

Loteprednol Etabonate Ophthalmic Suspension, 0.2%**Section 1 – IDENTIFICATION**

Product Identifier: Loteprednol Etabonate Ophthalmic Suspension, 0.2%

Synonyms: Chloromethyl 17 α -[(ethoxycarbonyl)oxy]-11 β -hydroxy-3-oxoandrosta-1,4-diene-17 β -carboxylate

NDC Code: 72485-653-0 Per Bottle: 5 mL
72485-653-10 Per Bottle: 10 mL

Recommended Use: Loteprednol Etabonate Ophthalmic Suspension, 0.2% is indicated for the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis.

Manufacturer: Ophtapharm AG
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Switzerland

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Section 2 – HAZARD(S) IDENTIFICATION

Physical Hazards: Not classifiable.

Health Hazards: Reproductive Toxicity Category 2

Symbol(s):



Signal Word: Warning.

Hazard Statement(s): H361 Suspected of damaging fertility or the unborn child.

Precautionary Statement(s):

- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P264 Wash hands and other exposed areas thoroughly after handling.
- P308 If exposed or concerned: Get medical advice/ attention.
- + P313
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified: None.

Supplementary Information: None.

Section 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Benzalkonium Chloride	CAS: 139-07-1 EINECS: 205-3515-2	<0.02%	UN GHS: NDA
Edetate Disodium Dihydrate	CAS: 139-33-3 EINECS: 205-358-3	<0.02%	UN GHS: NDA
Glycerine	CAS: 56-81-5 EINECS: 200-289-5	>3%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Loteprednol Etabonate	CAS: 82034-46-6	0.2%	UN GHS: NDA
Kollidon (polyvinyl pyrrolidone)	CAS: 9003-398-08 EINECS: 1312995-182-4	<2%	UN GHS: NDA
Tyloxapol	CAS: 25301-02-4	<0.5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A

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Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Not Classified
Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.			

Section 4 – FIRST AID MEASURES

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 7).

Signs and Symptoms: Ocular adverse reactions occurring in 5 % to 15 % of patients treated with loteprednol etabonate ophthalmic suspension (0.2% to 0.5 %) in clinical studies included abnormal vision/blurring, burning on instillation, chemosis, discharge, dry eyes, epiphora, foreign body sensation, itching, injection, and photophobia. Other ocular adverse reactions occurring in less than 5 % of patients include conjunctivitis, corneal abnormalities, eyelid erythema, keratoconjunctivitis, ocular irritation/pain/discomfort, papillae, and uveitis.

Medical Conditions Aggravated by Exposure: No data available.

Notes to Physician: Treat supportively and symptomatically.

Section 5 – FIREFIGHTING MEASURES

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or alcohol- resistant foam as necessary.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: None known.

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.

Section 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.

Section 7 – HANDLING AND STORAGE

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

Conditions for Safe Storage, Including Any Incompatibilities: Store upright between 15° to 25°C (59° to 77°F). Do not freeze.

Specific End Use: Pharmaceutical.

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Loteprednol Etabonate	Not established	Not established

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

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. 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.

Section 9– PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	White aqueous suspension.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	5.0 to 6.0.
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):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

Section 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):	Avoid extreme heat or cold. Do not freeze.
Incompatible Materials:	No data available.
Hazardous Decomposition Products:	No data available.

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Section 11 – TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation: Under normal conditions of use, not expected to cause respiratory tract irritation.

Ingestion: Not expected to be harmful if swallowed. May cause gastric and intestinal irritation if ingested.

Skin Contact: Not expected to cause skin irritation.

Eye Contact: Non-irritating to the eyes when used as directed.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 3. To the best of our knowledge, the 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
No data available	No data available	No data available	No data available	No data available

Irritation / Sensitization

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

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

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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: Eyes, skin, digestive tract, kidney and brain.

Systemic Effects: No data available.

Reproductive Effects: Pregnancy Category C. Loteprednol Etabonate has been shown to be embryotoxic (delayed ossification) and teratogenic (increased incidence of meningocele, abnormal left common carotid artery, and limb flexures) when administered orally to rabbits during organogenesis at a dose of 3 mg/kg/day (35 times the maximum daily clinical dose), a dose which caused no maternal toxicity.

Carcinogenicity: Long-term animal studies have not been conducted to evaluate the carcinogenic potential of Loteprednol Etabonate.

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.

Section 12 – ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

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.

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Section 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.

Section 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

Section 15 – REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Loteprednol Etabonate	No

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
Loteprednol Etabonate	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.

Section 16 – OTHER INFORMATION

The information given herein is in good faith and to the best of our knowledge, but no warranty expressed or implied is made.

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