

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): 59399-162-35

Recommended Use: For Animal Use Only. Use as lubricant to prevent further irritation or to relive 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

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| Ingestion: | 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. |
| Eye Contact: | 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. |
| Skin Contact: | 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. |
| Inhalation: | 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. |
| Protection of First-Aiders: | Use personal protective equipment (see section 8). |
| Signs and Symptoms: | Vision may be temporarily blurred when this product is first used. May cause eye pain, changes in vision, redness and/or irritation. |
| Medical Conditions Aggravated by Exposure: | No data available. |
| Notes to Physician: | Treat supportively and symptomatically. |

5. FIREFIGHTING MEASURES

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

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Specific Hazards Arising from the Chemical

Hazardous Combustion Products: Not determined.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment and Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Keep tightly closed.

Specific End Use: 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 ³ (Mist) |

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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| Respiratory Protection: | Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134). |
| Eyes Protection: | Not required for the normal use of this product. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area. |
| Hand Protection: | Not required for the normal use of this product. Chemically compatible gloves should be worn when working with large quantities. For handling solutions ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. |
| Skin Protection: | Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities. |
| General Hygiene Considerations: | 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. |

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| 9. PHYSICAL AND CHEMICAL PROPERTIES |
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|---|-------------------------------------|
| Physical State/Color: | Colorless to light yellow ointment. |
| Odor: | No data available. |
| Odor Threshold: | No data available. |
| pH: | No data available. |
| Melting Point: | No data available. |
| Freezing Point: | No data available. |
| Boiling Point: | No data available. |
| Flash Point: | No data available. |
| Evaporation Rate: | No data available. |
| Flammability (solid, gas): | No data available. |
| Flammability Limit - Lower: | No data available. |
| Flammability Limit - Upper: | No data available. |
| Vapor Pressure: | No data available. |
| Vapor Density: | No data available. |
| Relative Density: | No data available. |
| Solubility(ies): | Immiscible in water. |
| Partition Coefficient (n-octanol/water): | No data available. |
| Auto-Ignition Temperature: | No data available. |
| Decomposition Temperature: | No data available. |

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Viscosity: No data available.

10. STABILITY AND REACTIVITY

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): Extreme heat or cold. Do not freeze.

Incompatible Materials: Strong oxidizing agents.

Hazardous Decomposition Products: No data available.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation: May cause irritation.

Ingestion: May be harmful if swallowed.

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye pain, changes in vision, redness and/or irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

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 ₅₀ | >5000 mg/kg |
| Mineral Oil | Rat | Oral | LD ₅₀ | >5000 mg/kg |

Irritation / Sensitization

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

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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 |

Aspiration Hazard: No data available.
Toxicokinetics/Metabolism: No data available.
Target Organ Effects: No data available.
Systemic Effects: No data available.
Reproductive Effects: No data available.
Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): 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 ₅₀ | > 10000 mg/l | 96 hours |

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

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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 |

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.

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16. OTHER INFORMATION

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

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