

Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Diclofenac Sodium Ophthalmic Solution, 0.1%**
Product Code • AB45704; AB45707; Core No. 457; NDC 24208-0457-05; NDC 24208-0457-25

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

- Recommended use** • Finished Pharmaceutical Product; Diclofenac Sodium Ophthalmic 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.
- Restrictions on use** • Use in accordance with product literature. 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
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** • Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

- Hazard statements** • May cause eye irritation

Precautionary statements

- Prevention** • Use personal protective equipment as required.
Wash thoroughly after handling.
- Response** • 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.

- Storage/Disposal**
- Keep tightly closed. Store at room temperature 20-25°C (68-77°F), to maintain product integrity. Use before date marked on carton and/or container.
 - Protect from light.

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
Boric Acid	CAS:10043-35-3 EINECS:233-139-2	< 5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Castor Oil	CAS:61791-12-6	< 10%	UN GHS: NDA
Diclofenac Sodium	CAS:15307-79-6 EINECS:239-346-4	0.1%	UN GHS: NDA
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 1%	UN GHS: NDA
Sorbic Acid	CAS:110-44-1 EINECS:203-768-7	< 1%	UN GHS: NDA
Tromethamine	CAS:77-86-1 EINECS:201-064-4	< 1%	UN GHS: Skin Irrit. 2
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Classification criteria not met

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.

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 if eye irritation persists.

Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention 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

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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 controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

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 (10043-35-3)	STELs	6 mg/m ³ STEL (inhalable fraction, listed under Borate compounds, inorganic)
	TWAs	2 mg/m ³ TWA (inhalable fraction, listed under Borate compounds, inorganic)

Exposure Control Notations

ACGIH

● Boric Acid (10043-35-3): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))

Exposure Limits Supplemental

ACGIH

● 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

- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands

- Gloves are not required under normal handling conditions.

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	Not relevant	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	7.2
Specific Gravity/Relative Density	= 1.0105 Water=1	Water Solubility	No data available
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	Heat of Combustion (ΔH_c)	Not relevant

Flame Height	Not relevant	Ignition Distance	Not relevant
Autoignition	Not relevant	Burning Rate Test	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

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.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

- Other Material Information**
- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Diclofenac Sodium (0.1%)	15307-79-6	Acute Toxicity: Ingestion/Oral-Rat LD50 • 53 mg/kg; <i>Behavioral:Altered sleep time (including change in righting reflex); Behavioral:Ataxia; Lungs, Thorax, or Respiration:Respiratory stimulation</i>
Castor Oil (< 10%)	61791-12-6	Acute Toxicity: Intravenous-Mouse LD50 • 6500 mg/kg
Boric Acid (< 5%)	10043-35-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2500 mg/kg; <i>Behavioral:Convulsions or effect on seizure threshold; Behavioral:Ataxia</i>
Tromethamine (< 1%)	77-86-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • >3000 mg/kg
Sorbic Acid (< 1%)	110-44-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • 7360 mg/kg
Edetate Disodium Dihydrate (< 1%)	139-33-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2 g/kg

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 • Eye Mild Irritation 2B

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

Eye

- Acute (Immediate)**
 - May cause mild irritation. Transient ocular burning and stinging.
- Chronic (Delayed)**
 - 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)**
 - Under normal conditions of use, no health effects are expected.

Other

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

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
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
Tromethamine	77-86-1	Yes	Yes	Yes
Edetate Disodium Dihydrate	139-33-3	Yes	Yes	Yes
Diclofenac Sodium	15307-79-6	Yes	Yes	No
Boric Acid	10043-35-3	Yes	Yes	Yes
Castor Oil	61791-12-6	Yes	No	Yes
Sorbic Acid	110-44-1	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada**Labor****Canada - WHMIS - Classifications of Substances**

• Edetate Disodium Dihydrate	139-33-3	Uncontrolled product according to WHMIS classification criteria (including 3.5%)
• Tromethamine	77-86-1	D2B
• Sorbic Acid	110-44-1	Uncontrolled product according to WHMIS classification criteria
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	D2A
• Diclofenac Sodium	15307-79-6	Not Listed

• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
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Canada - WHMIS - Ingredient Disclosure List

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Tromethamine	77-86-1	Not Listed
• Sorbic Acid	110-44-1	1 %
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	1 %
• Diclofenac Sodium	15307-79-6	Not Listed
• Water	7732-18-5	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Tromethamine	77-86-1	Not Listed
• Sorbic Acid	110-44-1	Not Listed
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	Repr.Cat.2; R60-61
• Diclofenac Sodium	15307-79-6	Not Listed
• Water	7732-18-5	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Tromethamine	77-86-1	Not Listed
• Sorbic Acid	110-44-1	Not Listed
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	5.5%<=C: Repr.Cat.2; R:60-61
• Diclofenac Sodium	15307-79-6	Not Listed
• Water	7732-18-5	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Tromethamine	77-86-1	Not Listed
• Sorbic Acid	110-44-1	Not Listed
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	T R:60-61 S:53-45
• Diclofenac Sodium	15307-79-6	Not Listed
• Water	7732-18-5	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Tromethamine	77-86-1	Not Listed
• Sorbic Acid	110-44-1	Not Listed
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	S:53-45
• Diclofenac Sodium	15307-79-6	Not Listed
• Water	7732-18-5	Not Listed

United States

Environment**U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Tromethamine	77-86-1	Not Listed
• Sorbic Acid	110-44-1	Not Listed
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	Not Listed
• Diclofenac Sodium	15307-79-6	Not Listed
• Water	7732-18-5	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Tromethamine	77-86-1	Not Listed
• Sorbic Acid	110-44-1	Not Listed
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	Not Listed
• Diclofenac Sodium	15307-79-6	Not Listed
• Water	7732-18-5	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Tromethamine	77-86-1	Not Listed
• Sorbic Acid	110-44-1	Not Listed
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	Not Listed
• Diclofenac Sodium	15307-79-6	Not Listed
• Water	7732-18-5	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Tromethamine	77-86-1	Not Listed
• Sorbic Acid	110-44-1	Not Listed
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	Not Listed
• Diclofenac Sodium	15307-79-6	Not Listed
• Water	7732-18-5	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Tromethamine	77-86-1	Not Listed
• Sorbic Acid	110-44-1	Not Listed
• Castor Oil	61791-12-6	Not Listed
• Boric Acid	10043-35-3	Not Listed
• Diclofenac Sodium	15307-79-6	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information**Last Revision Date**

● 19/May/2015

Preparation Date

- 19/May/2015

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