



**Diclofenac Sodium Ophthalmic Solution, 0.1%  
MATERIAL SAFETY DATA SHEET**

Effective Date: 9/25/07

Supersedes: None

Page 1 of 8

**Section 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

**Product Name:** Diclofenac Sodium Ophthalmic Solution, 0.1%  
**Product Code(s):**  
**NDC No.(s):** NDC 24208-457-01 (1 ml)  
 NDC 24208-457-25 (2.5 ml)  
 NDC 24208-457-05 (5 ml)

**For Information:** 1-800-553-5340  
**For Emergency:** 1-800-535-5053

**Chemical Family:** Topical Non-Steroidal Anti-Inflammatory  
**Manufacturer:** Bausch & Lomb Incorporated  
**Address:** 1400 N. Goodman Street  
 Rochester, New York 14609

**Section 2: COMPOSITION / INFORMATION ON INGREDIENTS**

CAS #	COMPONENT NAME	% W/W	OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES										UNITS	
			OSHA PEL TWA / STEL	ACGIH TLV TWA / STEL	NIOSH REL TWA / STEL	IRELAND TWA / STEL	HSE TWA / STEL							
15307-79-6	Diclofenac Sodium, USP	0.1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
61791-12-6	Polyoxyl 35 Castor Oil, NF	< 10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
10043-35-3	Boric Acid, NF	< 5	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
77-86-1	Tromethamine, USP	< 1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
110-44-1	Sorbic Acid, NF	< 1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
6381-92-6	Edetate Disodium Dihydrate, USP	< 1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7732-18-5	Purified Water, USP	> 90	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
TOTAL		100												

N/E: Not Established      OSHA: Occupational Safety & Health Administration  
 N/A: Not Applicable      PPM: Parts Per Million  
 ACGIH: American Conference of Governmental Industrial Hygienists  
 NIOSH: National Institute for Occupational Safety & Health

TWA: 8-Hour Time-Weighted Average  
 STEL: Short-Term Exposure Limit  
 C: Ceiling Limit  
 REL: Recommended Exposure Limit

**Section 3: HAZARDS IDENTIFICATION**

**EMERGENCY OVERVIEW**

**Caution!! Pharmacologically Active Material. Diclofenac Sodium Ophthalmic Solution, 0.1% is a sterile, topical non-steroidal, anti-inflammatory product for ophthalmic use. Do Not Use if there exists hypersensitivity to any ingredient in this product. WARNING: Keep out of reach of children.**

# Diclofenac Sodium Ophthalmic Solution, 0.1%

## MATERIAL SAFETY DATA SHEET

Page 2 of 8

### Section 3: HAZARDS IDENTIFICATION (cont.)

#### PRECAUTIONS:

##### ***Caution! Pharmacologically Active Material***

Diclofenac Sodium Ophthalmic Solution, 0.1% is a sterile, topical non-steroidal, anti-inflammatory product for ophthalmic use. It is indicated for the treatment of postoperative inflammation in patients who have undergone cataract extraction and for the temporary relief of pain and photophobia in patients undergoing corneal refractive surgery.

**Do Not Use:** if there exists hypersensitivity to any ingredient in this product.

Use only in accordance with product literature and prescribing information.

**WARNING:** *Keep out of reach of children.*

#### **POTENTIAL HEALTH EFFECTS**

##### **EYE:**

May cause transient burning and stinging upon application.

##### **SKIN:**

Not expected to be irritating to skin or mucous membranes when used as directed.

##### **INGESTION:**

May be harmful if swallowed.

##### **INHALATION:**

Unlikely to be hazardous when used as directed. However, if actively concentrated and inhaled, it may cause respiratory tract irritation.

#### **CHRONIC HEALTH EFFECTS**

Use of topical non-steroidal anti-inflammatory drugs (NSAIDs) may result in keratitis. In some susceptible patients, continued use of NSAIDs may result in epithelial breakdown, corneal infiltrates, corneal erosion, corneal ulceration, and corneal perforation.

Refer to the product insert for additional information.

#### **CARCINOGENICITY:**

**NTP:** No ingredients listed.

**IARC:** No ingredients listed.

**OSHA:** No ingredients listed.

**Section 3: HAZARDS IDENTIFICATION (cont.)**

**MEDICAL CONDITIONS AGGRAVATED BY OVER EXPOSURE:**

With some NSAIDs, there exists the potential for increase bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied NSAIDs may cause increase bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other non-steroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

**Section 4: FIRST AID MEASURES**

**EYES:**

If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional. For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention.

**SKIN:**

Wash contaminated area with soap and water. Get medical attention if irritation develops.

**INGESTION:**

Do Not Induce Vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If Diclofenac Sodium Ophthalmic Solution, 0.1% is accidentally ingested, fluids should be taken to dilute the medication. Contact a physician immediately and provide product-prescribing information.

**INHALATION:**

No inhalation exposure expected with this formulation under normal conditions of use. If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Contact a physician immediately.

**ADDITIONAL NOTES TO PHYSICIAN:**

For additional guidance, refer to the product insert. Contact the local Poison Control Center.

**Section 5: FIRE FIGHTING MEASURES**

**FLAMMABLE PROPERTIES:**

**Flash Point:** Not Applicable

**Method:** NA

**EXTINGUISHING MEDIA:**

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

**Section 5: FIRE FIGHTING MEASURES (cont.)**

**HAZARDOUS COMBUSTION PRODUCTS:**

Carbon dioxides, nitrogen oxides, sulfur oxides, halogenated compounds, hydrogen chloride and other hazardous products of combustion.

**SPECIAL FIRE FIGHTING INSTRUCTIONS:**

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

**Section 6: ACCIDENTAL RELEASE MEASURES**

**General Information:**

Use appropriate protective equipment and engineering controls (refer to Section 8).

**Specific Information:**

Ventilate area. 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. Minimize contact of spilled material with soils to prevent runoff to surface waterways.

Dispose of in accordance with Section 13.

**Section 7: HANDLING AND STORAGE**

**HANDLING:**

Use only in accordance with product literature. Wash thoroughly with warm water and soap after handling.

**STORAGE:**

Store product in original container, with cap tightly closed, at room temperature: 20-25°C (68-77°F). Protect from light. Shelf Life: Expiration date is listed on each package.

**Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

**ENGINEERING CONTROLS:**

Not required during normal clinical use. Local exhaust ventilation should be provided when handling bulk product.

**RESPIRATORY PROTECTION:**

Not required during normal clinical use.

**SKIN PROTECTION:**

Not required during normal clinical use. Wash thoroughly with warm water and soap after handling. Impervious chemical resistant gloves and appropriate protective clothing are recommended when directly handling bulk product.

MATERIAL SAFETY DATA SHEET

**Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION (cont.)**

**EYE PROTECTION:**

Not required during normal clinical use. Appropriate eye protection is required when handling bulk product.

**ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:**

No special recommendations during normal clinical use.

**Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

**PHYSICAL PROPERTIES:**

**Appearance / Physical State:** Clear, slightly yellow, aqueous solution  
**Odor/Threshold Limit:** Not Available

**CHEMICAL PROPERTIES:**

<b>Boiling Point:</b>	Not Available	<b>Melting Point:</b>	Not Applicable
<b>Vapor Pressure:</b>	Not Available	<b>Vapor Density:</b>	Not Available
<b>Solubility In Water:</b>	Soluble	<b>Specific Gravity (H<sub>2</sub>O = 1):</b>	Not Determined
<b>Ph:</b>	7.2	<b>Evaporation Rate:</b>	Not Available
<b>Freezing Point:</b>	Not Available	<b>Molecular Weight:</b>	Not Available

**Section 10: STABILITY AND REACTIVITY**

**GENERAL:**

Stable

**CONDITIONS TO AVOID:**

Extreme heat or cold. Protect from light.

**INCOMPATIBLE MATERIALS:**

None identified.

**HAZARDOUS POLYMERIZATION:**

Will not occur.

**HAZARDOUS DECOMPOSITION PRODUCTS:**

Carbon dioxides, nitrogen oxides, sulfur oxides, halogenated compounds, and hydrogen chloride.

## MATERIAL SAFETY DATA SHEET

## Section 11: TOXICOLOGICAL INFORMATION

**Diclofenac Sodium Ophthalmic:*****Carcinogenesis, Mutagenesis, Impairment of Fertility:***

Long-term carcinogenicity studies in rats given Diclofenac Sodium Ophthalmic in oral doses up to 2 mg/kg/day (approximately 500 times the human topical ophthalmic dose) revealed no significant increases in tumor incidence. A 2-year carcinogenicity study conducted in mice employing oral Diclofenac Sodium Ophthalmic up to 2 mg/kg/day did not reveal any oncogenic potential. Diclofenac Sodium Ophthalmic did not show mutagenic potential in various mutagenicity studies including the Ames test. Diclofenac Sodium Ophthalmic administered to male and female rats at 4 mg/kg/day (approximately 1000 times the human topical ophthalmic dose) did not affect fertility.

***Teratogenic Effects:***

Reproduction studies performed in mice at oral doses up to 5,000 times (20 mg/kg/day) and in rats and rabbits at oral doses up to 2,500 times (10 mg/kg/day) the human topical dose have revealed no evidence of teratogenicity due to Diclofenac Sodium Ophthalmic despite the induction of maternal toxicity and fetal toxicity. In rats, maternally toxic doses were associated with dystocia, prolonged gestation reduced fetal weights and growth, and reduced fetal survival. Diclofenac Sodium Ophthalmic has been shown to cross the placental barrier in mice and rats.

**RTECS No.: AG6330000**

**Diclofenac Sodium**

**Toxicity Data:** ORL-RAT LD50: 53 MG/KG

**RTECS No.: GO5661000**

**Polyoxyl 35 Castor Oil**

**Toxicity Data:** INTRAVENOUS-MOUSE LD50: 6500 MG/KG

**RTECS No.: ED4550000**

**Boric Acid**

**Toxicity Data:** ORL-RAT LD50: 2660 MG/KG

**RTECS No.: TY2900000**

**Tromethamine**

**Toxicity Data:** ORL-RAT LD50: 5900 MG/KG

**RTECS No.: WG2100000**

**Sorbic Acid**

**Toxicity Data:** ORL-RAT LD50: 7360 MG/KG

# Diclofenac Sodium Ophthalmic Solution, 0.1%

## MATERIAL SAFETY DATA SHEET

Page 7 of 8

### Section 11: TOXICOLOGICAL INFORMATION (cont.)

RTECS No.: AH4410000

Edetate Disodium Dihydrate

Toxicity Data: ORL-RAT LD50: NOT LISTED

**NOTE:** Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information.

Refer to Section 3 for additional acute / chronic hazard information.

### Section 12: ECOLOGICAL INFORMATION

No data available on the environmental impact of this product.

### Section 13: DISPOSAL CONSIDERATIONS

All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

### Section 14: TRANSPORT INFORMATION

	US DOT	IATA	IMO	RID/ADR	Canadian DG
<b>Shipping Name:</b>	Not Regulated	Not Regulated	No Information Available	No Information Available	No Information Available
<b>Hazard Class:</b>	NA	NA			
<b>UN Number:</b>	NA	NA			
<b>Package Group:</b>	NA	NA			

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.

### Section 15: REGULATORY INFORMATION

#### OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):

Although technically exempt from the Occupational Safety & Health Administration (OSHA) Hazard Communication Standard, this product would be considered hazardous.

#### TOXIC SUBSTANCE CONTROL ACT (TSCA):

CAS# 61791-12-6 is listed on the TSCA inventory.  
CAS# 10043-35-3 is listed on the TSCA inventory.  
CAS# 77-86-1 is listed on the TSCA inventory.  
CAS# 110-44-1 is listed on the TSCA inventory.

# Diclofenac Sodium Ophthalmic Solution, 0.1%

## MATERIAL SAFETY DATA SHEET

Page 8 of 8

### Section 15: REGULATORY INFORMATION

#### SARA TITLE III (Superfund Amendments and Reauthorization Act):

SECTION 302 (Extremely Hazardous Substances): No Components Listed

SECTION 311, 312 (Hazard Categories): Acute, Chronic

SECTION 313 (Toxic Chemicals): No Components Listed

#### CALIFORNIA PROPOSITION 65:

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels that would require a warning under the statute.

### Section 16: OTHER INFORMATION

*To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb Incorporated nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb Incorporated or any of its subsidiaries be liable for any special, incidental or consequential damages.*