Safety Data Sheet

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Section 1: Identification

Product identifier

Product Name • **Loteprednol Etabonate Ophthalmic Ointment, 0.5%**

Product Code • AB44334; Core No. 443; NDC 24208-0443-35

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Finshed Pharmaceutical Product; LOTEMAX ointment is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb

1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com

Telephone (General) • 1-800-553-5340

Emergency telephone number

Manufacturer • 1-800-535-5053 - Infotrac

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 consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Reproductive Toxicity 2

Label elements

UN GHS

WARNING

Hazard statements • Suspected of damaging fertility or the unborn child.

Precautionary statements

Prevention • Do not handle until all safety precautions have been read and understood.

Wash thoroughly after handling.
Use personal protective equipment as required.

Response
- IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.

Storage/Disposal
- Keep tightly closed. Store at room temperature 15-25ºC (59-77ºF), to maintain product integrity. Use before date marked on carton and/or container.
Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

UN GHS
- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	**Identifiers**	**%**	**Classifications According to Regulation/Directive**
Loteprednol Etabonate	**CAS:**82034-46-6	0.5%	**UN GHS:** NDA
Mineral oil	**CAS:**8012-95-1 **EINECS:**232-384-2	10% TO 20%	**UN GHS:** NDA
White Petrolatum	**CAS:**8009-03-8 **EINECS:**232-373-2	> 80%	**UN GHS:** NDA

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation
- No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.

Skin
- Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.

Eye
- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention. If eye irritation persists: Get medical advice/attention.

Ingestion
- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- Ocular adverse reactions occurring in 5-15% of patients treated with loteprednol etabonate ophthalmic suspension (0.2%-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.

Indication of any immediate medical attention and special treatment needed

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media
- SMALL FIRES: Dry chemical, CO2, water spray or regular foam.
  LARGE FIRE: Water spray, fog or regular foam.

Unsuitable Extinguishing Media
- No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards
- None known.

Hazardous Combustion Products
- None known.

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection.
  Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures
- Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures
- 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.
  Dispose of in accordance with Section 13.

Section 7 - Handling and Storage

Precautions for safe handling

Handling
- No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage
- Keep tightly closed. Store at room temperature 15-25ºC (59-77ºF), to maintain product integrity. Use before date marked on carton and/or container.

Incompatible Materials or
- None specified.

Ignition Sources

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines					
	Result	**ACGIH**	**Canada Quebec**	**NIOSH**	**OSHA**
Mineral oil (8012-95-1)	STELs	Not established	10 mg/m3 STEV (mist)	10 mg/m3 STEL	Not established
	TWAs	5 mg/m3 TWA (excluding metal working fluids, highly & severely refined, inhalable fraction)	5 mg/m3 TWAEV (mist)	5 mg/m3 TWA	5 mg/m3 TWA

Exposure Control Notations

ACGIH

•Mineral oil (8012-95-1): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (highly and severely refined); A2 - Suspected Human Carcinogen (poorly and mildly refined))

Exposure controls

Engineering Measures/Controls

- 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 to an acceptable level.

Personal Protective Equipment

Respiratory

- In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.

Hands

- Wear appropriate gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations

- Wash thoroughly after handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Ointment	Color	off-white to yellowish.
Odor	No odor.	Aerosol Type	Not relevant

Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point	No data available
Decomposition Temperature	No data available	pH	Not relevant
Specific Gravity/Relative Density	Not relevant	Water Solubility	Immiscible
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
White Petrolatum (> 80%)	8009-03-8	**Acute Toxicity:** Intraperitoneal-Mouse LD50 • >50 g/kg
Mineral oil (10% TO 20%)	8012-95-1	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • >24 g/kg; *Gastrointestinal*:**Hypermotility, diarrhea**

GHS Properties	Classification
Acute toxicity	**UN GHS** • Classification criteria not met
Aspiration Hazard	**UN GHS** • Classification criteria not met
Carcinogenicity	**UN GHS** • Classification criteria not met
Germ Cell Mutagenicity	**UN GHS** • Classification criteria not met

Skin corrosion/Irritation	**UN GHS** • Classification criteria not met
Skin sensitization	**UN GHS** • Classification criteria not met
STOT-RE	**UN GHS** • Classification criteria not met
STOT-SE	**UN GHS** • Classification criteria not met
Toxicity for Reproduction	**UN GHS** • Toxic to Reproduction 2
Respiratory sensitization	**UN GHS** • Classification criteria not met
Serious eye damage/Irritation	**UN GHS** • Classification criteria not met

Potential Health Effects

Inhalation

Acute (Immediate)
- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)
- No data available.

Skin

Acute (Immediate)
- Not expected to cause skin irritation.

Chronic (Delayed)
- No data available.

Eye

Acute (Immediate)
- Non-irritating to the eyes when used as directed. Ocular adverse reactions occurring in 5-15% of patients treated with loteprednol etabonate ophthalmic suspension (0.2%-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.

Chronic (Delayed)
- Reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Ingestion

Acute (Immediate)
- Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.

Chronic (Delayed)
- No data available.

Reproductive Effects
- Teratogenic 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. The no-observed-effect-level (NOEL) for these effects was 0.5 mg/kg/day (6 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at ≥5 mg/kg/day doses, and cleft palate and umbilical hernia at ≥50 mg/kg/day) and embryotoxicity (increased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with ≥50 mg/kg/day). Treatment of rats with 0.5 mg/kg/day (6 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 ≥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.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available.

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste
- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user
- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
- No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications
- No data available

Inventory				
Component	**CAS**	**Canada DSL**	**EU EINECS**	**TSCA**
Loteprednol Etabonate	82034-46-6	No	No	No
Mineral oil	8012-95-1	Yes	Yes	Yes
White Petrolatum	8009-03-8	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• White Petrolatum	8009-03-8	Uncontrolled product according to WHMIS classification criteria
• Mineral oil	8012-95-1	Uncontrolled product according to WHMIS classification criteria
• Loteprednol Etabonate	82034-46-6	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	1 %
• Loteprednol Etabonate	82034-46-6	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• White Petrolatum	8009-03-8	Carc.Cat.2; R45
• Mineral oil	8012-95-1	Not Listed
• Loteprednol Etabonate	82034-46-6	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• White Petrolatum	8009-03-8	T R:45 S:53-45
• Mineral oil	8012-95-1	Not Listed
• Loteprednol Etabonate	82034-46-6	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Notes - Substances and Preparations

• White Petrolatum	8009-03-8	N
• Mineral oil	8012-95-1	Not Listed
• Loteprednol Etabonate	82034-46-6	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• White Petrolatum	8009-03-8	S:53-45
• Mineral oil	8012-95-1	Not Listed
• Loteprednol Etabonate	82034-46-6	Not Listed

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Loteprednol Etabonate	82034-46-6	Not Listed

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Loteprednol Etabonate	82034-46-6	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List		
• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Loteprednol Etabonate	82034-46-6	Not Listed
U.S. - California - Proposition 65 - Developmental Toxicity		
• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Loteprednol Etabonate	82034-46-6	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Loteprednol Etabonate	82034-46-6	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Loteprednol Etabonate	82034-46-6	Not Listed

Section 16 - Other Information

Last Revision Date
- 05/May/2015

Preparation Date
- 05/May/2015

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