supplements, and specifically highly concentrated liquid protein supplements, are desirable as an alternative to powders as these liquids have the significant benefit of being commercially sterile as they can be subjected to sufficient heat treatment during manufacturing, including ultra high temperature (UHT) treatment.

[0006] To date, however, liquid protein supplements are typically highly acidic, which can be problematic as the acidity of the supplement can change its natural properties, e.g., proteins may denature, which may have an adverse impact, when fed to an infant. Moreover, many protein supplements are based wholly or in large part on collagen as the protein source. Collagen, however, is an inferior protein source, and as such, supplements including significant amounts of collagen are not acceptable for neonate consumption.

[0007] As such, there is a need for sterilized liquid protein supplements that are sufficiently long term stable that include hypoallergenic proteins, such as extensively hydrolyzed casein proteins. Additionally, it would be very beneficial if the sterilized liquid protein supplements could be made to have a neutral pH such as to prevent protein denaturation when added to human milk and have the milk remain a neutral pH.

SUMMARY OF THE DISCLOSURE

[0008] The present disclosure is directed to long term stable sterilized liquid protein supplements including extensively hydrolyzed casein. In some embodiments, the extensively hydrolyzed casein is the sole source of protein in the sterilized liquid protein supplement. The sterilized liquid protein supplements may be, in some embodiments, clear and/or hypoallergenic.

[0008a] The present disclosure is directed to a sterilized liquid protein supplement comprising more than 10 grams of protein per 100 mL of supplement, wherein at least 75% by weight of the protein is hydrolyzed casein having a degree of hydrolysis of at least 20%, wherein the protein comprises at least 50% by weight free amino acids, dipeptides, and tripeptides, and wherein the sterilized liquid protein supplement has a pH of from 5.0 to 8.0.

[0008b] The present disclosure is directed to a sterilized liquid protein supplement comprising more than 10 grams of hydrolyzed casein per 100 mL of supplement, wherein the hydrolyzed casein has a degree of hydrolysis of at least 20%, wherein the hydrolyzed casein comprises at least 50% by weight free amino acids, dipeptides, and tripeptides, and the supplement comprises less than 1% by weight collagen.

[0008c] The present disclosure is directed to a method of manufacturing a liquid protein supplement, the method comprising:

suspending a protein in an aqueous solution using agitation to form a protein suspension mixture, wherein at least 75% by weight of the protein is hydrolyzed casein having a degree of hydrolysis of at least 20%, wherein the protein comprises at least 50% by weight free amino acids, dipeptides, and tripeptides, and wherein the protein suspension mixture has a protein concentration of greater than 30% by weight of the protein suspension mixture;

diluting the protein suspension mixture with water to form a diluted mixture having a protein concentration of from 25% to 30% by weight of the diluted mixture;

heating the diluted mixture with agitation to a temperature of from 150°F (65.6°C) to 210°F (98.9°C);

emulsifying the heated mixture at up to 500 psig (34.5 bar);

heating the emulsified mixture at a first temperature of from 240°F (115.6°C) to 260°F (126.6°C);

further heating the emulsified mixture at a second temperature of from 275°F (135°C) to 305°F (151.7°C), and holding the heated emulsified mixture at the second temperature for a period of from 1 second to 5 seconds;

cooling the further heated emulsified mixture to a temperature of from 150°F (65.6°C) to 200°F (93.3°C);

homogenizing the cooled mixture at up to 500 psig (34.5 bar), and holding the homogenized cooled mixture at the temperature of from 150°F (65.6°C) to 200°F (93.3°C) for a period of from 10 seconds to 20 seconds;

further cooling the homogenized mixture to a temperature of less than 100°F (37.8°C); and

diluting the further cooled homogenized mixture with water to form a cooled homogenized mixture comprising more than 10 grams of protein per 100 mL of diluted homogenized mixture.

[0008d] The present disclosure is directed to a method of fortifying breast milk comprising mixing a sterilized liquid protein supplement as described herein with breast milk.

[0008e] The present disclosure is directed to a method of fortifying infant formula comprising mixing a sterilized liquid protein supplement as described herein with infant formula.

[0009] The present disclosure is specifically directed to a sterilized liquid protein supplement comprising more than 10 grams protein per 100 mL. At least a portion of the protein is extensively hydrolyzed casein. The sterilized liquid protein supplement has a pH of from about 5.0 to about 8.0.

WHAT IS CLAIMED IS:

1. A sterilized liquid protein supplement comprising more than 10 grams of protein per 100 mL of supplement, wherein at least 75% by weight of the protein is hydrolyzed casein having a degree of hydrolysis of at least 20%, and wherein the sterilized liquid protein supplement has a pH of from about 5.0 to about 8.0.

2. The sterilized liquid protein supplement of claim 1, which comprises from about 17 grams to about 24 grams of protein per 100 mL of supplement.

3. The sterilized liquid protein supplement of claim 1, which comprises from about 20 grams to about 23.5 grams of protein per 100 mL of supplement.

4. The sterilized liquid protein supplement of claim 1, wherein the protein is 100% by weight hydrolyzed casein.

5. The sterilized liquid protein supplement of claim 1, wherein the protein is at least 50% by weight free amino acids, dipeptides, and tripeptides.

6. The sterilized liquid protein supplement of claim 1, which comprises from about 10% by weight to about 50% by weight solids.

7. The sterilized liquid protein supplement of claim 6, which comprises less than 5 grams of insoluble solids per 100 grams of the sterilized liquid protein supplement.

8. The sterilized liquid protein supplement of claim 1, which comprises less than 1% by weight collagen.

9. The sterilized liquid protein supplement of claim 1, which comprises less than 1% by weight carbohydrate and less than 1% by weight fat.

10. A sterilized liquid protein supplement comprising more than 10 grams of hydrolyzed casein per 100 mL of supplement, wherein the hydrolyzed casein has a degree of hydrolysis of at least 20% and the supplement comprises less than 1% by weight collagen.

11. The sterilized liquid protein supplement of claim 10, which comprises from about 20 grams to about 23.5 grams of hydrolyzed casein per 100 mL of supplement.

12. The sterilized liquid protein supplement of claim 10, which comprises from about 10% by weight to about 50% by weight solids.

13. The sterilized liquid protein supplement of claim 12, which comprises from about 0.5 grams to less than 5 grams of insoluble solids per 100 grams of the sterilized liquid protein supplement.

14. The sterilized liquid protein supplement of claim 10, which has a pH of from about 5.0 to about 8.0.

15. The sterilized liquid protein supplement of claim 10, which comprises less than 1% by weight carbohydrate and less than 1% by weight fat.

16. The sterilized liquid protein supplement of any one of claims 1-15, wherein the sterilized liquid protein supplement is clear.

17. The sterilized clear liquid protein supplement of claim 16, which has a pH of from about 5.5 to about 7.0.

18. A method of manufacturing a liquid protein supplement, the method comprising:

suspending a protein in an aqueous solution using agitation to form a protein suspension mixture, wherein at least 75% by weight of the protein is hydrolyzed casein having a degree of hydrolysis of at least 20%, and wherein the protein suspension mixture has a protein concentration of greater than 30% by weight of the protein suspension mixture;

diluting the protein suspension mixture with water to form a diluted mixture having a protein concentration of from about 25% to about 30% by weight of the diluted mixture;

heating the diluted mixture with agitation to a temperature of from about 150°F (65.6°C) to about 210°F (98.9°C);

emulsifying the heated mixture at up to about 500 psig (34.5 bar);

heating the emulsified mixture at a first temperature of from about 240°F (115.6°C) to about 260°F (126.6°C);

further heating the emulsified mixture at a second temperature of from about 275°F (135°C) to about 305°F (151.7°C), and holding the heated emulsified mixture at the second temperature for a period of from 1 second to about 5 seconds;

cooling the further heated emulsified mixture to a temperature of from about 150°F (65.6°C) to about 200°F (93.3°C);

homogenizing the cooled mixture at up to about 500 psig (34.5 bar), and holding the homogenized cooled mixture at the temperature of from about 150°F (65.6°C) to about 200°F (93.3°C) for a period of from about 10 seconds to about 20 seconds;

further cooling the homogenized mixture to a temperature of less than about 100°F (37.8°C); and

diluting the further cooled homogenized mixture with water to form a cooled homogenized mixture comprising more than 10 grams of protein per 100 mL of diluted homogenized mixture.

19. The method of claim 18, wherein the protein suspension mixture has a protein concentration of from about 35% to about 57% by weight of the protein suspension mixture, and after dilution, the diluted mixture has a protein concentration of about 27.5% by weight of the diluted mixture.

20. The method of claim 18, wherein suspending the protein occurs at a temperature of from about 120°F (48.9°C) to about 180°F (82.2°C).

21. The method of claim 18, wherein the heated emulsified mixture is cooled in a two-step cooling process, wherein a first cooling step comprises cooling the heated emulsified mixture to a first temperature of from about 225°F (107.2°C) to about 265°F (129.4°C) and a second cooling step comprises cooling the heated emulsified mixture to a temperature of from about 150°F (65.6°C) to about 200°F (93.3°C).

22. The method of claim 18, wherein the cooled homogenized mixture is diluted with water to form a cooled homogenized mixture comprising from 20 grams to 23.5 grams of protein per 100 mL of diluted homogenized mixture.

23. A method of fortifying breast milk comprising mixing a sterilized liquid protein supplement according to any one of claims 1-15 with breast milk.

24. The method of claim 23, wherein about 1 mL to about 5 mL of sterilized liquid protein supplement is added per 100 mL of breast milk.

25. A method of fortifying infant formula comprising mixing a sterilized liquid protein supplement according to any one of claims 1-15 with infant formula.

26. The method of claim 25, wherein about 1 mL to about 5 mL of sterilized liquid protein supplement is added per 100 mL of infant formula.

WHAT IS CLAIMED IS:

1. A sterilized liquid protein supplement comprising more than 10 grams of protein per 100 mL of supplement, wherein at least 75% by weight of the protein is hydrolyzed casein having a degree of hydrolysis of at least 20%, wherein the protein comprises at least 50% by weight free amino acids, dipeptides, and tripeptides, and wherein the sterilized liquid protein supplement has a pH of from 5.0 to 8.0.

2. The sterilized liquid protein supplement of claim 1, which comprises from 17 grams to 24 grams of protein per 100 mL of supplement.

3. The sterilized liquid protein supplement of claim 1, which comprises from 14 grams to 24 grams of protein per 100 mL of supplement.

4. The sterilized liquid protein supplement of claim 1, wherein the protein is 100% by weight hydrolyzed casein.

5. The sterilized liquid protein supplement of claim 1, which comprises from 10% by weight to 50% by weight solids.

6. The sterilized liquid protein supplement of claim 5, which comprises less than 5 grams of insoluble solids per 100 grams of the sterilized liquid protein supplement.

7. The sterilized liquid protein supplement of claim 1, which comprises less than 1% by weight collagen.

8. The sterilized liquid protein supplement of claim 1, which comprises less than 1% by weight carbohydrate and less than 1% by weight fat.

9. A sterilized liquid protein supplement comprising more than 10 grams of hydrolyzed casein per 100 mL of supplement, wherein the hydrolyzed casein has a degree of hydrolysis of at least 20%, wherein the hydrolyzed casein comprises at least 50% by weight free amino acids, dipeptides, and tripeptides, and the supplement comprises less than 1% by weight collagen.

10. The sterilized liquid protein supplement of claim 9, which comprises from 14 grams to 24 grams of hydrolyzed casein per 100 mL of supplement.

11. The sterilized liquid protein supplement of claim 9, which comprises from 10% by weight to 50% by weight solids.

12. The sterilized liquid protein supplement of claim 11, which comprises from 0.5 grams to less than 5 grams of insoluble solids per 100 grams of the sterilized liquid protein supplement.

13. The sterilized liquid protein supplement of claim 9, which has a pH of from 5.0 to 8.0.

14. The sterilized liquid protein supplement of claim 9, which comprises less than 1% by weight carbohydrate and less than 1% by weight fat.

15. The sterilized liquid protein supplement of any one of claims 1-14, wherein the sterilized liquid protein supplement is clear.

16. The sterilized clear liquid protein supplement of claim 15, which has a pH of from 5.5 to 7.0.

17. A method of manufacturing a liquid protein supplement, the method comprising:

suspending a protein in an aqueous solution using agitation to form a protein suspension mixture, wherein at least 75% by weight of the protein is hydrolyzed casein having a degree of hydrolysis of at least 20%, wherein the protein comprises at least 50% by weight free amino acids, dipeptides, and tripeptides, and wherein the protein suspension mixture has a protein concentration of greater than 30% by weight of the protein suspension mixture;

diluting the protein suspension mixture with water to form a diluted mixture having a protein concentration of from 25% to 30% by weight of the diluted mixture;

heating the diluted mixture with agitation to a temperature of from 150°F (65.6°C) to 210°F (98.9°C);

emulsifying the heated mixture at up to 500 psig (34.5 bar);

heating the emulsified mixture at a first temperature of from 240°F (115.6°C) to 260°F (126.6°C);

further heating the emulsified mixture at a second temperature of from 275°F (135°C) to 305°F (151.7°C), and holding the heated emulsified mixture at the second temperature for a period of from 1 second to 5 seconds;

cooling the further heated emulsified mixture to a temperature of from 150°F (65.6°C) to 200°F (93.3°C);

homogenizing the cooled mixture at up to 500 psig (34.5 bar), and holding the homogenized cooled mixture at the temperature of from 150°F (65.6°C) to 200°F (93.3°C) for a period of from 10 seconds to 20 seconds;

further cooling the homogenized mixture to a temperature of less than 100°F (37.8°C); and

diluting the further cooled homogenized mixture with water to form a cooled homogenized mixture comprising more than 10 grams of protein per 100 mL of diluted homogenized mixture.

18. The method of claim 17, wherein the protein suspension mixture has a protein concentration of from 35% to 57% by weight of the protein suspension mixture, and after dilution, the diluted mixture has a protein concentration of 27.5% by weight of the diluted mixture.

19. The method of claim 17, wherein suspending the protein occurs at a temperature of from 120°F (48.9°C) to 180°F (82.2°C).

20. The method of claim 17, wherein the heated emulsified mixture is cooled in a two-step cooling process, wherein a first cooling step comprises cooling the heated emulsified mixture to a first temperature of from 225°F (107.2°C) to 265°F (129.4°C) and a second cooling step comprises cooling the heated emulsified mixture to a temperature of from 150°F (65.6°C) to 200°F (93.3°C).

21. The method of claim 17, wherein the cooled homogenized mixture is diluted with water to form a cooled homogenized mixture comprising from 14 grams to 24 grams of protein per 100 mL of diluted homogenized mixture.

22. A method of fortifying breast milk comprising mixing a sterilized liquid protein supplement according to any one of claims 1-14 with breast milk.

23. The method of claim 22, wherein 1 mL to 5 mL of sterilized liquid protein supplement is added per 100 mL of breast milk.

24. A method of fortifying infant formula comprising mixing a sterilized liquid protein supplement according to any one of claims 1-14 with infant formula.

25. The method of claim 24, wherein 1 mL to 5 mL of sterilized liquid protein supplement is added per 100 mL of infant formula.