fortifiers in many countries around the world. When stabilizers cannot be used in highly concentrated human milk fortifiers, it can be very difficult to produce a long term stable highly concentrated human milk fortifier.

[0013] As such, there is a need for highly concentrated liquid human milk fortifiers that have sufficient long term stability and include hypoallergenic proteins, such as extensively hydrolyzed casein proteins. Additionally, it would be very beneficial if the highly concentrated human milk fortifier could be formulated to provide additional nutrients such as lutein to protect pre-term infants from oxidative stress, without unwanted fallout during storage.

SUMMARY OF THE DISCLOSURE

[0014] The present disclosure is directed to long term stable concentrated liquid human milk fortifiers including extensively hydrolyzed casein, a stabilizer system comprised of an octenyl succinic anhydride modified corn starch and a low acyl gellan gum, and carotenoids, such as lutein. The stabilizer system allows for the use of an extensively hydrolyzed casein protein without the associated problems of mineral fallout and poor emulsion stability, and allows for the fortifier, in some embodiments, to be carrageenan-free. In some embodiments, the long term concentrated liquid human milk fortifiers are hypoallergenic.

[0014a] The present disclosure is directed to a concentrated liquid human milk fortifier comprising from about 5% to about 50% by weight extensively hydrolyzed casein protein, on a dry weight basis, lutein and a stabilizer system comprising an octenyl succinic anhydride modified corn starch and a low acyl gellan gum.

[0014b] The present disclosure is directed to a concentrated liquid human milk fortifier comprising from about 10% to about 50% by weight extensively hydrolyzed casein protein, on a dry weight basis, at least 50 mcg/liter lutein, as fed, and a stabilizer system comprising from about 0.6% to about 2.0% by weight of an octenyl succinic anhydride modified corn starch and from about 125 to about 800 ppm low acyl gellan gum.

[0014c] The present disclosure is directed to an aseptically-sterilized concentrated liquid human milk fortifier comprising from about 10% to about 50% by weight extensively hydrolyzed casein protein, on a dry weight basis, and at least 170 mcg/liter lutein, and a stabilizer system

comprising from about 0.6% to about 2. % by weight of an octenyl succinic anhydride modified corn starch and from about 125 to about 800 ppm low acyl gellan gum.

[0015] The present disclosure is specifically directed to a liquid human milk fortifier comprising from about 5% to about 50% by weight extensively hydrolyzed casein protein, on a dry weight basis. The supplemental carotenoids may be provided by a liquid human milk fortifier, containing from about 100 to about 2200 mcg/liter of total carotenoids, wherein the total carotenoids include at least about 50 mcg/liter of lutein, as fed, for the product nutrient levels. The human milk fortifier may further comprise docosahexaenoic acid in a weight ratio of lutein (mcg) to docosahexaenoic acid (mg) of from about 1:2 to about 10:1.

[0016] The liquid human milk fortifier also comprises a stabilizer system comprising from about 0.1% to about 3.5% by weight of the concentrated liquid human milk fortifier, or from about 0.8% to about 1.5% by weight of the concentrated liquid human milk fortifier, of an octenyl succinic anhydride modified corn starch, and from about 125 to about 800 ppm low acyl gellan gum.

WHAT IS CLAIMED IS:

1. A concentrated liquid human milk fortifier comprising from about 5% to about 50% by weight extensively hydrolyzed casein protein, on a dry weight basis, ~~and~~ lutein, ~~wherein the concentrated liquid human milk fortifier comprises~~ and a stabilizer system comprising an octenyl succinic anhydride modified corn starch and a low acyl gellan gum.

2. The concentrated liquid human milk fortifier of claim 1 comprising from about 20% to about 40% by weight extensively hydrolyzed casein, on a dry weight basis.

3. The concentrated liquid human milk fortifier of claim 1, wherein the lutein concentration is at least about 50 mcg/liter, based on an as-fed basis.

4. The concentrated liquid human milk fortifier of claim 3, wherein the concentrated human milk fortifier ~~further~~ comprises at least about 30 mg/liter docosahexaenoic acid, based on an as-fed basis, wherein the weight ratio of lutein (mcg) to docosahexaenoic acid (mg) is from about 1:2 to about 10:1.

5. The concentrated liquid human milk fortifier of claim 4, wherein the concentrated human milk fortifier further comprises from about 54 to about 360 mg/liter docosahexaenoic acid, based on an as-fed basis, wherein the weight ratio of lutein (mcg) to docosahexaenoic acid (mg) is from about 1:2 to about 10:1.

6. The concentrated liquid human milk fortifier of claim 4 wherein the octenyl succinic anhydride modified corn starch is present in an amount of from about 0.1% to about 3.5% by weight of the concentrated liquid human milk fortifier.

7. The concentrated liquid human milk fortifier of any one of claims 1-5 wherein the octenyl succinic anhydride modified corn starch is present in an amount of from about 0.8% to about 1.5% by weight of the concentrated liquid human milk fortifier.

8. The concentrated liquid human milk fortifier of claim 4 wherein the low acyl gellan gum is present in an amount of from greater than 125 to about 800 ppm.

9. The concentrated liquid human milk fortifier of any one of claims 1-6 wherein the low acyl gellan gum is present in an amount of from about 150 ppm to about 400 ppm.

10. The concentrated liquid human milk fortifier of any one of claims 1-6 and 8 further including carbohydrate, fat, vitamins and minerals.

11. The concentrated liquid human milk fortifier of any one of claims 1-6 and 8 wherein the concentrated liquid human milk fortifier is carrageenan-free.

12. The concentrated liquid human milk fortifier of any one of claims 1-6 and 8, wherein the concentrated liquid human milk fortifier comprises from about 170 to about 1360 mcg/liter of lutein.

13. The concentrated liquid human milk fortifier of claim 12, wherein the concentrated liquid human milk fortifier further comprises from about 30 to about 1200 mg/liter of docosahexaenoic acid, wherein the weight ratio of lutein (mcg) to docosahexaenoic acid (mg) is from about 1:2 to about 10:1.

14. The concentrated liquid human milk fortifier of claim 12, wherein the lutein comprises at least about 20% by weight of added lutein.

15. The concentrated liquid human milk fortifier of claim 12, wherein the human milk fortifier comprises a combination of free lutein and zeaxanthin from a single source being a crystalline extract of *Tagetes erecta* in which the free lutein represents from 85% to 95% by weight of the combination and the free zeaxanthin represents from about 5% to about 15% by weight of the combination.

16. A concentrated liquid human milk fortifier comprising from about 10% to about 50% by weight extensively hydrolyzed casein protein, on a dry weight basis, ~~and~~ at least 50 mcg/liter lutein, as fed, ~~wherein the concentrated liquid human milk fortifier comprises~~ and a stabilizer system comprising from about 0.6% to about 2.0 %

by weight of an octenyl succinic anhydride modified corn starch and from about 125 to about 800 ppm low acyl gellan gum.

17. The concentrated liquid human milk fortifier of claim 16 comprising from about 20% to about 40% by weight extensively hydrolyzed casein protein, on a dry weight basis.

18. The concentrated liquid human milk fortifier of claim 17 comprising from about 0.8% to about 1.5% by weight of an octenyl succinic anhydride modified corn starch.

19. The concentrated liquid human milk fortifier of claim 18 comprising from about 150 to about 400 ppm low acyl gellan gum.

20. The concentrated liquid human milk fortifier of any one of claims 16-19, wherein the concentrated liquid human milk fortifier comprises from about 50 to about 1150 mcg/liter of lutein, on an as-fed basis.

21. The concentrated liquid human milk fortifier of any one of claims 16-19, wherein the concentrated liquid human milk fortifier comprises a combination of free lutein and zeaxanthin from a single source being a crystalline extract of *Tagetes erecta* in which the free lutein represents from 85% to 95% by weight of the combination and the free zeaxanthin represents from about 5% to about 15% by weight of the combination.

22. An aseptically-sterilized concentrated liquid human milk fortifier comprising from about 10% to about 50% by weight extensively hydrolyzed casein protein, on a dry weight basis, and at least 170 mcg/liter lutein, ~~wherein the concentrated liquid human milk fortifier comprises~~ and a stabilizer system comprising from about 0.6% to about 2. % by weight of an octenyl succinic anhydride modified corn starch and from about 125 to about 800 ppm low acyl gellan gum.