULATORY INFORMATION

TSCA Status Exempt.
CERCLA Status Not listed
SARA 302 Status Not listed
SARA 313 Status Not listed
RCRA Status Not listed
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

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

SECTION 16: OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number



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CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable,
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
IOEL	International Occupational Exposure Limit
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances



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SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations