



## Safety Data Sheet

### Section 1: Identification

#### Product identifier

**Product Name** • **Alaway™ (Ketotifen Fumarate Ophthalmic Solution, 0.025% as base)**

**Product Code** • AB60109; AB60188; AB60190; Core No. 601; NDC 24208-601-10

#### Relevant identified uses of the substance or mixture and uses advised against

**Recommended use** • This product is intended for the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.

**Restrictions on use** • Use in accordance with product literature.

#### Details of the supplier of the safety data sheet

**Manufacturer** • Bausch & Lomb  
1400 North Goodman Street  
Rochester, NY 14609  
United States  
bausch.com

**Telephone (General)** • 1-800-553-5340

#### Emergency telephone number

**Manufacturer** • 1-800-535-5053 - Infotrac

*This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.*

### Section 2: Hazard Identification

#### UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

#### Classification of the substance or mixture

**UN GHS** • Classification criteria not met

#### Label elements

**UN GHS**

#### Precautionary statements

**Storage/Disposal** • Keep tightly closed and store in upright position.  
Store product at 4-25°C (39-77°F).  
Use before expiration date marked on carton and/or container.

#### Other hazards

**UN GHS** • No data available

## Section 3 - Composition/Information on Ingredients

### Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

### Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Benzalkonium Chloride, 50%	CAS:139-07-1 EINECS:205-351-5	0.01%	UN GHS: NDA
Glycerin 99.7%	CAS:56-81-5 EINECS:200-289-5	< 10%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Ketotifen Fumarate	CAS:34580-13-7 EINECS:252-099-7	0.035%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Not Classified

Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

*The exact percentage of composition has been withheld as a trade secret.*

## Section 4: First-Aid Measures

### Description of first aid measures

#### Inhalation

- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

#### Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

#### Eye

- No specific treatment is necessary since this material is not irritating to the eye.

#### Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

### Most important symptoms and effects, both acute and delayed

- No data available

### Indication of any immediate medical attention and special treatment needed

## Section 5: Fire-Fighting Measures

### Extinguishing media

**Suitable Extinguishing Media** • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

**Unsuitable Extinguishing Media** • No data available

### Special hazards arising from the substance or mixture

**Unusual Fire and Explosion Hazards** ● None known - product is not flammable or combustible.

**Hazardous Combustion Products** ● No data available

**Advice for firefighters**

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

**Section 6 - Accidental Release Measures**

**Personal precautions, protective equipment and emergency procedures**

**Personal Precautions** ● No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8.

**Emergency Procedures** ● No emergency procedures are expected to be necessary when used in accordance with product literature.

**Environmental precautions**

- No data available

**Methods and material for containment and cleaning up**

**Containment/Clean-up Measures** ● Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

**Section 7 - Handling and Storage**

**Precautions for safe handling**

**Handling** ● No special handling is required. Refer to Section 8. Use only in accordance with product literature.

**Conditions for safe storage, including any incompatibilities**

**Storage** ● Keep tightly closed and store in upright position. Keep tightly closed. Store between 4-25°C (39-77°F), to maintain product integrity. use before expiration date marked on carton and/or container.

**Section 8 - Exposure Controls/Personal Protection**

**Control parameters**

**Exposure Limits/Guidelines** ● Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines			
	Result	Canada Quebec	OSHA
Glycerin 99.7% (56-81-5)	TWAs	10 mg/m3 TWA <sub>EV</sub> (mist)	15 mg/m3 TWA (mist, total particulate); 5 mg/m3 TWA (mist, respirable fraction)

**Exposure controls**

**Engineering Measures/Controls** ● Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

**Personal Protective Equipment****Respiratory**

- No respiratory protection required during normal handling.

**Eye/Face**

- No eye protection is required during normal handling.

**Hands**

- Gloves are not required under normal handling conditions.

**Skin/Body**

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

**Environmental Exposure Controls**

- No data available

**Section 9 - Physical and Chemical Properties****Information on Physical and Chemical Properties**

<b>Material Description</b>			
Physical Form	Liquid	Color	Clear, colorless to pale yellow.
Odor	No odor.	Odor Threshold	Not relevant
<b>General Properties</b>			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	4.4 to 6
Specific Gravity/Relative Density	= 1.013	Water Solubility	Soluble in water
Viscosity	No data available	Oxidizing Properties:	Not relevant
<b>Volatility</b>			
Vapor Pressure	No data available	Vapor Density	Not relevant
Evaporation Rate	No data available		
<b>Flammability</b>			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
<b>Environmental</b>			
Octanol/Water Partition coefficient	Not relevant		

**Section 10: Stability and Reactivity****Reactivity**

- No dangerous reactions known.

**Chemical stability**

- Stable under normal temperatures and pressures.

**Possibility of hazardous reactions**

- No data available

**Conditions to avoid**

- Extreme heat or cold. Do not freeze.

**Incompatible materials**

- None.

**Hazardous decomposition products**

- None expected.

## Section 11 - Toxicological Information

### Information on toxicological effects

**Other Material Information** • Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Ketotifen Fumarate (0.035%)	34580-13-7	<b>Acute Toxicity:</b> Ingestion/Oral-Mouse LD50 • 179 mg/kg
Benzalkonium Chloride, 50% (0.01%)	139-07-1	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 400 mg/kg
Glycerin 99.7% (< 10%)	56-81-5	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 12600 mg/kg; <i>Behavioral:General anesthetic;</i> <i>Behavioral:Muscle weakness; Liver:Other changes</i>

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

### Potential Health Effects

#### Inhalation

**Acute (Immediate)** • Under normal conditions of use, no health effects are expected.

**Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

#### Skin

**Acute (Immediate)** • Under normal conditions of use, no health effects are expected.

**Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

#### Eye

**Acute (Immediate)** • Under normal conditions of use, no health effects are expected.

**Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

#### Ingestion

**Acute (Immediate)** • Under normal conditions of use, no health effects are expected.

**Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

#### Other

**Acute (Immediate)** • Under normal conditions of use, no health effects are expected.

**Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

## Section 12 - Ecological Information

### Toxicity

- This material has not been tested for environmental effects.

### Persistence and degradability

- No data available

### Bioaccumulative potential

- No data available

### Mobility in Soil

- No data available

### Other adverse effects

## Section 13 - Disposal Considerations

### Waste treatment methods

#### Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

#### Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

## Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

#### Special precautions for user

- No data available

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

## Section 15 - Regulatory Information

### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### SARA Hazard Classifications

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Ketotifen Fumarate	34580-13-7	No	Yes	No
Benzalkonium Chloride, 50%	139-07-1	Yes	Yes	Yes
Glycerin 99.7%	56-81-5	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

**Canada****Labor****Canada - WHMIS - Classifications of Substances**

• Glycerin 99.7%	56-81-5	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium Chloride, 50%	139-07-1	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Ketotifen Fumarate	34580-13-7	Not Listed

**United States****Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Glycerin 99.7%	56-81-5	Not Listed
• Benzalkonium Chloride, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Ketotifen Fumarate	34580-13-7	Not Listed

**United States - California****Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Glycerin 99.7%	56-81-5	Not Listed
• Benzalkonium Chloride, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Ketotifen Fumarate	34580-13-7	Not Listed

**U.S. - California - Proposition 65 - Developmental Toxicity**

• Glycerin 99.7%	56-81-5	Not Listed
• Benzalkonium Chloride, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Ketotifen Fumarate	34580-13-7	Not Listed

**U.S. - California - Proposition 65 - Reproductive Toxicity - Female**

• Glycerin 99.7%	56-81-5	Not Listed
• Benzalkonium Chloride, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Ketotifen Fumarate	34580-13-7	Not Listed

**U.S. - California - Proposition 65 - Reproductive Toxicity - Male**

• Glycerin 99.7%	56-81-5	Not Listed
• Benzalkonium Chloride, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Ketotifen Fumarate	34580-13-7	Not Listed

**Section 16 - Other Information****Last Revision Date**

● 23/April/2015

**Preparation Date**

- 31/January/2007

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