

SAFETY DATA SHEETS

This SDS packet was issued with item:

078950365

N/A



MSDS: Ketotifen Fumarate Ophthalmic Solution

Manufacturer: Ophtapharm AG
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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/m³)	PEL(mg/m³)	%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: $C_{23}H_{23}NO_5S$
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



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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

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| 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

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



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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.
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