



MSDS: Ketotifen Fumarate Ophthalmic Solution

Manufacturer: Ophtapharm AG
Riethofstrasse 1
CH-8442 Hettlingen
Switzerland

Telephone: +1855-473-6847

Email: quality@sentiss.ch

Section 1 – IDENTIFICATION

TRADE NAME: Ketotifen Fumarate Ophthalmic Solution
NDC # 72485-617-10

Description: Clear, colorless solution free from visible particles

| Composition | CAS# | TLV(mg/m ³) | PEL(mg/m ³) | %Content |
|---------------------------|------------|-------------------------|-------------------------|----------|
| Ketotifen Fumarate | 34580-14-8 | NE | NE | 0.035 |
| Glycerin, USP | 56-81-5 | 10 | 15 total | <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: C₂₃H₂₃NO₅S

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

Physical State: Liquid

Appearance: Clear, colorless solution

Odor: Odorless

Boiling Point: Not Established

Vapor Density (air = 1): Not Established



MSDS: Ketotifen Fumarate Ophthalmic Solution

| | |
|--------------------------------|-----------------|
| Vapor Pressure (mm Hg): | Not Established |
| Viscosity: | Not Established |
| Solubility in Water: | Soluble |
| Specific Gravity: | ~1.00 |
| Volatile: | Not Established |
| Evaporation Rate: | Not Established |
| Reactivity in Water: | Aqueous |
| pH: | 4.4 to 5.8 |
| Melting Point: | Not Applicable |
| Latex Free: | Yes |

Section 4 – FIRE AND EXPLOSION HAZARD DATA

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

Section 5 – REACTIVITY DATA

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

Section 6 – HEALTH HAZARDS

Chemical Listed as Carcinogen or Potential Carcinogen:

| | |
|---|-----------------|
| National Toxicology Program: | No |
| I.A.R.C Monographs: | No |
| OSHA: | No |
| OSHA Permissible Exposure Limit: | Not Established |
| ACGIH Threshold Limit Value: | 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



MSDS: Ketotifen Fumarate Ophthalmic Solution

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

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

Section 9 – TOXICOLOGY INFORMATION

| | | |
|------------------------------|---|------------------------------|
| LD ₅₀ rat, oral | = | 360 mg/kg ketotifen fumarate |
| LD ₅₀ mouse, oral | = | 585 mg/kg ketotifen fumarate |



MSDS: Ketotifen Fumarate Ophthalmic Solution

Section 10 – ECOLOGICAL INFORMATION

| | |
|--|--|
| Ecotoxicity: | Not Established |
| BOD₅ and COD: | Not Available |
| Environmental fate information: | Not Available |
| Other Precautions: | There are no unreasonable risks (health, safety, or property) that this product would pose when transported in commerce. |

Section 11 - REGULATORY INFORMATION

| | |
|-------------------------|--|
| SARA 313 listed: | No |
| CERCLA listed: | No |
| RCRA listed: | No |
| TSCA Inventory: | 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. |
|-----------------------------|---|

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 MSDS 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 MSDS 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.