


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	KETOROLAC TROMETHAMINE, USP
PRODUCT CODE	2249
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 3) Skin Irritation (Category 2) Eye Irritation (Category 2A) Toxic to Reproduction (Category 2) Specific Target Organ Toxicity - Repeated Exposure (Category 1) (cardiovascular system, gastrointestinal tract)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Toxic if swallowed. Causes skin irritation. Causes serious eye irritation. Causes damage to organs through prolonged or repeated exposure (cardiovascular system, gastrointestinal tract) Suspected of damaging fertility or the unborn child. May cause respiratory irritation.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not applicable

PRECAUTIONARY STATEMENT(S)	Prevention	Wash hands thoroughly after handling. Do not touch eyes. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Do not eat, drink or smoke when using this product. Do not breathe dust/fume/gas/mist/ vapors/spray. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Use only outdoors or in a well-ventilated area.		
	Response	IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth. IF ON SKIN: Wash with plenty of water. If skin irritation occurs, get medical help. Take off contaminated clothing and wash it before reuse. 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 help. IF EXPOSED OR CONCERNED: Get medical advice. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help if you feel unwell.		
	Storage	Store in a well ventilated place. Keep container tightly closed. Store locked up.		
	Disposal	Dispose of contents/container in accordance with local regulation		
	HMIS CLASSIFICATION	Health Hazard	2	Flammability
	Reactivity	0	Personal Protection	G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	(±)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)								
BOTANICAL NAME	Not applicable								
SYNONYM	Ketorolac Trometamol								
CHEMICAL FORMULA	C ₁₅ H ₁₃ NO ₃ ·C ₄ H ₁₁ NO ₃								
CHEMICAL FAMILY	Pyrrolizine carboxylic acid derivative								
CAS NUMBER	74103-07-4								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	376.4066								
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>KETOROLAC TROMETHAMINE</td> <td>74103-07-4</td> <td>620-545-3</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	KETOROLAC TROMETHAMINE	74103-07-4	620-545-3	100
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KETOROLAC TROMETHAMINE	74103-07-4	620-545-3	100						

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

MEDICAL ATTENTION AND
SPECIAL TREATMENT

Get emergency medical help.

SYMPTOMS CAUSED BY
EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING
FROM THE CHEMICAL

Not applicable.

FLAMMABLE PROPERTIES

May be combustible at high temperature.

HAZARDOUS COMBUSTION
PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE
EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND
PRECAUTIONS FOR
FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, fumes, spray, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR
CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER
SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE
HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Store at 25°C, excursions permitted between 15° and 30°C.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: KETOROLAC TROMETHAMINE CAS #: 74103-07-4

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

USP: ELV: Industrial Use: TWA: 0.025 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White to off-white, crystalline powder.

SOLUBILITY	Freely soluble in water and in methanol; slightly soluble in alcohol, in dehydrated alcohol, and in tetrahydrofuran; practically insoluble in acetone, in dichloromethane, in toluene, in ethyl acetate, in dioxane, in hexane, in butyl alcohol, and in acetonitrile.				
ODOR	Not available.				
FLAMMABILITY	May be combustible at high temperature				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	(165-170)°C, (329-338)°F
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	- 0.59	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(165 - 170)°C, (329-338)°F (decomposition)
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	5.7 - 6.7 (1%)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25 °C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established.
CHEMICAL STABILITY	Not established.
INCOMPATIBLE MATERIALS	Strong oxidants.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.
HAZARDOUS POLYMERIZATION	Will not occur.
POSSIBILITY OF HAZARDOUS REACTION	Not established.
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 189 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Causes skin irritation (pH 5.7 - 6.7)
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes serious eye irritation (pH 5.7 - 6.7)

RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	Due to lack of data the classification is not possible.
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible.
CARCINOGENICITY	<p>OSHA KETOROLAC TROMETHAMINE is not listed.</p> <p>NTP KETOROLAC TROMETHAMINE is not listed.</p> <p>IARC KETOROLAC TROMETHAMINE is not evaluated.</p> <p>California Proposition This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</p>
ADDITIONAL CARCINOGENICITY INFORMATION	Due to lack of data the classification is not possible.
REPRODUCTIVE TOXICITY	<p>Suspected of damaging fertility or the unborn child.</p> <p>Therapeutic use of nonsteroidal anti-inflammatory agents (NSAIDs) during the second half of pregnancy is associated with adverse effects in the fetus such as premature closure of the ductus arteriosus, which may lead to persistent pulmonary hypertension in the newborn.</p> <p>Animal studies have shown that NSAIDs administered during late pregnancy can cause prolonged gestation, difficult labor, delayed birth, and decreased pup survival rates.</p> <p>Animal studies have not shown ketorolac tromethamine to cause birth defects in rats receiving oral doses up to 10 mg/kg/day and rabbits receiving up to 3.6 mg/kg/day. In rats chronically administered 1.5 mg/kg/day of ketorolac after day 17 of gestation, problems during labor, decreased birthweight, and decreased offspring survival were found.</p>
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Due to lack of data the classification is not possible.
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Causes damage to organs through prolonged or repeated exposure.
ASPIRATION HAZARDS	Based on available data, the classification criteria are not met.
SIGNS AND SYMPTOMS OF EXPOSURE	<p>ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact</p> <p>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available</p> <p>DELAYED HEALTH EFFECT FROM EXPOSURE: Gastrointestinal ulceration or bleeding. Hypertension. Kidney impairment. Blood disorders. Cardiovascular thrombotic events. Stroke. Central nervous system effects. Coma.</p> <p>Symptoms related to the physical, chemical, and toxicological characteristics: Nausea. Vomiting. Diarrhea. Constipation. Heartburn. Stomach pain. Black or tarry stools. Bleeding or bruising. Swelling. Sores, ulcers, or white spots on lips or mouth. Sweating. Bluish-colored skin. Insomnia. Mood, mental or behavioral changes. Confusion. Dizziness. Drowsiness. Headache. Itching. Rash. Weight gain. Vision, speech, or walking problems. Ringing in ears. Tremors. Trouble breathing. Fast heartbeat or palpitations.</p> <p>Medical conditions aggravated by exposure: Asthma. Aspirin allergy. Active alcoholism. Anemia. Impaired kidney or liver function. Cardiovascular disorders. Bleeding disorders. Peptic ulcer or gastrointestinal bleeding. Hypertension. Stomatitis.</p>
POTENTIAL HEALTH EFFECTS	<p>Inhalation May be harmful if inhaled. May cause irritation to mucous membranes and respiratory track.</p> <p>Ingestion Toxic if swallowed. Symptoms may include dizziness, headache, nausea and loss of coordination.</p> <p>Skin May be harmful if absorbed through skin. Causes skin irritation.</p> <p>Eyes Causes serious eye irritation.</p>

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): 1480 EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL	log Pow: -0.59
MOBILITY IN SOIL	Water Solubility: 1.37E+04 mg/L (25°C) Henry's Law Constant: 3.34E-28 atm-m ³ /mole (25°C)
OTHER ADVERSE EFFECTS	Not available This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER	2811
CLASS	6.1
PACKING GROUP	III
<u>AUSTRALIA</u> HAZCHEM	2X
<u>EU</u> TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not listed
ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A Appendix B		Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
KETOROLAC TROMETHAMINE 74103-07-4	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
KETOROLAC TROMETHAMINE 74103-07-4	N/L	Listed as Schedule 4*	N/L	Listed*	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
KETOROLAC TROMETHAMINE 74103-07-4	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT

Not applicable

NOTES

*Listed as Ketorolac (includes Ketorolac Tromethamine)

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** - American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** - Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** - Chemical Abstract Service; **CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** - Effective Concentration, 50%; **EPA** - Environmental Protection Agency; **GHS** - Global Harmonized System; **HMS** - Hazardous Materials Information System; **HSE** - Health and Safety Executive; **HSIS** - Hazardous Substances Information System; **IARC** - International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** - Ready Biodegradability Model; **ISS** - Istituto Superiore Sanità; **LC50** - Lethal Concentration, 50%; **LD50** - Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** - National Institute for Occupational Safety and Health; **NTP** - National Toxicology Program; **OSHA PEL** - Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** - Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** - Superfund Amendments and Reauthorization Act; **STEL** - Short Term Exposure Limit; **TLV** - Threshold Limit Value; **TWA** - Time Weighted Average; **WHMIS** - Workplace Hazardous Materials Information System

LAST REVISION

03/2023

SUPERSEDES

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.