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, an inorganic salt of ascorbic acid, 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 Polysorbate 20, Polysorbate 40, Polysorbate 60, Polysorbate 65, Polysorbate 80, 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, 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, or polyoxyethylene (200) polyoxypropylene (70) glycol.

5. The formulation according to any one of claims 2 to 4, wherein the lipophilic surfactant is sorbitan fatty acid ester, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, sorbitan sesquioleate, sorbitan trioleate, medium-chain triglyceride, glycerin fatty acid ester, glyceryl monostearate, glyceryl monomyristate, glyceryl monooleate, glyceryl triisooctanoate, sucrose fatty acid ester, sucrose stearate, sucrose palmitate, propylene glycol fatty acid ester, or propylene glycol monostearate.

6. The formulation according to any one of claims 1 to 5, further comprising an antioxidant B selected from the group consisting of α-tocopherol, β-tocopherol, γ-tocopherol, δ-tocopherol, tocopherol acetate, and butyl hydroxyanisole.

7. The formulation according to any one of claims 1 to 6, wherein the antioxidant A is selected from the group consisting of L-ascorbic stearate, ascorbyl palmitate, potassium ascorbate, sodium ascorbate, calcium ascorbate, and ascorbic acid.

8. The formulation according to any one of claims 1 to 7, wherein the excipient A is sucrose, trehalose, sorbitol, erythritol, xylitol, maltitol, or lactitol.

9. The formulation according to any one of claims 1 to 8, 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.

10. The formulation according to any one of claims 2 to 9, wherein the blending amount of the hydrophilic surfactant is

0.5 to 250 times the weight of Compound A,

5 to 100 times the weight of Compound A, or

10 to 50 times the weight of Compound A.

11. The formulation according to any one of claims 2 to 10, wherein the blending amount of the lipophilic surfactant is

0.5 to 250 times the weight of Compound A,

5 to 100 times the weight of Compound A, or

10 to 50 times the weight of Compound A.

12. The formulation according to any one of claims 1 to 11, 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.

13. The formulation according to any one of claims 1 to 12, 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.

14. The formulation according to any one of claims 6 to 13, wherein the blending amount of the antioxidant B is

5 to 250 times the weight of Compound A,

12.5 to 125 times the weight of Compound A, or

25 to 50 times the weight of Compound A.

15. The formulation according to any one of claims 1 to 14, 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.

16. The formulation according to any one of claims 1 to 15, wherein a D_{90} value of particle sizes of an emulsion reconstituted after 6-month storage at 25°C as the lyophilized formulation is 1000 nm or less.

17. The formulation according to any one of claims 1 to 16, 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.

18. The formulation according to any one of claims 1 to 17,

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.

19. The formulation according to any one of claims 1 to 18, wherein a D_{90} value of particle sizes of an emulsion reconstituted after 6-month storage at 5°C as the lyophilized formulation is 1000 nm or less.

20. The formulation according to any one of claims 1 to 19, wherein a D_{90} value of particle sizes of an emulsion during preparation is 1000 nm or less.

21. A vaccine adjuvant comprising the formulation according to any one of claims 1 to 20.

22. A vaccine comprising the formulation according to any one of claims 1 to 20 and an antigen.

23. The vaccine according to claim 22, wherein the antigen is derived from a pathogen.

24. A kit comprising the formulation according to any one

of claims 1 to 20 and an antigen.