



Material Safety Data Sheet

Material Name: Fluocinolone Acetonide Oil, 0.01%

*** Section 1 - Chemical Product and Company Identification ***

Manufacturer Information

Amneal Pharmaceuticals
85 Adams Ave.
Hauppauge, NY 11788

Phone: 631.952.0214
Fax: 631.656.1009

*** Section 2 - Hazards Identification ***

Emergency Overview

May cause eye, skin and respiratory tract irritation.

Potential Health Effects: Eyes

May cause eye irritation.

Potential Health Effects: Skin

May cause skin irritation.

Potential Health Effects: Ingestion

Not considered a likely route of exposure under normal industrial use. May cause adverse effects as described in product insert when ingested.

Potential Health Effects: Inhalation

May cause respiratory tract irritation.

HMIS Ratings: Health: 1 Fire: 0 HMIS Reactivity 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

*** Section 3 - Composition / Information on Ingredients ***

CAS #	Component
8002-03-7	Peanut oil
8042-47-5	White mineral oil
110-27-0	Isopropyl myristate
9004-98-2	Polyethylene glycol monooleyl ether
67-63-0	Isopropyl alcohol
67-73-2	Fluocinolone acetonide

*** Section 4 - First Aid Measures ***

First Aid: Eyes

Flush eye(s) immediately with plenty of water. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

First Aid: Skin

Rinse immediately with plenty of water for at least 15 minutes.

First Aid: Ingestion

Acute overdosage should be followed by immediate gastric lavage or emesis followed by supportive and symptomatic therapy. Contact a physician.

First Aid: Inhalation

Remove the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms appear.

*** Section 5 - Fire Fighting Measures ***

General Fire Hazards

See Section 9 for Flammability Properties.
None anticipated.

Hazardous Combustion Products

Not Determined

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Extinguishing Media

Use appropriate extinguishing media for surrounding fire.

Fire Fighting Equipment/Instructions

Firefighters should wear full protective gear.

NFPA Ratings: Health: 1 Fire: 0 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

*** Section 6 - Accidental Release Measures ***

Containment Procedures

Stop the flow of material, if this is without risk.

Clean-Up Procedures

Wipe up spills and rinse area with water. Dispose of these materials in accordance with federal, state, and local regulations.

Evacuation Procedures

Isolate area. Keep unnecessary personnel away.

Special Procedures

Wear appropriate personal protective equipment.

*** Section 7 - Handling and Storage ***

Handling Procedures

No special handling procedures needed.

Storage Procedures

Store at controlled temperatures. Keep tightly closed and out of reach of children.

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

A: Component Exposure Limits

Isopropyl alcohol (67-63-0)

ACGIH: 200 ppm TWA

400 ppm STEL

OSHA: 400 ppm TWA; 980 mg/m3 TWA

500 ppm STEL; 1225 mg/m3 STEL

NIOSH: 400 ppm TWA; 980 mg/m3 TWA

500 ppm STEL; 1225 mg/m3 STEL

Engineering Controls

Ensure adequate ventilation, especially in confined areas.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Safety glasses with side-shields

Personal Protective Equipment: Skin

Use impervious gloves.

Personal Protective Equipment: Respiratory

Breathing apparatus only if aerosol or dust is formed.

Personal Protective Equipment: General

Eye wash fountain is recommended.

*** Section 9 - Physical & Chemical Properties ***

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Appearance:	Clear, colorless	Odor:	None
Physical State:	Liquid	pH:	ND
Vapor Pressure:	ND	Vapor Density:	ND
Boiling Point:	ND	Melting Point:	NA
Solubility (H2O):	Slight	Specific Gravity:	ND
Evaporation Rate:	ND	VOC:	ND
Octanol/H2O Coeff.:	ND	Flash Point:	ND
Flash Point Method:	ND	Upper Flammability Limit (UFL):	ND
Lower Flammability Limit (LFL):	ND	Burning Rate:	ND
Auto Ignition:	ND		

*** Section 10 - Chemical Stability & Reactivity Information ***

Chemical Stability

This is a stable material.

Chemical Stability: Conditions to Avoid

Not Determined

Incompatibility

Not Determined

Hazardous Decomposition

None

Possibility of Hazardous Reactions

Will not occur.

*** Section 11 - Toxicological Information ***

Acute Dose Effects

A: General Product Information

No information available for the product.

B: Component Analysis - LD50/LC50

White mineral oil (8042-47-5)

Oral LD50 Rat >5000 mg/kg

Isopropyl myristate (110-27-0)

Oral LD50 Rat >10000 mg/kg; Dermal LD50 Rabbit >5000 mg/kg; Inhalation LC50 Rat >41 mg/L

Polyethylene glycol monooleyl ether (9004-98-2)

Oral LD50 Rat 2700 mg/kg

Isopropyl alcohol (67-63-0)

Inhalation LC50 Rat 72.6 mg/L 4 h; Oral LD50 Rat 4396 mg/kg; Dermal LD50 Rat 12800 mg/kg; Dermal LD50 Rabbit 12870 mg/kg

Fluocinolone acetonide (67-73-2)

Oral LD50 Rat >4 g/kg

Carcinogenicity

A: General Product Information

No information available for the product.

B: Component Carcinogenicity

Isopropyl alcohol (67-63-0)

ACGIH: A4 - Not Classifiable as a Human Carcinogen

IARC: Monograph 71 [1999]; Supplement 7 [1987]; Monograph 15 [1977] (Group 3 (not classifiable))

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*** Section 12 - Ecological Information ***

Ecotoxicity

A: General Product Information

No information available for the product.

B: Component Analysis - Ecotoxicity - Aquatic Toxicity

White mineral oil (8042-47-5)

Test & Species

96 Hr LC50 Lepomis macrochirus >10000 mg/L

Conditions

Isopropyl myristate (110-27-0)

Test & Species

96 Hr LC50 Brachydanio rerio 8400 mg/L [semi-static]

96 Hr LC50 Brachydanio rerio 8400 mg/L

72 Hr EC50 Desmodesmus subspicatus >100 mg/L

48 Hr EC50 Daphnia magna 100 mg/L

Conditions

Isopropyl alcohol (67-63-0)

Test & Species

96 Hr LC50 Pimephales promelas 9640 mg/L [flow-through]

96 Hr LC50 Pimephales promelas 11130 mg/L [static]

96 Hr LC50 Lepomis macrochirus >1400000 µg/L

96 Hr EC50 Desmodesmus subspicatus >1000 mg/L

72 Hr EC50 Desmodesmus subspicatus >1000 mg/L

48 Hr EC50 Daphnia magna 13299 mg/L

Conditions

*** Section 13 - Disposal Considerations ***

US EPA Waste Number & Descriptions

Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

Disposal Instructions

All wastes must be handled in accordance with local, state and federal regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

*** Section 14 - Transportation Information ***

US DOT Information

Shipping Name: Not Regulated

*** Section 15 - Regulatory Information ***

US Federal Regulations

Component Analysis

This material contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4).

Isopropyl alcohol (67-63-0)

SARA 313: 1.0 % de minimis concentration (only if manufactured by the strong acid process, no supplier notification)

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State Regulations

Component Analysis - State

The following components appear on one or more of the following state hazardous substances lists:

Component	CAS	CA	MA	MN	NJ	PA	RI
Peanut oil	8002-03-7	No	No	No	No	Yes	Yes
Isopropyl alcohol	67-63-0	Yes	Yes	Yes	Yes	Yes	Yes

Component Analysis - WHMIS IDL

The following components are identified under the Canadian Hazardous Products Act Ingredient Disclosure List:

Component	CAS #	Minimum Concentration
Polyethylene glycol monooleyl ether	9004-98-2	1 %
Isopropyl alcohol	67-63-0	1 %

Additional Regulatory Information

Component Analysis - Inventory

Component	CAS #	TSCA	CAN	EEC
Peanut oil	8002-03-7	Yes	DSL	EINECS
White mineral oil	8042-47-5	Yes	DSL	EINECS
Isopropyl myristate	110-27-0	Yes	DSL	EINECS
Polyethylene glycol monooleyl ether	9004-98-2	Yes	DSL	No
Isopropyl alcohol	67-63-0	Yes	DSL	EINECS
Fluocinolone acetonide	67-73-2	No	DSL	EINECS

*** Section 16 - Other Information ***

Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial, and local laws.

Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration., NJTSR = New Jersey Trade Secret Registry.

End of Sheet