



MATERIAL SAFETY DATA SHEET

MSDS Identifier: Fluocinolone Acetonide Cream USP, 0.01 %

SECTION 1: IDENTITY

Name/Address

IGI Laboratories Inc.
105 Lincoln Avenue
Buena, New Jersey 08310
Phone: 856-697-1441

Poison Control Center: 1 – 800 – 222 – 1222

This MSDS is written to provide health and safety information for individuals who will be handling the product during manufacture and packaging. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 2: COMPOSITION AND INGREDIENTS

<u>Ingredients</u>	<u>CAS No.</u>	<u>Quantity (%)</u>	<u>LD50 (Oral Rat)</u>
Fluocinolone Acetonide	67-73-2	0.01%	>4 g/Kg

Other ingredients: Beeswax, Butylated Hydroxy Toluene, Cetyl Alcohol, Citric Acid, Edetate Disodium, Fluocinolone Acetonide, Methylparaben, Mineral Oil, Polyoxyl-20-Cetostearyl Ether, Propylene Glycol, Propylparaben, Purified Water, Simethicone Emulsion, and Stearyl Alcohol.

SECTION 3: HAZARDS IDENTIFICATION

This pharmaceutical product is for human use under prescribed dosage form. Under normal handling and use, and in a manner consistent with the labeled instructions, this product is not chemically hazardous. This product is not meant for oral consumption or for ophthalmic use.

Inhalation: May cause irritation of nose and throat
Ingestion: May be harmful if swallowed
Skin Contact: None.
Eye Contact: Will cause irritation to the eyes

SECTION 4: FIRST AID MEASURES

After Eye Contact: Immediately flush with plenty amounts of water for at least 15 minutes. If irritation continues, seek medical attention.
After Skin Contact: Wash exposed areas with plenty amounts of water. If adverse skin effects occur, discontinue use. Seek medical attention
After Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention or call Poison Control Center immediately.
After Ingestion: Flush out mouth with water, consult a physician immediately.



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SECTION 5: FIRE FIGHTING MEASURES

- Fire Fighting Instructions:** Wear approved breathing apparatus and full protective turn out gear.
- Explosion Hazards:** This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and hydrogen fluoride).
- Extinguishing Media:** Use extinguishing media appropriate to surrounding fire conditions, such as Water fog, spray, dry chemical, regular foam, carbon dioxide.
- Flash Point:** Not available
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SECTION 6: ACCIDENTAL RELEASE MEASURES

- Personal Safeguards:** Avoid excessive contact and contact with eyes. Wear safety goggles or shield.
- Environmental Precautions:** Treat dispose in accordance with all regulations.
- Spill Clean-up Procedures:** This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.
- Industrial / large spill:* Contain the source of the spill or leak if it is safe to do so. Collect spill with non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Dispose of in accordance with applicable Federal, State, and local procedures.
- Household / small spill:* Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly. Wear gloves during clean-up.
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SECTION 7: HANDLING AND STORAGE

- Handling procedures:** Avoid contact with eyes. Do not eat, drink, smoke while handling this product. Follow all MSDS and label precautions.
- Storage:** Store at room temperature 15°- 25°C (59°- 77°F) in its original container. Avoid freezing and excessive heat above 40°C
- Other Precautions:** Avoid direct sunlight, read label and package insert carefully.
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SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure Levels	OSHA		ACGIH	
NA	NA	<u>PEL</u>	NA	<u>TLV</u>



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Personal Protection Equipment:

Ventilation: Good general ventilation is sufficient to control airborne levels.
Eye Protection: Wear safety glasses or goggles if eye contact is possible.
Skin Protection: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.
Hand Protection: Wear protective gloves to avoid repeated skin contact.
Respiratory Protection: Wear an appropriate respirator or mask.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Description: A smooth white cream, free of foreign matter.
Specific Gravity: ~0.95 (water = 1)
Boiling Point: Mixture
Freezing Point: Mixture
Flash Point: Not available
Vapor Density: Not available
Vapor Pressure: Not available
Evaporation Rate: Not available
Solubility in Water: Dispersible

SECTION 10: STABILITY AND REACTIVITY

Stable: Yes
Hazardous Polymerization: Will not occur
Conditions to Avoid: Direct sunlight, conditions that might generate heat, and sources of ignition. Protect from freezing
Incompatibility: Strong bases, acids and oxidizing agents
Hazardous Decomposition: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides and hydrogen fluoride).

SECTION 11: TOXIOLOGICAL INFORMATION

Individuals who have had allergic reactions to products containing any component of this product may experience allergic reactions to this product. This product may be mildly to moderately irritating.
Hazardous Scale [0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe]

Health	1
Fire Hazard	0
Reactivity	0



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Acute & Chronic Toxicity

Skin Sensitivity: NA
Eye Sensitivity: NA
Respiratory Sensitization: None
Carcinogenicity: **NTP** None **IARC** None

Reproductive Toxicity: No human data is available for this product.
Teratogenicity: No human data is available for this product.
Embryotoxicity: No human data is available for this product.
Mutagenicity: No human data is available for this product.

SECTION 12: ECOLOGICAL INFORMATION

The environmental characteristics of this product have not been fully evaluated. Releases to the environment in pure form should be avoided.

SECTION 13: DISPOSAL CONSIDERATIONS

Product Disposal: Dispose of in accordance with all applicable federal, state and local regulations.
Packaging: Disposal in compliance with official regulations. Handle packaging in the same way as the product itself. If not officially specified differently, packaging may be treated like household waste or recycled.

SECTION 14: TRANSPORTATION INFORMATION

Not regulated for transport under USDOT (transportation by land), IATA (transportation by sea) or IMDG (transportation by air) regulations.

SECTION 15: REGULATORY INFORMATION

The product described in this MSDS are regulated under the Federal Food, Drug and Cosmetics Act and are safe to use as per directions on container, box or accompanying literature (where applicable).

SECTION 16: OTHER INFORMATION

The information contained in this Material Safety Data Sheet has been compiled from information believed to be accurate and from past experience. While we believe that the data presented is factual, IGI, Inc. and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.