

SAFETY DATA SHEETS

This SDS packet was issued with item:

078475216

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078602490 078797684 078930691 078934754 078949212

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

Issued: 09/14/95
Revised: 01/25/02
Revision: 01

Prepared by: Gary Wong
Manager EHS
Core No. 041

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension USP
Generic Name: Same
NDC No. 24208-830-60 (5 ml)

Legal Category: Prescription only medicine, filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

Drug Composition: Antibiotics/Glucocorticoid

BAUSCH & LOMB PHARMACEUTICALS, INC.
8500 Hidden River Parkway
Tampa, FL 33637

Information: (800) 323-0000 (M-F) 8am-5pm EST
Emergency: (800) 227-1427 24 hrs

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS #	TLV (mg/m ³)	PEL(mg/m ³)	% Content
Dexamethasone	50-02-2	NE	NE	<1
Neomycin Sulfate	1405-10-3	NE	NE	<1
Polymyxin B Sulfate	1405-20-5	NE	NE	<1
Purified Water	7732-18-5	NE	NE	qs

Ingredients <1% - Sodium Chloride, Hydroxypropyl Methylcellulose 2910, Polysorbate 20, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. White aqueous suspension.

POTENTIAL HEALTH HAZARDS

Carcinogenicity: (NTP) No (IARC) No (OSHA) No

Eye: May cause irritation or burning sensation on installation. Can cause hypersensitivity (anaphylactic) in some individuals. The most frequent adverse reactions are localized hypersensitivity with itching, swelling of the conjunctiva and eyelid, and diffused redness of the eye (conjunctival erythema). It may be manifest as a failure to heal. It has been shown, though not in humans, that through large doses or prolonged topical administration, glucocorticoids may be systemically adsorbed by pregnant mothers and produce fetal abnormalities. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Systemic toxicity reactions include reversible hypothalamic-pituitary-adrenal axis gland suppression, manifestations of Cushing's syndrome, intercranial hypertension, hyperglycemia, and glycosuria. Neomycin sulfate causes cutaneous sensitization. A precise incidence of allergic reactions (primarily skin rash) due to topical neomycin is not known.

Skin: May cause irritation and hypersensitivity in some individuals. Neomycin sulfate causes cutaneous sensitization. The most frequent adverse reactions are localized hypersensitivity with itching, swelling and diffused redness of the skin (erythema).

Ingestion: May cause irritation and hypersensitivity in some individuals. Large doses may induce vomiting, diarrhea, adrenal gland suppression, Cushing's syndrome, hyper-glycemia, and possibly birth defects in pregnant mothers.

Inhalation: May cause irritation and hypersensitivity in some individuals.

Chronic Effects: May cause irritation and hypersensitivity. As with other antibiotic preparations, prolonged use may result in the overgrowth of non-susceptible organisms, including fungi. Appropriate measures should be taken if this occurs. Prolonged use may result in glaucoma, with damage to the optic nerve, and other visual effects. Response to secondary infections may be impaired. In purulent infections of the eye, steroids may mask infection or enhance existing infection.

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

Medical Conditions Aggravated by Long Term Exposure: Anaphylactic cross-reactions may occur for corticosteroids and antibiotics including kanamycin, paromomycin, streptomycin and possibly gentamicin. This medication is contraindicated for patients with herpes simplex, vaccinia and varicella infections. As with other anti-microbial preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Preexisting conjunctival or systemic fungal infections may be aggravated. Appropriate measures should be taken if this occurs.

4. FIRST AID MEASURES

Eyes: Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

Skin: Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

Ingestion: Wash out mouth and drink plenty of water and bland fluids. Do not give anything to an unconscious person. Contact physician.

Inhalation: Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

Note to Physicians: Corticosteroids have been known to appear in the milk of nursing mothers when orally administered. Additional details are available on the package insert or in the Physicians Desk Reference.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Emits toxic fumes.

Extinguishing Media: Dry chemical, carbon dioxide, halon, water fog and foam for surrounding materials. Water spray will froth if sprayed into the burning material.

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

6. ACCIDENTAL RELEASE MEASURES

Large/Small Spills: Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

7. HANDLING AND STORAGE

Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 15⁰-30⁰ C (59⁰- 86⁰ F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical materials and use current Material Safety Data Sheets.

Eye Protection: (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

Skin Protection: Thick impermeable gloves and protective clothing.

Respiratory Protection: (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

Warning: **Do not use air purifying respirators in oxygen depleted environments.** No respiratory protection is required in the clinical or home environment.

Other: None

Ventilation: Recommended

Contaminated Equipment: Wash contaminated clothing separately. Wash

equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor:	White aqueous suspension.		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	NE	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Miscible	Percent Volatile by Volume:	<1

10. STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to avoid: Extreme heat or cold.

Incompatibility: This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

Hazardous Decomposition Products: Emits toxic fumes.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

Summary of Risks: Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

CAS #

50-02-2

Dexamethasone Base

May cause irritation to eyes, skin and respiratory tract. May also cause pain, redness, and pus containing blisters. Prolonged or repeated contact may cause hypersensitivity (anaphylactic) in some individuals. May cause allergic reaction if inhaled, ingested or in contact with the skin. Adverse reactions include suppression of adrenal gland secretion, Cushing's syndrome, water retention, electrolyte imbalance and hyperglycemia. Studies in animals indicate that topical adrenocorticoids, when used in large amounts, can be systemically absorbed and may cause fetal abnormalities. Human pregnancy studies have not been done. IP-rat LD50 54 mg/kg, SC-rat LD50 14 mg/kg.

1404-04-2

Neomycin Sulfate

Prolonged or repeated contact can cause hypersensitivity (anaphylactic) in some individuals. People sensitive to one aminoglycoside antibiotic may also be sensitive to neomycin sulfate. High level overdosage is toxic to kidneys (nephrotoxicity) and may cause hearing difficulties (ototoxicity) and diminished balance. Oral-rat LD₅₀ 2750 mg/kg.

1404-26-8

Polymyxin B Sulfate

May cause irritation to skin, mucous membranes and respiratory tract. Prolonged and repeated contact can produce hypersensitivity (anaphylactic) in some individuals. Overexposure may produce dizziness, diminished muscular coordination, kidney damage (nephrotoxicity) and sensory disturbances. This material is not readily absorbed into the gut and does not present a toxicological hazard. IV-mouse LD₅₀ 5.4mg/kg, IP-mouse 20.5 mg/kg, oral-mouse 790 mg/kg, SC-mouse LD₅₀ 59.5 mg/kg.

12. ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.

13. DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

EPA Designations: RCRA Hazardous Waste: Not Listed

SARA Title III: Not Listed

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations: RCRA Hazardous Waste
(40 CFR 261.33) Not Listed

BAUSCH & LOMB Pharmaceuticals Division
MSDS: Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic
Suspension USP

FDA Designations: Prescription only medication.
NDC No. 24208-830-60 (5 ml)

OSHA Designations: (29 CFR 1910.1000, Table Z)
Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

CALIFORNIA PROPOSITION 65: Not Listed

16. OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established

< - Less Than

> - Greater Than



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name

- **Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension**

Product Code

- AB04107; Core No. 041; NDC 24208-0830-60

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

Recommended use

- Finished Pharmaceutical Product; For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists.

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

- Skin Sensitization 1B
Reproductive Toxicity 2

Label elements

UN GHS

WARNING



Hazard statements • May cause an allergic skin reaction

Suspected of damaging fertility or the unborn child.

Precautionary statements

Prevention ● Wash thoroughly after handling.

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

Storage/Disposal ● Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.
Store protected from light and heat.

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
Benzalkonium Chloride	CAS:139-07-1 EINECS:205-351-5	0.004%	UN GHS: NDA
Dexamethasone	CAS:50-02-2 EINECS:200-003-9	<= 1%	UN GHS: NDA
Hypromellose	CAS:9004-65-3	<= 1%	UN GHS: NDA
Neomycin Sulfate	CAS:1405-10-3 EINECS:215-773-1	<= 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Polymyxin B sulfate	CAS:1405-20-5 EINECS:215-774-7	<= 1%	UN GHS: NDA
Polysorbate 20	CAS:9005-64-5	<= 1%	UN GHS: NDA
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	<= 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Not Classified

Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

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

- No data available

Indication of any immediate medical attention and special treatment needed

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.

Conditions for safe storage, including any incompatibilities

- Storage**
- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.
- Incompatible Materials or Ignition Sources**
- None specified.

Section 8 - Exposure Controls/Personal Protection

Control parameters

- Exposure Limits/Guidelines**
- Refer to the occupational exposure limits / guidelines for the individual product components.

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

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile 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	Appearance/Description	white aqueous suspension.
Color	White	Odor	Not relevant
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	3.5 to 6
Specific Gravity/Relative Density	= 1.01 Water=1	Water Solubility	Water soluble
Viscosity	No data available	Oxidizing Properties:	Not relevant
Volatility			

Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available	Volatiles (Vol.)	Not relevant
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	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. Protect from light and heat.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

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 • Skin Sensitizer 1B
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)** • Repeated and prolonged exposure may cause irritation.

Eye

- Acute (Immediate)** • May cause irritation.
- Chronic (Delayed)** • Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects. Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)** • Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- Chronic (Delayed)** • No data available.

Carcinogenic Effects

- Long-term studies in animals to evaluate carcinogenic or mutagenic potential have not been conducted with polymyxin B sulfate. Treatment of cultured human lymphocytes in vitro with neomycin increased the frequency of chromosome aberrations at the highest concentration (80 µg/mL) tested. However, the effects of neomycin on carcinogenesis and mutagenesis in humans are unknown.

Reproductive Effects

- There are no adequate and well-controlled studies in humans. Pregnancy Category C. Corticosteroids have been found to be teratogenic in rabbits when applied topically at concentrations of 0.5% on days 6 to 18 of gestation and in mice when applied topically at a concentration of 15% on days 10 to 13 of gestation. There are no adequate and well-controlled studies in pregnant women. Polymyxin B has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown.

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	Canada NDSL	EU EINECS	TSCA
Benzalkonium Chloride	139-07-1	Yes	No	Yes	Yes
Hypromellose	9004-65-3	Yes	No	No	Yes
Neomycin Sulfate	1405-10-3	Yes	No	Yes	Yes
Polymyxin B sulfate	1405-20-5	Yes	No	Yes	No
Polysorbate 20	9005-64-5	Yes	No	No	Yes
Dexamethasone	50-02-2	No	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	No	Yes	Yes
Water	7732-18-5	Yes	No	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Hypromellose	9004-65-3	Uncontrolled product according to WHMIS classification criteria
• Polysorbate 20	9005-64-5	Uncontrolled product according to WHMIS classification criteria
• Neomycin Sulfate	1405-10-3	D2B
• Polymyxin B sulfate	1405-20-5	Not Listed
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium Chloride	139-07-1	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Hypromellose	9004-65-3	Not Listed
• Polysorbate 20	9005-64-5	Not Listed
• Neomycin Sulfate	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Water	7732-18-5	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Hypromellose	9004-65-3	Not Listed
• Polysorbate 20	9005-64-5	Not Listed
• Neomycin Sulfate	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Water	7732-18-5	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Hypromellose	9004-65-3	Not Listed
• Polysorbate 20	9005-64-5	Not Listed
• Neomycin Sulfate	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Hypromellose	9004-65-3	Not Listed
• Polysorbate 20	9005-64-5	Not Listed
• Neomycin Sulfate	1405-10-3	developmental toxicity, initial date 10/1/92 (internal use)
• Polymyxin B sulfate	1405-20-5	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Hypromellose	9004-65-3	Not Listed
• Polysorbate 20	9005-64-5	Not Listed
• Neomycin Sulfate	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed

• Dexamethasone	50-02-2	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Hypromellose	9004-65-3	Not Listed
• Polysorbate 20	9005-64-5	Not Listed
• Neomycin Sulfate	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information

Last Revision Date

- 29/April/2015

Preparation Date

- 23/April/2015

Disclaimer/Statement of Liability

- To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb, Inc. 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, Inc. or any of its subsidiaries be liable for any special, incidental or consequential damages.