



## MSDS: Ketotifen Fumarate Ophthalmic Solution

**Manufacturer:** Akorn Incorporated  
72-6 Veronica Avenue  
Somerset, NJ 00873  
**Telephone:** (732) 846-8066  
**Email:** customer.service@akorn.com

### Section 1 - IDENTIFICATION

**TRADE NAME:** Ketotifen Fumarate Ophthalmic Solution  
NDC # 17478-717-10  
**Description:** Clear, colorless solution free from visible particles

<b>Composition</b>	<b>CAS#</b>	<b>TLV(mg/m<sup>3</sup>)</b>	<b>PEL(mg/m<sup>3</sup>)</b>	<b>%Content</b>
Ketotifen Fumarate	34580-14-8	NE	NE	0.035
Glycerin, USP	56-81-5	10	15 <sub>total</sub>	<10
Benzalkonium Chloride, NF	8001-54-5	NE	NE	0.01
Sodium Hydroxide, NF	1310-73-2	NE	NE	QS
Hydrochloric Acid, NF	7647-01-0	NE	NE	QS
Purified Water, USP	7732-18-5	NE	NE	QS

**Common name of active ingredient:** Ketotifen Fumarate  
**Molecular Formula:** C<sub>23</sub>H<sub>23</sub>NO<sub>5</sub>S  
**Molecular Weight:** 425.5  
**Legal Category:** Over the Counter, antihistamine

### Section 2 - HAZARDOUS INGREDIENTS

**Principal Hazardous Ingredient:** Ketotifen  
**% Threshold Limit Value:** Not Established  
**Carcinogenicity:** Not Established  
**NTP -** No ingredients listed  
**IARC -** No ingredients listed  
**OSHA -** No ingredients listed

**Section 3 – PHYSICAL AND CHEMICAL CHARACTERISTICS**

<b>Physical State:</b>	Liquid
<b>Appearance:</b>	Clear, colorless solution
<b>Odor:</b>	Odorless
<b>Boiling Point</b>	Not Established
<b>Vapor Density (air = 1):</b>	Not Established
<b>Vapor Pressure (mm Hg):</b>	Not Established
<b>Viscosity:</b>	Not Established
<b>Solubility in Water:</b>	Soluble
<b>Specific Gravity:</b>	~1.00
<b>Volatile:</b>	Not Established
<b>Evaporation Rate:</b>	Not Established
<b>Reactivity in Water:</b>	Aqueous
<b>pH:</b>	4.4 to 5.8
<b>Melting Point:</b>	Not Applicable
<b>Latex Free:</b>	Yes

**Section 4 – FIRE AND EXPLOSION HAZARD DATA**

<b>Extinguisher Media:</b>	Use water, chemical type foam, carbon dioxide, dry chemical
<b>Hazardous Products:</b>	None identified
<b>Explosion:</b>	None
<b>Fire Fighting Instructions:</b>	Respiratory and eye protection for fire-fighting personnel

**Section 5 – REACTIVITY DATA**

<b>Stability:</b>	Stable under normal ambient conditions of temperature and pressure
<b>Incompatibility:</b>	Not Available
<b>Hazardous Decomposition Products:</b>	Not Established
<b>Hazardous Polymerization:</b>	Will not occur
<b>Conditions to Avoid:</b>	Avoid exposure to heat

**Section 6 – HEALTH HAZARDS****Chemical Listed as Carcinogen or Potential Carcinogen:**

<b>National Toxicology Program:</b>	No
<b>I.A.R.C Monographs:</b>	No
<b>OSHA:</b>	No
<b>OSHA Permissible Exposure Limit:</b>	Not Established
<b>ACGIH Threshold Limit Value:</b>	Not Established

- 1. Inhalation:** Not expected to cause significant irritation of the lungs, upper respiratory tract or nose
- 2. Eyes:** Non-irritating to the eyes when used as directed
- 3. Skin:** Non-irritating to skin or mucous membranes when used as directed
- 4. Ingestion:** May be harmful if swallowed; may cause moderate irritation of the digestive tract

**First Aid Measures**

1. **Skin:** Remove source of contamination such as affected clothing. Wash with plenty of soap and water. Seek medical attention if irritation persists.
2. **Eyes:** If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional. Remove contact lenses. Flush eyes with running water for at least 15 minutes.
3. **Ingestion:** Do not induce vomiting. Wash out mouth with water and keep at rest. Seek medical attention immediately and provide Drug Facts information.
4. **Inhalation:** Not likely to be hazardous by inhalation. If exposed to excessive levels of mist, remove to fresh air and seek medical attention if cough or other symptoms develop.

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

**Storage:** Store in unopened containers in a cool, dry and well-ventilated place. This material should be handled and stored per label instructions to ensure product integrity. Expiration is listed on each package.

**Handling:** When handling, do not eat or drink. Use only in well ventilated areas.

**Neutralizing Chemical Agent:** Not relevant

**Steps to be taken in case material is released or spilled:** Using appropriate protective equipment, absorb spillage in absorbent material and remove to a safe place appropriate for chemical waste disposal.

**Waste Disposal Methods:** Do not empty into drains. Use appropriate containment to avoid environmental contamination. Dispose of waste in accordance with all applicable Federal, State and local laws.

**Section 8 – PROTECTION INFORMATION**

<b>Engineering Controls:</b>	No special handling is required Use in accordance with product literature Unlikely to be hazardous when used as directed
<b>Airborne Exposure Limits:</b>	Not Established
<b>Ventilation:</b>	In case of insufficient ventilation, wear suitable respiratory equipment
<b>Skin Protection:</b>	Lab coat, sleeves
<b>Eye Protection:</b>	Safety glasses or goggles
<b>Respiratory Protection:</b>	Not required during normal clinical use

**Section 9 – TOXICOLOGY INFORMATION**

LD <sub>50</sub> rat, oral	=	360 mg/kg ketotifen fumarate
LD <sub>50</sub> mouse, oral	=	585 mg/kg ketotifen fumarate



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### Section 10 – ECOLOGICAL INFORMATION

<b>Ecotoxicity:</b>	Not Established
<b>BOD<sub>5</sub> and COD:</b>	Not Available
<b>Environmental fate information:</b>	Not Available
<b>Other Precautions:</b>	There are no unreasonable risks (health, safety, or property) that this product would pose when transported in commerce.

### Section 11 - REGULATORY INFORMATION

<b>SARA 313 listed:</b>	No
<b>CERCLA listed:</b>	No
<b>RCRA listed:</b>	No
<b>TSCA Inventory:</b>	CAS# 8001-54-5 is listed CAS# 56-81-5 is listed CAS# 7732-18-5 is listed

### Section 12 - TRANSPORT INFORMATION

**Transportation Data:** Not classified as Hazardous by DOT regulations; not regulated  
Hazard class definitions (49CFR, Part 173) are not applicable to this product.

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