[0007] Provided herein for the first time are data demonstrating the viscosity-lowering effects of certain excipients for high concentration antibody formulation. The data support the viscosity-lowering effects of basic amino acids, or a salt thereof, as well as calcium salts or magnesium salts. The data also support the stability of such high concentration antibody formulations.

[0007a] In one aspect, the present disclosure refers to an aqueous composition comprising (a) an anti-TSLP antibody at a concentration greater than 140 mg/mL and less than 300 mg/ml, (b) a surfactant which is a polysorbate at a concentration less than or equal to 0.005% (w/v) to 0.015% (w/v), and (c) at least one basic amino acid or a salt thereof selected from the group consisting of arginine, histidine or lysine, wherein the composition comprises 10 mM to 200 mM basic amino acid or a salt thereof, wherein i) the arginine salt is arginine acetate, arginine aspartate, arginine glutamate, arginine glycolate, arginine lactate, arginine methanesulfonate, arginine propionate, or a combination thereof; ii) the histidine salt is histidine acetate, histidine aspartate, histidine glutamate, histidine glycolate, histidine lactate, histidine methanesulfonate, histidine propionate, or a combination thereof; or iii) the lysine salt is lysine acetate, lysine aspartate, lysine glutamate, lysine glycolate, lysine lactate, lysine methanesulfonate, lysine propionate, or a combination thereof, having a pH of 4.5 to 6.75 and wherein the viscosity of the aqueous composition is less than 100 cP at 23 °C, 1000s^{-1}, wherein the anti-TSLP antibody comprises (A) a light chain variable domain comprising: (i) a light chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:3; (ii) a light chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:4; and (iii) a light chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO:5; and (B) a heavy chain variable domain comprising: (i) a heavy chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:6; (ii) a heavy chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:7, and (iii) a heavy chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO: 8.

[0007b] In another aspect, the present disclosure refers to an aqueous composition comprising (a) an anti-TSLP antibody at a concentration greater than 140 mg/mL and less than 300 mg/ml, (b) a surfactant which is a polysorbate at a concentration less than or equal to 0.005% (w/v) to 0.015% (w/v), and (c) at least one calcium salt or magnesium salt, wherein the composition comprises 15 mM to 150 mM calcium salt or magnesium salt, having a pH of 4.5 to 6.75 and wherein the viscosity of the aqueous composition is less than 100 cP at 23 °C, 1000s^{-1}, wherein the anti-TSLP antibody comprises (A) a light chain variable domain comprising: (i) a light chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:3; (ii) a light chain

CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:4; and (iii) a light chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO:5; and (B) a heavy chain variable domain comprising: (i) a heavy chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:6; (ii) a heavy chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:7, and (iii) a heavy chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO: 8.

[0007c] In another aspect, the present disclosure refers to an article of manufacture comprising the aqueous composition disclosed herein, optionally, comprising 1 mL to 5 mL of the aqueous composition.

[0007d] In another aspect, the present disclosure refers to a pre-filled syringe comprising the aqueous composition disclosed herein, optionally, comprising 1 mL to 5 mL of the aqueous composition.

[0007e] In another aspect, the present disclosure refers to a vial comprising the aqueous composition disclosed herein, optionally, comprising 1 mL to 5 mL of the aqueous composition.

[0007f] In another aspect, the present disclosure refers to an autoinjector containing the aqueous composition disclosed herein.

[0007g] In another aspect, the present disclosure refers to use of the aqueous composition disclosed herein in the manufacture of a medicament for treating an inflammatory disease, wherein the inflammatory disease is selected from the group consisting of: asthma, atopic dermatitis, chronic obstructive pulmonary disease (COPD), nasal polyps, chronic spontaneous urticaria, eosinophilic esophagitis (EoE), Ig-driven disease, IgA nephropathy, lupus nephritis, eosinophilic gastritis, chronic sinusitis without nasal polyps and idiopathic pulmonary fibrosis (IPF).

[0007h] In another aspect, the present disclosure refers to a method of making a stable, liquid antibody composition having a viscosity of less than about 100 cP and comprising (A) an anti-TSLP antibody at a concentration greater than about 140 mg/mL and less than 300 mg/ml, (B) a surfactant which is a polysorbate, and (C) a basic amino acid or a salt thereof selected from the group consisting of arginine, histidine or lysine, a calcium salt, a magnesium salt, or a combination thereof, said method comprising: (i) combining the antibody with an aqueous solution comprising 50 mM to 150 mM basic amino acid or a salt thereof, a calcium salt, a magnesium salt, or a combination thereof and (ii) adding a surfactant to achieve a final concentration of 0.01% (w/v) ± 0.005% (w/v) surfactant, having a pH of 4.5 to 6.75, wherein the anti-TSLP antibody comprises (A) a light chain variable domain comprising: (i) a light chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:3; (ii) a light chain

CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:4; and (iii) a light chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO:5; and (B) a heavy chain variable domain comprising: (i) a heavy chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:6; (ii) a heavy chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:7, and (iii) a heavy chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO: 8.

[0008] Accordingly, in one example, the present disclosure provides a composition, e.g., aqueous composition, comprising (a) an anti-TSLP antibody at a concentration greater than about 140 mg/mL, (b) a surfactant, and (c) at least one basic amino acid or a salt thereof. Also contemplated is an aqueous composition, comprising (a) an anti-TSLP antibody at a concentration greater than about 140 mg/mL, (b) a surfactant, and (c) at least one basic amino acid or a salt thereof, wherein the composition comprises about 10 mM to about 200 mM basic amino acid or a salt thereof. In exemplary examples, the basic amino acid is arginine. Optionally, the salt is an organic salt of arginine. In various examples, the arginine salt is arginine acetate, arginine aspartate, arginine glutamate, arginine glycolate, arginine lactate, arginine methanesulfonate, arginine propionate, or a combination thereof. In exemplary examples, the basic amino acid is histidine. Optionally, the salt is an organic salt of histidine. In exemplaryexamples, the histidine salt is histidine acetate, histidine aspartate, histidine glutamate, histidine glycolate, histidine lactate, histidine methanesulfonate, histidine propionate, or a combination thereof. In various examples, the basic amino acid is lysine. Optionally the salt is an organic salt of lysine. In various examples, the lysine salt is lysine acetate, lysine aspartate, lysine glutamate, lysine glycolate, lysine lactate, lysine methanesulfonate, lysine propionate, or a combination thereof.

[0009] In one example, the present disclosure also provides a composition, e.g., aqueous composition, comprising (a) an anti-TSLP antibody at a concentration greater than about 140 mg/mL, (b) a surfactant, and (c) at least one calcium salt or magnesium salt. Also contemplated is an aqueous composition, comprising (a) an anti-TSLP antibody at a concentration greater than about 140 mg/mL, (b) a surfactant, and (c) at least one calcium salt or magnesium salt, wherein the composition comprises about 15 mM to about 150 mM calcium salt or magnesium salt. In exemplaryexamples, the calcium salt or magnesium salt comprises a counterion lacking chloride. Optionally, the counterion is acetate, aspartate, glutamate, glycolate, lactate, methanesulfonate, propionate, or a combination thereof. In various examples, the calcium salt is calcium acetate, calcium aspartate, calcium glutamate, calcium glycolate, calcium lactate, calcium methanesulfonate, calcium propionate, or a combination thereof. In exemplary examples, the magnesium salt is magnesium acetate, magnesium aspartate, magnesium glutamate,

WHAT IS CLAIMED:

1. An aqueous composition comprising (a) an anti-TSLP antibody at a concentration greater than 140 mg/mL and less than 300 mg/ml, (b) a surfactant which is a polysorbate at a concentration less than or equal to 0.005% (w/v) to 0.015% (w/v), and (c) at least one basic amino acid or a salt thereof selected from the group consisting of arginine, histidine or lysine, wherein the composition comprises 10 mM to 200 mM basic amino acid or a salt thereof, wherein i) the arginine salt is arginine acetate, arginine aspartate, arginine glutamate, arginine glycolate, arginine lactate, arginine methanesulfonate, arginine propionate, or a combination thereof; ii) the histidine salt is histidine acetate, histidine aspartate, histidine glutamate, histidine glycolate, histidine lactate, histidine methanesulfonate, histidine propionate, or a combination thereof; or iii) the lysine salt is lysine acetate, lysine aspartate, lysine glutamate, lysine glycolate, lysine lactate, lysine methanesulfonate, lysine propionate, or a combination thereof,

having a pH of 4.5 to 6.75 and wherein the viscosity of the aqueous composition is less than 100 cP at 23 °C, $1000s^{-1}$,

wherein the anti-TSLP antibody comprises

(A) a light chain variable domain comprising: (i) a light chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:3; (ii) a light chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:4; and (iii) a light chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO:5; and

(B) a heavy chain variable domain comprising: (i) a heavy chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:6; (ii) a heavy chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:7, and (iii) a heavy chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO: 8.

2. The aqueous composition of claim 1, wherein i) the arginine salt is arginine acetate, arginine aspartate, arginine glutamate, arginine glycolate, arginine lactate, arginine methanesulfonate, arginine propionate, or a combination thereof; ii) the histidine salt is histidine acetate, histidine aspartate, histidine glutamate, histidine glycolate, histidine lactate, histidine methanesulfonate, histidine propionate, or a combination thereof; or iii) the lysine salt is lysine acetate, lysine aspartate, lysine glutamate, lysine glycolate, lysine lactate, lysine methanesulfonate, lysine propionate, or a combination thereof.

3. An aqueous composition comprising (a) an anti-TSLP antibody at a concentration greater than 140 mg/mL and less than 300 mg/ml, (b) a surfactant which is a polysorbate at a concentration less than or equal to 0.005% (w/v) to 0.015% (w/v), and (c) at least one calcium salt or magnesium salt, wherein the composition comprises 15 mM to 150 mM calcium salt or magnesium salt, having a pH of 4.5 to 6.75 and wherein the viscosity of the aqueous composition is less than 100 cP at 23 °C, $1000s^{-1}$,

wherein the anti-TSLP antibody comprises

(A) a light chain variable domain comprising: (i) a light chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:3; (ii) a light chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:4; and (iii) a light chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO:5; and

(B) a heavy chain variable domain comprising: (i) a heavy chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:6; (ii) a heavy chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:7, and (iii) a heavy chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO: 8.

4. The aqueous composition of claim 3, wherein the calcium salt or magnesium salt comprises a counterion lacking chloride, optionally wherein the counterion is acetate, aspartate, glutamate, glycolate, lactate, methanesulfonate, propionate, or a combination thereof.

5. The aqueous composition of claim 4, wherein i) the calcium salt is calcium acetate, calcium aspartate, calcium glutamate, calcium glycolate, calcium lactate, calcium methanesulfonate, calcium propionate, or a combination thereof; or ii) the magnesium salt is magnesium acetate, magnesium aspartate, magnesium glutamate, magnesium glycolate, magnesium lactate, magnesium methanesulfonate, magnesium propionate, or a combination thereof.

6. The aqueous composition of any one of the preceding claims, further comprising N-acetyl arginine (NAR), N-acetyl lysine, methionine, glycine, proline, sodium acetate, tris acetate, a histidine salt, or a calcium salt, optionally, in an amount of 50 mM to 250 mM.

7. The aqueous composition of claim 6, comprising an arginine salt and NAR or methionine or a combination thereof.

8. The aqueous composition of claim 7, wherein the arginine salt is arginine glutamate.

9. The aqueous composition of claim 8, comprising 25-190 mM arginine base and 25-200 mM glutamic acid, optionally comprising 140 mM arginine base and 150 mM glutamic acid.

10. The aqueous composition of any one of claims 8 to 9, comprising proline from 25 mM to 250 mM.

11. The aqueous composition of claim 10, comprising 80 mM arginine base, 85 mM glutamic acid and 100 mM L-Proline.

12. The aqueous composition of any one of claims 8 to 11, comprising 0.01% (w/v) Polysorbate 80.

13. The composition of claim 12, comprising 140 mM arginine base, 150 mM glutamic acid, 0.01% (w/v) Polysorbate 80, optionally comprising 80 mM arginine base, 85 mM glutamic acid, 100 mM L-Proline, 0.01% (w/v) Polysorbate 80.

14. The aqueous composition of claim 8, comprising 10-125 mM arginine base and 25-225 mM glutamic acid.

15. The aqueous composition of claim 8 or 14, comprising 95 mM arginine base and 170 mM glutamic acid.

16. The aqueous composition of any one of claims 14 to 15, comprising proline from 25 mM to 220 mM.

17. The aqueous composition of claim 16, comprising 50 mM arginine base, 95 mM glutamic acid and 85 mM L-Proline.

18. The aqueous composition of any one of claims 14 to 17, comprising 0.01% (w/v) polysorbate 80.

19. The aqueous composition of claim 18, comprising 95 mM arginine base, 170 mM glutamic acid, 0.01% (w/v) polysorbate 80, optionally comprising 50 mM arginine base, 95 mM glutamic acid and 85 mM L-Proline, 0.01% (w/v) polysorbate 80.

20. The aqueous composition of any one of the preceding claims, wherein the anti-TSLP antibody comprises:

(A) a light chain variable domain selected from the group consisting of:

i. a sequence of amino acids at least 80% identical to SEQ ID NO:12; or

ii. a sequence of amino acids encoded by a polynucleotide sequence that is at least 80% identical to SEQ ID NO:11; and

(B) a heavy chain variable domain selected from the group consisting of:

i. a sequence of amino acids that is at least 80% identical to SEQ ID NO:10; or

ii. a sequence of amino acids encoded by a polynucleotide sequence that is at least 80% identical to SEQ ID NO:9.

21. The aqueous composition of claim 6, comprising a calcium salt and NAR or methionine or a combination thereof.

22. The aqueous composition of claim 21, wherein the calcium salt is calcium glutamate.

23. The aqueous composition of claim 22, comprising 15-130 mM calcium and 30-300 mM glutamate, optionally comprising 100 mM calcium and 230 mM glutamate.

24. The aqueous composition of any one of claims 21 to 23, comprising proline from 25 to 250 mM.

25. The aqueous composition of claim 24, comprising 60 mM calcium, 140 mM glutamate and 70 mM L-Proline.

26. The aqueous composition of claim 21, comprising 15-195 mM calcium and 25-320 mM glutamate, optionally comprising 110 mM calcium and 240 mM glutamate.

27. The aqueous composition of any one of claims 21 or 26, comprising proline from 25 to 220 mM.

28. The aqueous composition of claim 27, comprising 70 mM calcium, 145 mM glutamate and 60 mM L-Proline.

29. The aqueous composition of any one of claims 21 to 28, comprising 0.01% (w/v) polysorbate 80.

30. The aqueous composition of claim 29, comprising 100 mM calcium, 230 mM glutamate, and 0.01% (w/v) polysorbate 80, optionally comprising 60 mM calcium, 140 mM glutamate, 70 mM L-Proline, 0.01% (w/v) polysorbate 80.

31. The aqueous composition of claim 29, comprising 110 mM calcium, 240 mM glutamate, 0.01% (w/v) polysorbate 80, optionally comprising 70 mM calcium, 145 mM glutamate, 60 mM L-Proline, 0.01% (w/v) polysorbate 80.

32. The aqueous composition of any one of claims 20 to 31, wherein the anti-TSLP antibody comprises:

(A) a light chain variable domain selected from the group consisting of:

i. a sequence of amino acids at least 80% identical to SEQ ID NO:12; or

ii. a sequence of amino acids encoded by a polynucleotide sequence that is at least 80% identical to SEQ ID NO:11; and

(B) a heavy chain variable domain selected from the group consisting of:

i. a sequence of amino acids that is at least 80% identical to SEQ ID NO:10; or

ii. a sequence of amino acids encoded by a polynucleotide sequence that is at least 80% identical to SEQ ID NO:9.

33. The aqueous composition of any one of the preceding claims, wherein the concentration of the anti-TSLP antibody is 160 mg/mL to 250 mg/mL.

34. The aqueous composition of claim 33, wherein the concentration of the anti-TSLP antibody is 175 mg/mL to 185 mg/mL, optionally, about 180 mg/mL.

35. The aqueous composition of claim 33, wherein the concentration of the anti-TSLP antibody is 189 mg/mL to 231 mg/mL, or 205 mg/mL to 215 mg/mL, optionally, about 210 mg/mL.

36. The aqueous composition of any one of the preceding claims, having a pH of 4.8 to 6.0.

37. The aqueous composition of claim 36, comprising 140 mM arginine base, 150 mM glutamic acid, 0.01% (w/v) polysorbate 80, pH 5.4, or comprising 80 mM arginine base, 85 mM glutamic acid, 100 mM L-Proline, 0.01% (w/v) polysorbate 80, pH 5.4.

38. The aqueous composition of claim 37, comprising 10-125 mM arginine base and 25-225 mM glutamic acid.

39. The aqueous composition of claim 36, comprising 95 mM arginine base, 170 mM glutamic acid, 0.01% (w/v) polysorbate 80, at pH 5.4, or comprising 50 mM arginine base, 95 mM glutamic acid, 85 mM L-Proline, 0.01% (w/v) polysorbate 80, at pH 5.4.

40. The aqueous composition of claim 36, comprising i) 100 mM calcium, 230 mM glutamate, 0.01% (w/v) polysorbate 80, at pH 5.0; ii) 60 mM calcium, 140 mM glutamate, 70 mM L-Proline, 0.01% (w/v) polysorbate 80, at pH 5.0; iii) comprising 110 mM calcium, 240 mM glutamate, 0.01% (w/v) polysorbate 80, at pH 5.0; or iv) comprising 70 mM calcium, 145 mM glutamate, 60 mM L-Proline, 0.01% (w/v) polysorbate 80, at pH 5.0.

41. The aqueous composition of any one of the preceding claims, wherein the viscosity of the aqueous composition is less than 75 cP at 23 °C, $1000s^{-1}$.

42. The composition of any one of the preceding claims, wherein the composition is isotonic or has an osmolality in a range of 200 mOsm/kg to 500 mOsm/kg, or 225 mOsm/kg to 400 mOsm/kg, or 250 mOsm/kg to 350 mOsm/kg.

43. The aqueous composition of any one of the preceding claims, wherein less than 5% of the antibody is degraded after storage at 2ºC to 8ºC for at least or about 12 months, as determined by Size Exclusion Chromatography (SEC).

44. The aqueous composition of claim 44, wherein less than 5% of the antibody is degraded after storage at 2ºC to 8ºC for 20 months to 26 months, as determined by Size Exclusion Chromatography (SEC).

45. The aqueous composition of any one of the preceding claims, wherein the anti-TSLP antibody is an IgG2 antibody.

46. The aqueous composition of any one of claims 20 to 46, wherein the anti-TSLP antibody is tezepelumab.

47. The aqueous composition of any one of claims 20 to 47, wherein the anti-TSLP antibody specifically binds to a TSLP polypeptide as set forth in amino acids 29-159 of SEQ ID NO: 2.

48. The aqueous composition of any one of claims 1 to 48, wherein both binding sites of the anti-TSLP antibody have identical binding to TSLP.

49. An article of manufacture comprising the aqueous composition of any one of the preceding claims, optionally, comprising 1 mL to 5 mL of the aqueous composition.

50. A pre-filled syringe comprising the aqueous composition of any one of claims 1-49, optionally, comprising 1 mL to 5 mL of the aqueous composition.

51. A vial comprising the aqueous composition of any one of claims 1-48, optionally, comprising 1 mL to 5 mL of the aqueous composition.

52. An autoinjector containing the aqueous composition of any one of claims 1-48.

53. The auto-injector of claim 53 wherein the auto-injector is an Ypsomed YpsoMate®.

54. Use of the aqueous composition of any one of the preceding claims in the manufacture of a medicament for treating an inflammatory disease, wherein the inflammatory disease is selected from the group consisting of: asthma, atopic dermatitis, chronic obstructive pulmonary disease (COPD), nasal polyps, chronic spontaneous urticaria, eosinophilic esophagitis (EoE), Ig-driven disease, IgA nephropathy, lupus nephritis, eosinophilic gastritis, chronic sinusitis without nasal polyps and idiopathic pulmonary fibrosis (IPF).

55. The use of claim 55, wherein the aqueous composition is to be administered to the subject by subcutaneous administration.

56. The use of any one of claims 55 to 56, wherein 1 mL to 5 mL of the aqueous composition is to be administered to the subject.

57. A method of making a stable, liquid antibody composition having a viscosity of less than 100 cP and comprising (A) an anti-TSLP antibody at a concentration greater than about 140 mg/mL and less than 300 mg/ml, (B) a surfactant which is a polysorbate, and (C) a basic amino acid or a salt thereof selected from the group consisting of arginine, histidine or lysine, a calcium salt, a magnesium salt, or a combination thereof, said method comprising: (i) combining the antibody with an aqueous solution comprising 50 mM to 150 mM basic amino acid or a salt thereof, a calcium salt, a magnesium salt, or a combination thereof and (ii) adding a surfactant to achieve a final concentration of 0.01% (w/v) ± 0.005% (w/v) surfactant, having a pH of 4.5 to 6.75,

wherein the anti-TSLP antibody comprises

(A) a light chain variable domain comprising: (i) a light chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:3; (ii) a light chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:4; and (iii) a light chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO:5; and

(B) a heavy chain variable domain comprising: (i) a heavy chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:6; (ii) a heavy chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:7, and (iii) a heavy chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO: 8.