CLAIMS

1 . A composition comprising:

pure silk fibroin-based protein fragments that are substantially devoid of sericin,

wherein the composition has an average weight average molecular weight ranging from 5 kDa to 200 kDa,

wherein the composition has a polydispersity of between about 1.5 and about 3.0,

wherein the composition is substantially homogeneous,

wherein the composition includes between 0 ppm to about 500 ppm of inorganic residuals, and

wherein the composition includes between 0 ppm to about 500 ppm of organic residuals.

2. The composition of claim 1 wherein the inorganic residuals include lithium bromide and wherein the organic residuals include sodium carbonate.

3. The composition of claim 2 comprising between 10 ppm and 300 ppm of lithium bromide residuals and between 10 ppm and 100 ppm of sodium carbonate residuals.

4. The composition of claim 3 wherein the lithium bromide residuals are measurable using a high-performance liquid chromatography lithium bromide assay, and the sodium carbonate residuals are measurable using a high-performance liquid chromatography sodium carbonate assay.

5. The composition of claim 1 further comprising less than 10% water.

6. The composition of claim 1 wherein the pure silk fibroin-based protein fragments are from about 0.1 wt% to about 30.0 wt%.

7 The composition of claim 1 in the form of a lyophilized form or structure.

8. The composition of claim 1 in the form of a solution.

9. The composition of claim 8 wherein the pure silk fibroin-based protein fragments are stable in the solution.

10. The composition of claim 8 wherein the solution is an aqueous solution.

11. The composition of claim 8 wherein the solution is an organic solution.

12. The composition of claim 1 in a sealed container.

13. The composition of claim 1 further comprising one or more molecules selected from the group consisting of therapeutic agents, growth factors, antioxidants, proteins, vitamins, carbohydrates, polymers, nucleic acids, salts, acids, bases, biomolecules, glycosamino glycans, polysaccharides, extracellular matrix molecules, metals, metal ion, metal oxide, synthetic molecules, polyanhydrides, cells, fatty acids, fragrance, minerals, plants, plant extracts, preservatives and essential oils.

14. The composition of claim 13 in the form of a solution.

15. The composition of claim 14 wherein the pure silk fibroin-based protein fragments are stable in the solution.

16. The composition of claim 13 wherein the vitamin is vitamin C or a derivative thereof.

17. The composition of claim 13 further comprising an alpha hydroxy acid selected from the group consisting of glycolic acid, lactic acid, tartaric acid and citric acid.

18. The composition of claim 13 further comprising hyaluronic acid or its salt form at a concentration of about 0.5% to about 10.0%.

19. The composition of claim 13 further comprising at least one of zinc oxide or titanium dioxide.

20. The composition of claim 1 wherein the pure silk fibroin-based protein fragments are hypoallergenic.

21. The composition of claim 1 having less than 10 colony forming units per gram.

22. A film comprising:

pure silk fibroin-based protein fragments substantially devoid of sericin and comprising:

an average weight average molecular weight ranging from 5 kDa to 200 kDa; and

a polydispersity of between 1.5 and about 3.0,

wherein the film has a water content ranging from about 2.0 wt % to about 20.0 wt. %,

wherein the film includes between 0 ppm and 500 ppm of inorganic residuals,

wherein the film, includes between 0 ppm and 500 ppm of organic residuals, and

wherein the film is sufficiently flexible to conform to anatomical topographies.

23. The film of claim 22 comprising between about 1.0% and about 50.0% crystalline protein domains and being soluble when submersed in water at room temperature.

24. The film of claim 22 comprising from about 30.0 wt. % to about 99.5 wt. % of pure silk fibroin-based protein fragments.

25. The film of claim 22 having a pH from about 1.0 to about 7.0.

26. The film of claim 22 further comprising from about 0.5 wt. % to about 2.5 wt. % of caffeine.

27. The film of claim 22 further comprising from about 1.0 wt. % to about 50.0 wt. % of vitamin C or a derivative thereof.

28. The film of claim 27 wherein the vitamin C or a derivative thereof remains stable within the film for a period of from about 5 days to about 5 years.

29. The film of claim 27 wherein the vitamin C or a derivative thereof is stable within the film so as to result in release of the vitamin C in a biologically active form.

30. The film of claim 22 further comprising one or more molecules selected from the group consisting of therapeutic agents, growth factors, antioxidants, proteins, carbohydrates, polymers, nucleic acids, salts, acids, bases, biomolecules, glycosamino glycans, polysaccharides, extracellular matrix molecules, metals, metal ion, metal oxide, synthetic molecules, polyanhydrides, cells, fatty acids, fragrance, minerals, plants, plant extracts, preservatives and essential oils.

31. The film of claim 22 further comprising an alpha hydroxy acid selected from the group consisting of glycolic acid, lactic acid, tartaric acid and citric acid.

32. The film of claim 22 further comprising hyaluronic acid or its salt form at a concentration ranging from about 0.5 wt. % to about 10.0 wt. %.

33. The film of claim 22 further comprising at least one of zinc oxide or titanium dioxide.

34. The film of claim 22 packaged in a foil based package that is air tight and light proof.

35. The film of claim 22 sufficiently designed for topical application.

36. The film of claim 22 sufficiently designed for administration within a body.

37. The film of claim 22 wherein the pure silk fibroin-based protein fragments are hypoallergenic.

38. A method of reducing fine lines and wrinkles comprising:

applying a film having the properties of claim 22 daily to human skin for a period of at least one week; and

observing a reduction in fine lines and wrinkles on the human skin.

39. A gel comprising:

pure silk fibroin-based protein fragments substantially devoid of sericin and comprising:

an average weight average molecular weight ranging from 5 kDa to 200 kDa; and

a polydispersity of between about 1.5 and about 3.0; and

water from about 20 wt. % to about 99.9 wt. %,

wherein the gel includes between 0 ppm and 500 ppm of inorganic residuals, and

wherein the gel includes between 0 ppm and 500 ppm of organic residuals.

40. The gel of claim 39 comprising between about 1.0% and about 50.0% crystalline protein domains.

41. The gel of claim 39 comprising from about 0.1 wt. % to about 6.0 wt. % of pure silk fibroin-based protein fragments.

42. The gel of claim 39 having a pH from about 1.0 to about 7.0.

43. The gel of claim 39 further comprising from about 0.5 wt. % to about 20.0 wt. % of vitamin C or a derivative thereof.

44. The gel of claim 43 wherein the vitamin C or a derivative thereof remains stable within the gel for a period of from about 5 days to about 5 years.

45. The gel of claim 43 wherein the vitamin C or a derivative thereof is stable within the gel so as to result in release of the vitamin C in a biologically active form.

46. The gel of claim 39 further comprising an additive selected from the group consisting of vitamin E, rosemary oil, rose oil, lemon juice, lemon grass oil and caffeine.

47. The gel of claim 39 packaged in an airtight container.

48. The gel of claim 39 wherein the pure silk fibroin-based protein fragments are hypoallergenic.

49. The gel of claim 39 having less than 10 colony forming units per milliliter.

50. A method of smoothing and rejuvenating human skin comprising:

applying a gel having the properties of claim 39 daily to human skin for a period of at least one week; and

observing an improvement in skin texture.

51. A serum comprising:

pure silk fibroin-based protein fragments substantially devoid of sericin and comprising:

an average weight average molecular weight ranging from 5 kDa to 200 kDa; and

a polydispersity of between 1.5 and about 3.0; and

hyaluronic acid or its salt form from about 0.5% to about 10.0%,

wherein the serum includes between 0 ppm and 500 ppm of inorganic residuals, and

wherein the serum includes between 0 ppm and 500 ppm of organic residuals.

52. The serum of claim 51 comprising between about 1.0% and about 50.0% crystalline protein domains.

53. The serum of claim 51 comprising from about 0.1 wt. % to about 6.0 wt. % of pure silk fibroin-based protein fragments.

54. The serum of claim 51 having a pH from about 1.0 to about 7.0.

55. The serum of claim 51 further comprising an additive selected from the group consisting of vitamin E, rosemary oil, rose oil, lemon juice, lemon grass oil, vanilla, geranium, and green tea.

56. The serum of claim 51 further comprising from about 0.5 wt. % to about 30.0 wt. % of vitamin C or a derivative thereof.

57. The serum of claim 56 wherein the vitamin C or a derivative thereof remains stable within the serum for a period of from about 5 days to about 5 years.

58. The serum of claim 56 wherein the vitamin C or a derivative thereof is stable within the serum so as to result in release of the vitamin C in a biologically active form.

59. The serum of claim 51 packaged in an airtight container.

60. The serum of claim 51 wherein the pure silk fibroin-based protein fragments are hypoallergenic.

61. A method of moisturizing human skin comprising;

applying daily a serum having the properties of claim 51 to human skin for a period of at least one week; and

observing an improvement in skin hydration.

62. A skin peel composition comprising; pure silk fibroin-based protein fragments that are substantially devoid of sericin, the fragments having an average weight average molecular weight ranging from 5 kDa to 200 kDa and a polydispersity of between about 1.5 and about 3.0 in combination with at least one skin exfoliating agent.

63. The skin peel composition of claim 62 wherein the at least one skin exfoliating agent is selected from the group consisting of glycolic acid and lactic acid.

64. The skin peel composition of claim 62 comprising between about 1.0% and about 50.0% crystalline protein domains.

65. The skin peel composition of claim 62 having a pH from about 1.0 to about 6.0.

66. The skin peel composition of claim 62 wherein the pure silk fibroin-based protein fragments are hypoallergenic.

67. A method for preparing an aqueous solution of pure silk fibroin-based protein fragments having an average weight average molecular weight ranging from 5 kDa to 200 kDa, the method comprising:

degumming a silk source by adding the silk source to a boiling aqueous solution of sodium carbonate for a treatment time of between about 30 minutes to about 60 minutes;

removing sericin from the solution to produce a silk fibroin extract substantially devoid of sericin;

draining the solution from the silk fibroin extract;

dissolving the silk fibroin extract in a solution of lithium bromide having a starting temperature upon placement of the silk fibroin extract in the lithium bromide solution that ranges from about 60°C to about 140°C;

maintaining the solution of silk fibroin-lithium bromide in an oven having a temperature in the range of 60°C to 100°C for a period of at least 1 hour;

removing the lithium bromide from the silk fibroin extract; and

producing an aqueous solution of pure silk fibroin-based protein fragments,

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises lithium bromide residuals of between 0 ppm and about 300 ppm,

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises sodium carbonate residuals of between 0 ppm and about 100 ppm,

wherein the aqueous solution of pure silk fibroin-based protein fragments have an average weight average molecular weight ranging from 5 kDa to 200 kDa, and

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises a polydispersity of between about 1.0 and about 3.0.

68. The method of claim 67 further comprising drying the silk fibroin extract prior to the dissolving step.

69. The method of claim 67 wherein the aqueous solution of pure silk fibroin-based protein fragments comprise lithium bromide residuals of less than 300 ppm as measured using a high-performance liquid chromatography lithium bromide assay.

70. The method of claim 67 wherein the aqueous solution of pure silk fibroin-based protein fragments comprise sodium carbonate residuals of less than 100 ppm as measured using a high-performance liquid chromatography sodium carbonate assay.

71. The method of claim 67 further comprising adding a therapeutic agent to the aqueous solution of pure silk fibroin-based protein fragments.

72. The method of claim 67 further comprising adding a molecule selected from one of an antioxidant or an enzyme to the aqueous solution of pure silk fibroin-based protein fragments.

73. The method of claim 67 further comprising adding a vitamin to the aqueous solution of pure silk fibroin-based protein fragments.

74. The method of claim 73 wherein the vitamin is vitamin C or a derivative thereof.

75. The method of claim 67 further comprising lyophilizing the aqueous solution of pure silk fibroin-based protein fragments.

76. The method of claim 67 further comprising adding an alpha hydroxy acid to the aqueous solution of pure silk fibroin-based protein fragments.

77. The method of claim 76 wherein the alpha hydroxy acid is selected from the group consisting of glycolic acid, lactic acid, tartaric acid and citric acid.

78. The method of claim 76 further comprising adding hyaluronic acid or its salt form at a concentration of about 0.5% to about 10.0% to the aqueous solution of pure silk fibroin-based protein fragments.

79. The method of claim 67 further comprising adding at least one of zinc oxide or titanium dioxide.

80. A film fabricated from an aqueous solution of pure silk fibroin-based protein fragments produced by the method of claim 67 and comprising from about 1.0 wt. % to about 50.0 wt. % of vitamin C or a derivative thereof, wherein the cosmetic film has a water content ranging from about 2.0 wt. % to about 20.0 wt. %.

81. The film of claim 80 comprising from about 30.0 wt. % to about 99.5 wt. % of pure silk fibroin-based protein fragments.

82. A gel fabricated from an aqueous solution of pure silk fibroin-based protein fragments produced by the method of claim 67 and comprising from about 0.5 wt. % to about 20.0 wt. % of vitamin C or a derivative thereof.

83. The gel of claim 82 having a silk content of at least 2% and a vitamin content of at least 20%.

84. A method for preparing an aqueous solution of pure silk fibroin-based protein fragments having an average weight average molecular weight ranging from about 17 kDa to about 38 kDa, the method comprising:

adding a silk source to a boiling aqueous solution of sodium carbonate for a treatment time of between about 30 minutes and about 60 minutes so as to result in degummmg;

removing sericin from the solution to produce a silk fibroin extract substantially devoid of sericin;

draining the solution from the silk fibroin extract;

dissolving the silk fibroin extract in a solution of lithium bromide having a starting temperature upon placement of the silk fibroin extract in the lithium bromide solution that ranges from about 80°C to about 140°C;

maintaining the solution of silk fibroin-lithium bromide in a dry oven having a temperature in the range between about 60°C to about 100°C for a period of at least 1 hour;

removing the lithium bromide from the silk fibroin extract; and

producing an aqueous solution of pure silk fibroin-based protein fragments,

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises lithium bromide residuals of between 0 ppm and about 300 ppm,

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises sodium carbonate residuals of between 0 ppm and about 100 ppm,

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises fragments having an average weight average molecular weight ranging from about 17 kDa to about 38 kDa, and

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises a polydispersity of between about 1.0 and about 3.0.

85. The method of claim 84 further comprising drying the silk fibroin extract prior to the dissolving step.

86. The method of claim 84 wherein the aqueous solution of pure silk fibroin-based protein fragments comprise lithium bromide residuals of less than 300 ppm as measured using a high-performance liquid chromatography lithium bromide assay.

87. The method of claim 84 wherein the aqueous solution of pure silk fibroin-based protein fragments comprise sodium carbonate residuals of less than 100 ppm as measured using a high-performance liquid chromatography sodium carbonate assay.

88. The method of claim 84 further comprising adding a therapeutic agent to the aqueous solution of pure silk fibroin-based protein fragments.

89. The method of claim 84 further comprising adding a molecule selected from one of an antioxidant or an enzyme to the aqueous solution of silk pure silk fibroin-based fragments.

90. The method of claim 84 further comprising adding a vitamin to the aqueous solution of pure silk fibroin-based protein fragments.

91. The method of claim 84 wherein the vitamin is vitamin C or a derivative thereof.

92. The method of claim 84 further comprising lyophilizing the aqueous solution of pure silk fibroin-based protein fragments.

93. The method of claim 84 further comprising adding an alpha hydroxy acid to the aqueous solution of pure silk fibroin-based protein fragments.

94. The method of claim 93 wherein the alpha hydroxy acid is selected from the group consisting of glycolic acid, lactic acid, tartaric acid and citric acid.

95. The method of claim 82 further comprising adding hyaluronic acid or its salt form at a concentration of about 0.5% to about 10.0% to the aqueous solution of pure silk fibroin-based protein fragments.

96. The method of claim 82 further comprising adding at least one of zinc oxide or titanium dioxide.

97. A film fabricated from an aqueous solution of pure silk fibroin-based protein fragments produced by the method of claim 84 and comprising from about 1.0 wt. % to about 50.0 wt. % of vitamin C or a derivative thereof, wherein the cosmetic film has a water content ranging from about 2.0 wt. % to about 20.0 wt. %.

98. The film of claim 97 comprising from about 30.0 wt. % to about 99.5 wt. % of pure silk fibroin-based protein fragments.

99. A gel fabricated from an aqueous solution of pure silk fibroin-based protein fragments produced by the method of claim 84 and comprising from about 0.5 wt. % to about 20.0 wt. % of vitamin C or a derivative thereof.

100. The gel of claim 99 having a silk content of at least 2% and a vitamin content of at least 20%.

101. A method for preparing an aqueous solution of pure silk fibroin-based protein fragments having an average weight average molecular weight ranging from about 39 kDa to about 80 kDa, the method comprising:

adding a silk source to a boiling aqueous solution of sodium carbonate for a treatment time of about 30 minutes so as to result in degumming;

removing sericin from the solution to produce a silk fibroin extract substantially devoid of sericin;

draining the solution from the silk fibroin extract;

dissolving the silk fibroin extract in a solution of lithium bromide having a starting temperature upon placement of the silk fibroin extract in the lithium bromide solution that ranges from about 80°C to about 140°C;

maintaining the solution of silk fibroin-lithium bromide in a dry oven having a temperature in the range between about 60°C to about 100°C for a period of at least 1 hour;

removing the lithium bromide from the silk fibroin extract; and

producing an aqueous solution of pure silk fibroin-based protein fragments,

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises lithium bromide residuals of between 0 ppm and about 300 ppm,

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises sodium carbonate residuals of between 0 ppm and about 100 ppm,

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises fragments having an average weight average molecular weight ranging from about 39 kDa to about 80 kDa, and

wherein the aqueous solution of pure silk fibroin-based protein fragments comprises a polydispersity of between about 1.0 and about 3.0.

102. The method of claim 101 further comprising drying the silk fibroin extract prior to the dissolving step.

103. The method of claim 101 wherein the aqueous solution of pure silk fibroin-based protein fragments comprise lithium bromide residuals of less than 300 ppm as measured using a high-performance liquid chromatography lithium bromide assay.

104. The method of claim 101 wherein the aqueous solution of pure silk fibroin-based protein fragments comprise sodium carbonate residuals of less than 100 ppm as measured using a high-performance liquid chromatography sodium carbonate assay.

105. The method of claim 101 further comprising adding a therapeutic agent to the aqueous solution of pure silk fibroin-based protein fragments.

106. The method of claim 101 further comprising adding a molecule selected from one of an antioxidant or an enzyme to the aqueous solution of pure silk fibroin-based protein fragments.

107. The method of claim 101 further comprising adding a vitamin to the aqueous solution of pure silk fibroin-based protein fragments.

108. The method of claim 107 wherein the vitamin is vitamin C or a derivative thereof.

109. The method of claim 101 further comprising lyophilizing the aqueous solution of pure silk fibroin-based protein fragments.

110. The method of claim 101 further comprising adding an alpha hydroxy acid to the aqueous solution of pure silk fibroin-based protein fragments.

111. The method of claim 110 wherein the alpha hydroxy acid is selected from the group consisting of glycolic acid, lactic acid, tartaric acid and citric acid.

112. The method of claim 101 further comprising adding hyaluronic acid or its salt form at a concentration of about 0.5% to about 10.0% to the aqueous solution of pure silk fibroin-based protein fragments.

113. The method of claim 101 further comprising adding at least one of zinc oxide or titanium dioxide.

114. A film fabricated from an aqueous solution of pure silk fibroin-based protein fragments produced by the method of claim 100 and comprising from about 1.0 wt. % to about 50.0 wt. % of vitamin C or a derivative thereof, wherein the cosmetic film has a water content ranging from about 2.0 wt. % to about 20.0 wt. %.

115. The film of claim 114 comprising from about 30.0 wt. % to about 99.5 wt. % of pure silk fibroin-based protein fragments.

116. A gel fabricated from an aqueous solution of pure silk fibroin-based protein fragments produced by the method of claim 100 and comprising from about 0.5 wt. % to about 20.0 wt. % of vitamin C or a derivative thereof.

117. The gel of claim 116 having a silk content of at least 2% and a vitamin content of at least 20%.

118. The composition of claim 1, wherein the composition has an average weight average molecular weight ranging from 6 kDa to 16 kDa, or 17 kDa to 38 kDa, or 39 kDa to 80 kDa.

119. The method of claim 67, wherein the pure silk fibroin-based protein fragments have an average weight average molecular weight ranging from 6 kDa to 16 kDa, or 17 kDa to 38 kDa, or 39 kDa to 80 kDa.