degradation by oxidation and hydrolysis. U.S. Patent Publication Nos. 2007/0265341, 2008/0153909 and 2010/0305045, for example, teach certain omega-3 oil containing compositions, but do not address this stability issue. U.S. 2007/0265341 teaches the use of vitamin E as an antioxidant, but vitamin E is not effective in preserving omega-3 oils as described herein. Thus, there is a need for stable ophthalmic compositions containing omega-3 oils.

SUMMARY

[0005] Provided herein are stabilized ophthalmic compositions containing omega-3 oils and one or more antioxidants. Specifically, the antioxidants are selected from butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT), alone or in combination. These compositions may be used, among other things, as artificial tears and as ophthalmic compositions to diagnose, treat, or prevent keratoconjunctivitis or dry eye syndrome in a human or other mammal in need of such diagnosis, treatment, or prevention.

[0005a] In one aspect, there is provided an ophthalmic composition comprising one or more omega-3 oils; BHT and/or BHA; one or more hydrogels; one or more tonicity agents; one or more surfactants; and an acrylates/C10-30 alkyl acrylate crosspolymer; and wherein the ophthalmic composition does not include an antimicrobial preservative.

[0005b] In one aspect, there is provided an ophthalmic composition comprising about 0.1% to about 1% w/w flaxseed oil; about 0.1% to about 1% w/w castor oil; about 0.001% to about 0.05% w/w BHT; about 0.25% to about 1% w/w sodium CMC; about 0.1% to about 0.5% w/w carnitine; about 0.1% to about 2% w/w glycerin; about 0.1% to about 0.5% w/w erythritol; about 0.5% to about 3% w/w trehalose; about 0.1% to about 2% w/w boric acid; about 0.1% to about 2% w/w polysorbate 80; about 0.1% to about 2% w/w POE 40 stearate; about 0.05% to about 1% w/w acrylates/C10-30 alkyl acrylate crosspolymer; and water; and wherein the composition does not include an antimicrobial preservative.

[0005c] In one aspect, there is provided an ophthalmic composition comprising about 0.1% to about 1% w/w flaxseed oil; about 0.1% to about 1% w/w castor oil; about 0.001% to about 0.05% w/w BHT; about 0.001% to about 0.05% w/w BHA; about 0.25% to about 1% w/w sodium CMC; about 0.1% to about 0.5% w/w carnitine; about 0.1% to about 2% w/w glycerin; about 0.1% to about 0.5% w/w erythritol; about 0.5% to about 3% w/w trehalose; about 0.1% to about 2% w/w boric acid; about 0.1% to about 2% w/w polysorbate 80; about 0.1% to about 2% w/w POE 40 stearate; about 0.1% to about 1% w/w acrylates/C10-30 alkyl acrylate crosspolymer; and water; and wherein the composition does not include an antimicrobial preservative.

[0005d] In one aspect, there is provided a use of an effective amount of an ophthalmic composition as described herein, in the manufacture of a medicament for treating *keratoconjunctivitis sicca* or dry eye syndrome in a human or other mammal.

BRIEF DESCRIPTION OF THE FIGURES

[0006] **FIG. 1** shows the improved chemical stability of omega-3 oils in emulsions containing BHA and BHT, as compared to emulsions containing omega-3 oil without BHA/BHT.

[0007] **FIG. 2** shows flaxseed oil emulsion formulation stability over time.

[0008] **FIG. 3** shows *in vivo* tolerability results of omega-3 oil emulsions.

0.005% to about 0.02% w/w BHT; about 0.005% to about 0.02% w/w BHA; about 0.25% to about 1% w/w sodium CMC; about 0.1% to about 0.5% w/w carnitine; about 0.5% to about 2% w/w glycerin; about 0.1% to about 0.5% w/w erythritol; about 1% to about 2% w/w trehalose; about 0.25% to about 1% w/w boric acid; about 0.25% to about 1% w/w polysorbate 80; about 0.1% to about 1% w/w POE 40 stearate; and about 0.05% to about 0.25% w/w acrylates/C10-30 alkyl acrylate crosspolymer.

23. The ophthalmic composition of claim 16, wherein the composition comprises about 0.1% to about 0.25% w/w flaxseed oil; about 0.1% to about 0.25% w/w castor oil; about 0.005% to about 0.02% w/w BHT; about 0.005% to about 0.02% w/w BHA; about 0.25% to about 1% w/w sodium CMC; about 0.1% to about 0.5% w/w carnitine; about 0.5% to about 2% w/w glycerin; about 0.1% to about 0.5% w/w erythritol; about 1% to about 2% w/w trehalose; about 0.25% to about 1% w/w boric acid; about 0.25% to about 1% w/w polysorbate 80; about 0.1% to about 1% w/w POE 40 stearate; and about 0.05% to about 0.25% w/w acrylates/C10-30 alkyl acrylate crosspolymer.

24. Use of an effective amount of an ophthalmic composition according to any one of claims 1-18, in the manufacture of a medicament for treating *keratoconjunctivitis sicca* or dry eye syndrome in a human or other mammal.

25. The use of claim 24, wherein amount of the ophthalmic composition is effective to reduce one or more symptoms of *keratoconjunctivitis sicca* or dry eye syndrome.