Safety Data Sheet

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Section 1: Identification

Product identifier

Product Name • **Atropine Sulfate Ophthalmic Solution, 1%**

Product Code • AB05007; Core No. 050; NDC 24208-750-60

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

Recommended use • Finshed Pharmaceutical Product; Atropine sulfate ophthalmic solution is used to produce mydriasis (pupil dilation).

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 Mild Irritation 3

Label elements

UN GHS

WARNING

Hazard statements • May cause mild skin irritation

Precautionary statements

Response • If skin irritation 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.

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**
Atropine Sulfate	**CAS:**51-55-8 **EINECS:**200-104-8	1%	**UN GHS:** Acute Tox. Oral 2; Acute Tox. Inhal. 2
Benzalkonium Chloride Solution	**CAS:**139-07-1 **EINECS:**205-351-5	0.01%	**UN GHS:** NDA
Boric acid	**CAS:**10043-35-3 **EINECS:**233-139-2	1% TO 5%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Hypromellose 2906	**CAS:**9004-65-3	< 1%	**UN GHS:** NDA
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 specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention if cough or other symptoms develop.

Skin

- Contact with skin can lead to irritation. If skin irritation occurs, discontinue use; remove source of exposure. Flush skin with copious amounts of water. Seek medical attention if irritation persists or signs of toxicity occur. Provide symptomatic or supportive care as necessary.

Eye

- If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional.

Ingestion

- If swallowed, get medical help or contact a Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

- Systemic atropine toxicity is manifested by flushing and dryness of the skin (a rash may be present in pediatric patients), blurred vision, a rapid and irregular pulse, fever, abdominal distension in infants, mental aberration (hallucinosis) and loss of neuromuscular coordination.

Indication of any immediate medical attention and special treatment needed

Notes to Physician

- Atropine poisoning, although distressing, is rarely fatal, even with large doses of atropine, and is self-limited if the cause is recognized and the atropine medication is discontinued. In severe intoxication, physostigmine salicylate may be administered

parenterally to provide more prompt relief of the intoxication. Give physostigmine salicylate as 1-5 mL IV of dilution containing 1 mg in 5 mL of saline. The smaller dose is for pediatric patients, and injection should take not less than two minutes. EKG control is advisable. Dosage can be repeated every five minutes up to a total dose of 2 mg in pediatric patients and 6 mg in adults every 30 minutes. Physostigmine is contraindicated in hypotensive reactions. Atropine (1 mg) should be available for immediate injection if physostigmine causes bradycardia, convulsions or bronchoconstriction. In pediatric patients, the body surface must be kept moist.

Other information

- Additional details are provided on the product packaging and/or the product insert.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media
- Water spray, carbon dioxide, dry chemical powder, or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media
- No data available.

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

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards
- None known.

Hazardous Combustion Products
- None known.

Advice for firefighters

- Refer to Section 5 Firefighting Procedures.

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
- No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available on the environmental impact of this product.

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.

Prohibited Materials
- None known.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling
- When using this product: do not touch tip of container to any surface to avoid contamination, remove contact lenses before using, and always replace the cap after use. 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.

Special Packaging Materials
- Maintain product in original container only.

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**
Boric acid (10043-35-3)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)
	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)

Exposure Control Notations

ACGIH

•Boric acid (10043-35-3): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))

Exposure controls

Engineering Measures/Controls
- No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory
- No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. 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
- No special personal protection required under conditions of intended use. In the event of a bulk 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.

Thermal hazards
- None known.

General Industrial Hygiene Considerations
- Wash thoroughly with soap and water after handling.

Environmental Exposure Controls
- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Clear Colorless .
Odor	No odor.	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	= 1.003	Water Solubility	Water soluble
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

- Stable under normal temperatures and pressures.

Chemical stability

- Stable when stored at room temperature 15-25ºC (59-77ºF). Use before expiration date marked on carton and/or container.

Possibility of hazardous reactions

- Will not occur.

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None known.

Hazardous decomposition products

- None known.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Atropine Sulfate (1%)	51-55-8	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 500 mg/kg
Boric acid (1% TO 5%)	10043-35-3	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 2500 mg/kg; *Behavioral*:**Convulsions or effect on seizure threshold**; *Behavioral*:**Ataxia**
Hypromellose 2906 (< 1%)	9004-65-3	**Acute Toxicity:** Ingestion/Oral-Mammal LD50 • >10000 mg/kg
Benzalkonium Chloride Solution (0.01%)	139-07-1	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 400 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** • Skin Mild Irritation 3
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** • Classification criteria not met
Respiratory sensitization	**UN GHS** • Classification criteria not met
Serious eye damage/Irritation	**UN GHS** • Classification criteria not met

Potential Health Effects

Inhalation

Acute (Immediate)
- No hazard when used as directed.

Chronic (Delayed)
- No data available.

Skin

Acute (Immediate)
- May cause mild irritation.

Chronic (Delayed)
- No data available.

Eye

Acute (Immediate)
- Non-irritating to the eyes when used as directed.

Chronic (Delayed)
- Prolonged use may produce local irritation characterized by follicular conjunctivitis, vascular congestion, edema, exudate, and an eczematoid dermatitis.

Ingestion

Acute (Immediate)
- May be harmful if swallowed.

Chronic (Delayed)
- No data available.

Carcinogenic Effects		
	CAS	**NTP**
Boric acid	10043-35-3	Evidence of Carcinogenicity

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 Solution	139-07-1	Yes	No	Yes	Yes
Atropine Sulfate	51-55-8	No	Yes	Yes	Yes
Boric acid	10043-35-3	Yes	No	Yes	Yes
Hypromellose 2906	9004-65-3	Yes	No	No	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
• Boric acid	10043-35-3	D2A
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Hypromellose 2906	9004-65-3	Not Listed
• Boric acid	10043-35-3	1 %
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	Not Listed
• Water	7732-18-5	Not Listed

Europe

Other

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

• Hypromellose 2906	9004-65-3	Not Listed
• Boric acid	10043-35-3	Repr.Cat.2; R60-61
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	T+; R26/28
• Water	7732-18-5	Not Listed

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

• Hypromellose 2906	9004-65-3	Not Listed
• Boric acid	10043-35-3	5.5%<=C: Repr.Cat.2; R:60-61
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Hypromellose 2906	9004-65-3	Not Listed
• Boric acid	10043-35-3	T R:60-61 S:53-45
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	T+ R:26/28 S:(1/2)-25-45
• Water	7732-18-5	Not Listed

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

• Hypromellose 2906	9004-65-3	Not Listed
• Boric acid	10043-35-3	S:53-45
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	S:(1/2)-25-45
• Water	7732-18-5	Not Listed

United States

Environment

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

• Hypromellose 2906	9004-65-3	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	Not Listed
• Water	7732-18-5	Not Listed

United States - California

Environment

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

• Hypromellose 2906	9004-65-3	Not Listed
• Boric acid	10043-35-3	Not Listed

• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Hypromellose 2906	9004-65-3	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Hypromellose 2906	9004-65-3	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Hypromellose 2906	9004-65-3	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Atropine Sulfate	51-55-8	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information

Last Revision Date
- 04/May/2015

Preparation Date
- 04/May/2015

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