SUMMARY OF THE PRESENT DISCLOSURE

[006a] In an aspect of the present disclosure, there is provided a sterile oleogel comprising about 1 wt. % to about 20 wt. % of particles of a solid birch bark extract having an average particle size of less than about 50 μm, dispersed in one or more nonpolar liquids;
wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and
wherein the oleogel is sterilized by ionizing irradiation at doses ranging from about 11 to about 40 kGy.

[006b] In another aspect of the present disclosure, there is provided an oleogel comprising about 1 wt. % to about 20 wt. % of particles of a solid birch bark extract having an average particle size of less than about 50 μm, dispersed in one or more nonpolar liquids;
wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and
the oleogel has a consistency ranging from about 300-3000 mN; wherein the consistency is the force (mN) needed to penetrate 1 cm into the oleogel as measured using a texture analyser with a 1.27 cm cylindrical penetrating object, and the speed of penetration is 0.4 mm/s.

[006c] In a further aspect of the present disclosure, there is provided an oleogel, prepared by a process comprising:
dispersing about 1 wt.% to about 20 wt.% of a dried solid birch bark extract having an average particle size of less than about 50 μm in one or more non-polar liquids;
wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and
wherein the nonpolar liquid has a peroxide value less than about 3.

[006d] In another aspect of the present disclosure, there is provided a use of a sterile oleogel in the manufacture of a medicament for treating epidermolysis bullosa in a subject in need thereof, wherein the sterile oleogel comprises about 1 wt. % to about 20 wt. % of particles of a solid birch bark extract having an average particle size of less than about 50 μm, dispersed in one or more nonpolar liquids;

wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and
wherein the oleogel is sterilized by ionizing irradiation at doses ranging from about 11 to about 40 kGy.

[006e]In a further aspect of the present disclosure, there is provided a use of an oleogel in the manufacture of a medicament for treating epidermolysis bullosa in a subject in need thereof, wherein the oleogel comprises about 1 wt. % to about 20 wt. % of particles of a solid birch bark extract having an average particle size of less than about 50 µm, dispersed in one or more nonpolar liquids;
wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and
the oleogel has a consistency ranging from about 300-3000 mN; wherein the consistency is the force (mN) needed to penetrate 1 cm into the oleogel as measured using a texture analyser with a 1.27 cm cylindrical penetrating object, and the speed of penetration is 0.4 mm/s.

[006f] In another aspect of the present disclosure, there is provided a use of an oleogel in the manufacture of a medicament for treating epidermolysis bullosa in a subject in need thereof, wherein the oleogel is prepared by a process comprising:
dispersing about 1 wt.% to about 20 wt.% of a dried solid birch bark extract having an average particle size of less than about 50 µm in one or more non-polar liquids;
wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and
wherein the nonpolar liquid has a peroxide value less than about 3.

[006g] In a further aspect of the present disclosure, there is provided a sterile oleogel disclosed herein, or an oleogel disclosed herein, or an oleogel prepared by a process disclosed herein, for use in therapy.

[007] The present disclosure provides a solid birch bark extract that contains at least about 70% by weight of betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol and lupeol. The solid birch bark extracts described

herein may be formulated in an oleogel that possesses clinically-advantageous rheological properties.

[008] The present disclosure also provides a method of making a solid birch bark extract that may be dispersed in a nonpolar solvent to provide a clinically-advantageous oleogel comprising the steps of (a) contacting birch bark with a suitable solvent to form an extraction solution containing betulin and at least one triterpene; (b) separating the birch bark from the extraction solution; (c) cooling the extraction solution to crystallize a portion of the betulin and triterpene from the solution; (d) separating the crystallized betulin and triterpene; (e) drying the separated, crystallized betulin and triterpene to form a solid birch bark extract. The present disclosure also provides the solid birch bark extracts that are prepared according to these methods.

[009] The present disclosure provides a clinically-advantageous oleogel comprising about 1% to about 20% by weight of particles of the solid birch bark extract dispersed in about 80% to about 99% of one or more nonpolar liquids the solid birch bark extracts are dispersed in a suitable nonpolar liquid to form an oleogel. A sterile wound dressing comprising a pad and a therapeutically effective amount of the oleogel is also provided.

[010] The present disclosure provides an emulsion comprising an oleogel of the present ~~invention~~ disclosure and further provides a foam comprising an emulsion of the present disclosure.

[011] The present disclosure also provides methods of treating a wound in a patient by topically administering an effective amount of an oleogel, an emulsion or a foam of the present disclosure to at least a portion of the wound.

[012] The present disclosure also provides methods of treating epidermolysis bullosa in a patient in need thereof comprising topically administering an effective amount of an oleogel, an emulsion or a foam of the present disclosure to an area of epidermolysis bullosa of the patient.

[013] The present disclosure provides a solid birch bark extract, oleogel, sterile wound dressing, process of preparation, emulsion, foam, pressurized container, method of treating a wound, and method of treating epidermolysis bullosa according to the following numbered ~~embodiments~~examples:

1. A solid birch bark extract comprising at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol.

2. The sold birch bark extract of ~~embodiment~~example 1, wherein the solid birch extract has an HPLC chromatogram substantially identical to Figure 1 when chromatographed according to the following HPLC method:

Time (min)	Acetonitrile	Water	H_3PO_4 (v/v)	Flow rate (ml/min)
0	30	70	0.1%	0.6
5	30	30	0.1%	0.6
15	98	2	0.1%	0.6
20	98	2	0.1%	0.6
21	30	70	0.1%	0.6
30	30	70	0.1%	0.6

Column: C18, 2.6 µm, 150 x 2.1 mm; detector: 210 and 320 nm;

wherein the betulinic acid has a relative retention time of about 0.75 – 0.90, the oleanolic acid has a relative retention time of about 0.84-0.97, the betulin has a relative retention time of 1.00, the erythrodiol has a relative retention time of about 1.25-1.40, and the lupeol has a relative retention time of about 3.50-4.15.

3. The solid birch bark extract of ~~embodiment~~example 1 or 2, prepared by a process comprising:
    (a) contacting birch bark with a pharmaceutically acceptable solvent, thereby forming an extraction solution comprising betulin and one or more triterpenes;
    (b) separating the birch bark from the extraction solution;
    (c) cooling the extraction solution whereby a portion of the betulin and one or more triterpenes crystallizes from the cooled extraction solution;

(d) separating the crystallized betulin and one or more triterpenes from the cooled extraction solution;

(e) drying the separated, crystallized betulin and one or more triterpenes to provide the solid birch bark extract;

wherein if after drying, about 1 wt.% to about 20 wt.% of the dried solid birch bark extract of step (e) dispersed in refined sunflower oil forms an oleogel.

4. The solid birch bark extract of ~~embodiment~~example 3, wherein one or more of steps (a), (c), and (e) is carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

5. The solid birch bark extract of ~~embodiment~~example 3, wherein two or more of steps (a), (c), and (e) are carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

6. The solid birch bark extract of ~~embodiment~~example 3, wherein steps (a), (c), and (e) are carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

7. The solid birch bark extract of any one of ~~embodiment~~examples 3-6, wherein the pharmaceutically acceptable solvent is a hydrocarbon or alcohol, or combinations thereof.

8. The solid birch bark extract of any one of ~~embodiment~~examples 3-7, wherein the pharmaceutically acceptable solvent is a hydrocarbon selected from the group consisting of n-pentane, n-hexane, or n-heptane.

9. The solid birch bark extract of ~~embodiment~~example 8, wherein the pharmaceutically acceptable solvent is n-heptane, and said contacting is carried out at a temperature of about 60 °C to about 130 °C for about 8-12 minutes.

10. The solid birch bark extract of any one of ~~embodiment~~examples 3-9, wherein in step (c) the cooled extraction solution is supersaturated at least about 2-fold.

11. The solid birch bark extract of ~~embodiment~~example 10, wherein the cooled extraction solution is supersaturated about 5-fold.

12. The solid birch bark extract of any of ~~embodiment~~examples 3-11, wherein the amount of residual extraction solvent is no more than about 0.5 wt.%.

13. An oleogel comprising about 1 wt. % to about 20 wt. % of particles of the solid birch bark extract of any one of ~~embodiment~~examples 1-12, having an average particle size of less than about 50 μm, dispersed in about 80 wt.% to about 99 wt.% of one or more nonpolar liquids.

14. The oleogel of ~~embodiment~~example 13, wherein the dispersed solid birch bark extract particles are the only oleogel forming agent in the oleogel.

15. The oleogel of ~~embodiment~~example 13 or 14, comprising about 10 wt. % of particles of the solid birch bark extract.

16. The oleogel of any one of ~~embodiment~~examples 13 to 15, wherein the nonpolar liquid comprises at least one triglyceride.

17. The oleogel of any one of ~~embodiment~~examples 13 to 16, wherein the nonpolar liquid comprises at least one C7 or greater hydrocarbon.

18. The oleogel of ~~embodiment~~example 16, wherein the nonpolar liquid comprises one or more vegetable oils.

19. The oleogel of ~~embodiment~~example 18, wherein the nonpolar liquid comprises sunflower oil.

20. The oleogel of any one of ~~embodiment~~examples 13-19, wherein the nonpolar liquid has a peroxide value less than about 10.

21. The oleogel of ~~embodiment~~example 20, wherein the peroxide value is no more than about 3.

22. The oleogel of any one of ~~embodiment~~examples 13 - 21, wherein the oleogel is substantially free of solid birch bark extract particles having a size greater than about 50 μm.

23. The oleogel of any one of ~~embodiment~~examples 13-22, wherein the oleogel is sterile.

24. The oleogel of ~~embodiment~~example 23, wherein the oleogel is sterilized by ionizing irradiation at doses less than about 20 kGy.

25. The oleogel of ~~embodiment~~example 24, wherein the oleogel is sterilized by ionizing irradiation at doses ranging from about 11 to about 20 kGy.

26. The oleogel of any one of ~~embodiment~~examples 13-25, wherein the segregation of the nonpolar liquid from the oleogel is less than about 10% after centrifuging at 25°C for 30 min at 2750 g.

27. The oleogel of any one of ~~embodiment~~examples 13-26, wherein the viscosity at 200/s of the oleogel ranges from about 0.5 to about 4.0 Pa.s and the thixotropy value of the oleogel ranges from about 200 to about 1200 Pa.s as measured according to the rotating viscometer method described in Ph. Eur. 2.2.10 using a cone-plate viscometer.

28. The oleogel of any one of ~~embodiment~~examples 13-27, wherein the consistency of the oleogel ranges from about 300-3000 mN as measured according using a texture analyser.

29. The oleogel of any one of ~~embodiment~~examples 13-28, further comprising a disinfectant.

30. The oleogel of ~~embodiment~~example 29, wherein the disinfectant is selected from the group consisting of ethanol, n-propanol, and isopropanol.

31. The oleogel of any one of ~~embodiment~~examples 13-28, further comprising a lipophilic antibiotic.

32. A sterile wound dressing comprising:
(a) a pad, and
(b) a therapeutically effective layer comprising the oleogel of any of ~~embodiment~~examples 13-31 disposed on at least one surface of the pad.

33. The sterile wound dressing of ~~embodiment~~example 32, wherein the pad is an absorbent pad.

34. A process for preparing the solid birch bark extract of ~~embodiment~~example 1 or 2, comprising:

(a) contacting birch bark with a pharmaceutically acceptable solvent, thereby forming an extraction solution comprising betulin and one or more triterpenes;
(b) separating the birch bark from the extraction solution;
(c) cooling the extraction solution whereby a portion of the betulin and one or more triterpenes crystallizes from the cooled extraction solution;
(d) separating the crystallized betulin and one or more triterpenes from the cooled extraction solution;
(e) drying the separated, crystallized betulin and one or more triterpenes to provide the solid birch bark extract;

wherein after drying, about 1 wt.% to about 20 wt.% of the dried solid birch bark extract of step (e) dispersed in refined sunflower oil forms an oleogel.

35. The process of ~~embodiment~~example 34, wherein one or more of steps (a), (c), and (e) is carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

36. The process of ~~embodiment~~example 34, wherein two or more of steps (a), (c), and (e) are carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

37. The process of ~~embodiment~~example 34, wherein steps (a), (c), and (e) are carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

38. The process of any one of ~~embodiment~~examples 34-37, wherein the pharmaceutically acceptable solvent is a hydrocarbon selected from the group consisting of n-pentane, n-hexane, or n-heptane.

39. The process of any one of ~~embodiment~~examples 34-38, wherein the pharmaceutically acceptable solvent is n-heptane, and said contacting is carried out at a temperature of about 115 °C to about 130 °C for about 8-12 minutes.

40. The process of any one of ~~embodiment~~examples 34-39, wherein in step (c) the cooled extraction solution is supersaturated at least about 2-fold.

41. The process of ~~embodiment~~example 40, wherein the cooled extraction solution is supersaturated about 5-fold.

42. The process of any of ~~embodiment~~examples 34-41, wherein the amount of residual extraction solvent is no more than about 0.5 wt.%.

43. An emulsion comprising the solid birch bark extract of any of ~~embodiment~~examples 1-12.

44. An emulsion comprising the oleogel of any of ~~embodiment~~examples 13-31.

45. The emulsion of ~~embodiment~~example 43 or 44, wherein said emulsion is a water-in-oil emulsion.

46. The emulsion of ~~embodiment~~example 45, substantially free of emulsifier.

47. The emulsion of any one of ~~embodiment~~examples 43-46, consisting essentially of the solid birch bark extract or oleogel, oil, and water.

48. The emulsion of any one of ~~embodiment~~examples 44-46, consisting of the oleogel, oil and water.

49. The emulsion of any one of ~~embodiment~~examples 43-46, further comprising a disinfectant.

50. The emulsion of ~~embodiment~~example 49, wherein the disinfectant is selected from the group consisting of ethanol, n-propanol, and isopropanol.

51. The emulsion of any one of ~~embodiment~~examples 43-46, further comprising a lipophilic antibiotic.

52. A foam comprising the emulsion of any one of ~~embodiment~~examples 43-51.

53. The foam of ~~embodiment~~example 52, further comprising a disinfectant.

54. The foam of ~~embodiment~~example 53, wherein the disinfectant is selected from the group consisting of ethanol, n-propanol, and isopropanol.

55. The foam of ~~embodiment~~example 52, further comprising a lipophilic antibiotic.

56. The foam of any of ~~embodiment~~examples 52-55, wherein the interfacial surface tension of the emulsion is greater than about 4 mN/m.

57. The foam of any of ~~embodiment~~examples 52-56, wherein the foam index is greater than about 2.

58. The foam of ~~embodiment~~example 52, wherein the oleogel consists of about 5 wt.% to about 10 wt.% solid birch bark extract and the emulsion is a water-in-oil emulsion consisting of the oleogel and about 20 wt.% to about 30 wt.% of water.

59. The foam of ~~embodiment~~example 58, wherein the oleogel consists of about 7 wt.% solid birch bark extract and the amount of water in the emulsion is about 25 wt.%.

60. The foam of any of ~~embodiment~~examples 52-56, further comprising an emulsifier selected from the group consisting of phosphatidyl choline, polyglyceryl-3-methyl glucose distearate, and combinations thereof.

61. A pressurized container filled with a mixture comprising the emulsion of any one of ~~embodiment~~examples 43-51 and a pharmaceutically acceptable propellant, whereby the emulsion forms a foam upon decanting at least a portion of the mixture from the container.

62. A method of treating a wound in a patient comprising topically administering the oleogel of any one of ~~embodiment~~examples 13-31 to at least a portion of the wound.

63. The oleogel of any one of ~~embodiment~~examples 13-31, for use in a method of treating a wound.

64. The method or oleogel for use of ~~embodiment~~example 63, wherein the wound is selected from the group consisting of a burns, surgical skin lesions, superficial injuries, chronic wounds, pressure ulcers, diabetic foot ulcers, chronic venous ulcers, artery insufficiency ulcers, wounds from aesthetic skin treatments, wounds from ablative laser skin treatments, wounds from chemical peels, wounds from dermabrasion, wounds resulting from adverse drug reactions, wounds resulting from toxic epidermal necrolysis, wounds resulting from Lyell syndrome, wounds resulting from Stevens-Johnson syndrome, and wounds resulting from radiation dermatitis.

65. A method of treating a wound in a patient comprising topically administering the emulsion of any one of ~~embodiment~~examples 43-51 to at least a portion of the wound.

66. The emulsion of any one of ~~embodiment~~examples 43-51, for use in a method of treating a wound.

67. The method or emulsion for use of ~~embodiment~~example 66, wherein the wound is selected from the group consisting of burns, surgical skin lesions, superficial injuries, chronic wounds, pressure ulcers, diabetic foot ulcers, chronic venous ulcers, artery insufficiency ulcers, wounds from aesthetic skin treatments, wounds from ablative laser skin treatments, wounds from chemical peels, wounds from dermabrasion, wounds resulting from adverse drug reactions, wounds resulting from toxic epidermal necrolysis, wounds resulting from Lyell syndrome, wounds resulting from Stevens-Johnson syndrome, and wounds resulting from radiation dermatitis.

68. A method of treating a wound in a patient comprising topically administering the foam of any one of ~~embodiment~~examples 52-60 to at least a portion of the wound.

69. The foam of any one of ~~embodiment~~examples 52-60, for use in a method of treating a wound.

70. The method or foam for use of ~~embodiment~~example 69, wherein the wound is selected from the group consisting of burns, surgical skin lesions, superficial injuries, chronic

wounds, pressure ulcers, diabetic foot ulcers, chronic venous ulcers, artery insufficiency ulcers, wounds from aesthetic skin treatments, wounds from ablative laser skin treatments, wounds from chemical peels, wounds from dermabrasion, wounds resulting from adverse drug reactions, wounds resulting from toxic epidermal necrolysis, wounds resulting from Lyell syndrome, wounds resulting from Stevens-Johnson syndrome, and wounds resulting from radiation dermatitis.

71. A method of treating epidermolysis bullosa in a patient in need thereof comprising topically administering to an area of epidermolysis bullosa of the patient the oleogel of any one of ~~embodiment~~examples 13-31.

72. The oleogel of any one of ~~embodiment~~examples 13-31, for use in a method of treating epidermolysis bullosa.

73. A method of treating epidermolysis bullosa in a patient in need thereof comprising topically administering to an area of epidermolysis bullosa of the patient the emulsion of any one of ~~embodiment~~examples 43-51.

74. The emulsion of any one of ~~embodiment~~examples 43-51, for use in a method of treating epidermolysis bullosa.

75. A method of treating epidermolysis bullosa in a patient in need thereof comprising topically administering to an area of epidermolysis bullosa of the patient the foam of any one of ~~embodiment~~examples 52-60.

76. The foam of any one of ~~embodiment~~examples 52-60, for use in a method of treating epidermolysis bullosa.

DETAILED DESCRIPTION OF THE DRAWINGS

[014] FIG. 1. shows the HPLC chromatograph taken from a solid birch bark extract monitoring 210 nm (top figure) and 320 nm (bottom figure). The x-axis in FIG. 1 is the retention time (min), and the y-axis is the peak intensity (mAU).

CLAIMS

What is claimed is:

1. A solid birch bark extract comprising at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol.

2. The solid birch bark extract of claim 1, wherein the solid birch extract has an HPLC chromatogram substantially identical to Figure 1 when chromatographed according to the following HPLC method:

Time (min)	Acetonitrile	Water	H_3PO_4 (v/v)	Flow rate (ml/min)
0	30	70	0.1%	0.6
5	30	30	0.1%	0.6
15	98	2	0.1%	0.6
20	98	2	0.1%	0.6
21	30	70	0.1%	0.6
30	30	70	0.1%	0.6

Column: C18, 2.6 µm, 150 x 2.1 mm; detector: 210 and 320 nm;

wherein the betulinic acid has a relative retention time of about 0.75 – 0.90, the oleanolic acid has a relative retention time of about 0.84-0.97, the betulin has a relative retention time of 1.00, the erythrodiol has a relative retention time of about 1.25-1.40, and the lupeol has a relative retention time of about 3.50-4.15.

3. The solid birch bark extract of claim 1 or claim 2, prepared by a process comprising:

(a) contacting birch bark with a pharmaceutically acceptable solvent, thereby forming an extraction solution comprising betulin and one or more triterpenes;

(b) separating the birch bark from the extraction solution;

(c) cooling the extraction solution whereby a portion of the betulin and one or more triterpenes crystallizes from the cooled extraction solution;

(d) separating the crystallized betulin and one or more triterpenes from the cooled extraction solution;

(e) drying the separated, crystallized betulin and one or more triterpenes to provide the solid birch bark extract;

wherein if after drying, about 1 wt.% to about 20 wt.% of the dried solid birch bark extract of step (e) dispersed in refined sunflower oil forms an oleogel.

4. The solid birch bark extract of claim 3, wherein one or more of steps (a), (c), and (e) is carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

5. The solid birch bark extract of claim 3, wherein two or more of steps (a), (c), and (e) are carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

6. The solid birch bark extract of claim 3, wherein steps (a), (c), and (e) are carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

7. The solid birch bark extract of any one of claims 3-6, wherein the pharmaceutically acceptable solvent is a hydrocarbon or alcohol, or combinations thereof.

~~8. The solid birch bark extract of any one of claims 3-7, wherein the pharmaceutically acceptable solvent is a hydrocarbon selected from the group consisting of n-pentane, n-hexane, or n-heptane.~~

~~9. The solid birch bark extract of claim 8, wherein the pharmaceutically acceptable solvent is n-heptane, and said contacting is carried out at a temperature of about 60 °C to about 130 °C for about 8-12 minutes.~~

~~10. The solid birch bark extract of any one of claims 3-9, wherein in step (c) the cooled extraction solution is supersaturated at least about 2-fold.~~

~~11. The solid birch bark extract of claim 10, wherein the cooled extraction solution is supersaturated about 5-fold.~~

~~12. The solid birch bark extract of any of claims 3-11, wherein the amount of residual extraction solvent is no more than about 0.5 wt.%.~~

~~13~~1. A~~n~~ sterile oleogel comprising about 1 wt. % to about 20 wt. % of particles of ~~the~~ a solid birch bark extract ~~of any one of claims 1-12,~~ having an average particle size of less than about 50 μm, dispersed in ~~about 80 wt.% to about 99 wt.% of~~ one or more nonpolar liquids;

wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and

wherein the oleogel is sterilized by ionizing irradiation at doses ranging from about 11 to about 40 kGy.

2. The sterile oleogel of claim 1, wherein the oleogel is sterilized by ionizing irradiation at doses ranging from about 11 to about 20 kGy.

3. The sterile oleogel of claim 1, wherein the ionizing radiation is X-ray or gamma radiation.

~~1~~4. The sterile oleogel of claim 1~~3~~, wherein the dispersed solid birch bark extract particles are the only oleogel forming agent in the oleogel.

~~1~~5. The sterile oleogel of claim 1~~3~~, ~~comprising~~ wherein the oleogel comprises about 10 wt. % of particles of the solid birch bark extract.

~~16. The oleogel of claim 13 or 15, wherein the nonpolar liquid comprises at least one triglyceride.~~

~~17~~6. The sterile oleogel of claim 1~~3 or 15~~, wherein the nonpolar liquid comprises at least one C7 or greater hydrocarbon.

~~18~~7. The sterile oleogel of claim 1~~6~~, wherein the nonpolar liquid comprises one or more vegetable oils.

~~19~~8. The sterile oleogel of claim 7~~18~~, wherein the nonpolar liquid ~~comprises~~ is sunflower oil.

~~20. The oleogel of any one of claims 13-19, wherein the nonpolar liquid has a peroxide value less than about 10.~~

~~21. The oleogel of claim 20, wherein the peroxide value is no more than about 3.~~

~~22~~9. The sterile oleogel of ~~any one of~~ claim~~s~~ 1~~3-21~~, wherein the oleogel is substantially free of solid birch bark extract particles having a size greater than about 50 μm.

~~23. The oleogel of any one of claims 13-22, wherein the oleogel is sterile.~~

~~24. The oleogel of claim 23, wherein the oleogel is sterilized by ionizing irradiation at doses less than about 20 kGy.~~

~~25. The oleogel of claim 24, wherein the oleogel is sterilized by ionizing irradiation at doses ranging from about 11 to about 20 kGy.~~

~~26~~10. The sterile oleogel of ~~any one of~~ claim~~s~~ 1~~3-25~~, wherein the segregation of the nonpolar liquid from the oleogel is less than about 10% after centrifuging at 25°C for 30 min at 2750 g.

~~27~~11. The sterile oleogel of ~~any one of~~ claim~~s~~ 1~~3-26~~, wherein the viscosity at 200/s of the oleogel ranges from about 0.5 to about 4~~.0~~ Pa.s and the thixotropy value of the oleogel ranges from about 200 to about 1200 Pa.s as measured according to the rotating viscometer method described in Ph. Eur. 2.2.10 using a cone-plate viscometer.

12. An oleogel comprising about 1 wt. % to about 20 wt. % of particles of a solid birch bark extract having an average particle size of less than about 50 μm, dispersed in one or more nonpolar liquids;

wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and

the oleogel has a consistency ranging from about 300-3000 mN; wherein the consistency is the force (mN) needed to penetrate 1 cm into the oleogel as measured using a texture analyser with a 1.27 cm cylindrical penetrating object, and the speed of penetration is 0.4 mm/s.

13. The oleogel of claim 12, wherein the dispersed solid birch bark extract particles are the only oleogel forming agent in the oleogel.

14. The oleogel of claim 12, wherein the oleogel comprises about 10 wt. % of particles of the solid birch bark extract.

15. The oleogel of claim 12, wherein the nonpolar liquid comprises at least one C7 or greater hydrocarbon.

16. The oleogel of claim 12, wherein the nonpolar liquid comprises one or more vegetable oils.

17. The oleogel of claim 16, wherein the nonpolar liquid is sunflower oil.

18. The oleogel of claim 12, wherein the oleogel is substantially free of solid birch bark extract particles having a size greater than about 50 μm.

19. The oleogel of claim 12, wherein the segregation of the nonpolar liquid from the oleogel is less than about 10% after centrifuging at 25°C for 30 min at 2750 g.

20. The oleogel of claim 12, wherein the viscosity at 200/s of the oleogel ranges from about 0.5 to about 4 Pa·s and the thixotropy value of the oleogel ranges from about 200 to about 1200 Pa·s as measured according to the rotating viscometer method described in Ph. Eur. 2.2.10 using a cone-plate viscometer.

21. An oleogel, prepared by a process comprising:

dispersing about 1 wt.% to about 20 wt.% of a dried solid birch bark extract having an average particle size of less than about 50 μm in one or more non-polar liquids;

wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and

wherein the nonpolar liquid has a peroxide value less than about 3.

22. The oleogel of claim 21, wherein the oleogel comprises about 10 wt. % of particles of the solid birch bark extract.

23. The oleogel of claim 21, wherein the nonpolar liquid comprises at least one C7 or greater hydrocarbon.

24. The oleogel of claim 21, wherein the nonpolar liquid comprises one or more vegetable oils.

25. The oleogel of claim 24, wherein the nonpolar liquid is sunflower oil.

26. The oleogel of claim 21, wherein the oleogel is substantially free of solid birch bark extract particles having a size greater than about 50 μm.

27. The oleogel of claim 21, wherein the segregation of the nonpolar liquid from the oleogel is less than about 10% after centrifuging at 25°C for 30 min at 2750 g.

28. The oleogel of claim 21, wherein the viscosity at 200/s of the oleogel ranges from about 0.5 to about 4 Pa·s and the thixotropy value of the oleogel ranges from about 200 to about 1200 Pa·s as measured according to the rotating viscometer method described in Ph. Eur. 2.2.10 using a cone-plate viscometer.

~~28. The oleogel of any one of claims 13-27, wherein the consistency of the oleogel ranges from about 300-3000 mN as measured according using a texture analyser.~~

~~29. The oleogel of any one of claims 13-28, further comprising a disinfectant.~~

~~30. The oleogel of claim 29, wherein the disinfectant is selected from the group consisting of ethanol, n-propanol, and isopropanol.~~

~~31. The oleogel of any one of claims 13-28, further comprising a lipophilic antibiotic.~~

~~32. A sterile wound dressing comprising:~~

~~(a) a pad, and~~

~~(b) a therapeutically effective layer comprising the oleogel of any of claims 13-31 disposed on at least one surface of the pad.~~

~~33. The sterile wound dressing of claim 32, wherein the pad is an absorbent pad.~~

~~34. A process for preparing the solid birch bark extract of claim 1 or claim 2 comprising:~~

~~(a) contacting birch bark with a pharmaceutically acceptable solvent, thereby forming an extraction solution comprising betulin and one or more triterpenes;~~

~~(b) separating the birch bark from the extraction solution;~~

~~(c) cooling the extraction solution whereby a portion of the betulin and one or more triterpenes crystallizes from the cooled extraction solution;~~

(d) separating the crystallized betulin and one or more triterpenes from the cooled extraction solution;

(e) drying the separated, crystallized betulin and one or more triterpenes to provide the solid birch bark extract;

wherein after drying, about 1 wt.% to about 20 wt.% of the dried solid birch bark extract of step (e) dispersed in refined sunflower oil forms an oleogel.

35. The process of claim 34, wherein one or more of steps (a), (c), and (e) is carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

36. The process of claim 34, wherein two or more of steps (a), (c), and (e) are carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

37. The process of claim 34, wherein steps (a), (c), and (e) are carried out under the following conditions:

(i) said contacting of step (a) is carried out at a temperature of about 60° C to about 130° C;

(ii) said cooling of step (c) is carried out at a temperature of about -20° C to about 35° C;

(iii) said drying of step (e) is carried out at a temperature of about 75° C to about 95° C at a pressure of less than about 70 mbar.

~~38. The process of claim 34, wherein the pharmaceutically-acceptable solvent is a hydrocarbon selected from the group consisting of n-pentane, n-hexane, or n-heptane.~~

~~39. The process of any one of claims 34-38, wherein the pharmaceutically-acceptable solvent is n-heptane, and said contacting is carried out at a temperature of about 115 °C to about 130 °C for about 8-12 minutes.~~

~~40. The process of any one of claims 34-39, wherein in step (c) the cooled extraction solution is supersaturated at least about 2-fold.~~

~~41. The process of claim 40, wherein the cooled extraction solution is supersaturated about 5-fold.~~

~~42. The process of any of claims 34-41, wherein the amount of residual extraction solvent is no more than about 0.5 wt.%.~~

~~43. An emulsion comprising the solid birch bark extract of any of claims 1-12.~~

~~44. An emulsion comprising the oleogel of any of claims 13-31.~~

~~45. The emulsion of claim 43 or 44, wherein said emulsion is a water-in-oil emulsion.~~

~~46. The emulsion of claim 45, substantially free of emulsifier.~~

~~47. The emulsion of any one of claims 43-46, consisting essentially of the solid birch bark extract or oleogel, oil, and water.~~

~~48. The emulsion of any one of claims 44-46, consisting of the oleogel, oil and water.~~

~~49. The emulsion of any one of claims 43-46, further comprising a disinfectant.~~

~~50. The emulsion of claim 49, wherein the disinfectant is selected from the group consisting of ethanol, n-propanol, and isopropanol.~~

~~51. The emulsion of any one of claims 43-46, further comprising a lipophilic antibiotic.~~

~~52. A foam comprising the emulsion of any one of claims 43-51.~~

~~53. The foam of claim 52, further comprising a disinfectant.~~

~~54. The foam of claim 53, wherein the disinfectant is selected from the group consisting of ethanol, n-propanol, and isopropanol.~~

~~55. The foam of claim 52, further comprising a lipophilic antibiotic.~~

~~56. The foam of any of claims 52-55, wherein the interfacial surface tension of the emulsion is greater than about 4 mN/m.~~

~~57. The foam of any of claims 52-56, wherein the foam index is greater than about 2.~~

~~58. The foam of claim 52, wherein the oleogel consists of about 5 wt.% to about 10 wt.% solid birch bark extract and the emulsion is a water-in-oil emulsion consisting of the oleogel and about 20 wt.% to about 30 wt.% of water.~~

~~59. The foam of claim 58, wherein the oleogel consists of about 7 wt.% solid birch bark extract and the amount of water in the emulsion is about 25 wt.%.~~

~~60. The foam of any of claims 52-56, further comprising an emulsifier selected from the group consisting of phosphatidyl choline, polyglyceryl-3-methyl glucose distearate, and combinations thereof.~~

~~61. A pressurized container filled with a mixture comprising the emulsion of any one of claims 43-51 and a pharmaceutically acceptable propellant, whereby the emulsion forms a foam upon decanting at least a portion of the mixture from the container.~~

~~62. A method of treating a wound in a patient comprising topically administering the oleogel of any one of claims 13-31 to at least a portion of the wound.~~

~~63. The oleogel of any one of claims 13-31, for use in a method of treating a wound.~~

~~64. The method or oleogel for use of claim 63, wherein the wound is selected from the group consisting of a burns, surgical skin lesions, superficial injuries, chronic wounds, pressure ulcers, diabetic foot ulcers, chronic venous ulcers, artery insufficiency ulcers, wounds from aesthetic skin treatments, wounds from ablative laser skin treatments, wounds from chemical peels, wounds from dermabrasion, wounds resulting from adverse drug reactions, wounds resulting from toxic epidermal necrolysis, wounds resulting from Lyell syndrome, wounds resulting from Stevens-Johnson syndrome, and wounds resulting from radiation dermatitis.~~

~~65. A method of treating a wound in a patient comprising topically administering the emulsion of any one of claims 43-51 to at least a portion of the wound.~~

~~66. The emulsion of any one of claims 43-51, for use in a method of treating a wound.~~

~~67. The method or emulsion for use of claim 66, wherein the wound is selected from the group consisting of burns, surgical skin lesions, superficial injuries, chronic wounds, pressure ulcers, diabetic foot ulcers, chronic venous ulcers, artery insufficiency ulcers, wounds from aesthetic skin treatments, wounds from ablative laser skin treatments, wounds from chemical peels, wounds from dermabrasion, wounds resulting from adverse drug reactions, wounds resulting from toxic epidermal necrolysis, wounds resulting from Lyell syndrome, wounds resulting from Stevens-Johnson syndrome, and wounds resulting from radiation dermatitis.~~

~~68. A method of treating a wound in a patient comprising topically administering the foam of any one of claims 52-60 to at least a portion of the wound.~~

~~69. The foam of any one of claims 52-60, for use in a method of treating a wound.~~

~~70. The method or foam for use of claim 69, wherein the wound is selected from the group consisting of burns, surgical skin lesions, superficial injuries, chronic wounds, pressure ulcers, diabetic foot ulcers, chronic venous ulcers, artery insufficiency ulcers, wounds from aesthetic skin treatments, wounds from ablative laser skin treatments,~~

~~wounds from chemical peels, wounds from dermabrasion, wounds resulting from adverse drug reactions, wounds resulting from toxic epidermal necrolysis, wounds resulting from Lyell syndrome, wounds resulting from Stevens-Johnson syndrome, and wounds resulting from radiation dermatitis.~~

~~71~~29. Use of a sterile oleogel in the manufacture of a medicament for~~A method of~~ treating epidermolysis bullosa in a ~~patient~~ subject in need thereof~~ comprising topically administering to an area of epidermolysis bullosa of the patient the oleogel of any one of claims 13-31~~, wherein the sterile oleogel comprises about 1 wt. % to about 20 wt. % of particles of a solid birch bark extract having an average particle size of less than about 50 μm, dispersed in one or more nonpolar liquids;

wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and

wherein the oleogel is sterilized by ionizing irradiation at doses ranging from about 11 to about 40 kGy.

30. The use of claim 29, wherein the oleogel is sterilized by ionizing irradiation at doses ranging from about 11 to about 20 kGy.

31. The use of claim 29, wherein the ionizing radiation is X-ray or gamma radiation.

32. The use of claim 29, wherein the dispersed solid birch bark extract particles are the only oleogel forming agent in the oleogel.

33. The use of claim 29, wherein the oleogel comprises about 10 wt. % of particles of the solid birch bark extract.

34. The use of claim 29, wherein the nonpolar liquid comprises one or more vegetable oils.

35. The use of claim 34, wherein the nonpolar liquid is sunflower oil.

36. The use of claim 29, wherein the oleogel is substantially free of solid birch bark extract particles having a size greater than about 50 μm.

37. The use of claim 29, wherein the segregation of the nonpolar liquid from the oleogel is less than about 10% after centrifuging at 25°C for 30 min at 2750 g.

38. The use of claim 29, wherein the viscosity at 200/s of the oleogel ranges from about 0.5 to about 4 Pa·s and the thixotropy value of the oleogel ranges from about 200 to about 1200 Pa·s as measured according to the rotating viscometer method described in Ph. Eur. 2.2.10 using a cone-plate viscometer.

39. Use of an oleogel in the manufacture of a medicament for treating epidermolysis bullosa in a subject in need thereof, wherein the oleogel comprises about 1 wt. % to about 20 wt. % of particles of a solid birch bark extract having an average particle size of less than about 50 μm, dispersed in one or more nonpolar liquids;

wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and

the oleogel has a consistency ranging from about 300-3000 mN; wherein the consistency is the force (mN) needed to penetrate 1 cm into the oleogel as measured using a texture analyser with a 1.27 cm cylindrical penetrating object, and the speed of penetration is 0.4 mm/s.

40. The use of claim 39, wherein the dispersed solid birch bark extract particles are the only oleogel forming agent in the oleogel.

41. The use of claim 39, wherein the oleogel comprises about 10 wt. % of particles of the solid birch bark extract.

42. The use of claim 39, wherein the nonpolar liquid comprises one or more vegetable oils.

43. The use of claim 42, wherein the nonpolar liquid is sunflower oil.

44. The use of claim 39, wherein the oleogel is substantially free of solid birch bark extract particles having a size greater than about 50 μm.

45. The use of claim 39, wherein the segregation of the nonpolar liquid from the oleogel is less than about 10% after centrifuging at 25°C for 30 min at 2750 g.

46. The use of claim 39, wherein the viscosity at 200/s of the oleogel ranges from about 0.5 to about 4 Pa·s and the thixotropy value of the oleogel ranges from about 200 to about 1200 Pa·s as measured according to the rotating viscometer method described in Ph. Eur. 2.2.10 using a cone-plate viscometer.

47. Use of an oleogel in the manufacture of a medicament for treating epidermolysis bullosa in a subject in need thereof, wherein the oleogel is prepared by a process comprising:

dispersing about 1 wt.% to about 20 wt.% of a dried solid birch bark extract having an average particle size of less than about 50 μm in one or more non-polar liquids;

wherein the solid birch bark extract comprises at least about 70 wt. % betulin and one or more triterpenes selected from the group consisting of betulinic acid, oleanolic acid, erythrodiol, and lupeol; and

wherein the nonpolar liquid has a peroxide value less than about 3.

48. The use of claim 47, wherein the oleogel comprises about 10 wt. % of particles of the solid birch bark extract.

49. The use of claim 47, wherein the nonpolar liquid comprises one or more vegetable oils.

50. The use of claim 49, wherein the nonpolar liquid is sunflower oil.

51. The use of claim 47, wherein the oleogel is substantially free of solid birch bark extract particles having a size greater than about 50 μm.

52. The use of claim 47, wherein the segregation of the nonpolar liquid from the oleogel is less than about 10% after centrifuging at 25°C for 30 min at 2750 g.

53. The use of claim 47, wherein the viscosity at 200/s of the oleogel ranges from about 0.5 to about 4 Pa·s and the thixotropy value of the oleogel ranges from about 200 to about 1200 Pa·s as measured according to the rotating viscometer method described in Ph. Eur. 2.2.10 using a cone-plate viscometer.

54. The use of claim 29, comprising topically administering the sterile oleogel to an area of epidermolysis bullosa.

55. The use of claim 39, comprising topically administering the oleogel to an area of epidermolysis bullosa.

56. The use of claim 47, comprising topically administering the oleogel to an area of epidermolysis bullosa.

~~72~~57. ~~The~~ A sterile oleogel of any one of claims 1~~3~~-~~3~~11, or an oleogel of any one of claims 12-20, or an oleogel prepared by a process of any one of claims 21-28, for use in therapy ~~a method of treating epidermolysis bullosa~~.

~~73. A method of treating epidermolysis bullosa in a patient in need thereof comprising topically administering to an area of epidermolysis bullosa of the patient the emulsion of any one of claims 43-51.~~

~~74. The emulsion of any one of claims 43-51, for use in a method of treating epidermolysis bullosa.~~

~~75. A method of treating epidermolysis bullosa in a patient in need thereof comprising topically administering to an area of epidermolysis bullosa of the patient the foam of any one of claims 52-60.~~

~~76. The foam of any one of claims 52-60, for use in a method of treating epidermolysis bullosa.~~