

**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

Product Name : Ketorolac Tromethamine Ophthalmic Solution 0.5%

Chemical Family : A pyrrolizine carboxylic acid derivative (NSAID)

Synonyms : Ketorolac trometamol

Manufacturer or supplier's details

Details of the Supplier of the Safety Data Sheet : Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.

Emergency Telephone Number : +91-44 67901901/02/03

Recommended use of the chemical and restrictions on use

Recommended use : Ketorolac Tromethamine ophthalmic solution is indicated for the temporary relief of ocular itching due to seasonal allergic conjunctivitis and also indicated for the treatment of postoperative inflammation in patients who have undergone cataract extraction.

Restrictions on use : Not applicable

SECTION 2: HAZARDS IDENTIFICATION**Classification of the Substance or Mixture**

Physical Hazards : Not classifiable.

Health Hazards : Not classifiable.

Symbol(s) : None.

Signal Word : None.

Hazard Statement(s) : None.

Precautionary Statement(s) : None.

Hazards Not Otherwise Classified : Not classifiable.

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.

**SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS#	Ingredient Percent
Ketorolac Tromethamine	74103-06-3	0.5%
Benzalkonium Chloride	63449-41-2	0.01%
Disodium Edetate	6381-92-6	0.1%
Sodium Chloride	7647-14-5	0.9%
Octoxynol 40	9036-19-5	0.01%
Water for Injection	7732-18-5	Balance

Note: Hydrochloric Acid (CAS:7647010, EINECS:2315957) and/or Sodium Hydroxide (CAS# 131073 2, EINECS: 2151855) may be added to adjust the pH.

SECTION 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.
- Skin** : 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.
- Eye** : Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. 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.
- 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. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively.



Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Protection of First-Aiders : Use personal protective equipment (see section 8).

Medical Conditions Aggravated by Exposure : Hypersensitivity to material and impaired liver or kidney function.

Notes to Physician : Treat supportively and symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media : Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Unsuitable Extinguishing Media : Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products : At burning condition emits toxic fumes.

Other Specific Hazards : Not determined.

Special Protective Equipment/ Precautions for Firefighters: : Wear self-contained breathing apparatus and full and protective gear.

SECTION 6 :ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personnel Precautions : Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment : For personal protection see section 8.



Methods for Cleaning Up : Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions : No data available

Reference to Other Sections : Refer to Sections 8, 12 and 13 for further information.

SECTION 7 : HANDLING and STORAGE

Precautions of safe handling

Handling : Avoid contact with product and use caution to prevent puncturing containers. 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 : Store product upright in original containers with cap tightly closed at a controlled room temperature 20°C –25°C (68°F – 77°F). Store according to label and/or product insert information.

Specific End Use : Pharmaceuticals.

SECTION 8 : EXPOSURE CONTROLS, PERSONAL PROTECTION

Occupational Exposure Guidelines:

Common or Chemical Name	:	Employee Exposure Limits
Ketorolac Tromethamine	:	Not established.

Exposure controls

Engineering Measures/Controls : Provide exhaust ventilation or other engineering controls to keep the air born concentrations of vapors below their threshold limit value. Ensure that eye wash stations and safety showers are proximal to the work station location.

Personal Protective Equipment

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).



Eyes 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.
Hand Protection	: 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.
Skin Protection	: Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
Environmental Exposure Controls	: No data available

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES**Material Description**

Physical State/Color	: Clear, colorless to light yellow color solution
Odor	: Odorless.
Odor Threshold	: No data available.

General Properties

Boiling Point	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Flash Point	: No data available
pH	: No data available
Evaporation Rate	: No data available
Flammability (solid, gas)	: No data available
Flammability Limit - Lower	: No data available
Flammability Limit - Upper	: No data available
Vapor Pressure	: No data available
Vapor Density	: No data available
Relative Density	: No data available
Solubility(ies)	: Soluble in water.
Partition Coefficient (n-octanol /water)	: No data available



Auto-Ignition Temperature : No data available
Decomposition Temperature : No data available
Viscosity : No data available
Specific Gravity : 1.00 – 1.04.

SECTION 10 : Stability and Reactivity

Reactivity : No data available.
Chemical stability : Stable under recommended storage conditions.
Possibility of hazardous reactions : No data available
Conditions to Avoid (e.g., static discharge, shock, or vibration) : 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 : When heated to decomposition, material emits toxic fumes. Emits toxic fumes under fire conditions.
Hazardous Polymerization : Should not occur.

SECTION 11 : TOXICOLOGICAL INFORMATION**Information on the Likely Routes of Exposure:**

Inhalation : Avoid inhalation. May cause irritation and slight systematic absorption.
Ingestion : May cause irritation and bitter aftertaste. This material is poorly absorbed from the gastrointestinal tract.
Skin Contact : May cause skin irritation.
Eye Contact : May cause eye irritation, burning or stinging on installation. Can cause hypersensitivity to some individuals.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics : See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure : No data available.

**Acute Toxicity:**

Species	Route	Test Type	Dose
Rat	Oral	LD50	189 mg/kg
Mouse	Oral	LD50	293 mg/kg

Acute Toxicity – Dermal	No data available.
Acute Toxicity – Inhalation	No data available.
Corrosivity	No data available.
Dermal Irritation	No data available.
Eye Irritation	No data available.
Sensitization	No data available.
Toxicokinetics/Metabolism	No data available.
Target Organ Effects	No data available.
Reproductive Effects	No data available.
Carcinogenicity	No data available.
National Toxicology Program (NTP)	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC)	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA)	Not considered to be a carcinogen.
Mutagenicity	No data available.
Aspiration Hazard	No data available.
Adverse Effects	May cause ocular inflammation, ocular irritation, ocular pain, headache, superficial ocular infections and allergic reactions.

SECTION 12 : ECOLOGICAL INFORMATION**Ecotoxicity**

Aquatic	: No data available
Terrestrial	: No data available
Persistence and Degradability	: No data available
Biodegradation	: No data available
Bioaccumulative potential	: No data available
Mobility in soil	: No data available
Other Adverse Effects	: No data available



SECTION 13: DISPOSAL CONSIDERATIONS

Dispose of all waste in accordance with Federal, State and Local regulations.

SECTION 14 : TRANSPORT INFORMATION

UN Number	: Not applicable.
UN Proper Shipping Name	: Not applicable.
Transport Hazard Class(es)	: Not applicable.
Packing Group	: Not applicable.
Department of Transportation	: Not regulated as a hazardous material.
International Air Transport Association (IATA)	: Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG)	: Not regulated as a dangerous good.

SECTION 15: REGULATORY INFORMATION

International Inventories

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Not Listed
CERCLA Hazardous Substance and Reportable Quantity	Not Listed

US Federal Regulations

SARA 313 Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

**US State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations**SECTION 16: ADDITIONAL INFORMATION****SDS creation date** : Mar 12, 2024**SDS Revision date** : NA**Version #** : 00

Disclaimer : This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.

---End of Safety Data Sheet---