



MATERIAL SAFETY DATA SHEET

KETOROLAC TROMETHAMINE OPHTHALMIC SOLUTION 0.5%

1. IDENTIFICATION

Material Identification	:	Ketorolac Tromethamine Ophthalmic Solution 0.5%w/v		
Active ingredient	:	1H-Pyrrolizine-1-carboxylic acid, 5-benzoyl-2,3-dihydro, (+/-)-, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol(1:1)		
Molecular Formula	:	$C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$	Molecular Weight	: 376.40 g/mol
CAS Number	:	74103-07-4		
Product Use	:	Non Steroidal Anti-Inflammatory		
Manufactured by	:	Micro Labs Limited Plot no. 113-116, KIADB, Bommasandra Industrial Area, Bommasandra-Jigani Link Road, Anekal taluk, Bangalore-560099, Karnataka, India	Manufactured for	: Micro Labs USA Inc. 106 Allen Road, Suite 102, Basking Ridge, New Jersey- 07920
Emergency Contact	:	+91-80-27839033		

2. HAZARDS IDENTIFICATION

Label Elements

Signal	:	None
Physical hazards	:	Not classified
Classification of the substance	:	Reproductive toxicity - Category 2
Hazard statements	:	H361 - Suspected of damaging fertility or the unborn child
Precautionary statements	:	P201: Obtain special instructions before use P202: Do not handle until all safety precautions have been read and understood P281 : Use personal protective equipment as required P308 + P313: If exposed or concerned: Get medical advice/attention P405: Store locked up P501: Dispose of contents/ container to an approved waste disposal plant P280: Wear protective gloves/protective clothing/eye protection / face protection
Supplementary Information	:	While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.
Hazard(s) not otherwise classified (HNOC)	:	Not known.

3. COMPOSITION/INFORMATION ON INGREDIENTS



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Chemical Name	CAS #	EINECS #	%w/w	Label Elements EU classification (67/548/EEC) GHS & EU classification (1272/2008 EC) Risk phrases/Hazard statements
Ketorolac Tromethamine USP 1H-Pyrrolizine-1-carboxylic acid, 5-benzoyl-2,3- dihydro, (+/-)-, compound with 2-amino-2- (hydroxymethyl)-1,3- propanediol(1:1)	74103-07-4	Not listed	Proprietary	EU 67/548/EEC: Classification: Toxic if swallowed GHS & EU 1272/2008: Classification: Acute toxicity, Oral (Category 3) Hazard codes: H301, H311, H331 Hazard symbol/Pictogram: GHS06
Benzalkonium Chloride Solution 50% USP/NF	63449-41-2	264-151-6	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Acute oral toxicity, Skin corrosion, Acute aquatic toxicity Hazard codes: H302, H312, H314, H400 Hazard symbol/Pictogram: GHS05, GHS07, GHS09
Sodium Chloride USP	7647-14-5	231-598-3	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Not Classified
Edetate Disodium USP/NF	6381-92-6	205-358-3	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Acute toxicity, Category 4, Inhalation, Specific target organ toxicity- repeated exposure, Category 2, Inhalation, Respiratory tract Hazard codes: H332, H373 Hazard symbol/Pictogram: GHS07, GHS08



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Octoxynol 40 IH	9036-19-5	Not listed	Proprietary	<p>EU 67/548/EEC: Classification: Not classified under European Union Legislation</p> <p>GHS & EU 1272/2008: Classification: Acute toxicity, Oral (Category 4), Skin irritation (Category 2), Serious eye damage (Category 1), Short term (acute) aquatic hazard (Category 1), Long term (chronic) aquatic hazard (Category 1)</p> <p>Hazard codes: H302, H315, H318, H400, H410</p> <p>Hazard symbol/Pictogram: GHS05, GHS07, GHS09</p>
Sodium Hydroxide USPNF	1310-73-2	215-185-5	Proprietary	<p>EU 67/548/EEC: Classification: Corrosive</p> <p>Risk phrase code: R35</p> <p>Hazard symbol: C</p> <p>GHS & EU 1272/2008: Classification: Category 1/1A</p> <p>Hazard codes: H290, H314</p> <p>Hazard symbol/Pictogram: GHS05</p>
Hydrochloric Acid USPNF	7647-01-0	231-595-7	Proprietary	<p>EU 67/548/EEC: Classification: Corrosive</p> <p>Risk phrase code: R34, R37</p> <p>Hazard symbol: C, Xi</p> <p>GHS & EU 1272/2008: Classification: Category 1/1B</p> <p>Hazard codes: H290, H314, H335</p> <p>Hazard symbol/Pictogram: GHS05, GHS07</p>

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eyes Contact	:	Remove from source of exposure. Keep eye wide open while rinsing. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Do not rub affected area. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact	:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.



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Ingestion	: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. Never give anything by mouth if victim is rapidly losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing has stopped, trained personnel should begin artificial respiration (use protective mask with one -way valve), or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention. Treat symptomatically and supportively. Overdose treatment should be symptomatic and supportive and may include the following: 1. To decrease absorption, administer activated charcoal followed by a cathartic (if the charcoal is not pre-mixed with sorbitol). Gastric lavage or induced vomiting may also be helpful. 2. For abdominal pain, administer antacids. 3. For gastrointestinal ulceration or bleeding, administer antacids, histamine H2-receptor antagonists, misoprostol, omeprazole, and/or sucralfate, depending on the site and severity of ulcer. 4. For kidney failure, dialysis may be needed; however, hemodialysis does not remove significant amounts of ketorolac from the body. 5. Institute supportive measures such as establishment of intravenous lines, hydration, plasma volume expanders, and ventilatory function support as needed. (USP DI 2006)
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4. FIRST AID MEASURES

Inhalation	: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves. Persons developing serious hypersensitivity reactions must receive immediate medical attention.
Protection of First-Aiders:	: Use personal protective equipment.
Signs and Symptoms:	: Not determined
Medical Conditions Aggravated by Exposure:	: Hypersensitivity to material and impaired liver or kidney function.
Notes to Physician:	: Ketorolac Tromethamine: Delayed healing; Cross-sensitivity or hypersensitivity; Increased bleeding time due to interference with thrombocyte aggregation; Corneal effects including keratitis. Benzalkonium Chloride: Treat symptomatically.



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General information	:	Remove from exposure. Remove contaminated clothing. For treatment advice, get the guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
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5. FIRE FIGHTING MEASURES

Extinguishing media	:	Use extinguishing media suitable for surrounding materials. Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self contained breathing equipment and protective clothing.
Specific hazards arising from the chemical	:	The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating and toxic gases and vapors. In the event of fire and/or explosion do not breathe fumes.

General Information

As in any fire, wear self-contained breathing apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.
Environmental precautions	:	Do not allow into any sewer, on the ground or into any body of water. Should not be released into the environment. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.
Methods and material for containment and cleaning up	:	Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal. Dike far ahead of liquid spill for later disposal. Soak up with inert absorbent material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations. Clean contaminated surface thoroughly. Prevent product from entering drains. Dam up. After cleaning, flush away traces with water.

7. HANDLING AND STORAGE

Precautions for safe handling	:	Avoid contact with product and use caution to prevent puncturing containers. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Ensure adequate ventilation, especially in confined areas. In case of insufficient ventilation, wear suitable respiratory equipment. Use only with adequate ventilation and in closed
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		systems. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
Conditions for safe storage, including any incompatibilities		
Storage conditions	:	Store at 15°C to 25°C (59°F to 77°F) with protection from light.
Specific end use(s)	:	Pharmaceutical drug product for patients
8. EXPOSURE CONTROLS / PERSONAL PROTECTION		
Engineering Controls	:	The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable. Ensure that eyewash stations and safety showers are proximal to the work station location.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION		
Personal Protective Equipment	:	Under normal work conditions, the use of personal protective equipment is not expected to be required. However major spills should require the use of designated personal protective equipment. If engineering controls and work practices are not effective in controlling exposure to this material, then wear suitable personal protective equipment. Have appropriate equipment available for use in emergencies such as spills or fire.
Respiratory Protection	:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Hands	:	Wear chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Eye Protection	:	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	:	During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
9. PHYSICAL AND CHEMICAL PROPERTIES		
Physical State	:	Ophthalmic Solution
Color	:	Clear, colorless solution



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Appearance	:	Ketorolac Tromethamine Ophthalmic Solution 0.5%w/v: Clear, colorless to nearly colorless, slightly viscous solution, free from any visible particles.
Molecular Formula	:	C ₁₅ H ₁₃ NO ₃ ·C ₄ H ₁₁ NO ₃
Molecular Weight	:	376.40 g/mol

10. STABILITY AND REACTIVITY

Reactivity	:	Stable under recommended storage conditions.
Conditions to Avoid	:	Exposure to air or moisture over prolonged periods. Avoid exposure to light and strong oxidizing agent.
Incompatible Materials	:	Oxidizing agents, strong acid and alkaline solutions, alkali metals and silver preparations.
Hazardous Decomposition Products	:	Thermal decomposition can lead to release of irritating and toxic gases and vapors.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity	:	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th>Chemical Name</th> <th>Oral LD50</th> <th>Dermal LD50</th> <th>Inhalation LC50</th> </tr> </thead> <tbody> <tr> <td>Ketorolac Tromethamine</td> <td>189 mg/kg (rat) 293 mg/kg (mouse)</td> <td>NA</td> <td>NA</td> </tr> <tr> <td>Benzalkonium Chloride</td> <td>NA</td> <td>1420 mg/kg (Rat)</td> <td>NA</td> </tr> <tr> <td>Sodium Chloride</td> <td>=3000 mg/kg (Rat)</td> <td>> 10 g/kg (Rabbit)</td> <td>> 42 g/m³ (Rat) 1h</td> </tr> </tbody> </table>	Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Ketorolac Tromethamine	189 mg/kg (rat) 293 mg/kg (mouse)	NA	NA	Benzalkonium Chloride	NA	1420 mg/kg (Rat)	NA	Sodium Chloride	=3000 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 42 g/m ³ (Rat) 1h
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Skin Irritation/ Sensitization	:	May cause skin irritation.																
Eye irritation	:	May cause eye irritation.																
Germ cell mutagenicity	:	<p>Ketorolac tromethamine: It was not mutagenic in vitro in the Ames assay or in forward mutation assays. Similarly, it did not result in an in vitro increase in unscheduled DNA synthesis or an in vivo increase in chromosome breakage in mice. However, Ketorolac tromethamine did result in an increased incidence in chromosomal aberrations in Chinese hamster ovary cells.</p> <p>Benzalkonium Chloride: Not Suspected of being a Mutagen.</p>																
Carcinogenicity	:	<p>Ketorolac tromethamine: It was not carcinogenic in either rats given up to 5 mg/kg/day orally for 24 months or in mice given 2 mg/kg/day orally for 18 months. These doses are approximately 125 times and 50 times higher respectively than the maximum recommended human topical ophthalmic daily dose given as QID for itching to affected eyes on mg/kg basis.</p> <p>Benzalkonium Chloride: This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.</p>																
IARC:	:	Not considered to be a carcinogen.																



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NTP:	:	Not considered to be a carcinogen.
OSHA:	:	Not considered to be a carcinogen.
Reproductive toxicity:	:	<p>Teratogenic Effects. Pregnancy Category C : Ketorolac tromethamine, administered during organogenesis, was not teratogenic in rabbits and rats at oral doses of 3.6 mg/kg/day and 10 mg/kg/day, respectively. These doses are approximately 100 times and 250 times higher respectively than the maximum recommended human topical ophthalmic daily dose of 2 mg (5 mg/mL x 0.05 mL/drop, x 4 drops x 2 eyes) to affected eyes on a mg/kg basis. Additionally, when administered to rats after Day 17 of gestation at oral doses up to 1.5 mg/kg/day (approximately 40 times the typical human topical ophthalmic daily dose), Ketorolac tromethamine resulted in dystocia and increased pup mortality. There are no adequate and well-controlled studies in pregnant women. The product should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.</p> <p>Nonteratogenic Effects: Because of the known effects of prostaglandin-inhibiting drugs on the foetal cardiovascular system (closure of the ductus arteriosus), the use of this product during late pregnancy should be avoided.</p> <p>Benzalkonium Chloride: No information available.</p>

12. ECOLOGICAL INFORMATION

Toxicity:	:	Toxic to aquatic life with long lasting effects.
Persistence and degradability	:	No data available
Bioaccumulative potential	:	No data available
Mobility in soil	:	No data available
Results of PBT and vPvB	:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods	:	All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.
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14. TRANSPORTATION INFORMATION

Environmental hazards	:	No data available
Special precautions for user	:	No data available
Transport hazard class(es)	:	Not applicable
Packing group	:	Not applicable
IATA UN number	:	Not applicable

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.



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15. REGULATORY / STATUTORY INFORMATION

Seveso regulation (Directive 96/82/EC)	:	Not Available
Candidate list (art. 59-REACH):	:	Not Available
Ozone depletion substance (2000/2037/EC)	:	Not Available
Import/export dangerous chemical (2008/689/EC)	:	Not Available

16. OTHER INFORMATION

Date of preparation: 24/02/21

The information contained in this Material Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

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End of Safety Data Sheet