

MSDS: Diclofenac Sodium Ophthalmic Solution, 0.1%

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Section 1 - IDENTIFICATION

TRADE NAME: Diclofenac Sodium Ophthalmic Solution, 0.1%

Description: Diclofenac Sodium Ophthalmic Solution, 0.1% is a sterile, topical, non-steroidal anti-inflammatory product for ophthalmic use. It is an iso-osmotic solution, buffered at ~7.2 pH and has a faint characteristic odor of castor oil.

Common name of active ingredient: Diclofenac Sodium, USP

Molecular Formula: $C_{14}H_{10}Cl_2NNaO_2$

Molecular Weight: 318.13 g/mole

Legal Category: Prescription Only

Composition	CAS #	Each milliliter contains	Occupational Exposure Limits / Guidelines					
			OSHA PEL		ACGIH TLV		NIOSH REL	
			TWA	STEL	TWA	STEL	TWA	STEL
Diclofenac Sodium, USP	15307-79-6	1 mg	NE	NE	NE	NE	NE	NE
Boric Acid, NF	10043-35-3	QS	NE	NE	NE	NE	NE	NE
Edetate Disodium, USP	6381-92-6	1 mg	NE	NE	NE	NE	NE	NE
Polyoxyl 35 castor oil, NF	61791-12-6	QS	NE	NE	NE	NE	NE	NE
Sorbic Acid, NF	110-44-1	2 mg	NE	NE	NE	NE	NE	NE
Tromethamine, USP	77-86-1	QS	NE	NE	NE	NE	NE	NE
Purified Water, USP	7732-18-5	QS	NE	NE	NE	NE	NE	NE

Key

N/E: Not Established

OSHA: Occupational Safety & Health Administration

ACGIH: American Conference of Governmental Industrial Hygienists

NIOSH: National Institute for Occupational Safety & Health

REL: Recommended Exposure Limit

TWA: 8-Hour Time-Weighted Average

STEL: Short-Term Exposure Limit

EMERGENCY OVERVIEW

CAUTION: Pharmacologically Active Material
 Do not use if there exists hypersensitivity to any ingredient in this product.

WARNING: Keep out of reach of children

Section 2 – HAZARDOUS INGREDIENTS**Potential Acute Health Effects**

Overdosage will not ordinarily cause acute problems.

- 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.

Potential 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. These events may be sight threatening.

- Carcinogenic Effects: Not available.
- Mutagenic Effects: Not available.
- Teratogenic Effects: Not available.
- Developmental Toxicity: Not available.

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 increased 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 3 – PHYSICAL AND CHEMICAL CHARACTERISTICS

Appearance:	Clear, light yellow aqueous solution	Latex Free:	Yes
Odor:	Faint characteristic odor of castor oil	Boiling Point:	Not available
Vapor Density (air = 1):	Not available	Viscosity:	Not available
Vapor Pressure (mm Hg):	Not available	Specific Gravity:	1.00 to 1.04
Solubility in Water:	Soluble	Evaporation Rate:	Not available
Volatile Component:	Not available	pH:	6.5 to 7.5
Reactivity in Water:	Not available		

Section 4 – FIRE AND EXPLOSION HAZARD DATA**FLAMMABLE PROPERTIES:**

Flash Point:	Not Applicable
Method:	NA
Extinguisher Media:	Use extinguishing media suitable for surrounding materials such as water spray, carbon dioxide, dry chemical powder or appropriate foam
Hazardous Products:	Carbon dioxides, nitrogen oxides, sulfur oxides, halogenated compounds, hydrogen chloride and other hazardous products of combustion
Explosion:	None
Fire Fighting Instructions:	Firefighters should use self-contained breathing equipment with full-face piece operated in pressure-demand or positive-pressure mode and protective clothing.

Section 5 – REACTIVITY DATA

Stability:	Stable from a safety point of view
Conditions to avoid:	Extreme heat or cold, protect from light
Incompatibility:	None identified
Hazardous Decomposition Products:	Carbon dioxides, nitrogen oxides, sulfur oxides, halogenated compounds, and hydrogen chloride
Hazardous Polymerization:	Will not occur

Section 6 – 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 is 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 Physicians:

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

Section 7 – SPECIAL PRECAUTIONS AND SPILL / LEAK PROCEDURES

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 20° to 25°C (68° to 77°F). Protect from freezing and light.

Shelf Life: Expiration date is listed on each package.

Neutralizing Chemical Agent: Not relevant

Steps to be taken in-case material is released or spilled: Ventilate area. Contain spilled product by adding suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. Prevent runoff to surface waterways.

Waste Disposal Methods: Disposal should be conducted in accordance with local, state and federal environmental regulations.

Section 8 – PROTECTION INFORMATION

Engineering Controls: Not required during normal clinical use

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

Eye Protection: Not required during normal clinical use

Additional Protective Clothing and Equipment: No special recommendations during normal clinical use

Section 9 – TOXICOLOGY INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term carcinogenicity studies in rats revealed no significant increases in tumor incidence. A 2-year carcinogenicity study conducted in mice did not reveal any oncogenic potential. Diclofenac Sodium Ophthalmic Solution did not show mutagenic potential in various mutagenicity studies including the Ames test. Diclofenac Sodium Ophthalmic Solution administered to male and female rats did not affect fertility.

Teratogenic Effects:

Pregnancy Category C. Reproduction studies performed in mice have revealed no evidence of teratogenicity due to Diclofenac Sodium Ophthalmic Solution 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 Solution has been shown to cross the placental barrier in mice and rats.

Non-teratogenic Effects:

Because of the known effects of prostaglandin biosynthesis-inhibiting drugs on the fetal cardiovascular system, the use of Diclofenac Sodium Ophthalmic Solution during late pregnancy should be avoided.

TOXICITY DATA:

			RTECS No.
Diclofenac Sodium	Oral-Rat	LD50: 53 mg/kg	AG6330000
Polyoxyl 35 Castor Oil	Intravenous-Mouse	LD50: 6500 mg/kg	GO5661000
Boric Acid	Oral-Rat	LD50: 2660 mg/kg	ED4550000



Tromethamine	Oral-Rat	LD50: 5900 mg/kg	TY2900000
Sorbic Acid	Oral-Rat	LD50: 7360 mg/kg	WG2100000
Edetate Disodium Dihydrate	Oral-Rat	Not Listed	AH4410000

Section 10 – ECOLOGICAL INFORMATION and DISPOSAL CONSIDERATIONS

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

Appropriate Method of Disposal of Product, Preparation, Packaging:

Consult state, local and national governmental requirements

Section 11 - REGULATORY and TRANSPORT INFORMATION

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.

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

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.

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