CLAIMS:

1. An aqueous topical ophthalmic composition comprising at least 7.0 % w/v articaine and a buffer comprising a complex of boric acid and D-mannitol in an amount to provide a pH of pH 4.5 to pH 5.0 and said composition further comprises sodium acetate, acetic acid, and disodium edetate, where said composition has an osmolality for topical application for ophthalmic anesthesia and said buffer is included in an amount to stabilize and inhibit degradation of articaine during storage.

2. An aqueous topical ophthalmic anesthetic composition comprising at least 8.0% w/v articaine, a buffer complex obtained from 0.08% w/v to 0.10% w/v boric acid and 0.5% w/v to 0.60% w/v D-mannitol, 0.3 to 0.36% w/v sodium acetate, 0.05% w/v to 0.07% w/v disodium edetate, and the balance water, and where said composition has an osmolality of 280 to 320 mOsm/kg and the amounts are based on the total volume of the composition, where said composition has an osmolality for topical application for ophthalmic anesthesia and said buffer is included in an amount to stabilize and inhibit degradation of articaine during storage.

3. An aqueous topical ophthalmic anesthetic composition comprising at least 4% w/v articaine, and a buffer comprising NaOH and HCl, and said composition has a pH of pH 5.5, a pKa of 7.8, a viscosity of 20-25 cp, an osmolality of 275 to 1171 mOsm/kg, and a tonicity of 0.5 to 5.0%, where said composition has an osmolality for topical application for ophthalmic anesthesia and said buffer is included in an amount to stabilize and inhibit degradation of articaine during storage.

4. An aqueous ophthalmic composition comprising 80 mg/g articaine HCl, 1.373 mg/g sodium phosphate monobasic monohydrate, 1.413 mg/g sodium phosphate dibasic anhydrous, 8.1 mg/g hydroxypropylmethyl cellulose, 4 mg/g PEG400, and where said composition has a pH of pH 6.0 to pH 7.0, a viscosity of 743-803 cp, and an osmolality of 517 mOsm/kg, and where said buffer is non-reactive with and stabilizes said articaine to inhibit degradation of said articaine during storage.

5. An aqueous ophthalmic anesthetic composition comprising:

articaine in an amount of at least 7.0% w/v based on the volume of the composition; and a buffer in an amount to provide a pH of pH 4.0 to pH 5.5 and to stabilize articaine, and where said buffer is a complex obtained from a boric acid or a boric acid salt and a sugar alcohol in an amount to maintain said articaine in solution or suspension and to inhibit degradation of said articaine during storage;

wherein

said buffer is a borate/mannitol complex in an amount of 6.5 parts by weight to 7.5 parts by weight based on 100 parts by weight of articaine in the composition,

said borate/mannitol complex is obtained from a borate/mannitol ratio of 1:3 to 1:7 by weight, and

the composition further comprises sodium diacetate, acetic acid, and disodium edetate.

6. The composition of any one of claims 1-5 for use for topical application to the surface of the eye of a patient in an amount effective to anesthetize the surface of the eye and the internal aspect of the patient.

7. A composition for use for topical application to the surface of the eye of a patient in an amount effective to anesthetize the surface of the eye and the internal aspect of the patient, the composition comprising at least 7.5% w/v articaine; a buffer including a complex obtained from boric acid and D-mannitol in an amount that is non-reactive with articaine; sodium acetate; acetic acid; disodium edetate, and the balance water, and where said composition has a pH of pH 4.5 to pH 5.5.

8. A composition for use for topical application to the surface of the eye of a patient in an amount effective to anesthetize the surface of the eye and the internal aspect of the patient, the composition comprising at least 4% w/v articaine, a pH 5.5, a pKa of 7.8, a viscosity of 20 - 25 cp, an osmolality of 275-1171 mOsms/kg, a tonicity of 0.5% - 5.0%, a NaOH buffer, and a HCl buffer, where said buffer is non-reactive with and stabilizes articaine to inhibit degradation of said articaine during storage.

9. A composition for use for topical application to the surface of the eye of a patient in an amount effective to anesthetize the surface of the eye and the internal aspect of the patient, the composition comprising 80 mg/g articaine HCl, 1.373 mg/g sodium phosphate monobasic monohydrate, 1.413 mg/g sodium phosphate dibasic anhydrous, 8.1 mg/g hydroxypropylmethyl cellulose, 4 mg/g PEG400, and where said composition has a pH of pH 6.0 to pH 7.0, a viscosity of 743-803 cp, and an osmolality of 517 mOsm/kg.

10. A method of producing the composition of any one of claims 1-5, comprising the steps of:

mixing an acid or salt thereof and a sugar alcohol in a solution to form a complex;

adjusting the pH to be of said pH; and

adding articaine to the resulting solution in an amount to obtain said composition having said amount w/v based on the volume of the composition.

11. The method of claim 10, wherein said acid is selected from the group consisting of acetic acid, citric acid, and mixtures thereof, and said sugar alcohol is selected from the group consisting of D-mannitol, sorbitol, and mixtures thereof.

12. The method of claim 10, wherein said acid or salt thereof is a borate salt and said sugar alcohol is D-mannitol, and said complex is a borate/mannitol complex, and where said composition comprises at least 7.0% articaine, and has a pH of pH 6.0 to pH 7.0.

13. The method of claim 12, wherein said borate/mannitol complex is obtained from a borate/mannitol ratio of 1:3 to 1:7 by weight.