



# SAFETY DATA SHEET

## SECTION 1: IDENTIFICATION OF THE PRODUCT & THE COMPANY

- a) **Product Name** : Bromfenac Ophthalmic Solution, 0.09%
- b) **Common/ trade Name** : Bromfenac Ophthalmic Solution, 0.09%
- c) **Synonyms** : Sodium 2-amino-3-(4-bromobenzoyl) phenylacetate sesquihydrate
- d) **Product Use** : Finished pharmaceutical product  
**Product type** : Regulated prescription drug
- e) **Manufacture Name** : **Gland pharma Limited**  
**Address** : Survey No.: 143-148, 150 & 151  
Near Gandimaisamma Cross Roads,  
D.P.Pally, Quthubullapur Mandal  
Ranga Reddy District  
Hyderabad- 500043  
Telangana, India
- Telephone Number for Info** : +91-40-30510999

## SECTION 2: HAZARDS IDENTIFICATION

**Physical Hazards:** Not classifiable.

**Health Hazards**

**Symbol(s):** None.

**Signal Word:** None.

**Hazard Statement(s):** None.

**Precautionary Statement(s):** None.

**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.



# SAFETY DATA SHEET

## SECTION 3 – COMPOSITION AND INGREDIENTS

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Bromfenac Sodium Hydrate	120638-55-3	Sodium 2-amino-3-(4-bromobenzoyl) phenylacetate sesquihydrate	$C_{15}H_{11}BrNNaO_3 \cdot 1\frac{1}{2}H_2O$	383.17	0.1035%

\*The formula also contains Benzalkonium Chloride, 0.005% w/w; Boric Acid, Disodium Edetate, Polysorbate 80, Povidone K-30, Purified Water, Sodium Borate, and Sodium Sulfite Anhydrous. Sodium Hydroxide may be used to adjust pH.

## SECTION 4 - FIRST AID MEASURES

### Description of First Aid Measures

**Eye Contact** : Remove from source of exposure. Move individual(s) to fresh air. Check for and remove any contact lenses. Flush with copious amounts of water for at least 20 minutes. Effects of exposure may be delayed. 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. 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.



# SAFETY DATA SHEET

**Ingestion:** If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth. Keep victim warm and quiet. Loosen tight clothing such as a collar, tie, belt or waistband. 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. Effects of exposure (ingestion) to substance may be delayed.

**Protection of First-Aiders:** Use personal protective equipment (see section 8).

**Signs and Symptoms:** Eye and skin irritation with some individuals.

**Medical Conditions Aggravated**

**by Exposure:** Eye contact may cause irritation or an allergic type reaction. Avoid unnecessary exposure. Pre-existing liver or gastrointestinal conditions may be aggravated.

**Notes to Physician:** Treat supportively and symptomatically.

## SECTION 5: FIRE-FIGHTING MEASURES

**Suitable Extinguishing Media:** Use water, carbon dioxide, dry chemical or foam as necessary.

**Unsuitable Extinguishing Media:** With small quantities use carbon dioxide extinguisher. For large fires use ample quantities of water with dry chemicals or foam as necessary.

## Specific Hazards Arising from the Chemical:

**Hazardous Combustion Products:** Products of combustion are toxic.

**Other Specific Hazards:** Not determined.

**Special Protective Equipment/**

**Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Pick up in the most efficient manner. Absorb spill with inert material (e.g. vermiculite, sand or earth), then place in suitable con-



# SAFETY DATA SHEET

tainer. Contain the spill to prevent drainage into sewers, drains or streams.

**Environmental Precautions:** No data available.

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

## SECTION 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 container tightly closed in a cool, dry, well-ventilated location at 59°F – 77°F. Keep container closed when not in use. Protect from freezing, protect from light. Store according to label and/or product insert information.

**Specific End Use:** Pharmaceuticals.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### Occupational Exposure

Guidelines: Common or Chemical Name	Employee Exposure Limits
Bromfenac Sodium Hydrate	Not established.

**Engineering Controls:** Not required for the normal use of this product. 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 are recommended.. 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 (la-



# SAFETY DATA SHEET

tex) 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:** Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**Physical State/Color:** Clear, yellow to orange yellow solution.  
**Odor:** No data available.  
**Odor Threshold:** No data available.  
**pH:** 8.3.  
**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.

## SECTION 10: STABILITY AND REACTIVITY

**Reactivity:** No data available.  
**Chemical Stability:** Stable under recommended storage conditions. Avoid sources of ignition.  
**Possibility of Hazardous Reactions:** Will not occur.  
**Conditions to Avoid (e.g., static discharge, shock, or vibration):** No data available.  
**Incompatible Materials:** Strong oxidizer.



# SAFETY DATA SHEET

## Hazardous Decomposition

**Products:** Does not undergo explosive decomposition.

## SECTION 11: TOXICOLOGICAL INFORMATION

### Information on the Likely Routes of Exposure:

**Inhalation:** No data available.

**Ingestion:** Slightly toxic by ingestion. Harmful if swallowed. Ingestion of large doses may cause central nervous system effects, including drowsiness, dizziness and vision disorders. Effects of ingestion of lower doses, as present in the ophthalmic solution, are unknown. Avoid unnecessary exposure.

**Skin Contact:** May cause skin irritation to some individuals.

**Eye Contact:** May cause eye irritation to some individuals.

### **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 – Oral:** No data available.

**Acute Toxicity – Dermal:** No data available.

**Acute Toxicity – Inhalation:** No data available.

**Corrosivity:** No data available.

**Dermal Irritation:** No data available.

**Eye Irritation:** No data available.

**Sensitization:** No data available.

**Toxicokinetics/Metabolism:** No data available.

**Target Organ Effects:** No data available.

**Reproductive Effects:** No data available.

**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.



# SAFETY DATA SHEET

Occupational Safety and Health

Administration (OSHA): Not considered to be a carcinogen.

**Mutagenicity:** No data available.

**Aspiration Hazard:** No data available.

## SECTION 12: ECOLOGICAL INFORMATION

### Ecotoxicity

**Aquatic:** No data available.

**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.

## SECTION 13: DISPOSAL CONSIDERATIONS

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

## SECTION 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.

## SECTION 15: REGULATORY INFORMATION

### US Federal Regulations: **Toxic Substance Control Act**

**(TSCA):** Not listed.

### **CERCLA Hazardous Substance**

**and Reportable Quantity:** Not listed.

**SARA 313:** Not listed.

**SARA 302:** Not listed.

### **State Regulations**



# SAFETY DATA SHEET

California Proposition 65:

Not listed.

## **SECTION 16: OTHER INFORMATION:**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANYKIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULARPURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary terms will apply to this SDS.

AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet





# SAFETY DATA SHEET

MSHA	Mine Safety and Health Administration
NA	Not Applicable,
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
IOEL	International Occupational Exposure Limit
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations