



MSDS: Brimonidine Tartrate Ophthalmic Solution, 0.2%

Manufacturer: Akorn Incorporated
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Section 1 - IDENTIFICATION

TRADE NAME: Brimonidine Tartrate Ophthalmic Solution, 0.2%
Description: A relatively selective alpha-2 adrenergic receptor agonist, Brimonidine Tartrate Ophthalmic Solution, 0.2% is indicated for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

| Composition | CAS# | TLV (mg/m ³) | PEL (mg/m ³) | %Content |
|---|------------|--------------------------|--------------------------|----------|
| Brimonidine Tartrate (equivalent to 1.32 mg of brimonidine free base) | 70359-46-5 | Not Established | Not Established | 0.2 |
| Polyvinyl Alcohol USP | 9002-89-5 | Not Established | Not Established | 1.4 |
| Benzalkonium Chloride USP | 8001-54-5 | Not Established | Not Established | 0.005 |
| Sodium Citrate, dihydrate USP | 6132-04-3 | Not Established | Not Established | 0.525 |
| Citric Acid USP | 77-92-9 | Not Established | Not Established | 0.005 |
| Sodium Chloride USP | 7647-14-5 | Not Established | Not Established | 0.7 |
| Water for Injection USP | 7732-18-5 | Not Established | Not Established | qs |

Hydrochloric Acid and / or Sodium Hydroxide used to adjust pH

Brimonidine Tartrate is a filter-sterilized liquid drug provided in three presentations of 5mL/10cc, 10mL/10cc, and 15mL/15cc plastic bottles suitable for dispensing into the eye.

Common name of active ingredient: Brimonidine Tartrate
Synonym: 5-bromo-6-(2-imidazolidinylideneamino) quinoxaline L-tartrate
Chemical Formula: C₁₁H₁₀BrN₅.C₄H₆O₆
Molecular Weight: 442.24 g/mole as the tartrate salt
Legal Category: Prescription Only

Section 2 - HAZARDOUS INGREDIENTS

Principal Hazardous Ingredient: Brimonidine Tartrate
% Threshold Limit Value: Not Established
Carcinogenicity: Not Observed
NTP - No
IARC - No
OSHA - No

Section 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS

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|--------------------------------|---------------------------------|--------------------------|-----------------|
| Physical State: | Liquid | | |
| Appearance: | Clear, Greenish-Yellow Solution | | |
| Odor: | Almost Odorless | Boiling Point: | >100 °C |
| Vapor Density: | Not Established | Latex Free: | Yes |
| Vapor Pressure (mm Hg): | Not Established | Viscosity: | Not Established |
| Solubility in Water: | Miscible (34 mg/mL) | Specific Gravity: | 1.007 |
| Volatile by Volume: | <1 | Evaporation Rate: | Not Established |
| Reactivity in Water: | Not Established | pH: | 5.5 to 7.0 |

Section 4 - FIRE AND EXPLOSION HAZARD DATA

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| Explosion: | Risk of explosion of product in presence of mechanical or static discharge is not known. |
| Extinguisher Media: | Brimonidine Tartrate Ophthalmic Solution is non-flammable. Use water spray, dry chemical, water fog, foam, or carbon dioxide. |
| Special Information: | In the event of a fire, wear full protective clothing and NIOSH approved self-contained breathing apparatus with full-face piece operated in the pressure demand or other positive pressure mode. |

Section 5 - REACTIVITY DATA

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| Stable: | Yes |
| Incompatibility: | Store at or below 25 °C (77°F). Avoid excessive heat, water-reactive materials, and oxidizing agents. |
| Hazardous Decomposition Products: | Burning may produce hydrogen bromide and nitrogen oxides. |
| Hazardous Polymerization: | Yes |
| Conditions to Avoid: | Do not store near to strong oxidizers and heat. |

Section 6 - HEALTH HAZARDS

Route of Entry: Brimonidine Tartrate Ophthalmic Solution, 0.2% may cause mild to moderate irritation of eyes. Patients wearing soft contact lenses are instructed to wait at least 15 minutes after applying Brimonidine Tartrate Ophthalmic Solution, 0.2% to insert soft contact lenses. Brimonidine may be absorbed into skin, inhaled or accidentally ingested.

1. **Oral:** Moderate Toxicity
2. **Eyes:** Mild to moderate irritation
2. **Skin:** Mild irritation by prolonged contact
3. **Ingestion:** May cause mild irritation and sedation
4. **Inhalation:** Potential for a decrease in mental alertness

Acute and Chronic Effects: Brimonidine Tartrate Ophthalmic Solution contains benzalkonium chloride which may be absorbed by soft contact lenses and can cause allergic reactions.

Sign and Symptoms of Exposure: Possible irritation or allergic reaction to material if inhaled, ingested or applied onto skin.

Chemical Listed as Carcinogen or Potential Carcinogen:

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| National Toxicology Program: | No |
| I.A.R.C Monographs: | No |
| OSHA: | No |
| OSHA Permissible Exposure Limit: | Not Established |
| ACGIH Threshold Limit Value: | Not Established |

Emergency and First Aid Procedures:

- 1. Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
- 2. Eyes:** Immediately flush eyes with copious amounts of water for at least 15 minutes, lifting lower and upper eyelids. Get medical attention.
- 3. Skin:** Absorption through skin may occur. Immediately wash skin with soap and plenty of water for at least 15 minutes while removing contaminated clothing and shoes. If irritation persists, call a physician. Wash clothing before reuse.
- 4. Ingestion:** Overdose amounts may develop serious symptoms. Consult a physician. Never give anything by mouth to an unconscious person.

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| Section 7 - SPECIAL PRECAUTIONS AND SPILL / LEAK PROCEDURES |
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Storage: Store product upright in original container with the cap tightly closed in a cool, dry place. Keep out reach of children.

Neutralizing Chemical Agent: Not relevant

Steps to be taken in case material is released or spilled: Use personal protective equipment and devices. Ventilate area of large spills. Remove all sources of ignition. Isolate hazard areas. Keep unnecessary and unprotected personnel from entering. More than one individual should witness all clean-up operations. Carefully sweep up material into an approved container, seal and save for disposal. Do not drain into sewers or streams.

Waste Disposal Methods: Mix with flammable material and incinerate in an industrial or commercial facility in accordance with federal, state, and local regulations.

Section 8 - PROTECTION INFORMATION

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| Airborne Exposure Limits: | Not Established |
| Ventilation: | Recommended |
| Skin Protection: | Wear appropriate latex or nitrile gloves Cover exposed skin |
| Eye Protection: | Use chemical safety goggles Maintain eye wash fountain and quick-drench facilities in work area |

Section 9 - TOXICOLOGY INFORMATION**Oral toxicity of Brimonidine Tartrate:**LD₅₀ rat, oral = 100 mg/KgLD₅₀ mice, oral = 50 mg/Kg

Administration of a dose of 2.5mg Brimonidine Tartrate/kg/day for one year in monkeys resulted in sedation, hypertension, sinus bradycardia and sinus arrhythmia.

Ocular toxicity of Brimonidine Tartrate:

The studies indicate that 0.8% solution showed no local or systematic effects on monkeys.

Chronic Effects on Humans: Brimonidine Tartrate Ophthalmic Solution produces no evidence of impaired fertility or harm to the fetus. *In vitro* and *in vivo* tests indicate that it is not mutagenic or cytogenic.

Section 10 - ECOLOGICAL INFORMATION

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| Ecotoxicity: | Not established |
| BOD₅ and COD: | Not available |
| Environmental fate information: | The products of degradation are less toxic. |
| Other Precautions: | Do not drain into sewers or streams |

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