



# MSDS: Ketorolac Tromethamine Ophthalmic Solution

**Manufacturer:** Akorn  
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Somerset, N.J. 08873  
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## Section 1 - IDENTIFICATION

**TRADE NAME:** Ketorolac Tromethamine Ophthalmic Solution  
NDC # 17478-208-10 for 0.4% strength; Fill Size: 5 mL  
NDC # 17478-209-19 for 0.5% strength; Fill Size: 3 mL  
NDC # 17478-209-10 for 0.5% strength; Fill Size: 5 mL  
NDC # 17478-209-11 for 0.5% strength; Fill Size: 10 mL

**Description:** Clear, light yellowish solution

Composition	CAS#	TLV (mg/m <sup>3</sup> )	PEL (mg/m <sup>3</sup> )	%Content
Ketorolac Tromethamine, USP	74103-07-4	NE	NE	0.4/0.5
Edetate Sodium, USP	6381-92-6	NE	NE	0.015/0.1
Sodium Chloride, USP	7647-14-5	NE	NE	< 1
Octoxynol 40	9036-19-5	NE	NE	< 1
Benzalkonium Chloride 50% Sol.	8001-54-5	NE	NE	0.012/0.02
Purified Water, USP	7732-18-5	NE	NE	qs

**Common name of active ingredients:** Ketorolac Tromethamine

**Chemical Formula:** C<sub>15</sub>H<sub>13</sub>NO<sub>3</sub>. C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub>

## Section 2 – HAZARDOUS INGREDIENTS

**Principal Hazardous Ingredients:** Ketorolac Tromethamine  
**% Threshold Limit Value:** NE  
**Carcinogenicity:** NE  
**NTP-** No  
**IARC-** No  
**OSHA-** No  
**NE=** Not established

< = Greater Than

> = Less Than

<b>Section 3 – PHYSICAL AND CHEMICAL CHARACTERISTICS</b>
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<b>Physical State:</b>	Liquid		
<b>Appearance:</b>	Clear, colorless to light yellowish solution		
<b>Odor:</b>	Odorless	<b>Boiling Point:</b>	NE
<b>Vapor Density (air = 1):</b>	NE	<b>Vapor Pressure (mm Hg):</b>	NE
<b>Viscosity:</b>	NE	<b>Solubility in Water:</b>	Soluble
<b>Specific Gravity:</b>	1.00-1.04	<b>Volatile:</b>	NE
<b>Evaporation Rate:</b>	NE	<b>Reactivity in Water:</b>	NE
<b>pH:</b>	Between 6.5-7.8		
<b>Melting Point:</b>	NE	<b>Latex Free:</b>	Yes
<b>NE=</b>	Not established		

<b>Section 4 – FIRE AND EXPLOSION HAZARD DATA</b>
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<b>Extinguisher Media:</b>	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
<b>Hazardous Products:</b>	At burning condition emits toxic fumes
<b>Flammable Limits:</b>	Lower Flammable Limit: NE; Upper Flammable Limit: NE
<b>Fire Fighting Instructions:</b>	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

<b>Section 5 – REACTIVITY DATA</b>
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<b>Stability:</b>	Stable
<b>Incompatibility:</b>	Oxidizing agents, strong acid and alkaline solutions, alkali metals and silver preparations.
<b>Hazardous Decomposition Products:</b>	When heated to decomposition, material emits toxic fumes. Emits toxic fumes under fire conditions
<b>Hazardous Polymerization:</b>	Should not occur
<b>Conditions to Avoid:</b>	Avoid exposure to light and strong oxidizing agent.

**Section 6 – HEALTH HAZARDS**

**Adverse Effects:** May cause ocular inflammation, ocular irritation, ocular pain, headache, superficial ocular infections and allergic reactions.

<b>Chemical Listed as Carcinogen or Potential Carcinogen:</b>	Ketorolac Tromethamine
<b>National Toxicology Program:</b>	No
<b>I.A.R.C Monographs:</b>	No
<b>OSHA:</b>	No
<b>OSHA Permissible Exposure Limit:</b>	NE
<b>ACGIH Threshold Limit Value:</b>	NE
<b>NE=</b>	Not established

- 1. Inhalation:** May cause irritation and slight systemic absorption. Avoid inhalation. Remove to fresh air.
- 2. Eyes:** May cause irritation, burning or stinging on installation. Can cause hypersensitivity to some individuals. Flush with copious quantities of water for 15 minutes.
- 3. Skin:** May cause irritation. Flush with copious quantities of water.
- 4. Ingestion:** May cause irritation and bitter aftertaste. Flush out mouth with water. This material is poorly absorbed from the gastrointestinal tract.

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

**Section 7 – SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES**

**Storage:** Store product upright in original containers with cap tightly closed at a controlled room temperature 20°-25° C (68°-77° F). Protect from light.

**Handling:** Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical and home environment.

**Neutralizing Chemical Agent:** Not relevant

**Waste Disposal Methods:** Dispose of waste in accordance with all applicable Federal, State and local laws.

**Section 8 – PROTECTION INFORMATION**

**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.

**Airborne Exposure Limits:** NE

**Ventilation:** Recommended. Provide adequate ventilation

**Skin Protection:** Protect exposed skin and wear rubber gloves.

**Eye Protection:** Safety glasses

**Respiratory Protection:** When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.

**Section 9 – TOXICOLOGY INFORMATION**

**LD 50 (Acute oral toxicity of):** Ketorolac Tromethamine

LD 50 rat, oral: - 189 mg/kg

LD50 Mouse, oral: - 293 mg/kg

LD 50: Subcutaneous-mouse= NE

LD 50 intravenous-mouse = NE

**Section 10 – ECOLOGICAL INFORMATION**

**Ecotoxicity:** Not established

**BOD<sub>5</sub> and COD:** Not available

**Environmental fate information:** None

**Other Precautions:** None

**Section 11 – TRANSPORTATION INFORMATION**

This product does not pose an unreasonable risk to health and safety or property when transported in commerce. The hazard class definitions of 49 CFR, Part 173 are not applicable to this product.

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