

## SAFETY DATA SHEET

1. **Identification**

**Product Identifier:** Ketorolac Tromethamine Ophthalmic Solution, 0.5%

**Synonyms:** Ketorolac Trometamol

**National Drug Code (NDC):** 17478-209-19  
17478-209-10  
17478-209-11

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. **Hazard(s) Identification**

**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.

3. **Composition/Information on Ingredients**

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Ketorolac Tromethamine	74103-07-4	Ketorolac Trometamol	$C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$	376.40	0.5%

\*The formula also contains Benzalkonium Chloride, 0.01% as preservative; Edetate Disodium, 0.1%; Octoxynol 40; Sodium Chloride; Hydrochloric acid and/or Sodium Hydroxide may be added to adjust pH (6.8 – 7.4) and Purified Water.

**4. First Aid Measures**

<b>Ingestion:</b>	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.
<b>Eye Contact:</b>	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.
<b>Skin Contact:</b>	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.
<b>Inhalation:</b>	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.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Not determined.
<b>Medical Conditions Aggravated by Exposure:</b>	Hypersensitivity to material and impaired liver or kidney function.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

**5. Firefighting Measures**

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

**6. Accidental Release Measures**

**Personal 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.

**7. Handling and Storage**

**Precautions for Safe 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:** 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.

**8. Exposure Controls/Personal Protection****Occupational Exposure Guidelines:**

<b>Common or Chemical Name</b>	<b>Employee Exposure Limits</b>
Ketorolac Tromethamine	Not established.

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

<b>Respiratory Protection:</b>	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).
<b>Eyes Protection:</b>	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.
<b>Hand Protection:</b>	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.
<b>Skin Protection:</b>	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

## 9. Physical and Chemical Properties

<b>Physical State/Color:</b>	Clear, light yellowish liquid solution.
<b>Odor:</b>	Odorless.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	6.5 – 7.8.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.
<b>Specific Gravity:</b>	1.00 – 1.04.

## 10. Stability and Reactivity

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	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.

**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	LD <sub>50</sub>	189 mg/kg
Mouse	Oral	LD <sub>50</sub>	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.

## 12. Ecological Information

### Ecotoxicity

**Aquatic:** No data available.  
**Terrestrial:** No data available.  
**Persistence and Degradability:** No data available.  
**Bioaccumulative Potential:** No data available.  
**Mobility in Soil:** No data available.  
**Other Adverse Effects:** No data available.

## 13. Disposal Considerations

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

## 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.

## 15. Regulatory Information

### US Federal Regulations:

**Toxic Substance Control Act (TSCA):** Not Regulated.

**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.



## SDS: Ketorolac Tromethamine Ophthalmic Solution, 0.5%

**SARA 313:** Not listed.  
**SARA 302:** Not listed.

### State Regulations

**California Proposition 65:** Not listed.

### 16. Other Information

Not made with natural rubber latex.

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**Revision Number:** 1

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