Safety Data Sheet

acc. to OSHA HCS (29 CFR 1910.1200)

Printing date 05/29/2015 Reviewed on 05/29/2015

1 Identification

· **Product identifier**

· **Trade name: FLAREX®**
· **Other names:** Fluorometholone Acetate Ophthalmic Suspension

· **Recommended use and restriction on use**
· **Recommended use:** Pharmaceutical Product
· **Restrictions on use:** Contact manufacturer.

· **Details of the supplier of the Safety Data Sheet**
· **Manufacturer/Supplier:**
Alcon Laboratories, Inc.
6201 S. Freeway
Fort Worth, Texas 76134 USA
Tel 1-817-551-4444
E-mail: safety.datasheets@alcon.com

· **Emergency telephone number:**
ChemTel Inc.
(800) 255-3924, +1 (813) 248-0585

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified as hazardous according to the Globally Harmonized System (GHS).
· **Additional information:**
0 percent of the mixture consists of ingredient(s) of unknown toxicity.
There are no other hazards not otherwise classified that have been identified.

· **Label elements**
· **GHS label elements**
The product is not classified as hazardous according to OSHA GHS regulations within the United States.
· **Hazard pictograms** Not Regulated
· **Signal word** Not Regulated

· **Hazard-determining components of labeling:** None.
· **Hazard statements** Not Regulated
· **Precautionary statements** Not Regulated
· **Hazard description:**
· **WHMIS-symbols:** Not hazardous under WHMIS.
· **Classification system:**
· **NFPA ratings (scale 0 - 4)**

Health = 0
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 0
Fire = 0
Reactivity = 0

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.

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· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:** None in reportable quantities.
· **Additional information:**
For the listed ingredients, the identity and exact percentages are being withheld as a trade secret.

4 First-aid measures

· **Description of first aid measures**
· **General information:** No special measures required.
· **After inhalation:** Supply fresh air; consult doctor in case of complaints.
· **After skin contact:**
Generally the product does not irritate the skin.
Wash with soap and water.
If skin irritation is experienced, consult a doctor.
· **After eye contact:**
Product is indicated for ocular usage. In case of persistent or severe irritation after usage, discontinue use and seek medical advice.
· **After swallowing:**
Rinse out mouth and then drink plenty of water.
Do not induce vomiting; immediately call for medical help.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed**
Adverse health effects are not reasonably expected from normal use of product.
· **Danger** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
· **For safety reasons unsuitable extinguishing agents:** None.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.
· **Additional information** No further relevant information available.

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6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation.
For large spills, wear protective clothing.
· **Environmental precautions:** No special measures required.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Dispose contaminated material as waste according to item 13.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling:**
· **Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
Avoid storage near extreme heat, ignition sources or open flame.
· **Information about storage in one common storage facility:** Store away from foodstuffs.
· **Further information about storage conditions:**
Keep receptacle tightly sealed.
Storage Temperatures : 36 - 77 º F / 2 - 25 º C.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
· **Engineering controls:** No further relevant information available.
· **Breathing equipment:** Not required under normal conditions of use.

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· **Protection of hands:**
Gloves not required under normal conditions of use.
Wear protective gloves to handle contents of damaged or leaking units.
· **Material of gloves** Rubber gloves
· **Eye protection:**
Not required for normal handling. Wear protective eyewear while handling damaged or leaking product.
· **Body protection:** Not required under normal conditions of use.
· **Limitation and supervision of exposure into the environment** No special requirements.
· **Risk management measures** No special requirements.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**

Form:	Viscous
Color:	Unknown
· **Odor:**	Unknown
· **Odor threshold:**	Not determined.
· **pH-value at 20 °C (68 °F):**	7.3
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· **Flash point:**	The product is not flammable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Auto-ignition temperature:**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not self-igniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not determined.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Fully miscible.
· **Partition coefficient (n-octanol/water):**	Not determined.

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· **Viscosity:**
Dynamic: Not determined.
Kinematic: Not determined.

· **Solvent content:**
Organic solvents: Not determined.
Water: Not determined.

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** Possible in traces.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **LD/LC50 values that are relevant for classification:** None.
· **Primary irritant effect:**
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Subacute to chronic toxicity:** No further relevant information available.
· **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **NTP (National Toxicology Program)**
None of the ingredients is listed.
· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Probable Routes of Exposure**
Inhalation.
Eye contact.
Skin contact.

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· **Repeated Dose Toxicity:** No further relevant information available.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Not known to be hazardous to water.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation:**
Smaller quantities can be disposed of with household waste.
The user of this material has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state and federal laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Not Regulated
· **UN proper shipping name**	
· **DOT, ADR, ADN, IMDG, IATA**	Not Regulated
· **Transport hazard class(es)**	
· **DOT, ADR, ADN, IMDG, IATA**	
· **Class**	Not Regulated
· **Packing group**	
· **DOT, ADR, IMDG, IATA**	Not Regulated
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	-

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15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **United States (USA)**
· **SARA**

· **Section 355 (extremely hazardous substances):**
None of the ingredients is listed.
· **Section 313 (Specific toxic chemical listings):**
None of the ingredients are listed.
· **TSCA (Toxic Substances Control Act):**
All ingredients are listed.

· **Proposition 65 (California)**

· **Chemicals known to cause cancer:**
None of the ingredients are listed.
· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients are listed.
· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.
· **Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.
· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.
· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.
· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.
· **State Right to Know Listings**
None of the ingredients is listed.

· **Canadian substance listings:**

· **Canadian Domestic Substances List (DSL)**
All ingredients are listed.
· **Canadian Ingredient Disclosure list (limit 0.1%)**
None of the ingredients is listed.
· **Canadian Ingredient Disclosure list (limit 1%)**
None of the ingredients is listed.

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· **Other regulations, limitations and prohibitive regulations**
This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 05/29/2015 / -

· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
WHMIS: Workplace Hazardous Materials Information System (Canada)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

· **Sources**
SDS Prepared by:
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