

CLAIMS

1. A composition comprising greater than about 100 mg/ml of an anti-IL-33 antibody, at least 170 mM arginine or at least 150 mM lysine and a buffer, wherein the anti-IL-33 antibody comprises:
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- i. a heavy chain variable domain comprising a VHCDR1 having the sequence of SEQ ID NO: 1, a VHCDR2 having the sequence of SEQ ID NO: 2, a VHCDR3 having the sequence of SEQ ID NO: 3; and
 - ii. a light chain variable domain comprising a VLCDR1 having the sequence of SEQ ID NO: 5, a VLCDR2 having the sequence of SEQ ID NO: 6, and a VLCDR3 having the sequence of SEQ ID NO: 7.
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2. The composition of claim 1, wherein the anti-IL-33 antibody comprises:
- i. a heavy chain variable domain that is:

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 - i. a sequence of amino acids that is at least 95%, 90%, 85% or 80% identical to SEQ ID NO: 4; or
 - ii. a sequence of amino acids encoded by a polynucleotide sequence that is at least 80% identical to SEQ ID NO: 11;
 - ii. a light chain variable domain that is:

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 - i. a sequence of amino acids that is at least 95%, 90%, 85% or 80% identical to SEQ ID NO: 8; or
 - ii. a sequence of amino acids encoded by a polynucleotide sequence that is at least 80% identical to SEQ ID NO: 12; or
 - iii. a heavy chain variable domain of (a) and a light chain variable domain of (b).
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3. The composition of claim 1 or 2, wherein the anti-IL-33 antibody is an IgG1 antibody.
4. The composition of any preceding claim, wherein the anti-IL-33 antibody comprises a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO: 4, a light chain variable domain comprising the amino acid sequence of SEQ ID NO: 8, or a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO: 4 and a light chain comprising the amino acid sequence of SEQ ID NO: 8.
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5. The composition of any preceding claim, wherein the anti-IL-33 antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 9, a light chain comprising the amino acid sequence of SEQ ID NO: 10, or a heavy chain comprising the amino acid
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sequence of SEQ ID NO:9 and a light chain comprising the amino acid sequence of SEQ ID NO:10.

- 5 6. The composition of any preceding claim, wherein the anti-IL-33 antibody competes for binding to IL-33 with 33_640087-7B, in an *in vitro* HTRF competitive binding assay.
7. The composition of any preceding claim, wherein the anti-IL-33 antibody is present at a concentration less than about 200 mg/ml, optionally less than about 180 mg/ml, optionally from about 130 mg/ml to about 170 mg/ml.
- 10 8. The composition of any preceding claim, wherein the anti-IL-33 antibody is present at a concentration of 150 mg/ml $\pm$ 10%.
9. The composition of any preceding claim, further comprising a surfactant.
- 15 10. The composition of claim 9, wherein the surfactant is polysorbate, optionally wherein the surfactant is polysorbate 20, polysorbate 80 or a mixture thereof.
11. The composition of any one of claims 9 or 10, wherein the surfactant is at a concentration of about 0.005% (w/v) to about 0.05% (w/v).
- 20 12. The composition of claim 11, comprising 0.03% (w/v) $\pm$ 0.010% (w/v) surfactant.
13. The composition of any one of claims 10 to 12, wherein the surfactant is polysorbate 80.
- 25 14. The composition of any preceding claim, comprising at least about 190 mM arginine, optionally about 190 mM to about 250 mM arginine.
15. The composition of any preceding claim, comprising about 220 mM arginine.
- 30 16. The composition of any preceding claim, wherein the arginine is L-arginine hydrochloride.
17. The composition according to any of claims 1 to 13, comprising about 150 mM to about 250 mM lysine, optionally about 170 mM lysine.
- 35 18. The composition of any preceding claim, wherein the buffer is histidine, succinate or acetate.

19. The composition of claim 18, wherein the buffer is histidine, optionally wherein the buffer is L-histidine/L-histidine hydrochloride.
20. The composition of any preceding claim, wherein the buffer is at a concentration of about 10 mM to about 30 mM, optionally about 16 mM to about 24 mM, optionally about 17 mM to about 24 mM, optionally about 18 mM to about 24 mM.
21. The composition of either of claims 19 or 20, wherein the buffer is at a concentration of about 19 mM to about 21 mM, optionally 20 mM $\pm$ 10% buffer.
22. The composition of any preceding claim, which is a liquid.
23. The composition of any preceding claim, wherein the pH is less than about pH 6.0, optionally wherein the pH is about pH 5.0 to about pH 6.0.
24. The composition of any preceding claim, wherein the pH is about pH 5.5.
25. The composition of any one of claims 22 to 24, characterized by a reduced viscosity, relative to the viscosity of the anti-IL-33 antibody in a composition comprising 20 mM histidine, 80 mM arginine, 120 mM sucrose, 0.02% (w/v) polysorbate 80 at pH 6.0 and a lower concentration of the anti-IL-33 antibody, for example 50 mg/ml.
26. The composition of any of claims 22 to 25, wherein the viscosity is from about 5 cP to about 20 cP, optionally less than about 10 cP, such as about 9 cP.
27. The composition of any one of claims 22 to 26, characterized by the anti-IL-33 antibody having reduced reversible self-association relative to the reversible self-association of the anti-IL-33 antibody in a composition comprising 20 mM histidine, 80 mM arginine, 120 mM sucrose, 0.02% (w/v) polysorbate 80 at pH 6.0 and a lower concentration of the anti-IL-33 antibody, for example 50 mg/ml.
28. The composition of any preceding claim, comprising a weight % monomer of about 35% to about 50%.
29. The composition of any preceding claim, wherein less than about 5%, optionally less than about 2%, of the antibody aggregates after about 12 months to about 18 months of storage between about 2°C to about 8°C, as measured by size exclusion chromatography (SEC).

30. A composition comprising:

- i. about 130 mg/ml to about 170 mg/ml 33_640087-7B, about 0.03% (w/v) $\pm$ 0.015% polysorbate 80, about 220 mM arginine, and about 16 to about 24 mM histidine buffer, wherein the pH is pH 5.5 $\pm$ 0.5;
- 5 ii. about 130 mg/ml to about 170 mg/ml 33_640087-7B, about 0.02% (w/v) $\pm$ 0.015% polysorbate 80, about 170 mM lysine, and about 16 to about 24 mM histidine buffer, wherein the pH is pH 5.5 $\pm$ 0.5; or
- 10 iii. about 130 mg/ml to about 170 mg/ml 33_640087-7B, about 0.02% (w/v) $\pm$ 0.015% polysorbate 80, about 190 mM arginine, and about 16 to about 24 mM histidine buffer, wherein the pH is pH 5.5 $\pm$ 0.5

31. The composition of claim 30, comprising about 150 mg/ml 33_640087-7B.

15 32. The composition of either of claims 30 or 31, comprising about 18 mM to about 22 mM histidine buffer, optionally about 20 mM histidine buffer.

33. The composition of any of claims 30 to 32, which is a liquid.

20 34. An article of manufacture, comprising the composition of any preceding claim, optionally comprising 0.5 ml to about 5 ml (e.g., 1 ml to about 3 ml) of the composition.

35. A vial comprising the composition of any of claims 1 to 33, optionally comprising about 0.5 ml to about 5 ml (e.g., 1 ml to about 3 ml) of the composition.

25 36. A method of treating an IL-33-mediated disorder in a subject comprising administering to the subject a therapeutically effective amount of the composition of any one of claims 1 to 33.

30 37. The method of claim 36, wherein the IL-33-mediated disorder is asthma, atopic dermatitis or chronic obstructive pulmonary disorder, or diabetic kidney disease.

38. A method of making a stable, liquid composition having a viscosity of less than about 10 cP, and comprising greater than about 100 mg/ml of an anti-IL-33 antibody, at least about 170 mM arginine or about 150 mM lysine, a surfactant and a buffer, comprising the steps of:

- 35 i. combining in a solution the antibody, arginine and a buffer, to obtain a solution comprising about 100 mg/mL to about 200 mg/mL anti-IL-33 antibody, at least about 170 mM arginine or about 150 mM lysine, and buffer; and
- ii. adding a surfactant to the solution to achieve a final surfactant concentration of about 0.03% (w/v) $\pm$ 0.015% (w/v).

39. The method of claim 38, wherein the stable, liquid composition comprises about 220 mM arginine, optionally wherein the arginine is L-arginine hydrochloride.
- 5 40. The method of either claim 38 or 39, wherein the surfactant is polysorbate 80 and the buffer is made from histidine.
41. The method of any of claims 38 to 40, the method results in a stable, liquid formulation having a pH of from about pH 5 to about pH 6, optionally about pH 5.5.
- 10 42. The method of any one of claims 38 to 41, wherein the anti-IL-33 antibody is as defined in any of claims 1 to 5.
43. The method of any one of claims 38 to 42, wherein cP is measured at 23°C.

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