Safety Data Sheet

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Section 1: Identification

Product identifier

Product Name • **Opcon-A®**

Product Code • 622090; 622178B; FCP-4085

Product Description • Ophthalmic solution for eyes.

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

Recommended use • Opcon-A Itching and Redness Reliever Eye Drops combine an antihistamine for itch relief with a redness reliever. Temporarily relieve the itching and redness caused by pollen, ragweed, grass, animal hair, and dander.

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, Inc

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

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
Acute Toxicity Oral 5

Label elements

UN GHS

WARNING

Hazard statements • Causes mild skin irritation

Precautionary statements

Response • If skin irritation occurs: Get medical advice/attention.

Storage/Disposal • Store at 20-25°C (68-77°F)..
Keep tightly closed and store in upright position.

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:**8001-54-5	0.01%	**UN GHS:** Skin Corr. 1C; Eye Dam. 1; Acute Tox. Oral 3
Boric acid	**CAS:**10043-35-3 **EINECS:**233-139-2	< 1.2%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Edetate disodium	**CAS:**6381-92-6	0.1%	**UN GHS:** not classified
Hypromellose	**CAS:**9004-65-3	< 0.6%	**UN GHS:** not classified
Naphazoline hydrochloride	**CAS:**550-99-2 **EINECS:**208-989-2	0.02675%	**UN GHS:** not classified
Pheniramine maleate	**CAS:**132-20-7 **EINECS:**205-051-4	0.315%	**UN GHS:** not classified
Purified water	**CAS:**7732-18-5 **EINECS:**231-791-2	> 95%	**UN GHS:** not classified
Sodium borate	**CAS:**1330-43-4 **EINECS:**215-540-4	< 1%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; STOT SE 2
Sodium chloride	**CAS:**7647-14-5 **EINECS:**231-598-3	< 1%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- Get medical attention if symptoms occur. 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.

Skin

- IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

Eye

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion

- Small amounts (a tablespoon) swallowed are not likely to cause injury; swallowing amounts larger than that may cause gastrointestinal irritation.

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

Unsuitable Extinguishing Media
- No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards
- None known - product is not flammable or combustible.

Hazardous Combustion Products
- No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

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. 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

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
- 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 15-25ºC (59-77ºF), to maintain product integrity. Use before 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	Canada Quebec	NIOSH

Sodium borate (1330-43-4)	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	1 mg/m3 TWAEV	1 mg/m3 TWA
	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established
Boric acid (10043-35-3)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established
	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established

Exposure Control Notations

ACGIH

- Sodium borate (1330-43-4): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))
- Boric acid (10043-35-3): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))

Exposure Limits Supplemental

ACGIH

- Sodium borate (1330-43-4): **TLV Basis - Critical Effects:** (upper respiratory tract irritation (listed under Borate compounds, inorganic))
- Boric acid (10043-35-3): **TLV Basis - Critical Effects:** (upper respiratory tract irritation (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

- No respiratory protection required during normal handling.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. Wear protective eyewear (goggles, face shield, or safety glasses).

Hands

- Wear protective gloves .

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

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 .
Odor	No odor.		
General Properties			
Boiling Point	Not relevant	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	5.5 to 6.3
Specific Gravity/Relative Density	= 1.008	Water 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	Not relevant		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reactions known.

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.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Naphazoline hydrochloride (0.02675%)	550-99-2	**Acute Toxicity:** Ingestion/Oral-Rabbit LD50 • 50 mg/kg; *Lungs, Thorax, or Respiration*:**Respiratory stimulation**
Benzalkonium chloride (0.01%)	8001-54-5	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 240 mg/kg; *Behavioral*:**Somnolence (general depressed activity)**; *Gastrointestinal*:**Nausea or vomiting**; **Irritation:** Skin-Rabbit • 50 mg 24 Hour(s) • Moderate irritation
Hypromellose (< 0.6%)	9004-65-3	**Acute Toxicity:** Ingestion/Oral-Mammal LD50 • >10000 mg/kg
Pheniramine maleate (0.315%)	132-20-7	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 520 mg/kg; *Behavioral*:**Tremor**; *Behavioral*:**Changes in motor activity (specific assay)**; *Behavioral*:**Aggression**
Sodium chloride (< 1%)	7647-14-5	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 3000 mg/kg; **Irritation:** Eye-Rabbit • 10 mg • Moderate irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation
Sodium borate (< 1%)	1330-43-4	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 2660 mg/kg
Boric acid (< 1.2%)	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** • Acute Toxicity - Classification criteria not met; Acute Toxicity - Oral 5

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)
- Under normal conditions of use, no health effects are expected.

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

Skin

Acute (Immediate)
- May cause mild irritation.

Chronic (Delayed)
- Causes mild skin irritation.

Eye

Acute (Immediate)
- Under normal conditions of use, no health effects are expected.

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

Ingestion

Acute (Immediate)
- Small amounts (a tablespoonful) swallowed are not likely to cause injury: swallowing amounts larger than that may cause gastrointestinal irritation.

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
ADN	NDA	Not regulated	NDA	NDA	NDA
ADR/RID	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**
Naphazoline hydrochloride	550-99-2	Yes	Yes	No
Edetate disodium	6381-92-6	Yes	No	No
Benzalkonium chloride	8001-54-5	Yes	No	No
Purified water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Edetate disodium	6381-92-6	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium chloride	8001-54-5	D1B, E
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Edetate disodium	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed

Europe

Other

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

• Edetate disodium	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed

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

• Edetate disodium	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed

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

• Edetate disodium	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed

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

• Edetate disodium	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed

United States - California

Environment

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

• Edetate disodium	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed

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

• Edetate disodium	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed

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

• Edetate disodium	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed

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

• Edetate disodium	6381-92-6	Not Listed

• Benzalkonium chloride	8001-54-5	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed

Section 16 - Other Information

Revision Summary		
Date	**MSDS No.**	**Changes**
06/February/2015		• Section 1 changed. Changes include: added product code • Section 9 changed. Changes include: added specific gravity

Last Revision Date
- 03/February/2015

Preparation Date
- 03/February/2015

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