CLAIMS:

1. An aqueous topical ophthalmic anesthetic composition comprising:

articaine in an amount of 4.0% w/v to 12.0% w/v based on the volume of the composition; and a buffer in an amount to provide a pH of pH 3.5 to pH 7.0, and osmolality of 275-1171 mOsm/kg to facilitate topical application for ophthalmic anesthesia, where said buffer is non-reactive with and stabilizes articaine to inhibit degradation of said articaine during storage.

2. The composition of claim 1, wherein said composition has a pH of pH 4.5 to pH 5.5, and where said buffer comprises a complex obtained from a citrate, acetate or mixture thereof and a sugar alcohol selected from the group consisting of mannitol, sorbitol and mixtures thereof.

3. The composition of claim 1, wherein said composition comprises 7.5% w/v to 8.5% w/v articaine and said composition has a pH of pH 4.5 to pH 5.0.

4. The composition of claim 1, wherein said composition contains at least 7.0 % w/v articaine and has a pH of pH 4.5 to pH 5.0.

5. The composition of claim 1, wherein said buffer comprises a borate/mannitol complex obtained from a borate and D-mannitol, and wherein said borate/mannitol complex is included in an amount to provide an articaine concentration to anesthetize the surface of the eye and the internal aspect of the eye by topical application, and said composition has an osmolality of 500 to 700 mOsm/kg.

6. The composition of claim 5, wherein said borate/mannitol complex is included in an amount of 0.5 %w/v to 0.75% w/v based on the volume of the composition.

7. The composition of claim 5, wherein said borate/mannitol complex is included 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.

8. The composition of claim 5, wherein said borate/mannitol complex is obtained from a borate/mannitol ratio of 1:3 to 1:7 by weight, said borate/mannitol complex is included in an amount to maintain said articaine in solution or suspension in said topical anesthetic

composition, inhibit degradation of said articaine during long term storage, and to provide an osmolality of 500-700 mOsm/kg and a pH of 3.5 to pH 7.0 and a tonicity of 0.5 to 5.0%.

9. The composition of claim 5, wherein said composition further includes sodium acetate, acetic acid, and disodium edetate.

10. 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.

11. The composition of claim 5, wherein said articaine is present in an amount of at least 7.0% w/v, and said boric acid and D-mannitol complex is obtained from 0.08% w/v to 0.10% w/v boric acid and 0.50% w/v to 0.6% w/v D-mannitol based on the total volume of the composition.

12. The composition of claim 1, wherein said composition comprises 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.

13. The composition of claim 1, wherein said composition comprises 4% w/v articaine, and said buffer comprises 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%.

14. An aqueous ophthalmic composition comprising80 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.

15. 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.

16. The aqueous ophthalmic anesthetic composition of claim 15, 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.

17. The aqueous ophthalmic anesthetic composition of claim 16, wherein said borate/mannitol complex is obtained from a borate/mannitol ratio of 1:3 to 1:7 by weight.

18. The aqueous ophthalmic anesthetic composition of claim 17, further comprising sodium diacetate, acetic acid, and disodium edetate.

19. The composition of claim 1 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.

20. The composition of claim 19, wherein said composition comprises articaine in an amount of at least 5.0% , said buffer complex obtained from 0.08% w/v to 0.10% w/v boric acid and 0.50% w/v to 0.6% w/v D-mannitol based on the total volume of the composition.

21. The composition of claim 19, wherein said composition comprises 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.

22. The composition of claim 19, wherein said composition comprises at least 7% w/v articaine.

23. The composition of claim 22, wherein said composition has a pH of pH 4.5 to pH 5.0.

24. The composition of claim 19, wherein said formulation comprises 4% w/v articaine, has 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.

25. The composition of claim 19, wherein said composition comprises 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.

26. A method of producing the composition of claim 1, 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 3.5 to pH 7.0; and

adding articaine to the resulting solution in an amount to obtain said composition having 4.0% w/v to 12.0% w/v based on the volume of the composition.

27. The method of claim 26, 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.

28. The method of claim 26, 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.

29. The method of claim 28, wherein said borate/mannitol complex is obtained from a borate/mannitol ratio of 1:3 to 1:7 by weight.