

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

**Product identifier**

**Product Name** Fluorometholone

**Other means of identification**

**Product Code** FG00071  
**Synonyms** FML Forte

**Recommended use of the chemical and restrictions on use**

**Recommended Use** Corticosteroid Ophthalmic Anti-Inflammatory

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 medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Details of the supplier of the safety data sheet**

**Manufacturer**

Allergan plc  
 5 Giralda Farms  
 Madison, NJ USA 07940  
 +1-800-272-5525

**E-mail address** SDS@Allergan.com

**Emergency telephone number**

**Emergency Telephone** Call CHEMTREC Day or Night  
 Within USA or Canada: 1-800-424-9300  
 Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

## 2. HAZARDS IDENTIFICATION

**Classification**

**OSHA Regulatory Status**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)


Reproductive toxicity	Category 2
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**Label elements**

**Emergency Overview**

**Warning**

**Hazard statements**  
 H361 - Suspected of damaging fertility or the unborn child



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<b>Appearance</b> Liquid	<b>Physical state</b> Liquid	<b>Odor</b> No information available
<b>Chemical Name</b> Fluorometholone	<b>Symptoms</b> Adverse reactions include, in decreasing order of frequency, elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, and delayed wound healing. Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticism after use of topical dermatologic steroids applied to the skin. Corticosteroid-containing preparations have also been reported to cause acute anterior uveitis and perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids. The development of secondary ocular infection (bacterial, fungal and viral) has occurred. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids. The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used. Other adverse events reported with the use of this medication include: allergic reactions; foreign body sensation; erythema of eyelid; eyelid edema/eye swelling; eye discharge; eye pain; eye pruritus; lacrimation increased; rash; taste perversion; visual disturbance (blurry vision); and visual field defect.	
<b>Chemical Name</b> Polysorbate 80 Fluorometholone	<b>Medical Conditions Aggravated by Exposure</b> Hypersensitivity to the material. This medication is contraindicated in most viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye, and fungal diseases of ocular structures. The medication is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.	

**Precautionary statements**

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water  
P321 - Specific treatment (see supplemental first aid instructions on this label)  
P332 + P313 - If skin irritation occurs: Get medical advice/attention  
P362 - Take off contaminated clothing and wash before reuse  
P264 - Wash face, hands and any exposed skin thoroughly after handling  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required  
P308 + P313 - IF exposed or concerned: Get medical advice/attention  
P405 - Store locked up  
P501 - Dispose of contents/ container to an approved waste disposal plant  
P280 - Wear protective gloves/protective clothing/eye protection/face protection

**Other Information**

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS No.	EINECS	Weight-%
PURIFIED WATER USP	7732-18-5	231-791-2	60 - 100*
Benzalkonium Chloride	63449-41-2	264-151-6	1 - 5*
SODIUM CHLORIDE USP	7647-14-5	231-598-3	0.1 - 1*

Polysorbate 80	9005-65-6	N/A	0.1 - 1*
Fluorometholone	426-13-1	207-041-5	0.1 - 1*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

#### 4. FIRST AID MEASURES

##### First aid measures

<b>Eye contact</b>	Rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	Consult a physician if necessary.

**Chemical Name**  
Benzalkonium Chloride  
Fluorometholone

##### **Note to physicians**

Treat symptomatically.  
Prolonged use of corticosteroids may increase intraocular pressure in susceptible individuals, resulting in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections. Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation. Acute purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. If this product is used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently. The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.

#### 5. FIRE-FIGHTING MEASURES

##### **Suitable extinguishing media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

##### **Unsuitable extinguishing media**

None known.

##### **Specific hazards arising from the chemical**

Fire may produce irritating, corrosive and/or toxic gases.

##### **Explosion data**

**Sensitivity to Mechanical Impact**  
**Sensitivity to Static Discharge**

Not impact sensitive.

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

##### **Protective equipment and precautions for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full

protective gear.

**6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions** Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
- Environmental precautions** See Section 12 for additional ecological information.
- Methods for containment** Prevent further leakage or spillage if safe to do so.
- Methods for cleaning up** Avoid creating dust.

**7. HANDLING AND STORAGE**

- Advice on safe handling** Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.
- Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.
- Incompatible materials** None known based on information supplied.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

Control parameters

**Exposure Guidelines** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m <sup>3</sup> )
Fluorometholone 426-13-1	N/A	N/A	N/A	30

Appropriate engineering controls

**Engineering Controls** The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. 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 as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

- Eye/face protection** No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.
- Skin and body protection** During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).
- Respiratory protection** Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Information on basic physical and chemical properties

<b>Physical state</b>	Liquid	<b>Appearance</b>	Liquid
<b>Color</b>	clear	<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available		

<u>Property</u>	<u>Values</u>
<b>pH</b>	No information available
<b>Melting point/freezing point</b>	No information available
<b>Boiling point / boiling range</b>	No information available
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No information available
<b>Flammability (solid, gas)</b>	No information available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No information available
<b>Lower flammability limit:</b>	No information available
<b>Vapor pressure</b>	No information available
<b>Vapor density</b>	No information available
<b>Specific Gravity</b>	No information available
<b>Water solubility</b>	No information available
<b>Solubility in other solvents</b>	No information available
<b>Partition coefficient</b>	No information available
<b>Autoignition temperature</b>	No information available
<b>Decomposition temperature</b>	No information available
<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available

**Other Information**

<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. STABILITY AND REACTIVITY

**Reactivity**

Not defined As Reactive substance

**Chemical stability**

Stable under normal conditions.

**Possibility of Hazardous Reactions**

None under normal processing.

**Conditions to avoid**

Aerosol formation.

**Incompatible materials**

None known based on information supplied.

**Hazardous Decomposition Products**

None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure****Acute toxicity**

<b>Chemical Name</b>	<b>Oral LD50</b>	<b>Dermal LD50</b>	<b>Inhalation LC50</b>
PURIFIED WATER USP	> 90 mL/kg ( Rat )	N/A	N/A
Benzalkonium Chloride	N/A	= 1420 mg/kg ( Rat )	N/A
SODIUM CHLORIDE USP	= 3000 mg/kg ( Rat )	> 10 g/kg ( Rabbit )	> 42 g/m <sup>3</sup> ( Rat ) 1 h
Polysorbate 80	= 34500 µL/kg ( Rat )	N/A	N/A
Fluorometholone	=2000 mg/kg oral mouse	N/A	N/A

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Benzalkonium Chloride	Not Suspected of being a Mutagen.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	No information available.	No information available
Polysorbate 80	No information available.	Not suspected of being a human carcinogen.	This product does not contain any known or suspected reproductive hazards.	It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.
Fluorometholone	No information available.	No studies have been conducted in animals or in humans to evaluate the possibility of these effects.	Teratogenic Effects. Preganacy Cat C. This medication has been shown to be embryocidal and teratogenic in rabbits when administered at low multiples of the human ocular dose. This medication was applied ocularly to rabbits daily on days 6-18 of gestation, and dose-related fetal loss and fetal abnormalities including cleft palate, deformed rib cage, anomalous limbs and neural abnormalities such as encephalocele, craniorachischisis, and spina bifida were observed. There are no adequate and well-controlled studies of This medication in pregnant women, and it is not known whether This medication can cause fetal harm when administered to a pregnant woman. This medication should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.	It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemically-administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from this medication, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Numerical measures of toxicity - Product Information**

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral) 50000 mg/kg

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

Harmful to aquatic life with long lasting effects

1.66% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
SODIUM CHLORIDE USP 7647-14-5	N/A	4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static	340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static 1000: 48 h Daphnia magna mg/L EC50

		7050: 96 h Pimephales promelas mg/L LC50 semi-static 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static	
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**Other adverse effects** No information available

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse container. Dispose of contents/containers in accordance with local regulations.

**14. TRANSPORT INFORMATION**

**DOT** Not regulated

**TDG** Not regulated

**ICAO (air)** Not regulated

**IATA** Not regulated

**IMDG** Not regulated

**ADR** Not regulated

**ADN** Not regulated

**15. REGULATORY INFORMATION**

**International Inventories**

**TSCA** Not Listed

**DSL/NDSL** Not Listed

**EINECS/ELINCS** Not Listed

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**US Federal Regulations**

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

**SARA 311/312 Hazard Categories**

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No

**Reactive Hazard**

No

**CWA (Clean Water Act)**

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

**US State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals

**U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Dibasic Sodium Phosphate Anhydrous, USP 7558-79-4	X	X	X

**16. OTHER INFORMATION**

**Revision Date** 02-Oct-2018  
**Revision Note** No information available

**Disclaimer**

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**