

SAFETY DATA SHEETS

This SDS packet was issued with item:

078859807

N/A

SAFETY DATA SHEET

1. Identification

Product Identifier: Diclofenac Sodium Ophthalmic Solution, 0.1%

Synonyms: Diclofenac Sodium; 2-[(2,6-dichlorophenyl)amino] benzeneacetic acid, monosodium salt.

National Drug Code (NDC): 17478-892-25
17478-892-10

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.

Health Hazards:

Skin irritation	Category 3
Eye irritation	Category 2B
Specific target organ toxicity – single exposure (respiratory tract irritation)	Category 3
Reproductive toxicity	Category 2

Symbol(s):



Signal Word:

Warning.

Hazard Statement(s):

H316 Causes mild skin irritation.

H320 Causes eye irritation.

H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

Precautionary Statement(s):

P201 Obtain special instructions before use.

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- P202 Do not handle until all safety precautions have been read and understood.
- P233 Keep container tightly closed.
- P261 Avoid breathing dust/fume/gas/mist/vapor/spray.
- P271 Use only in a well-ventilated area.
- P264 Wash potentially exposed skin after handling.
- P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P304 + P312 IF INHALED: Call a POISON CENTER/doctor/physician if you feel unwell.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337 + P313 If eye irritation persists: Get medical advice/attention.
- P332 + P313 If skin irritation occurs: Get medical advice/attention.
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- P403 Store in a well-ventilated place.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/provincial/federal regulations.

Hazards Not Otherwise Classified:
Supplementary Information:

Not classifiable.
None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
2-[(2,6-dichlorophenyl)amino]benzeneacetic acid, monosodium salt	15307-79-6	Diclofenac Sodium	C ₁₄ H ₁₀ Cl ₂ NO ₂ Na	318.13	0.1%

*The formula also contains Boric Acid; Edetate Disodium, 0.1%; Polyoxyl 35 Castor Oil; Sorbic Acid, 0.2%; Tromethamine; and Purified Water.

4. First Aid Measures**Ingestion:**

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

Burning/stinging sensation in eyes; lacrimation of eyes; abnormal vision; acute elevated intraocular pressure; blurred vision; conjunctivitis; corneal deposits; corneal edema; corneal opacity; corneal lesions; discharge; eyelid swelling; iritis; irritation of eyes; itching of eyes;

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ocular allergy; abdominal pain; gastrointestinal disturbances; nausea; vomiting; weakness; dizziness; headache; facial edema; jaundice; liver damage.

Medical Conditions Aggravated by Exposure:

Porphyria; systemic lupus erythematosus; hypersensitivity to any of the components of the product. For nonsteroidal anti-inflammatory drugs (NSAIDs): asthma; aspirin allergy; active alcoholism; anemia; impaired kidney or liver function; cardiovascular disorders; bleeding disorders; peptic ulcer or gastrointestinal bleeding; hypertension; stomatitis.

Notes to Physician:

Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides, nitrogen oxides, sulfur oxides, sodium oxides, halogenated compounds, hydrogen chloride and other hazardous products of combustion.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment/Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. **Handling and Storage**

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.

Specific End Use: Pharmaceuticals.

8. **Exposure Controls/Personal Protection**

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Diclofenac Sodium	OEL*: 0.5 mg/m ³ , 8 Hour TWA

* An Occupational Exposure Level (OEL) has been established by private industry.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Protective laboratory coat, apron, or disposable garment.

9. **Physical and Chemical Properties**

Physical State/Color: Liquid/Colorless to light yellow.
Odor: No data available.
Odor Threshold: No data available.
pH: 6.5 – 7.5.
Melting Point: No data available.
Freezing Point: No data available.
Boiling Point: No data available.

Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Miscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Oxidizers, acids, and bases.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May cause skin irritation.
Eye Contact:	May cause eye irritation.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Diclofenac Sodium	Rat	Oral	LD ₅₀	53 mg/kg



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Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.

Irritation:

Compound	Species	Study Type	Severity
Castor Oil	Human	Dermal Irritation	Mild (48 Hours)
Castor Oil	Human	Eye Irritation	Mild

Sensitization: No data available.
Toxicokinetics/Metabolism: No data available.
Target Organ Effects: No data available.

Reproductive Effects: Suspected of damaging fertility or the unborn child.
(Boric Acid)

Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.
Aspiration Hazard: No data available.

12. Ecological Information

Ecotoxicity

Aquatic:

Compound	Species	Test Type	Dose
Diclofenac Sodium	Daphnia magna	EC ₅₀	56 mg/l (24 Hours)
Diclofenac Sodium	Oncorhynchus mykiss	EC ₅₀	130.6 mg/l (96 Hours)
Diclofenac Sodium	Danio rerio	EC ₅₀	214 mg/l (96 Hours)

Terrestrial: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.



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14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Diclofenac Sodium.
Pennsylvania:	Diclofenac Sodium.
California Proposition 65:	Not listed.

16. Other Information

Not made with natural rubber latex.

NFPA Rating:	HMIS Classification:
Health: 2	Health: 2
Flammability: 0	Flammability: 0
Reactivity: 0	Physical Hazard: 0

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