SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	**Ketorolac Tromethamine Tablets** Human Pharmaceutical
Manufacturer	**Hetero Labs Limited, Unit-III** **22-110, IDA,** Unit III, Jeedimetla, Hyderabad-500055, India.
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Health Hazards	In the workplace, dusts from damaged tablets may cause irritation of contaminated skin or eye. Inhalation of dusts may be harmful. Non-therapeutic ingestion may be harmful. Ingestion of large amount may be fatal due to serious gastrointestinal and/or cardiovascular system effects. In therapeutic use, the most common adverse effects reported are upset stomach and other gastric upset. Therapeutic use of Ketorolac Tromethamine can cause peptic ulcers, gastrointestinal bleeding and/or perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. As a NSAID, therapeutic use of Ketorolac Tromethamine may cause an increased risk of serious cardiovascular thrombotic events, sometimes fatal. This risk may increase with duration of use. Severe anaphylactic reactions can occur in persons allergic to NSAIDs. As a NSAID, may cause harm to the fetus during pregnancy. Limited evidence of mutagenic effect, based on animal information. These effects may be possible as a result of workplace exposure. Refer to Section 11 (Toxicological Information) for additional information on adverse effects)
Flammability Hazards	This product is combustible and can ignite if highly heated or if exposed to direct flame. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon, magnesium, titanium, and nitrogen oxides).
Reactivity Hazards	This product is not reactive
Environmental Hazards:	The active ingredient is toxic to aquatic organism and can cause long-term harm to aquatic organisms if accidentally released. All environmental release should be avoided

Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Ketorolac Tromethamine	74103-07-4
Hydroxypropyl Cellulose	9004-64-2
Lactose Monohydrate	10039-26-6
Magnesium Stearate	557-04-0
Microcrystalline Cellulose	9004-34-6
Opadry white	NA

Section 4: First-Aid Measures	
Description of first aid measures	Contaminated individuals must be taken for medical attention if any adverse effects occur. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.
Skin exposure	No specific effect is expected from skin contact. If this product contaminates the skin and adverse effect occurs, begin decontamination with running water. The contaminated individual must seek medical attention if any adverse effects occur after flushing.
Eye exposure	If dusts from product enter the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect continues after flushing.
Inhalation	If dusts of this product are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur.
Ingestion	If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, victim should drink up to three glasses of water. Do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain emergency medical attention.

Section 5: Fire-Fighting Measures	
Fire Extinguishing Media	Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product
Unsuitable Fire Extinguishing Media	None known
Special hazards arising from the substance	This product must be substantially pre-heated before ignition can occur. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon, magnesium, titanium and nitrogen oxides).
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows, a small scoop to collect glass fragments (if applicable) and two large waste disposal bags. Absorbents should be able to be incinerated. Avoid generating airborne dusts of this product during spill response procedures as described below
Environmental precautions	Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.
Methods and materials for containment and cleaning up	
Cleanup of Small Spills: Pick-up or wipe-up spilled tablets with damp absorbent sheets to prevent generation of dusts. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water. **Large Spills**: Restrict access to the spill areas. Gently wet down area and carefully sweep up spilled product, avoiding the generation of airborne dusts. The dispersion of particles into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water. **All Spills**: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered product and report spill per regulatory requirements.	

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

Section 7: Handling and Storage	
Handling **Precautions for safe handling**	All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. After handling this product, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this product is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection). Open containers slowly on a stable surface in areas that have been designated for use of this product. Minimize all exposures to this product. Avoid generation of dusts. Areas in which this product is used should be wiped down, so that this dusts from product does not accumulate.
Conditions for safe storage	Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F). Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual product; therefore, empty containers should be handled with care and disposed of properly.
Specific end use(s)	This product is a human pharmaceutical.
Protective Practices during maintenance of contaminated equipment	When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean up of equipment. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water

Section 8: Exposure Controls/Personal Protection	
Exposure Limits / Control parameters	
Ventilation and engineering controls	General Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Prevent accumulation of product on work surfaces by routinely cleaning areas appropriately
Protective equipment	The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132), equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02, Z94.3-M1982, Industrial Eye and Face Protectors and CSA Standard Z195-02, Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.
Respiratory protection	Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998).
Eye protection	Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.
Hand protection	Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double

	glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations
Skin protection	Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.

Section 9: Physical and Chemical Properties

Physical Form	Round tablets.
Description	Ketorolac Tromethamine Tablets, USP 10 mg are available as white to off-white colored, film-coated, round shaped, bevel edged biconvex tablets debossed with 'K' on one side and 'H' on other side. Bottles of 100 tablets N DC 31722-686-01

Section 10: Stability and Reactivity

Chemical stability	Stable under normal conditions
Decomposition products Combustion	Products of thermal decomposition may include carbon, magnesium, titanium, and nitrogen oxides
Hydrolysis	None known.
Materials with which substance is incompatible	Incompatible with strong oxidizing agents
Posibility of Hazardous reaction / Polymerization	Will not occur
Conditions to Aviod	Exposure to or contact with extreme temperatures, incompatible chemicals.

Section 11: Toxicological Information

Health effects OR Risks from Exposure:

Acute: Dusts from product may cause irritation if inhaled and in contact with skin or eyes. Non-therapeutic ingestion may be harmful. Acute exposure may cause effects described in “Other Potential Health Effects”.

Chronic: Dermatitis (inflammation and redness of the skin) may occur after chronic, low-level skin contact. Chronic ingestion may cause severe gastrointestinal, cardiovascular effects and severe

allergic reaction in susceptible individuals. As a NSAID, may cause fetal harm; limited mutagenic effects, based on animal data. No chronic effects have been reported from workplace exposure.

Ketorolac Tromethamine:
LDLo (Intramuscular-Woman) 15 mg/kg/6 days-intermittent: Kidney/Ureter/Bladder: changes in tubules (including acute renal failure, acute tubular necrosis); Nutritional and Gross Metabolic: changes in potassium, body temperature increase
LD50 (Oral-Rat) 189 mg/kg: Behavioral: somnolence (general depressed activity), ataxia; Skin and Appendages: hair
LD50 (Oral-Mouse) 293 mg/kg: Behavioral: somnolence (general depressed activity), ataxia; Skin and Appendages: hair
LD50 (Intraperitoneal-Mouse) 225 mg/kg: Behavioral: somnolence (general depressed activity), ataxia; Skin and Appendages: hair
Carcinogenic Potential of components: The following information is for the active ingredient. An 18 month study in mice with oral doses of Ketorolac Tromethamine at 2 mg/kg/day (0.9 times the human systemic exposure at the recommended IM or IV dose of 30 mg qid, based on area-under-the-plasma-concentration curve [AUC]), and a 24 month study in rats at 5 mg/kg/day (0.5 times the human AUC) showed no evidence of tumorigenicity.

Section 12: Ecological Information

All Work Practices Must be Aimed at Eliminating Environmental Contamination.

Mobility: This product has not been tested for mobility in soils. No predicted values are available.

Persistence and Biodegradability: This product has not been tested for persistence and biodegradability. No predicted values are available.

Bio-Accumulation Potential: This product has not been tested for bio-accumulation potential. No predicted values are available.

Ecotoxicity: This product may be harmful or fatal to contaminated plant and animal-life (especially if large quantities are released). This product has not been tested for aquatic toxicity. The following aquatic toxicity data are available for the active ingredient.

Ketorolac Tromethamine:
LC50 (Fish) 96 hours = 1480 g/L

Other Adverse Effects: The components of this product are not listed as having ozone depletion potential.

Environmental Exposure controls: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

Section 13: Disposal Considerations

Waste Treatment /Disposal methods: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All protective clothing, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters. Reusable equipment should be cleaned with soap and water and thoroughly rinsed.

Disposal containers: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

Precautions to be followed during waste Handling: Wear proper protective equipment when handling waste materials.

U.S. EPA WASTE NUMBER: Not applicable.

EWC WASTE CODE: Wastes from natal care, diagnosis, treatment, or prevention of disease in humans: chemicals consisting of or containing dangerous substances, 18-01-06

Section 14: Transport Information

U.S. DEPARTMENT OF TRANSPORTATION: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.
EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN); no component is specifically listed in Annex III under MARPOL 73/78.

Section 15: Regulatory Information

ADDITIONAL U.S. REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. SARA HAZARD CATEGORIES (SECTION 311/312, 40 CFR 370-21): ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No

U.S. CERCLA REPORTABLE QUANTITY (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; this product is not subject to requirements under TSCA.

ADDITIONAL U.S. REGULATIONS (continued):

OTHER U.S. FEDERAL REGULATIONS: Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No component of this product is listed on the California Proposition 65 Lists.

ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL/NDSL STATUS: This product is regulated by the Therapeutic Products Programme (TPP) of Health Canada; it is exempt from the requirements of CEPA.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITY SUBSTANCES LISTS: The components of this product are not on the CEPA Priority Substances Lists.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

ADDITIONAL EUROPEAN REGULATIONS:

SAFETY, HEALTH, AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE PRODUCT: Formulated, finished medicinal products for human use, are subject to Directive 2001/83/EC and subsequent amendments to the directive.

CHEMICAL SAFETY ASSESSMENT: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

Section 16: Other Information

Issue Date: 18-05-2023

Version: 00

Further information

Revision date: NA

Revision note: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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