

Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Dexamethasone Sodium Phosphate Ophthalmic Solution**
Product Code • AB04407; Core No. 044; NDC 24208-0720-02

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

- Recommended use** • Finished Pharmaceutical Product; Ophthalmic: For the treatment of steroid responsive inflammatory conditions of the eye. Otic: For the treatment of steroid responsive inflammatory conditions of the external auditory meatus.
- 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 15-25°C (59-77°F), 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
Benzalkonium Chloride	CAS:139-07-1 EINECS:205-351-5	0.02%	UN GHS: NDA
Creatinine	CAS:60-27-5 EINECS:200-466-7	< 1%	UN GHS: NDA
Dexamethasone Sodium Phosphate	CAS:2392-39-4 EINECS:219-243-0	0.1%	UN GHS: NDA
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 0.1%	UN GHS: NDA
Phenethyl alcohol	CAS:60-12-8 EINECS:200-456-2	0.25%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Polysorbate 80	CAS:9005-65-6	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Sodium Bisulfite	CAS:7681-38-1 EINECS:231-665-7	0.1%	UN GHS: Skin Corr. 1; Eye Dam. 1
Sodium Borate	CAS:1303-96-4	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 2
Sodium Citrate	CAS:68-04-2 EINECS:200-675-3	1% TO 5%	UN GHS: Eye Irrit. 2A
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) 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, 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 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

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 Limits/Guidelines				
	Result	ACGIH	Canada Quebec	NIOSH
Sodium Borate (1303-96-4)	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	5 mg/m3 TWAEV	5 mg/m3 TWA
	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established

Exposure Control Notations

ACGIH

- Sodium Borate (1303-96-4): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))

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	Color	Clear, colorless to pale yellow.
Odor	No odor.	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	6.6 to 7.8
Specific Gravity/Relative Density	= 1.018 Water=1	Water Solubility	Soluble
Solvent Solubility	Not relevant	Viscosity	No data available
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	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		
Dexamethasone Sodium Phosphate (0.1%)	2392-39-4	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 1800 mg/kg
Sodium Citrate (1% TO 5%)	68-04-2	Acute Toxicity: Intravenous-Mouse LD50 • 170 mg/kg; Behavioral: Convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration: Cyanosis; Gastrointestinal: Changes in structure or function of salivary glands

Sodium Borate (< 1%)	1303-96-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg; Reproductive: Ingestion/Oral-Rat TDLo • 70 g/kg (90D male); <i>Reproductive Effects:Paternal Effects:Testes, epididymis, sperm duct</i> ; Ingestion/Oral-Rat TDLo • 70 g/kg (90D pre); <i>Reproductive Effects:Maternal Effects:Ovaries, fallopian tubes</i> ; Ingestion/Oral-Rat TDLo • 37 g/kg (multigenerations); <i>Reproductive Effects:Effects on Newborn:Weaning or lactation index</i>
Benzalkonium Chloride (0.02%)	139-07-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • 400 mg/kg
Edetate Disodium Dihydrate (< 0.1%)	139-33-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2 g/kg
Polysorbate 80 (< 1%)	9005-65-6	Acute Toxicity: Ingestion/Oral-Rat LD50 • 34500 µL/kg
Phenethyl alcohol (0.25%)	60-12-8	Acute Toxicity: Intraperitoneal-Guinea Pig LD50 • 200 mg/kg

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.
- 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		
	CAS	NTP

Polysorbate 80	9005-65-6	Evidence of Carcinogenicity
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Reproductive Effects

- There are no adequate or well-controlled studies in pregnant women. Pregnancy Category C. Dexamethasone has been shown to be teratogenic in mice and rabbits following topical ophthalmic application in multiples of the therapeutic dose. In the mouse, corticosteroids produce fetal resorptions and a specific abnormality, cleft palate. In the rabbit, corticosteroids have produced fetal resorptions and multiple abnormalities involving the head, ears, limbs, palate, etc.

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	139-07-1	Yes	No	Yes	Yes
Sodium Borate	1303-96-4	Yes	No	No	Yes
Creatinine	60-27-5	Yes	No	Yes	Yes
Phenethyl alcohol	60-12-8	Yes	No	Yes	Yes
Dexamethasone Sodium Phosphate	2392-39-4	No	Yes	Yes	Yes
Sodium Bisulfite	7681-38-1	Yes	No	Yes	Yes
Polysorbate 80	9005-65-6	Yes	No	No	Yes
Sodium Citrate	68-04-2	Yes	No	Yes	Yes
Water	7732-18-5	Yes	No	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Sodium Borate	1303-96-4	D2B
• Sodium Citrate	68-04-2	Uncontrolled product according to WHMIS classification criteria
• Edetate Disodium Dihydrate	139-33-3	Uncontrolled product according to WHMIS classification criteria (including 3.5%)
• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	E
• Phenethyl alcohol	60-12-8	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Uncontrolled product according to WHMIS classification criteria
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Sodium Borate	1303-96-4	1 %
• Sodium Citrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	1 %
• Phenethyl alcohol	60-12-8	1 %
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Not Listed
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Not Listed

Europe

Other

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

• Sodium Borate	1303-96-4	Repr.Cat.2; R60-61
• Sodium Citrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	Xi; R41
• Phenethyl alcohol	60-12-8	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Not Listed
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium Borate	1303-96-4	8.5%≤C: Repr.Cat.2; R:60-61
• Sodium Citrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	Not Listed
• Phenethyl alcohol	60-12-8	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Not Listed
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium Borate	1303-96-4	T R:60-61 S:53-45
• Sodium Citrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	Xi R:41 S:(2)-24-26
• Phenethyl alcohol	60-12-8	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Not Listed
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium Borate	1303-96-4	S:53-45
• Sodium Citrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	S:(2)-24-26
• Phenethyl alcohol	60-12-8	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Not Listed
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Not Listed

United States

Environment

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

• Sodium Borate	1303-96-4	Not Listed
• Sodium Citrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	Not Listed
• Phenethyl alcohol	60-12-8	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Not Listed
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Sodium Borate	1303-96-4	Not Listed
• Sodium Citrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	Not Listed
• Phenethyl alcohol	60-12-8	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Not Listed
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium Borate	1303-96-4	Not Listed
• Sodium Citrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	Not Listed
• Phenethyl alcohol	60-12-8	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Not Listed
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium Borate	1303-96-4	Not Listed
• Sodium Citrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	Not Listed
• Phenethyl alcohol	60-12-8	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Not Listed
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium Borate	1303-96-4	Not Listed
• Sodium Citrate	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Bisulfite	7681-38-1	Not Listed
• Phenethyl alcohol	60-12-8	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Creatinine	60-27-5	Not Listed
• Dexamethasone Sodium Phosphate	2392-39-4	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information

Last Revision Date

- 29/April/2015

Preparation Date

- 29/April/2015

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