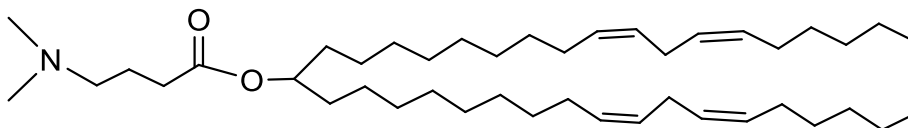


Allowed Claims USSN 12/813,448

1. A cationic lipid of formula I:



Formula I,

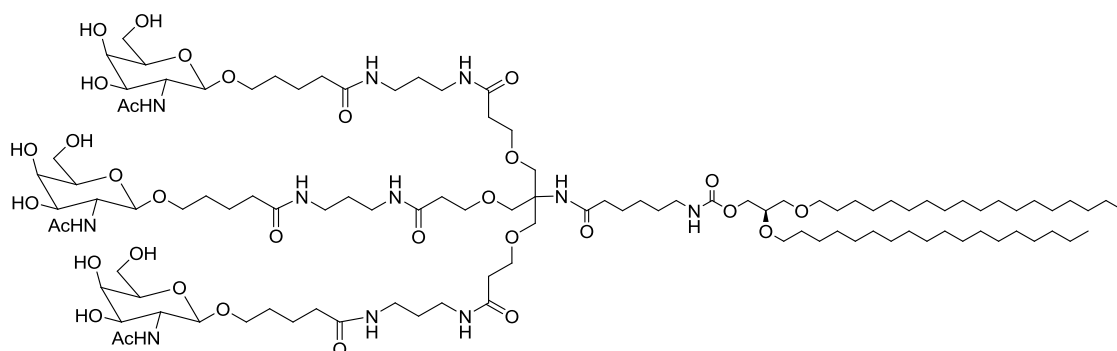
or a pharmaceutically acceptable salt thereof.

2. A lipid formulation comprising a cationic lipid of claim 1.
3. The lipid formulation of claim 2, comprising 40-65% of cationic lipid of formula I, 5-10% of a neutral lipid, 25-40% of a sterol, and 0.5-10% of a PEG or PEG-modified lipid.
4. The lipid formulation of claim 3, wherein the neutral lipid is selected from DSPC, DPPC, DMPC, POPC, DOPE and SM.
5. The lipid formulation of claim 3, wherein the sterol is cholesterol.
6. The lipid formulation of claim 3, wherein the PEG lipid is PEG-C₁₄ to PEG-C₂₂, PEG-Cer₁₄ to PEG-C₂₀, or PEG-DSPE.
7. The lipid formulation of claim 3, wherein the formulation is prepared by an in-line mixing method.
8. The lipid formulation of claim 3, comprising about 57.5% of cationic lipid of formula I, about 7.5% of the neutral lipid, about 31.5 % of the sterol, and about 3.5% of the PEG or PEG-modified lipid.
9. The lipid formulation of claim 8, wherein the formulation is prepared by an extrusion method.

10. The lipid formulation of claim 2, further comprising a therapeutic agent.
11. The lipid formulation of claim 10, wherein the therapeutic agent comprises a nucleic acid.
12. The lipid formulation of claim 11, wherein the nucleic acid is selected from the group consisting of an siRNA, an antisense nucleic acid, a microRNA, an antimicroRNA, an antagomir, a microRNA inhibitor, a microRNA activator, an immune stimulatory nucleic acid or a Ua adaptor.
13. The lipid formulation of claim 12, wherein the ratio of lipid:nucleic acid is about 3 to about 15.
14. The lipid formulation of claim 13, wherein the ratio of lipid:nucleic acid about 5 to about 13.
15. The lipid formulation of claim 2, further comprising at least one apolipoprotein.
16. The lipid formulation of claim 15, wherein the apolipoprotein is ApoE, active polymorphic forms, isoforms, variants and mutants, and fragments or truncated forms thereof.
17. The lipid formulation of claim 2, further comprising a targeting lipid.
18. The formulation of claim 17, wherein the targeting lipid comprises N-acetyl galactosamine.
19. The formulation of claim 18, wherein the N-acetyl galactosamide comprises at least a mono-, bi- or a triantennary sugar unit.

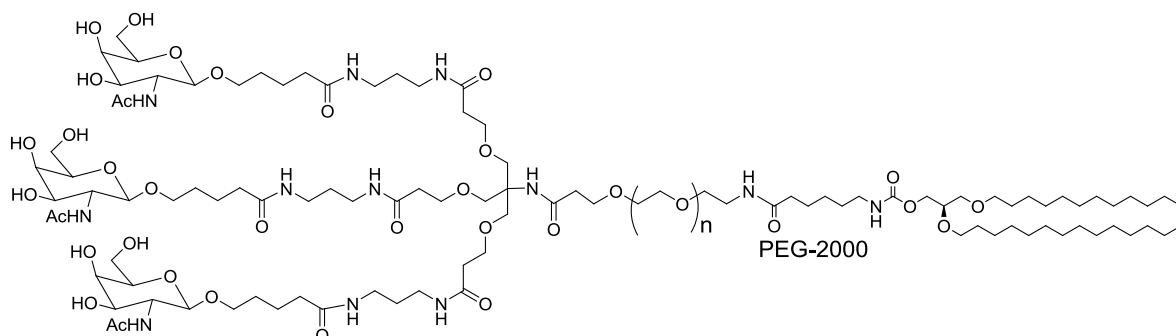
20. The formulation of claim 17, wherein said targeting lipid is present in the formulation in a molar amount of from about 0.001% to about 5%.

21. The formulation of claim 17, wherein said targeting lipid is the compound selected from the group consisting of Formula II, Formula III, Formula VI and Formula VII:



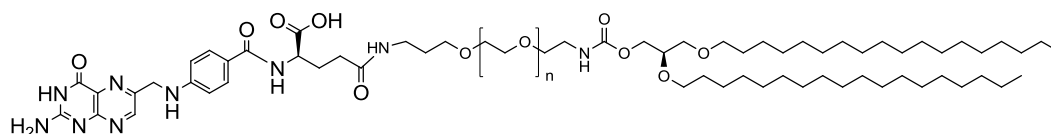
Formula II

GalNAc3-DSG



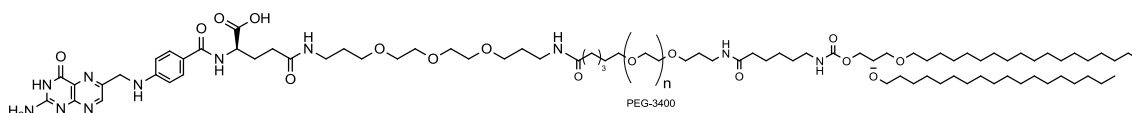
Formula III

GalNAc3-PEG-DSG



Folate-PEG2000-DSG

Formula VI



Folate-PEG3400-DSG

Formula VII.

22. The lipid formulation of claim 3, comprising about 50% of cationic lipid of formula I, about 10% of the neutral lipid, about 38.5 % of the sterol, and about 1.5% of the PEG or PEG-modified lipid.

23. The lipid formulation of claim 3, comprising about 50% of cationic lipid of formula I, about 10% of the neutral lipid, about 35% of the sterol, and about 5% of the PEG or PEG-modified lipid.

24. The lipid formulation of claim 3, comprising about 57.2% of cationic lipid of formula I, about 7.1% of the neutral lipid, about 34.3% of the sterol, and about 1.4% of the PEG or PEG-modified lipid.

25. A method of delivering a therapeutic agent to a cell comprising administering to a subject the lipid formulation of claim 10.

26. The method of claim 25, wherein the therapeutic agent is a dsRNA.

27. The method of claim 26, wherein the target gene is Factor VII.

28. The method of claim 26, further comprising comparing expression of the target gene with a preselected reference value.

29. The method of claim 26, wherein the therapeutic agent is an antisense, siRNA, ribozyme or microRNA.

30. A method of modulating the expression of a target gene in a cell, the method comprising providing to a cell the lipid formulation of claim 10.