SUMMARY OF THE INVENTION

It has now been discovered novel ophthalmic compositions for treating dry eye syndrome, which may include a combination of a demulcent or film forming material and a tonicity agent. These compositions may be used to treat dry eye, or to diagnose, cure, mitigate, treat, or prevent dry eye syndrome in man or other animals. These formulations are sterile, buffered, oil and water emulsion artificial tear products formulated for the relief of ocular surface irritation and symptoms of dryness.

In one embodiment, there is provided an ophthalmic composition comprising polyoxyethylene (20) sorbitan monooleate, carboxymethylcellulose sodium, glycerin, boric acid, acrylates/C10-30 alkyl acrylate crosspolymer, castor oil, erythritol, levocarnitine, sodium hydroxide, and water with the proviso that the composition does not comprise another oil.

In one embodiment, there is provided use of an effective amount of an ophthalmic composition as described herein in the manufacture of a medicament for treating, curing or mitigating dry eye syndrome, wherein the medicament is to be administered to an eye of a man or other animal in need thereof.

In one embodiment, there is provided an ophthalmic composition comprising polyoxyethylene (20) sorbitan monooleate, carboxymethylcellulose sodium, glycerin, boric acid, acrylates/C10-30 alkyl acrylate crosspolymer, castor oil, erythritol, levocarnitine, sodium hydroxide, a stabilized oxychloro complex and water with the proviso that the composition does not comprise another oil.

In one embodiment, there is provided an ophthalmic composition consisting of polyoxyethylene (20) sorbitan monooleate, carboxymethylcellulose sodium, glycerin, boric acid, acrylates/C10-30 alkyl acrylate crosspolymer, castor oil, erythritol, levocarnitine, sodium hydroxide, a stabilized oxychloro complex and water.

In one embodiment, there is provided use of an effective amount of an ophthalmic composition as described herein in the manufacture of a medicament for treating, mitigating or curing dry eye syndrome, wherein the medicament is to be administered to an eye of a man or other animal in need thereof.

In a first aspect there is provided an ophthalmic composition comprising polyoxyethylene (20) sorbitan monooleate, carboxymethylcellulose sodium, glycerin, boric acid, acrylates/C10-30 alkyl acrylate crosspolymer, castor oil, erythritol, levocarnitine, sodium hydroxide, and water.

In a second aspect there is provided a use of an ophthalmic composition as disclosed herein in the manufacture of a medicament for treating, diagnosing, curing, mitigating or preventing dry eye syndrome.

These compositions are typically ophthalmically acceptable liquids. An ophthalmically acceptable liquid includes a liquid formulated that is tolerable to a patient for topical ophthalmic use. Additionally, an ophthalmically acceptable liquid could either be packaged for single use, or for multiple uses containing a preservative to prevent contamination.

For ophthalmic application, solutions or medicaments may be prepared using a physiological saline solution as a major vehicle. Ophthalmic solutions may be maintained at a comfortable pH with an appropriate buffer system. The formulations may also contain conventional, pharmaceutically acceptable preservatives, stabilizers and surfactants.

An ophthalmically acceptable liquid may include demulcents or film forming materials. Examples of demulcents may include, but are not limited to polymers such as polyvinyl alcohol, povidone, hydroxypropyl methyl cellulose, poloxamers, carboxymethyl cellulose, hydroxyethyl cellulose, acrylates; surfactants such as polyoxyethylene (20) sorbitan monooleate and glycerin. The amount of demulcent may vary. In some embodiments, the amount of any demulcent such as those listed above may be from about 0.1% w/w to about 2% w/w, or from about 0.3% w/w to about 0.7% w/w, or from about 0.3% w/w to about 0.5% w/w, or about 0.5% w/w.

What is claimed is:

1. An ophthalmic composition comprising polyoxyethylene (20) sorbitan monooleate, carboxymethylcellulose sodium, glycerin, boric acid, acrylates/C10-30 alkyl acrylate crosspolymer, castor oil, erythritol, levocarnitine, sodium hydroxide, and water with the proviso that the composition does not comprise another oil.

2. The composition of claim 1, the composition consisting of polyoxyethylene (20) sorbitan monooleate, carboxymethylcellulose sodium, glycerin, boric acid, acrylates/C10-30 alkyl acrylate crosspolymer, castor oil, erythritol, levocarnitine, sodium hydroxide, and water with the proviso that the composition does not comprise another oil.

3. The composition of claim 1 or 2, wherein the polyoxyethylene (20) sorbitan monooleate is present at a concentration of about 0.1% w/w to about 2% w/w.

4. The composition of claim 1 or 2, wherein the carboxymethylcellulose sodium is present at a concentration of about 0.1% w/w to about 2% w/w.

5. The composition of claim 1 or 2, wherein the glycerin is present at a concentration of about 0.2% w/w to about 5% w/w.

6. The composition of claim 1 or 2, wherein the acrylates/C10-30 alkyl acrylate crosspolymer is present at a concentration of about 0.02% to about 0.5% w/w.

7. The composition of claim 1 or 2, wherein the castor oil is present at a concentration of about 0.05% to about 0.5% w/w.

8. The composition of claim 1 or 2, wherein the erythritol is present at a concentration of about 0.05% or about 3% w/w: and the levocarnitine is present at a concentration of about 0.05% or about 3% w/w.

9. The composition of claim 1 or 2, consisting of about 0.5% w/w polyoxyethylene (20) sorbitan monooleate, about 0.5% w/w carboxymethylcellulose sodium, about

1.0% w/w glycerin, about 0.6% w/w boric acid, about 0.1% w/w acrylates/C10-30 alkyl acrylate crosspolymer, about 0.25% w/w castor oil, about 0.25% w/w erythritol, about 0.25% w/w levocarnitine, sodium hydroxide, a pH of about 7.3 and water.

10. Use of an effective amount of an ophthalmic composition according to claim 1 or 2 in the manufacture of a medicament for treating, curing or mitigating dry eye syndrome, wherein the medicament is to be administered to an eye of a man or other animal in need thereof.

11. An ophthalmic composition comprising polyoxyethylene (20) sorbitan monooleate, carboxymethylcellulose sodium, glycerin, boric acid, acrylates/C10-30 alkyl acrylate crosspolymer, castor oil, erythritol, levocarnitine, sodium hydroxide, a stabilized oxychloro complex and water with the proviso that the composition does not comprise another oil.

12. An ophthalmic composition consisting of polyoxyethylene (20) sorbitan monooleate, carboxymethylcellulose sodium, glycerin, boric acid, acrylates/C10-30 alkyl acrylate crosspolymer, castor oil, erythritol, levocarnitine, sodium hydroxide, a stabilized oxychloro complex and water.

13. The composition of claim 11 or 12, wherein the stabilized oxychloro complex is present at a concentration of about 0.002% to about 0.05% w/w.

14. The composition of claim 11 or 12, wherein the polyoxyethylene (20) sorbitan monooleate is present at a concentration of about 0.1% w/w to about 2% w/w.

15. The composition of claim 11 or 12, wherein the carboxymethylcellulose sodium is present at a concentration of about 0.1% w/w to about 2% w/w.

16. The composition of claim 11 or 12, wherein the glycerin is present at a concentration of about 0.2% w/w to about 5% w/w.

17. The composition of claim 11 or 12, wherein the acrylates/C10-30 alkyl acrylate crosspolymer is present at a concentration of about 0.02% to about 0.5% w/w.

18. The composition of claim 11 or 12, wherein the castor oil is present at a concentration of about 0.05% to about 0.5% w/w.

19. The composition of claim 11 or 12, wherein the erythritol is present at a concentration of about 0.05% or about 3% w/w; and the levocarnitine is present at a concentration of about 0.05% or about 3% w/w.

20. The composition of claim 11 or 12, consisting of about 0.5% w/w polyoxyethylene (20) sorbitan monooleate, about 0.5% w/w carboxymethylcellulose sodium, about 1.0% w/w glycerin, about 0.6% w/w boric acid, about 0.1% w/w acrylates/C10-30 alkyl acrylate crosspolymer, about 0.25% w/w castor oil, about 0.25% w/w erythritol, about 0.25% w/w levocarnitine, about 0.01% w/w stabilized oxychloro complex, sodium hydroxide, and water; and wherein the pH of the composition is about 7.3.

21. Use of an effective amount of an ophthalmic composition according to claim 11 or 12 in the manufacture of a medicament for treating, mitigating or curing dry eye syndrome, wherein the medicament is to be administered to an eye of a man or other animal in need thereof.

22. Use of an effective amount of an ophthalmic composition according to claim 20 in the manufacture of a medicament for treating, mitigating or curing dry eye syndrome, wherein the medicament is to be administered to an eye of a man or other animal in need thereof.

What is claimed is:

1. An ophthalmic composition comprising polyoxyethylene (20) sorbitan monooleate, carboxymethylcellulose sodium, glycerin, boric acid, acrylates/C10-30 alkyl acrylate crosspolymer, castor oil, erythritol, levocarnitine, sodium hydroxide, and water .

2. The composition of claim 1, wherein the polyoxyethylene (20) sorbitan monooleate is present at a concentration of about 0.1% w/w to about 2% w/w.

3. The composition of claim 1 wherein the carboxymethylcellulose sodium is present at a concentration of about 0.1% w/w to about 2% w/w.

4. The composition of claim 1, wherein the glycerin is present at a concentration of about 0.2% w/w to about 5% w/w.

5. The composition of claim 1, wherein the boric acid is present at a concentration of about 0.02% to about 2% w/w.

6. The composition of claim 1, wherein the acrylates/C10-30 alkyl acrylate crosspolymer is present at a concentration of about 0.02% to about 0.5% w/w.

7. The composition of claim 1, wherein the castor oil is present at a concentration of about 0.05% to about 0.5% w/w.

8. The composition of claim 1, wherein the erythritol is present at a concentration of about 0.05% or about 3% w/w.

9. The composition of claim 1, wherein the levocarnitine is present at a concentration of about 0.05% or about 3% w/w.

10. The composition of claim 1, wherein the pH is about 7.3.

11. The composition of claim 1, comprising about 0.5% w/w polyoxyethylene (20) sorbitan monooleate, about 0.5% w/w carboxymethylcellulose sodium, about 1.0% w/w glycerin, about 0.6% w/w boric acid, about 0.1% w/w acrylates/C10-30 alkyl acrylate crosspolymer , about 0.25% w/w castor oil, about 0.25% w/w erythritol, about 0.25% w/w levocarnitine, sodium hydroxide , a pH of about 7.3 and water.

12. Use of an ophthalmic composition according to claim 1in the manufacture of a medicament for treating, diagnosing, curing, mitigating or preventing dry eye syndrome.

13. The use according to claim 12, wherein the medicament comprises about 0.5% w/w polyoxyethylene (20) sorbitan monooleate, about 0.5% w/w carboxymethylcellulose sodium, about 1.0% w/w glycerin, about 0.6% w/w boric acid, about 0.1% w/w acrylates/C10-30 alkyl acrylate crosspolymer, about 0.25% w/w castor oil, about 0.25% w/w erythritol, about 0.25% w/w levocarnitine, sodium hydroxide , a pH of about 7.3 and water.

14. The composition of claim 1, further comprising stabilized oxychloro complexes.

15. The composition of claim 14, wherein the stabilized oxychloro complex is present at a concentration of about 0.002% or about 0.05% w/w.

16. The ophthalmic composition of claim 11, further comprising about 0.01 % w/w of stabilized oxychloro complexes.

17. Use of an opthalmic

composition according to claim 14 in the manufacture of a medicament for treating, diagnosing, curing, mitigating or preventing dry eye syndrome.

18. The use according to claim 17, wherein the medicament comprises about 0.5% w/w polyoxyethylene (20) sorbitan monooleate, about 0.5% w/w carboxymethylcellulose sodium , about 1.0% w/w glycerin, about 0.01 % w/w of stabilized oxychloro complexes, about 0.6% w/w boric acid, about 0.1% w/w acrylates/C10-30 alkyl acrylate crosspolymer, about 0.25% w/w Castor Oil, about 0.25% w/w erythritol, about 0.25% w/w levocarnitine, sodium hydroxide to obtain a pH of about 7.3 and water.