

**Lotemax® Ointment**  
**MATERIAL SAFETY DATA SHEET**

Effective Date: 7/27/11      Supersedes: 10/1/10

Page 1 of 8

<b>Section 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION</b>
---------------------------------------------------------------

**PRODUCT:**

**Product Name:** Lotemax® Ointment  
**Product Code(s):** Core 443  
**NDC No(s):** NDC 24208-443-01  
NDC 24208-443-35  
**Chemical Family:** Corticosteroid  
**Manufacturer:** Bausch & Lomb, Incorporated  
**Address:** 1400 N. Goodman Street  
Rochester, New York 14609

**COMPANY IDENTIFICATION:**

Bausch & Lomb, Incorporated  
1400 N. Goodman Street  
Rochester, New York 14609

**For Information:** 1-800-553-5340

**EMERGENCY TELEPHONE NUMBER:**

**24-Hour Emergency:** 1-800-535-5053

<b>Section 2: HAZARDS IDENTIFICATION</b>
------------------------------------------

**CLASSIFICATION:** Acute toxicity; Category 5 (GHS)

**LABELING:**

**Pictograms:** (None required)

**Signal Word:** Warning

**Hazard Statements:** May be harmful if swallowed.  
May cause respiratory tract irritation.  
May cause eye irritation in sensitive individuals..  
May cause skin irritation in sensitive individuals.  
May cause hypersensitivity in some individuals.

**Precautionary Statements:** Use only in accordance with label instructions and supplied prescribing information.  
Avoid release to the environment.  
**Keep out of reach of children.**

**PRECAUTIONS:****Caution! Pharmacologically Active**

Lotemax® Ointment contains a potent corticosteroid formulated for topical ophthalmic use.

**Do Not Use:** if there exists hypersensitivity to any ingredient in this product.

**Section 2: HAZARDS IDENTIFICATION (cont.)**

Use only in accordance with product prescribing information.

**WARNING:** *Keep out of reach of children.*

**POTENTIAL HEALTH EFFECTS**

**EYE:**

May cause irritation, burning sensation upon application and hypersensitivity (anaphylactic).

**SKIN:**

May cause irritation and localized hypersensitivity, with itching, swelling and diffuse redness.

**INGESTION:**

May be harmful if swallowed. May cause vomiting, diarrhea, adrenal gland suppression, Cushing's Syndrome, water retention, electrolyte imbalance and hyperglycemia.

**INHALATION:**

Unlikely to be hazardous when used as directed. However, if actively concentrated and inhaled, it may cause respiratory tract irritation and hypersensitivity.

**CHRONIC HEALTH EFFECTS**

**Loteprednol Etabonate:**

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Steroids should be used with caution in the presence of glaucoma.

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. Refer to the product insert for additional information.

**CARCINOGENICITY:**

**NTP:** No ingredients listed.

**IARC:** No ingredients listed.

**OSHA:** No ingredients listed.

**MEDICAL CONDITIONS AGGRAVATED BY OVER EXPOSURE:**

**Loteprednol Etabonate:**

In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection.

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.

**MATERIAL SAFETY DATA SHEET**

**Section 3: COMPOSITION / INFORMATION ON INGREDIENTS**

CAS #	Chemical Identity	Concentration, % W/W	EINECS / ELINCS #
82034-46-6	Loteprednol Etabonate	0.5	NA
8009-03-8	White Petrolatum, USP	< 90	232-373-2
8042-47-5	Mineral Oil, USP	< 20	237-455-8

**Section 4: FIRST AID MEASURES**

**EYES:**

If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional. For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention.

**SKIN:**

Wash contaminated area with soap and water. Get medical attention if irritation develops.

**INGESTION:**

Do NOT Induce Vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Contact a physician immediately. Provide product prescribing information.

**INHALATION:**

No inhalation exposure expected with this formulation under normal conditions of use. If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Contact a physician immediately.

**ADDITIONAL NOTES TO PHYSICIAN:**

For additional guidance, refer to the product insert. Contact the local Poison Control Center.

**Section 5: FIRE FIGHTING MEASURES**

**FLAMMABLE PROPERTIES:**

**Flash Point:** Not Applicable

**Method:** NA

**EXTINGUISHING MEDIA:**

Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

**HAZARDOUS COMBUSTION PRODUCTS:**

Carbon dioxides, nitrogen oxides, sulfur oxides, halogenated compounds, hydrogen chloride and other hazardous products of combustion.

MATERIAL SAFETY DATA SHEET

**Section 5: FIRE FIGHTING MEASURES (cont.)**

**SPECIAL FIRE FIGHTING INSTRUCTIONS:**

As in any fire, wear self-contained breathing apparatus and full protective gear.

**Section 6: ACCIDENTAL RELEASE MEASURES**

**General Information:**

Use appropriate protective equipment and engineering controls (refer to Section 8).

**Specific Information:**

Ventilate area. Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways.

Dispose of in accordance with Section 13.

**Section 7: HANDLING AND STORAGE**

**HANDLING:**

Use only in accordance with product literature. Wash thoroughly with warm water and soap after handling.

**STORAGE:**

Store product in original container, with cap tightly closed, at room temperature: 15-25°C (59-77°F).  
Shelf Life: Expiration date is listed on each package.

**Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

**CONTROL PARAMETERS:**

CAS #	COMPONENT NAME	OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES										
		OSHA PEL		ACGIH TLV		NIOSH REL		IRELAND		HSE		UNITS
		TWA	STEL	TWA	STEL	TWA	STEL	TWA	STEL	TWA	STEL	
82034-46-6	Loteprednol Etabonate <sup>1</sup>	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
8009-03-8	White Petrolatum, USP	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
8042-47-5	Mineral Oil, USP	NE	NE	5I	NE	NE	NE	NE	NE	NE	NE	NA

<sup>1</sup> Bausch + Lomb Internal OEL: 1 ug/m<sup>3</sup> (TWA)

NOTE: Limits/standards shown for guidance only. Follow applicable regulations.

N/E: Not Established  
 OSHA: Occupational Safety & Health Administration  
 TWA: 8-Hour Time-Weighted Average  
 STEL: Short-Term Exposure Limit  
 ACGIH: American Conference of Governmental Industrial Hygienists  
 OEL: Occupational Exposure Limit

N/A: Not Applicable  
 PPM: Parts Per Million  
 C: Ceiling Limit  
 REL: Recommended Exposure Limit  
 NIOSH: National Institute for Occupational Safety & Health  
 I: Measured as inhalable fraction of the aerosol

MATERIAL SAFETY DATA SHEET

**Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION (cont.)**

**ENGINEERING CONTROLS:**

Not required during normal clinical use. Local exhaust ventilation should be provided when handling bulk product.

**RESPIRATORY PROTECTION:**

Not required during normal clinical use.

**SKIN PROTECTION:**

Not required during normal clinical use. Wash thoroughly with warm water and soap after handling. Impervious chemical resistant gloves and appropriate protective clothing are recommended when directly handling bulk product.

**EYE PROTECTION:**

Not required during normal clinical use. Appropriate eye protection is required when handling bulk product.

**ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:**

No special recommendations during normal clinical use.

**Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

<b>Physical State:</b>	Gel
<b>Color:</b>	Off-white to yellowish
<b>Odor:</b>	Odorless
<b>Odor Threshold:</b>	Not determined
<b>pH-Value:</b>	Not applicable
<b>Melting Point:</b>	Not applicable
<b>Freezing Point:</b>	Not determined
<b>Initial Boiling Point:</b>	Not determined
<b>Flash Point:</b>	Not applicable
<b>Evaporation Rate:</b>	Not determined
<b>Flammability:</b>	Not applicable
<b>Explosion Limits:</b>	Not determined
<b>Vapor Pressure:</b>	Not determined
<b>Vapor Density:</b>	Not determined
<b>Specific Gravity (H<sub>2</sub>O=1):</b>	Not determined
<b>Solubility [Loteprednol Etabonate]:</b>	Soluble in methanol, acetone, and methylene chloride
<b>Partition Coefficient:</b>	Not applicable
<b>Auto-Ignition Temperature:</b>	Not determined
<b>Decomposition Temperature:</b>	Not determined
<b>Osmolality:</b>	Not determined
<b>Viscosity:</b>	Not determined

## MATERIAL SAFETY DATA SHEET

**Section 10: STABILITY AND REACTIVITY****GENERAL:**

Stable

**CONDITIONS TO AVOID:**

Extreme heat or cold

**INCOMPATIBLE MATERIALS:**

Strong acids, bases, alkali metals, alkali hydrides and silver preparations

**HAZARDOUS POLYMERIZATION:**

Will not occur.

**HAZARDOUS DECOMPOSITION PRODUCTS:**

Carbon dioxides, nitrogen oxides, sulfur oxides, halogenated compounds, and hydrogen chloride.

**Section 11: TOXICOLOGICAL INFORMATION****Loteprednol Etabonate:*****Carcinogenesis, Mutagenesis, Reproductive Toxicity:***

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma tk assay, or in a chromosome aberration test in human lymphocytes, or *in vivo* in the single dose mouse micronucleus assay. Treatment of male and female rats with up to 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, (1500 and 750 times the maximum clinical dose, respectively) prior to and during mating did not impair fertility in either gender.

***Teratogenic Effects:***

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 (85 times the maximum daily clinical dose), a dose that caused no maternal toxicity. The no-observed-effect-level (NOEL) for these effects was 0.5 mg/kg/day (15 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at  $\geq 5$  mg/kg/day doses, and cleft palate and umbilical hernia at  $\geq 50$  mg/kg/day) and embryotoxicity (increased postimplantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with  $\geq 50$  mg/kg/day). Treatment of rats with 0.5 mg/kg/day (15 times the maximum clinical dose) during organogenesis did not result in any reproductive toxicity. Loteprednol etabonate was maternally toxic (significantly reduced body weight gain during treatment) when administered to pregnant rats during organogenesis at doses of  $\geq 5$  mg/kg/day.

Oral exposure of female rats to 50 mg/kg/day of loteprednol etabonate from the start of the fetal period through the end of lactation, a maternally toxic treatment regimen (significantly decreased body weight gain), gave rise to decreased growth and survival, and retarded development in the offspring during lactation; the NOEL for these effects was 5 mg/kg/day. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to pregnant rats at doses up to 50 mg/kg/day during the fetal period.

MATERIAL SAFETY DATA SHEET

**Section 11: TOXICOLOGICAL INFORMATION (cont.)**

RTECS No.: SE6780000

White Petrolatum, USP

Toxicity Data: INTRA-MOUSE LD50: > 50 GM/KG

RTECS No.: PY8047000

Mineral Oil, USP

Toxicity Data: ORL-RAT TDLo: 92 GM/KG/92D

**NOTE:** Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information.

Refer to Section 2 for additional acute / chronic hazard information.

**Section 12: ECOLOGICAL INFORMATION**

No data available on the environmental impact of this product. Avoid release to the environment.

**Section 13: DISPOSAL CONSIDERATIONS**

All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

**Section 14: TRANSPORT INFORMATION**

	US DOT	IATA	IMO	RID/ADR	Canadian DG
<b>Shipping Name:</b>	Not Regulated	Not Regulated	No Information Available	No Information Available	No Information Available
<b>Hazard Class:</b>	NA	NA			
<b>UN Number:</b>	NA	NA			
<b>Package Group:</b>	NA	NA			

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.

**Section 15: REGULATORY INFORMATION**

**OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):**

Although technically exempt from the Occupational Safety & Health Administration (OSHA) Hazard Communication Standard, this product would be considered hazardous.

**MATERIAL SAFETY DATA SHEET**

**Section 15: REGULATORY INFORMATION (cont.)**

**TOXIC SUBSTANCE CONTROL ACT (TSCA):**

CAS# 82034-46-6 is listed on the TSCA inventory.  
 CAS# 8009-03-8 is listed on the TSCA inventory.  
 CAS# 8042-47-5 is listed on the TSCA inventory.

**REACH:**

CAS #	REACH	SVHC	SIN
82034-46-6	NR	No	No
8009-03-8	PR	No	No
8042-47-5	PR	No	No

NR: Not Registered  
 PR: Pre-Registered  
 SVHC: Substance of Very High Concern  
 SIN: Substitute It Now

**SARA TITLE III (Superfund Amendments and Reauthorization Act):**

SECTION 302 (Extremely Hazardous Substances): No Components Listed  
 SECTION 311, 312 (Hazard Categories): Acute, Chronic  
 SECTION 313 (Toxic Chemicals): No Components Listed

**CALIFORNIA PROPOSITION 65:**

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels that would require a warning under the statute.

**Section 16: OTHER INFORMATION**

*To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb Incorporated nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb Incorporated or any of its subsidiaries be liable for any special, incidental or consequential damages.*