

CLAIMS

What is claimed is:

1. A method of sterilizing human milk to produce a sterilized human milk product, the method comprising:
 - receiving, by a sterilizer located within a closed in-line system, as an input, a human milk sample;
 - flowing the human milk sample through a tube of the sterilizer in a first direction at a first flow rate;
 - heating the human milk sample in the tube by flowing heating fluid in a second direction at a second flow rate, wherein the heating fluid is in contact with an exterior surface of the tube; and
 - cooling, by the sterilizer, the heated human milk sample.
2. The method of claim 1, wherein heating the human milk sample in the tube comprises:
 - raising a temperature of the human milk sample to within a temperature range of 130° C and 150° C; and
 - holding the temperature of the human milk sample within the temperature range for a duration of 3 to 15 seconds.
3. The method of claim 1, wherein heating the human milk sample in the tube comprises:
 - raising a temperature of the human milk sample to within a temperature range of 135° C and 145° C; and
 - holding the temperature of the human milk sample within the temperature range for a duration of 6 to 14 seconds.

4. The method of claim 1, wherein heating the human milk sample in the tube comprises:
raising a temperature of the human milk sample to within a temperature range of 138 C and 142° C; and
holding the temperature of the human milk sample within the temperature range for a duration of 8 to 13 seconds.
5. The method of claim 1, wherein heating the human milk sample in the tube comprises:
raising a temperature of the human milk sample to within a temperature range of 140° C and 141° C; and
holding the temperature of the human milk sample within the temperature range for a duration of 12 to 13 seconds.
6. The method of any one of claims 1-5, wherein a length of the portion of the tube and the first flow rate of the human milk sample are each previously chosen to hold the temperature of the human milk sample within the temperature range for the duration.
7. The method of any one of claims 1-6, wherein the first tube of the sterilizer has a diameter between 0.25 and 10 inches.
8. The method of any one of claims 1-7, wherein the first flow rate of the human milk sample through the tube of the sterilizer is between 0.25 gallons per minute and 25 gallons per minute.
9. The method of any one of claims 1-8, wherein the human milk sample received by the sterilizer is non-homogenized.

10. The method of any one of claims 1-8, wherein the human milk sample is homogenized prior to being received by the sterilizer or homogenized after being cooled by the sterilizer.

11. The method of any one of claims 1-10 further comprising the step, prior to the sterilizer receiving the human milk sample, of:

eliminating pathogens from a raw human breast milk sample through one or more clarification processes.

12. The method of claim 11 further comprising, after the one or more clarification processes and prior to the sterilizer receiving the human milk sample, the steps of:

separating a clarified human milk sample into a cream sample and a skim sample; generating a retentate by performing a concentration process on the skim sample; and engineering a standardized human milk sample to produce an engineered human milk product by combining a portion of the cream sample with a portion of the obtained retentate.

13. The method of claim 12, wherein combining a portion of the cream sample with a portion of the obtained retentate comprises:

detecting an initial characteristic of the cream sample; comparing the detected initial characteristic of the cream sample to a target characteristic for the engineered human milk product; and determining the portion of the cream sample and the portion of the obtained retentate based on the comparison.

14. The method of any one of claims 1-13 further comprising the step of, subsequent to cooling of the sterilized human milk product, packaging, through an aseptic process, the sterilized human milk product.

15. The method of any one of claims 1-14, wherein the sterilizer is a pharmaceutical grade sterilizer.

16. The method of any one of claims 1-15, wherein the sterilized human milk product has at least 63 calories per 100 milliliters of the sterilized human milk product.

17. The method of any one of claims 1-16, wherein the sterilized human milk product has a total fat content of at least 3.0 g/100 mL (3 wt%).

18. The method of any one of claims 1-17, wherein the sterilized human milk product retains above 88% of immunoglobulin A in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

19. The method of any one of claims 1-18, wherein the sterilized human milk product retains above 77% of immunoglobulin M in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

20. The method of any one of claims 1-19, wherein the sterilized human milk product retains above 93% of immunoglobulin G in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

21. The method of any one of claims 1-20, wherein the sterilized human milk product retains above 64% of anti-trypsin in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

22. The method of any one of claims 1-21, wherein the sterilized human milk product retains above 81% of lactoferrin in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

23. The method of any one of claims 1-22, wherein the sterilized human milk product retains above 78% of lysozyme in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

24. The method of any one of claims 1-23, wherein the sterilized human milk product retains above 72% of lactalbumin in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

25. The method of any one of claims 1-24, wherein the sterilized human milk product retains above 92% of Alpha Casein in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

26. The method of any one of claims 1-25, wherein the sterilized human milk product retains above 92% of Beta Casein in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

27. The method of any one of claims 1-26, wherein the sterilized human milk product retains above 92% of Kappa Casein in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

28. The method of any one of claims 1-27, wherein the sterilized human milk product retains above 87% of osteopontin in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

29. The method of any one of claims 1-28, wherein the sterilized human milk product retains above 92% of total human milk oligosaccharides in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

30. The method of any one of claims 1-29, wherein the sterilized human milk product retains above 90% of fucosylated human milk oligosaccharides in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

31. The method of any one of claims 1-30, wherein the sterilized human milk product retains above 90% of 2'-fucosyllactose in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

32. The method of any one of claims 1-31, wherein the sterilized human milk product retains above 90% of 3'-fucosyllactose in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

33. The method of any one of claims 1-32, wherein the sterilized human milk product retains above 90% of sialylated human milk oligosaccharides in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

34. The method of any one of claims 1-33, wherein the sterilized human milk product retains above 90% of non-fucosylated human milk oligosaccharides in comparison to a raw human breast milk sample that the sterilized human milk product derives from.

35. A closed, in-line processing system comprising:

a sterilizer comprising:

a tube configured to flow a human milk sample in a first direction at a first flow rate; and

a container that a portion of the tube resides within, wherein the container is configured to flow a heating fluid in contact with an exterior surface of the portion of the tube in a second direction at a second flow rate to heat the human milk sample flowing through the portion of the first tube to a predetermined temperature for a duration.

36. The system of claim 35, wherein the predetermined temperature is within a temperature range of 130° C and 150° C and the predetermined duration is between 3 and 15 seconds.

37. The system of claim 35, wherein the predetermined temperature is within a temperature range of 135° C and 145° C and the predetermined duration is between 6 and 14 seconds.

38. The system of claim 35, wherein the predetermined temperature is within a temperature range of 138° C and 142° C and the predetermined duration is between 8 and 13 seconds.

39. The system of claim 35, wherein the predetermined temperature is within a temperature range of 140° C and 141° C and the predetermined duration is between 12 and 13 seconds.

40. The system of any one of claims 35-39, wherein the first flow rate of the human milk sample through the tube of the sterilizer is between 0.25 gallons per minute and 25 gallons per minute.

41. The system of any one of claims 35-40 further comprising:

one or more bacterial clarifiers, each bacterial clarifier configured to eliminate pathogens from a raw human breast milk sample;

a milk separator in fluid communication with the last in series of the at least one bacterial clarifier, the milk separator configured to separate a clarified human milk sample into a cream sample and a skim sample;

a milk concentrator in fluid communication with the milk separator, the milk concentrator further configured to generate a retentate by performing a reverse osmosis process on the skim sample received from the milk separator; and

a milk combiner configured to combine a portion of the cream sample from the milk separator and a portion of the retentate from the milk concentrator.

42. The system of claim 41, wherein the milk combiner is in fluid communication with the sterilizer, and wherein a homogenizer is not located in the closed, in-line processing system prior to the sterilizer.
43. The system of any one of claims 35-42, wherein the system is capable of undergoing a clean-in-place (CIP) method of cleaning.
44. The system of any one of claims 35-43, wherein the sterilizer is a pharmaceutical grade sterilizer.
45. The system of any one of claims 35-43, wherein the sterilizer is a commercial grade sterilizer.
46. A sterilized human milk product comprising:
- a bacterial aerobic plate count of less than 10 CFUs per gram of the sterilized human milk product; and
- a concentration of lactoferrin between 0.81 grams per liter to 13.28 grams per liter of the sterilized human milk product.

47. The sterilized human milk product of claim 46, further comprising a concentration of lysozyme between 0.012 grams per liter to 0.105 grams per liter of the sterilized human milk product.
48. The sterilized human milk product of claim 46 or 47, further comprising a concentration of lactalbumin between 1.87 grams per liter to 2.68 grams per liter of the sterilized human milk product.
49. The sterilized human milk product of any one of claims 46-48, further comprising a concentration of anti-trypsin between 0.057 grams per liter to 0.40 grams per liter of the sterilized human milk product.
50. The sterilized human milk product of any one of claims 46-49, further comprising a concentration of human milk oligosaccharides between 8.8 grams per liter and 20.0 grams per liter of the sterilized human milk product.
51. The sterilized human milk product of any one of claims 46-50, further comprising a concentration of 2'fucosyllactose between 0.72 grams per liter and 4.3 grams per liter of the sterilized human milk product.
52. The sterilized human milk product of any one of claims 46-51, the product having, per 100 milliliters: (a) 63 to 67 calories, (b) 30 to 34 calories from fat, (c) 1.2 to 1.8 grams of saturated fat, (d) 10 to 16 mg of cholesterol, (e) 10 to 20 mg of sodium, (f) 4 to 10 grams of total carbohydrate, (g) 4 to 7 grams of sugars, (h) 1.2 to 1.6 grams of protein (i) 160 to 200 International Units of vitamin A, and (j) 27 to 35 mg of calcium.
53. The sterilized human milk product of any one of claims 46-52, wherein the product has a reduced amount of *Bacillus Cereus* as compared to the amount of *Bacillus Cereus* in a raw human breast milk sample that the sterilized human milk product was

sterilized from, wherein the reduced amount is at least a 500 log reduction of *Bacillus Cereus*.

54. The sterilized human milk product of any one of claims 46-53, wherein the product has a reduced amount of *Clostridium Botulinum* as compared to the amount of *Clostridium Botulinum* in the raw human breast milk sample that the sterilized human milk product was sterilized from, wherein the reduced amount is at least a 12 log reduction of *Clostridium Botulinum*.
55. An aseptically packaged product comprising the sterilized human milk product of any one of claims 46 – 54.
56. The aseptically packaged product of claim 55, wherein the aseptically packaged product is packaged in one of a bottle, booster cup, paper carton, paper brick, or a pouch.
57. An extended shelf life packaged product comprising the sterilized human milk product of any one of claims 46-54.
58. The extended shelf life packaged product of claim 57, wherein the extended shelf life packaged product is packaged in one of a bottle, booster cup, paper carton, paper brick, or a pouch.