



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **Fluorescein Sodium 0.25% & Benoxinate Hydrochloride 0.4% Ophthalmic Solution (Flurate)**

Product Code • AB30107; Core No. 301; NDC 24208-0732-05

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

Recommended use • Finished Pharmaceutical Product; Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4% is a disclosing agent with rapid anesthetic action and short duration.

Restrictions on use • Use in accordance with product literature.

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 • Classification criteria not met

Label elements

UN GHS

Classification criteria not met

Precautionary statements

Storage/Disposal • Keep tightly closed and store in upright position.
Store product refrigerated at 2-8°C (36-46°F).
Use before expiration 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
Benoxinate hydrochloride	CAS:5987-82-6 EINECS:227-808-8	0.4%	UN GHS: NDA
Boric acid	CAS:10043-35-3 EINECS:233-139-2	<= 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Chlorobutanol	CAS:57-15-8 EINECS:200-317-6	1%	UN GHS: NDA
Fluorescein Sodium	CAS:518-47-8 EINECS:208-253-0	0.25%	UN GHS: NDA
Povidone	CAS:9003-39-8	10% TO 20%	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) 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

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye

- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention.

Ingestion

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

- 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.

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 between 2-8°C (36-46°F), to maintain product integrity. use before expiration date marked on carton and/or container.

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	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)

(10043-35-3)	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)
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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	Appearance/Description	Clear, orange solution.
Color	Orange	Odor	Camphor-like
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	4.3 to 5.3
Specific Gravity/Relative Density	= 1.038	Water Solubility	Soluble
Viscosity	Not relevant	Oxidizing Properties:	Not relevant
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
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 refrigerated at 2-8C (36-46 F). Use before expiration date marked on carton and/or container. User may store at room temperature up to one month.

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		
Fluorescein Sodium (0.25%)	518-47-8	Acute Toxicity: Ingestion/Oral-Rat LD50 • 6721 mg/kg; Behavioral: Changes in motor activity (specific assay); Behavioral: Ataxia; Lungs, Thorax, or Respiration: Dyspnea
Benoxinate hydrochloride (0.4%)	5987-82-6	Acute Toxicity: Subcutaneous-Rat LD50 • 60 mg/kg
Chlorobutanol (1%)	57-15-8	Acute Toxicity: Ingestion/Oral-Rat LD50 • 510 mg/kg
Povidone (10% TO 20%)	9003-39-8	Acute Toxicity: Ingestion/Oral-Mouse LDLo • 3 g/kg
Boric acid (<= 1%)	10043-35-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2500 mg/kg; Behavioral: Convulsions or effect on seizure threshold; Behavioral: Ataxia

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 • 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)**
 - 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)**
 - Allergic contact dermatitis with drying and fissuring of the fingertips has been reported.

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)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - No data available.

Carcinogenic Effects			
	CAS	IARC	NTP
Boric acid	10043-35-3	Not Listed	Evidence of Carcinogenicity
Povidone	9003-39-8	Group 3-Not Classifiable	Not Listed

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

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
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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
Chlorobutanol	57-15-8	Yes	Yes	Yes
Benoxinate hydrochloride	5987-82-6	No	Yes	No
Boric acid	10043-35-3	Yes	Yes	Yes
Fluorescein Sodium	518-47-8	Yes	Yes	Yes
Povidone	9003-39-8	Yes	No	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Povidone	9003-39-8	Uncontrolled product according to WHMIS classification criteria (listed under Povidone)
• Fluorescein Sodium	518-47-8	Not Listed
• Boric acid	10043-35-3	D2A
• Benoxinate hydrochloride	5987-82-6	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Povidone	9003-39-8	Not Listed
• Fluorescein Sodium	518-47-8	Not Listed
• Boric acid	10043-35-3	1 %
• Benoxinate hydrochloride	5987-82-6	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

Europe

Other

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

• Povidone	9003-39-8	Not Listed
• Fluorescein Sodium	518-47-8	Not Listed
• Boric acid	10043-35-3	Repr.Cat.2; R60-61
• Benoxinate hydrochloride	5987-82-6	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Fluorescein Sodium	518-47-8	Not Listed
• Boric acid	10043-35-3	5.5%≤C: Repr.Cat.2; R:60-61
• Benoxinate hydrochloride	5987-82-6	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Fluorescein Sodium	518-47-8	Not Listed
• Boric acid	10043-35-3	T R:60-61 S:53-45
• Benoxinate hydrochloride	5987-82-6	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Fluorescein Sodium	518-47-8	Not Listed
• Boric acid	10043-35-3	S:53-45
• Benoxinate hydrochloride	5987-82-6	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Fluorescein Sodium	518-47-8	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benoxinate hydrochloride	5987-82-6	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Fluorescein Sodium	518-47-8	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benoxinate hydrochloride	5987-82-6	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Fluorescein Sodium	518-47-8	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benoxinate hydrochloride	5987-82-6	Not Listed

• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Fluorescein Sodium	518-47-8	Not Listed
• Boric acid	10043-35-3	Not Listed
• Benoxinate hydrochloride	5987-82-6	Not Listed
• Chlorobutanol	57-15-8	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information

Last Revision Date

- 07/May/2015

Preparation Date

- 05/May/2015

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