

**ISTA Pharmaceuticals, Inc.**  
**MATERIAL SAFETY DATA SHEET**  
**Xibrom (bromfenac ophthalmic solution) 0.09%**

**PRODUCT AND COMPANY INFORMATION**

**Product Name:** Xibrom (bromfenac ophthalmic solution) 0.09%

**Generic Name:** Bromfenac ophthalmic solution 0.09% (0.1% solution of Sodium 2-amino-3-(4-bromobenzoyl) phenylacetate sesquihydrate)

**NDC No.** 67425-004-50 (5mL) and 67425-004-25 (2.5mL)

**Legal Category:** Prescription only medication; filled in bottle with controlled tip and overpacked inside a cardboard carton.

**Drug Composition:** Contains a non steroidal anti-inflammatory

Company Name: ISTA Pharmaceuticals, Inc.  
Company Address: 15295 Alton Parkway, Irvine, CA 92618  
Telephone Number: 949-788-6000 (Monday-Friday: 8:00am – 5:00pm PST)

**Emergency Phone Number: 24 hours; Infotrack 1-800-535-5053**

Preparation Date: April 21, 2008 (Version 04-21-08 – 01)

**2. COMPOSITION/INFORMATION ON INGREDIENTS**

Description	CAS#	TLV (mg/m <sup>3</sup> )	PEL (mg/m <sup>3</sup> )	% Content
Bromfenac Sodium Sesquihydrate	91714-93-1	NE	NE	0.1%
Sodium Borate	1303-96-4	NE	NE	>1%
Polyvinylpyrrolidone	252498-54-1	NE	NE	>1%
Purified Water	7732-18-5	NE	NE	>1%

Ingredients <1% - Boric Acid, Sodium Sulfite, Disodium Edetate, Polysorbate 80, Benzalkonium Chloride

### 3. HAZARDS identification

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#### EMERGENCY OVERVIEW

Presents little or no hazards if spilled and no unusual hazard if involved in fire.

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#### POTENTIAL HEALTH HAZARDS

**Carcinogenicity:** (NTP) No (IARC) No (OSHA) No

**Eye:** Irritant with some individuals

**Skin:** Irritant

**Ingestion:** Gastric exposure of large doses has been associated with ulceration and necrosis of gastrointestinal structures, as well as severe liver damage. 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.

**Inhalation:** Irritant.

**Chronic Effects:** Chronic ingestion of larger doses can cause severe liver damage. Chronic oral exposure of large doses may be associated with gastrointestinal disturbances, such as nausea, vomiting, heartburn and epigastric pain. Central nervous system effects may include drowsiness, dizziness, and vision disorders.

**Target Organs:** Liver, gastrointestinal system and central nervous system.

**Medical Conditions Aggravated by Long Term Exposure:** Avoid unnecessary exposure. Pre-existing liver or gastrointestinal conditions may be aggravated.

### 4. FIRST AID MEASURES

**Eyes:** Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

**Skin:** Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

**Ingestion:** Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician.

**Inhalation:** Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

**Note to Physicians:** The safety of this product in children has not been established.

**Pregnancy:** The safety of this product in pregnant women has not been established. This product should be used by pregnant women, or women who may be pregnant, only if expected therapeutic benefits outweigh the possible risks associated with treatment.

**Nursing Mothers:** The safety of this product in nursing mothers has not been established. This product should be used by nursing mothers, only if expected therapeutic benefits outweigh the possible risks associated with treatment.

Additional details are available on the package insert or in the Physicians Desk Reference.

## 5. FIRE FIGHTING MEASURES

**Flammable Properties:** Flash point: NE Method: NE

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

**Extinguishing Media:** Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

**Fire Fighting Instructions:** Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

## 6. ACCIDENTAL RELEASE

**Large/Small Spills:** Use personal protective equipment. Absorb spill with inert material (e.g. vermiculite, sand or earth), then place in suitable container. Contain the spill to prevent drainage into sewers, drains or streams. Dispose of material according to Federal, State and Local regulations.

## 7. HANDLING AND STORAGE

**Handling:** Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

**Storage:** Store product upright in original containers with the cap tightly closed at a controlled room temperature 15<sup>0</sup>-30<sup>0</sup> C (59<sup>0</sup>- 86<sup>0</sup> F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

## 8. EXPOSURE CONTROL/PERSONAL PROTECTION

**Engineering Controls:** When manufacturing this product in the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process, which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

**Eye Protection:** (29 CFR 1910.133) Recommend goggles or chemical safety glasses when working with this product in the industrial setting.

**Skin Protection:** Thick impermeable gloves and protective clothing when manufacturing this product in the industrial setting.

**Respiratory Protection:** (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

**Warning:** **Do not use air-purifying respirators in oxygen-depleted environments.** No respiratory protection is required in the clinical or home environment.

**Other:** None

**Ventilation:** Recommended in the industrial setting.

**Contaminated Equipment:** Wash contaminated clothing separately. Wash contaminated equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

## 9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor: Clear Yellow Colored Solution

Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Miscible	Percent Volatile by Volume:	<1

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable

**Conditions to avoid:** Extreme heat or cold.

**Incompatibility:** This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

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

**Hazardous Polymerization:** Should not occur and has not been reported.

## 11. TOXICOLOGY

**Summary of Risks:** The toxicological information in this MSDS refers to the effects of the active ingredient (bromfenac sodium). Concentrations and toxicological effects are substantially reduced in the ophthalmic solution. For more detailed information see MSDS on bromfenac sodium (code 002990). Severe liver damage has been reported in patients who have taken multiple doses of an oral dosage form containing significantly higher concentrations of bromfenac sodium than are present in the ophthalmic solution.

### CAS # 91714-93-1 Bromfenac Sodium

Bromfenac Sodium is known to cause liver damage in humans and or death when administered orally at therapeutic doses (at a concentration significantly higher than for the ophthalmic solution) for greater than ten days.

## 12. ECOLOGICAL INFORMATION

**Chemical Fate Information:** Product administered to patients presents a negligible impact on the environment.

## 13. DISPOSAL INFORMATION

**Dispose of material according to Federal, State, and Local regulations.** The method typically used is incineration.

**EPA Designations:** RCRA Hazardous Waste: Not Listed

**SARA Title III:** Not Listed

## 14. TRANSPORTATION INFORMATION

**Transportation Data:** Not classified as hazardous by DOT regulations.

**15. REGULATORY INFORMATION**

**DOT Designations:** Not classified as hazardous by DOT regulations.

**EPA Designations:** RCRA Hazardous Waste (40 CFR 261.33) Not Listed

**FDA Designations:** Prescription only medication.  
NDC No.: 67425-004-050 (5mL  
and 67425-004-25 (2.5mL)

**OSHA Designations:** (29 CFR 1910.1000, Table Z)  
Not Listed

**SARA Title III:** Not listed under Section 313 of Toxic Release Reporting.

**CALIFORNIA PROPOSITION 65:** Not Listed

**16. OTHER INFORMATION**

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits of any special, indirect, incidental consequential or exemplary damages, however arising, even if the company has been advised of the possibility of such damages.

NE- Not Established

< - Less Than

> - Greater Than