

## Safety Data Sheet

### Section 1: Identification

#### Product identifier

- Product Name** • **Prednisolone Sodium Phosphate Ophthalmic Solution, 1.0%**  
**Product Code** • AB04309; Core No. 043; NDC 24208-0715-10

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

- Recommended use** • Finished Pharmaceutical Product; For the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation, corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies.

#### 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 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.
  - Protect from light.
  - 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
Benzalkonium Chloride Solution, 50%	CAS:139-07-1 EINECS:205-351-5	0.01%	UN GHS: NDA
Dibasic Sodium Phosphate	CAS:7558-79-4 EINECS:231-448-7	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 1%	UN GHS: NDA
Hypromellose 2906	CAS:9004-65-3	< 1%	UN GHS: NDA
Monobasic Sodium Phosphate	CAS:7558-80-7 EINECS:231-449-2	< 0.1%	UN GHS: NDA
Prednisolone Sodium Phosphate	CAS:125-02-0 EINECS:204-722-9	1%	UN GHS: Repro. 2, STOT RE 1
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: Classification criteria not met

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

### 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, CO<sub>2</sub>, 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 15-25°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	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point	Not relevant

Decomposition Temperature	No data available	pH	6.2 to 8.2
Specific Gravity/Relative Density	= 1.012	Water Solubility	Water soluble
Viscosity	No data available		
<b>Volatility</b>			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available		
<b>Flammability</b>			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
<b>Environmental</b>			
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

Components		
Prednisolone Sodium Phosphate (1%)	125-02-0	<b>Acute Toxicity:</b> Intravenous-Rabbit LD50 • 360 mg/kg
Monobasic Sodium Phosphate (< 0.1%)	7558-80-7	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 8290 mg/kg
Dibasic Sodium Phosphate (< 1%)	7558-79-4	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 17000 mg/kg
Sodium chloride (< 1%)	7647-14-5	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 3000 mg/kg
Edetate Disodium Dihydrate (< 1%)	139-33-3	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2 g/kg
Hypromellose 2906 (< 1%)	9004-65-3	<b>Acute Toxicity:</b> Ingestion/Oral-Mammal LD50 • >10000 mg/kg
Benzalkonium Chloride Solution, 50% (0.01%)	139-07-1	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 400 mg/kg

GHS Properties	Classification
<b>Acute toxicity</b>	UN GHS • Classification criteria not met

<b>Aspiration Hazard</b>	<b>UN GHS • Classification criteria not met</b>
<b>Carcinogenicity</b>	<b>UN GHS • Classification criteria not met</b>
<b>Germ Cell Mutagenicity</b>	<b>UN GHS • Classification criteria not met</b>
<b>Skin corrosion/Irritation</b>	<b>UN GHS • Classification criteria not met</b>
<b>Skin sensitization</b>	<b>UN GHS • Classification criteria not met</b>
<b>STOT-RE</b>	<b>UN GHS • Classification criteria not met</b>
<b>STOT-SE</b>	<b>UN GHS • Classification criteria not met</b>
<b>Toxicity for Reproduction</b>	<b>UN GHS • Toxic to Reproduction 2</b>
<b>Respiratory sensitization</b>	<b>UN GHS • Classification criteria not met</b>
<b>Serious eye damage/Irritation</b>	<b>UN GHS • Classification criteria not met</b>

## 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.
- 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.

### Reproductive Effects

- Teratogenic effects. Pregnancy Category C. Prednisolone has been shown to be teratogenic in rabbits, hamsters, and mice. In mice, prednisolone has been shown to be teratogenic when given in doses 1 to 10 times the human ocular dose. Dexamethasone, hydrocortisone and prednisolone were ocularly applied to both eyes of pregnant mice five times per day on days 10 through 13 of gestation. A significant increase in the incidence of cleft palate was observed in the fetuses of the treated mice. There are no adequate, well-controlled studies in pregnant women dosed with corticosteroids.

## 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
Edetate Disodium Dihydrate	139-33-3	Yes	No	Yes	Yes
Benzalkonium Chloride Solution, 50%	139-07-1	Yes	No	Yes	Yes
Hypromellose 2906	9004-65-3	Yes	No	No	Yes
Monobasic Sodium Phosphate	7558-80-7	Yes	No	Yes	Yes
Prednisolone Sodium Phosphate	125-02-0	No	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	No	Yes	Yes
Dibasic Sodium Phosphate	7558-79-4	Yes	No	Yes	Yes
Water	7732-18-5	Yes	No	Yes	Yes

## Canada

**Labor****Canada - WHMIS - Classifications of Substances**

• Hypromellose 2906	9004-65-3	Uncontrolled product according to WHMIS classification criteria
• Edetate Disodium Dihydrate	139-33-3	Uncontrolled product according to WHMIS classification criteria (including 3.5%)
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium Chloride Solution, 50%	139-07-1	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Prednisolone Sodium Phosphate	125-02-0	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Uncontrolled product according to WHMIS classification criteria

**Canada - WHMIS - Ingredient Disclosure List**

• Hypromellose 2906	9004-65-3	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Prednisolone Sodium Phosphate	125-02-0	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

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

• Hypromellose 2906	9004-65-3	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	5000 lb final RQ; 2270 kg final RQ
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Prednisolone Sodium Phosphate	125-02-0	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

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

• Hypromellose 2906	9004-65-3	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed



• Prednisolone Sodium Phosphate	125-02-0	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed
<b>U.S. - California - Proposition 65 - Developmental Toxicity</b>		
• Hypromellose 2906	9004-65-3	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Prednisolone Sodium Phosphate	125-02-0	developmental toxicity, initial date 8/20/99
• Monobasic Sodium Phosphate	7558-80-7	Not Listed
<b>U.S. - California - Proposition 65 - Reproductive Toxicity - Female</b>		
• Hypromellose 2906	9004-65-3	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Prednisolone Sodium Phosphate	125-02-0	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed
<b>U.S. - California - Proposition 65 - Reproductive Toxicity - Male</b>		
• Hypromellose 2906	9004-65-3	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution, 50%	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Prednisolone Sodium Phosphate	125-02-0	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

## Section 16 - Other Information

<b>Last Revision Date</b>	<ul style="list-style-type: none"> <li>24/April/2015</li> </ul>
<b>Preparation Date</b>	<ul style="list-style-type: none"> <li>24/April/2015</li> </ul>
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