

WHAT IS CLAIMED IS:

1. An aqueous antibody formulation comprising:
5 about 0.1 mg/mL to about 500 mg/mL of an antibody or an antigen-binding fragment thereof;
about 1 mM to about 100 mM of a buffer; and
about 1 mM to about 750 mM of a salt selected from the group consisting of:
10 magnesium glutamate, magnesium acetate, magnesium aspartate, magnesium sulfate, arginine acetate, arginine aspartate, arginine glutamate, arginine sulfate, lysine acetate, lysine aspartate, lysine glutamate, lysine sulfate, sodium acetate, sodium aspartate, sodium glutamate, sodium sulfate, lithium acetate, lithium aspartate, lithium glutamate, and lithium sulfate,
wherein the formulation has a pH of about 4 to about 8.
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2. An aqueous antibody formulation comprising:
about 0.1 mg/mL to about 500 mg/mL of an antibody or an antigen-binding fragment thereof; and
about 1 mM to about 750 mM of a salt selected from the group consisting of:
20 magnesium glutamate, magnesium acetate, magnesium aspartate, magnesium sulfate, arginine acetate, arginine aspartate, arginine glutamate, arginine sulfate, lysine acetate, lysine aspartate, lysine glutamate, lysine sulfate, sodium acetate, sodium aspartate, sodium glutamate, sodium sulfate, lithium acetate, lithium aspartate, lithium glutamate, and lithium sulfate,
25 wherein the formulation has a pH of about 4 to about 8, preferably wherein the formulation is a buffer-free formulation.
3. The formulation of any one of claims 1 or 2, wherein the salt is
30 (a) magnesium glutamate, magnesium acetate, magnesium aspartate, or magnesium sulfate, or a combination thereof;

- (b) the salt is sodium acetate, sodium aspartate, sodium glutamate, or sodium sulfate;
- (c) the salt is lithium acetate, lithium aspartate, lithium glutamate, or lithium sulfate.

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- 4. The formulation of any one of claim 1-3, wherein the formulation comprises about 10 mM to about 750 mM of the salt, preferably wherein the formulation comprises about 20 mM to about 750 mM of the salt.

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- 5. The formulation of any one of claim 1-4, wherein
 - (i) the formulation comprises about 10 mM to about 750 mM of the salt;
 - (ii) the formulation comprises about 20 mM to about 750 mM of the salt.

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- 6. The formulation of any one of claims 1 and 3-5, wherein the buffer is selected from the group consisting of: acetate, succinate, gluconate, histidine, citrate, and phosphate.

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- 7. The formulation of any one of claims 1 and 3-6, wherein the formulation comprises about 1 mM to about 100 mM of the buffer, preferably wherein
 - (i) the formulation comprises about 1 mM to about 75 mM of the buffer;
 - (ii) the formulation comprises about 1 mM to about 50 mM of the buffer;
 - (iii) the formulation comprises about 1 mM to about 20 mM of the buffer.

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- 8. The formulation of any one of claims 1-7, wherein the formulation has a pH of about 5 to about 6, preferably wherein the formulation has a pH of about 5.5.
- 9. The formulation of any one of claims 1-8, wherein the formulation comprises an antibody, preferably wherein the antibody is a monoclonal antibody, more preferably wherein

- (i) the monoclonal antibody is a human antibody or a humanized antibody;
and/or
- (ii) the monoclonal antibody has an Fc amino acid substitution that decreases its
conformational stability as compared to a similar antibody not including the
Fc amino acid substitution; and/or
- (iii) the monoclonal antibody is an IgG1 or an IgG4 antibody; and/or
- (iv) the monoclonal antibody is an anti-C-X-C motif chemokine receptor 3
(CXCR3) monoclonal antibody, even more preferably wherein the anti-
CXCR3 monoclonal antibody comprises a heavy chain comprising SEQ ID
NO: 1 and a light chain comprising SEQ ID NO: 2; and/or
- (v) the monoclonal antibody is an anti-carcinoembryonic antigen-related cell
adhesion molecule 5 (CEACAM5) monoclonal antibody; even more
preferably the anti-CEACAM5 monoclonal antibody comprises a heavy chain
comprising SEQ ID NO: 7 and a light chain comprising SEQ ID NO: 8;
and/or
- (vi) the monoclonal antibody is an anti-carcinoembryonic antigen-related cell
adhesion molecule 5 (CEACAM5)-Fc engineered monoclonal antibody, even
more preferably wherein
- (1) the anti-CEACAM5-Fc engineered monoclonal antibody comprises a
heavy chain comprising SEQ ID NO: 9 and a light chain comprising
SEQ ID NO: 10;
- (2) the anti-CEACAM5-Fc engineered monoclonal antibody comprises a
heavy chain comprising SEQ ID NO: 11 and a light chain comprising
SEQ ID NO: 12;
- (3) the anti-CEACAM5-Fc engineered monoclonal antibody comprises a
heavy chain comprising SEQ ID NO: 13 and a light chain comprising
SEQ ID NO: 14.

10. The formulation of any one of claims 1-9, wherein the formulation comprises about 0.1 mg/mL to 400 mg/mL of the antibody or the antigen-binding antibody fragment, preferably wherein
- (i) the formulation comprises about 0.1 mg/mL to 250 mg/mL of the antibody or the antigen-binding antibody fragment;
 - (ii) the formulation comprises about 0.1 mg/mL to about 200 mg/mL of the antibody or the antigen-binding antibody fragment;
 - (iii) the formulation comprises about 0.1 mg/mL to about 150 mg/mL of the antibody or the antigen-binding antibody fragment;
 - (iv) the formulation comprises about 0.1 mg/mL to about 100 mg/mL of the antibody or the antigen-binding antibody fragment;
 - (v) the formulation comprises about 0.1 mg/mL to about 50 mg/mL of the antibody or the antigen-binding antibody fragment;
 - (vi) the formulation comprises about 0.1 mg/mL to about 25 mg/mL of the antibody or the antigen-binding antibody fragment.
11. The formulation of any one of claims 1-10, wherein
- (i) the formulation has a viscosity of about 1 cP to about 50 cP;
 - (ii) the formulation has a viscosity of about 1 cP to about 40 cP;
 - (iii) the formulation has a viscosity of about 1 cP to about 30 cP;
 - (iv) wherein the formulation has a viscosity of about 1 cP to about 20 cP.
12. The formulation of any one of claims 1-11, wherein
- (i) the formulation has an osmolality of about 250 mOsm/kg to about 1500 mOsm/kg;
 - (ii) the formulation has an osmolality of about 250 mOsm/kg to about 750 mOsm/kg;
 - (iii) the formulation has an osmolality of about 250 mOsm/kg to about 500 mOsm/kg;

(iv) the formulation has an osmolality of about 250 mOsm/kg to about 400 mOsm/kg.

13. The formulation of any one of claims 1-12, wherein

- 5 (i) the formulation is stable at 25 °C for about 1 hour to about 2 years;
(ii) the formulation is stable at 40 °C about 1 hour to about 8 weeks; and/or
(iii) the formulation is suitable for intravenous, intramuscular, or subcutaneous administration; and/or

10 (iv) the formulation further comprises one or more of a stabilizer, an anti-oxidant, a metal chelator, a viscosity modifier, an amino acid, and a surfactant, preferably wherein

(1) the stabilizer is fructose, maltose, galactose, glucose, O-mannose, sorbose, lactose, sucrose, trehalose, cellobiose, raffinose, melezitose, a maltodextrin, a dextran, starch, mannitol, xylitol, maltitol, lactitol,
15 glucitol, sucrose, trehalose, raffinose, maltose, sorbitol, mannitol, an amino sugar, sodium chloride, and glycerol; and/or

(2) the antioxidant is methionine, ascorbic acid, or N-acetyl cysteine; and/or

20 (3) the metal chelator is sodium ethylenediaminetetraacetic acid (EDTA), calcium EDTA, or diethylenetriamine pentaacetate (DTPA); and/or.

(4) the viscosity modifier is arginine, histidine, lysine, proline, glycine, or sodium chloride; and/or

25 (5) the surfactant is selected from the group consisting of: sorbitan monocaprylate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan trioleate, glycerine monocaprylate, glycerine monomyristate, glycerine monostearate, decaglyceryl monostearate, decaglyceryl distearate, decaglyceryl monolinoleate, polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monocleate, polyoxyethylene sorbitan monostearate, polyoxyethylene sorbitan monopalmitate,
30 polyoxyethylene sorbitan trioleate, polyoxyethylene sorbitan tristearate,

- polyoxyethylene sorbitol tetrastearate, polyoxyethylene sorbitol tetraoleate, polyoxyethylene glyceryl monostearate, polyethylene glycol distearate, polyoxyethylene lauryl ether, polyoxyethylene polyoxypropylene glycol, polyoxyethylene polyoxypropylene propyl ether, polyoxyethylene polyoxypropylene cetyl ether, polyoxyethylene nonylphenyl ether, polyoxyethylene castor oil, polyoxyethylene hydrogenated castor oil, polyoxyethylene sorbitol beeswax, polyoxyethylene lanolin, polyoxyethylene stearic acid amide, sodium cetyl sulfate, sodium lauryl sulfate, sodium oleyl sulfate, sodium polyoxyethylene lauryl sulfate, sodium lauryl sulfosuccinate ester, lecithin, a glycerophospholipid, a sphingophospholipid, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80, poloxamer 188, triton-X, sodium lauryl sulfate, polyethylene glycol, and propylene glycol; and/or
- (6) the amino acid is selected from the group consisting of: arginine, lysine, histidine, proline, ornithine, isoleucine, leucine, alanine, glycine, glutamic acid, and aspartic acid.
14. An injection device comprising a formulation of any one of claims 1-13.
15. A kit comprising one or more vials containing a formulation of any one of claims 1-13, preferably wherein the kit further comprises an injection device for administration of the formulation to a subject in need thereof.
16. A method of making an aqueous antibody formulation, the method comprising mixing or combining:
- (i) an antibody or an antigen-binding fragment thereof;
 - (ii) a buffer;
 - (iii) a salt selected from the group consisting of: magnesium glutamate, magnesium acetate, magnesium aspartate, magnesium sulfate, arginine

acetate, arginine aspartate, arginine glutamate, arginine sulfate, lysine acetate, lysine aspartate, lysine glutamate, lysine sulfate, sodium acetate, sodium aspartate, sodium glutamate, sodium sulfate, lithium acetate, lithium aspartate, lithium glutamate, and lithium sulfate, and

(iv) a stabilizer;

(v) a surfactant; and

(vi) sterile water,

wherein (i) to (vi) are mixed or combined in amounts sufficient to generate the formulation of any one of claims 1-13,

preferably wherein the method further comprises mixing or combining one or more of an antioxidant, a metal chelator, and a viscosity modifier to (i) to (vi).

17. A method of making an aqueous antibody formulation, the method comprising mixing or combining:

(i) an antibody or an antigen-binding fragment thereof;

(ii) a salt selected from the group consisting of: magnesium glutamate, magnesium acetate, magnesium aspartate, magnesium sulfate, arginine acetate, arginine aspartate, arginine glutamate, arginine sulfate, lysine acetate, lysine aspartate, lysine glutamate, lysine sulfate, sodium acetate, sodium aspartate, sodium glutamate, sodium sulfate, lithium acetate, lithium aspartate, lithium glutamate, and lithium sulfate, and

(iv) a stabilizer;

(v) a surfactant; and

(vi) sterile water,

wherein (i) to (v) are mixed or combined in amounts sufficient to generate the formulation of any one of claims 1-13, preferably wherein

(1) the method does not comprise mixing or combining a buffer with (i) to (v);

(2) the method further comprises mixing or combining one or more of an antioxidant, a metal chelator, and a viscosity modifier to (i) to (vi).

18. An aqueous antibody formulation of any one of claims 1-13 for use in treating a subject in need thereof, comprising administering a therapeutically effective amount of the aqueous antibody formulation to said subject.