CLAIMS

1. A lyophilized formulation of an emulsion comprising:

i) (4E,8E,12E,16E,20E)-N-{2-[{4-[(2-amino-4-{[(3S)-1-hydroxyhexan-3-yl]amino}-6-methylpyrimidin-5-yl)methyl]benzyl}(methyl)amino]ethyl}-4,8,12,17,21,25-hexamethylhexacosa-4,8,12,16,20,24-hexaenamide (hereinafter referred to as "Compound A"), or a pharmaceutically acceptable salt thereof;

ii) squalane;

iii) an antioxidant A selected from the group consisting of an ascorbate ester (e.g., L-ascorbic stearate, ascorbyl palmitate, etc.), an inorganic salt of ascorbic acid (e.g., potassium ascorbate, sodium ascorbate, calcium ascorbate, etc.), and ascorbic acid; and

iv) an excipient A selected from the group consisting of a non-reducing sugar and a sugar alcohol, provided that mannitol is excluded.

2. The formulation according to claim 1, further comprising v) a hydrophilic surfactant and vi) a lipophilic surfactant.

3. The formulation according to claim 1 or 2, wherein the emulsion is an oil-in-water emulsion.

4. The formulation according to claim 2 or 3, wherein the hydrophilic surfactant is polyoxyethylene sorbitan fatty acid esters (e.g., Polysorbate 20, Polysorbate 40, Polysorbate 60, Polysorbate 65, Polysorbate 80, etc.); polyoxyethylene hydrogenated castor oils (e.g., polyoxyethylene hydrogenated castor oil 10, polyoxyethylene hydrogenated castor oil 20, polyoxyethylene hydrogenated castor oil 40, polyoxyethylene hydrogenated castor oil 50, polyoxyethylene hydrogenated castor oil 60, etc.); or polyoxyethylene polyoxypropylene glycols (e.g., polyoxyethylene (42) polyoxypropylene (67) glycol, polyoxyethylene (54) polyoxypropylene (39) glycol, polyoxyethylene (105) polyoxypropylene (5) glycol, polyoxyethylene (124) polyoxypropylene (39) glycol, polyoxyethylene (160) polyoxypropylene (30) glycol, polyoxyethylene (196) polyoxypropylene (67) glycol, polyoxyethylene (200) polyoxypropylene (70) glycol, etc.).

5. The formulation according to claim 2 or 3, wherein the hydrophilic surfactant is Polysorbate 20, Polysorbate 40, Polysorbate 80, polyoxyethylene hydrogenated castor oil 60, or polyoxyethylene (160) polyoxypropylene (30) glycol.

6. The formulation according to claim 2 or 3, wherein the

hydrophilic surfactant is Polysorbate 20, Polysorbate 40, or Polysorbate 80.

7. The formulation according to any one of claims 2 to 6, wherein the lipophilic surfactant is sorbitan fatty acid esters (e.g., sorbitan fatty acid ester, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, sorbitan sesquioleate, sorbitan trioleate, medium-chain triglyceride, etc.); glycerin fatty acid esters (e.g., glycerin fatty acid ester, glyceryl monostearate, glyceryl monomyristate, glyceryl monooleate, glyceryl triisooctanoate, etc.); sucrose fatty acid esters (e.g., sucrose fatty acid ester, sucrose stearate, sucrose palmitate, etc.); or propylene glycol fatty acid esters (e.g., propylene glycol fatty acid ester, propylene glycol monostearate, etc.).

8. The formulation according to any one of claims 2 to 6, wherein the lipophilic surfactant is sorbitan fatty acid ester, sorbitan monooleate, sorbitan sesquioleate, or sorbitan trioleate.

9. The formulation according to any one of claims 2 to 6, wherein the lipophilic surfactant is sorbitan trioleate.

10. The formulation according to any one of claims 1 to 9, further comprising an antioxidant B selected from the group consisting of tocopherol (e.g., α-tocopherol, β-tocopherol, γ-tocopherol, δ-tocopherol, etc.); tocopherol acetate; and butyl hydroxyanisole.

11. The formulation according to claim 10, wherein the antioxidant B is tocopherol selected from the group consisting of α-tocopherol, β-tocopherol, γ-tocopherol, and δ-tocopherol.

12. The formulation according to claim 10, wherein the antioxidant B is α-tocopherol.

13. The formulation according to any one of claims 1 to 12, wherein the antioxidant A is ascorbyl palmitate, potassium ascorbate, sodium ascorbate, or ascorbic acid.

14. The formulation according to any one of claims 1 to 12, wherein the antioxidant A is sodium ascorbate or potassium ascorbate.

15. The formulation according to any one of claims 1 to 14, wherein the excipient A is a non-reducing sugar (e.g., sucrose, and trehalose); or a sugar alcohol (e.g., sorbitol,

erythritol, xylitol, maltitol, and lactitol).

16. The formulation according to any one of claims 1 to 14, wherein the excipient A is sucrose, trehalose, sorbitol, or xylitol.

17. The formulation according to any one of claims 1 to 14, wherein the excipient A is sucrose or trehalose.

18. The formulation according to any one of claims 1 to 17, wherein the blending amount of squalane is

50 to 500 times the weight of Compound A,

100 to 400 times the weight of Compound A, or

200 to 300 times the weight of Compound A.

19. The formulation according to any one of claims 1 to 18, wherein the blending amount of the antioxidant A is

0.5 to 500 times the weight of Compound A in terms of the weight of sodium ascorbate,

2.5 to 250 times the weight of Compound A in terms of the weight of sodium ascorbate, or

5 to 100 times the weight of Compound A in terms of the weight of sodium ascorbate.

20. The formulation according to any one of claims 1 to 19,

wherein the blending amount of the excipient A is

50 to 1000 times the weight of Compound A,

100 to 750 times the weight of Compound A, or

200 to 625 times the weight of Compound A.

21. The formulation according to any one of claims 1 to 20, wherein the weight of Compound A is

0.0001 to 0.65 times the weight obtained by excluding Compound A from the lyophilized formulation,

0.0002 to 0.35 times the weight obtained by excluding Compound A from the lyophilized formulation, or

0.0005 to 0.065 times the weight obtained by excluding Compound A from the lyophilized formulation.

22. The formulation according to any one of claims 1 to 21, wherein both D_{90} values of particle sizes of an emulsion immediately after preparation and an emulsion reconstituted after 6-month storage at 25°C as the lyophilized formulation are 1000 nm or less.

23. The formulation according to any one of claims 1 to 22, wherein an increased amount in the area percentage values of an impurity UK-1.02 after 6-month storage at 5°C as the lyophilized formulation is

5.0% or less, or

1.0% or less.

24. A vaccine adjuvant comprising the formulation according to any one of claims 1 to 23.

25. A vaccine comprising the formulation according to any one of claims 1 to 23 and an antigen.

26. The vaccine according to claim 25, wherein the antigen is derived from a pathogen.

27. A kit comprising the formulation according to any one of claims 1 to 23 and an antigen.