

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078908152

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078414071 078708006

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

078908151



# SAFETY DATA SHEET

## Artificial Tears Lubricant Ophthalmic Ointment

### 1. IDENTIFICATION

**Product Identifier:** Artificial Tears Lubricant Ophthalmic Ointment

**Synonyms:** Artificial Tears Ointment; Lubricant Eye Ointment

**National Drug Code (NDC):** 17478-062-35

**Recommended Use:** Use as lubricant to prevent further irritation or to relieve dryness of the eye(s).

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. HAZARD(S) IDENTIFICATION

**Physical Hazards:** Not classifiable.

**Health Hazards:** Not classifiable.

**Symbol(s):** None.

**Signal Word:** None.

**Hazard Statement(s):** None.

**Precautionary Statement(s):** None.

**Hazards Not Otherwise Classified:** None.

**Supplementary Information:** While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Chemical Name	CAS Number	Chemical Formula	Molecular Weight	Percentage
White Petrolatum	Petroleum jelly	8009-03-8	No data available	No data available	83%
Mineral Oil	Oil mist, Mineral	8012-95-1	No data available	No data available	15%
Lanolin	Wool fat, Anhydrous Lanolin	8006-54-0	No data available	No data available	2%

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#### 4. FIRST AID MEASURES

<b>Ingestion:</b>	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
<b>Eye Contact:</b>	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Contact:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Vision may be temporarily blurred when this product is first used. May cause eye pain, changes in vision, redness and/or irritation.
<b>Medical Conditions Aggravated by Exposure:</b>	No data available.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

#### 5. FIREFIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use water, carbon dioxide, dry chemical or alcohol-resistant foam as necessary.
<b>Unsuitable Extinguishing Media:</b>	Not determined.

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### Specific Hazards Arising from the Chemical

<b>Hazardous Combustion Products:</b>	Not determined.
<b>Other Specific Hazards:</b>	Closed containers may explode from the heat of fire.
<b>Special Protective Equipment and Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.
<b>Methods for Cleaning Up:</b>	Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.
<b>Environmental Precautions:</b>	Contain material and prevent release to basements, confined spaces, waterways or soil.
<b>Reference to Other Sections:</b>	Refer to Sections 8, 12 and 13 for further information.

### 7. HANDLING AND STORAGE

<b>Precautions for Safe Handling:</b>	Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
<b>Conditions for Safe Storage, Including Any Incompatibilities:</b>	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Keep tightly closed.
<b>Specific End Use:</b>	Pharmaceutical drug product.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Occupational Exposure Guidelines:

Ingredient	Type	Value
White Petrolatum	Not established	Not established
Mineral Oil	OSHA PEL	5 mg/m <sup>3</sup> (Mist)

<b>Engineering Controls:</b>	None required for the normal use of this product.
<b>Respiratory Protection:</b>	None required for the normal use of this product.
<b>Eyes Protection:</b>	None required for the normal use of this product.

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<b>Hand Protection:</b>	None required for the normal use of this product.
<b>Skin Protection:</b>	None required for the normal use of this product.
<b>General Hygiene Considerations:</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State/Color:</b>	Semi-solid, colorless to light yellowish translucent
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	No data available.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Immiscible in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Extreme heat or cold. Do not freeze.
<b>Incompatible Materials:</b>	Strong oxidizing agents.
<b>Hazardous Decomposition Products:</b>	No data available.

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### 11. TOXICOLOGICAL INFORMATION

#### Information on the Likely Routes of Exposure

<b>Inhalation:</b>	May cause irritation.
<b>Ingestion:</b>	May be harmful if swallowed.
<b>Skin Contact:</b>	May causes skin irritation.
<b>Eye Contact:</b>	May cause eye pain, changes in vision, redness and/or irritation.
<b>Symptoms Related to the Physical, Chemical and Toxicological Characteristics:</b>	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
<b>Delayed and Immediate Effects of Exposure:</b>	No data available.

#### Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
White Petrolatum	Rat	Oral	LD <sub>50</sub>	>5000 mg/kg
Mineral Oil	Rat	Oral	LD <sub>50</sub>	>5000 mg/kg

#### Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

#### Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

#### Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

#### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

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<b>Aspiration Hazard:</b>	No data available.
<b>Toxicokinetics/Metabolism:</b>	No data available.
<b>Target Organ Effects:</b>	No data available.
<b>Systemic Effects:</b>	No data available.
<b>Reproductive Effects:</b>	No data available.
<b>Carcinogenicity:</b>	No data available.
<b>National Toxicology Program (NTP):</b>	Not considered to be a carcinogen.
<b>International Agency for Research on Cancer (IARC):</b>	Not considered to be a carcinogen.
<b>Occupational Safety and Health Administration (OSHA):</b>	Not considered to be a carcinogen.

### 12. ECOLOGICAL INFORMATION

#### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Mineral Oil	Bluegill ( <i>Lepomis macrochirus</i> )	LC <sub>50</sub>	> 10000 mg/l	96 hours

<b>Terrestrial Toxicity:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

### 13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. TRANSPORT INFORMATION

**Department of Transportation (DOT):** Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable



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### 15. REGULATORY INFORMATION

#### US FEDERAL REGULATIONS

##### Toxic Substance Control Act (TSCA):

Ingredient	Inventory
White Petrolatum	No
Mineral Oil	Yes

##### CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

##### EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

#### U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
White Petrolatum	Listed	Listed	Not listed
Mineral Oil	Listed	Listed	Not listed

##### California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

### 16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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