CLAIMS

1. An immunogenic composition comprising an Rv1196 related antigen which comprises a sequence having at least 90% identity to SEQ ID No: 1 or a fragment of SEQ ID No: 1 which is at least 350 amino acids in length, wherein:
(i) the conductivity of the composition is 13 mS/cm or lower; and/or
(ii) the concentration of salts in said composition is 130 mM or lower; and/or
(iii) the concentration of sodium chloride in said composition is 130 mM or lower.

2. The immunogenic composition according to claim 1, wherein the conductivity of the composition is 10 mS/cm or lower.

3. The immunogenic composition according to claim 2, wherein the conductivity of the composition is 3 mS/cm or lower.

4. The immunogenic composition according to any one of claims 1 to 3, wherein the concentration of salts in said composition is 100 mM or lower.

5. The immunogenic composition according to claim 4, wherein the concentration of salts in said composition is 40 mM or lower.

6. The immunogenic composition according to any one of claims 1 to 5, wherein the concentration of sodium chloride in said composition is 100 mM or lower.

7. The immunogenic composition according to claim 6, wherein the concentration of sodium chloride in said composition is 40 mM or lower.

8. The immunogenic composition according to any one of claims 1 to 7, wherein the concentration of $CaCl_2$ in the immunogenic composition is 30 mM or lower.

9. The immunogenic composition according to any one of claims 1 to 8, wherein the concentration of $MgSO_4$ in the immunogenic composition is 60 mM or lower.

10. The immunogenic composition according to any one of claims 1 to 9, total concentration of NH_4^+, Mg^{2+} and Ca^{2+} ions is 40 mM or lower.

11. The immunogenic composition according to claim any one of claims 1 to 10, further comprising a non-ionic tonicity agent.

12. The immunogenic composition according to claim 11, wherein the non-ionic tonicity agent is a polyol.

13. The immunogenic composition according to claim 12, wherein the polyol is sorbitol.

14. The immunogenic composition according to claim 13, wherein the concentration of sorbitol is between about 4 and about 6% (w/v).

15. The immunogenic composition according to any one of claims 1 to 13, wherein the concentration of sucrose is between about 4 and about 6% (w/v).

16. The immunogenic composition according to any one of claims 1 to 15, further comprising one or more immunostimulants.

17. The immunogenic composition according to claim 16, wherein the immunostimulant is a saponin and/or a TLR4 agonist.

18. The immunogenic composition according to claim 17, wherein the immunostimulant(s) is/are in the form of liposomes.

19. The immunogenic composition according to either claim 17 or 18, wherein the saponin is QS21.

20. The immunogenic composition according to any one of claims 17 to 19, wherein the TLR4 agonist is 3-de-O-acylated monophoshoryl lipid A.

21. The immunogenic composition according to any one of claims 1 to 20, wherein the osmolality is 250 to 750 mOsm/kg.

22. The immunogenic composition according to any one of claims 1 to 21, wherein the composition is provided as a unit dose of between 50 ul and 1 ml.

23. The immunogenic composition according to claim 22, wherein the unit dose is between 100 ul and 750 ul.

24. The immunogenic composition according to claim 22 or 23, wherein a unit dose contains 1 to 100 ug of Rv1196 related protein.

25. The immunogenic composition according to claim 24, wherein a unit dose contains 5 to 50 ug of Rv1196 related protein.

26. The immunogenic composition according to any one of claims 22 to 25, wherein the unit dose is a human dose and contains between 1 and 100 ug of 3D-MPL.

27. The immunogenic composition according to any one of claims 22 to 26, wherein the unit dose is a human dose and contains between 1 and 100 ug of QS21.

28. The immunogenic composition according to any one of claims 1 to 27, wherein the pH of said composition is in the range 7.0 to 9.0.

29. The immunogenic composition according to any one of claims 1 to 28, wherein the Rv1196 related antigen comprises a fragment of SEQ ID No: 1 which is at least 350 amino acids in length.

30. The immunogenic composition according to any one of claims 1 to 28, wherein the Rv1196 related antigen comprises a sequence having at least 90% identity to SEQ ID No: 7.

31. The immunogenic composition according to any one of claims 1 to 28, wherein the Rv1196 related antigen consists of a sequence having at least 90% identity to SEQ ID No: 7.

32. The immunogenic composition according to claim 31, wherein the Rv1196 related antigen comprises the amino acid sequence of SEQ ID No: 7.

33. The immunogenic composition according to claim 32, wherein the Rv1196 related antigen consists of the amino acid sequence of SEQ ID No: 7.

34. The immunogenic composition according to any one of claims 1 to 33, for use in medicine.

35 Use of an immunogenic composition according to any one of claims 1 to 33 in the manufacture of a medicamentfor the prophylaxis, treatment or amelioration of infection by mycobacteria, such as infection by *Mycobacterium tuberculosis*..

36. A process for the making an immunogenic composition according to any one of claims 1 to 33 comprising the steps:

a) lyophilising an Rv1196 related antigen which comprises a sequence having at least 90% identity to SEQ ID No: 1 or a fragment of SEQ ID No: 1 which is at least 350 amino acids in length; and

b) reconstituting the lyophilised Rv1196 related antigen of step a) with an aqueous solution wherein:

(i) the conductivity of the solution is 13 mS/cm or lower; and/or

(ii) the concentration of salts in said solution is 130 mM or lower; and/or

(iii) the concentration of sodium chloride in said solution is 130 mM or lower.

37. A kit comprising:

a) a lyophilised Rv1196 related antigen which comprises a sequence having at least 90% identity to SEQ ID No: 1 or a fragment of SEQ ID No: 1 which is at least 350 amino acids in length; and

b) an aqueous solution wherein:

(i) the conductivity of the solution is 13 mS/cm or lower; and/or

(ii) the concentration of salts in said solution is 130 mM or lower; and/or

(iii) the concentration of sodium chloride in said solution is 130 mM or lower.

38. The process according to claim 36 or kit according to claim 37 wherein the aqueous solution comprises an immunostimulant.

39. The process or kit according to claim 38, wherein the aqueous solution comprises a saponin and a TLR4 agonist, in a liposomal formulation, and a non-ionic tonicity agent.

40. The process or kit according to claim 39, wherein the non-ionic tonicity agent is sorbitol.

41. The process or kit according to claim 40, wherein the concentration of sorbitol is between about 2.5 and about 15% (w/v).

42. The process or kit according to any one of claims 39 to 41, wherein the saponin is QS21.

43. The process or kit according to any one of claims 39 to 42, wherein the TLR4 agonist is 3-de-O-acylated monophoshoryl lipid A.

CLAIMS

1. An immunogenic composition comprising an Rv1196 related antigen, wherein the pH of said composition is in the range 6.0 to 9.0 and:
(i) the conductivity of the composition is 13 mS/cm or lower; and/or
(ii) the concentration of salts in said composition is 130 mM or lower; and/or
(iii) the concentration of sodium chloride in said composition is 130 mM or lower.

2. The immunogenic composition according to claim 1, wherein the conductivity of the composition is 5 mS/cm or lower.

3. The immunogenic composition according to claim 2, wherein the conductivity of the composition is 3 mS/cm or lower.

4. The immunogenic composition according to claim 1, wherein the concentration of salts in said composition is 40 mM or lower.

5 The immunogenic composition according to claim 1, wherein the concentration of sodium chloride in said composition is 40 mM or lower.

6. The immunogenic composition according to claim any one of claims 1 to 5, further comprising a non-ionic tonicity agent.

7. The immunogenic composition according to claim 6, wherein the non-ionic tonicity agent is a polyol.

8. The immunogenic composition according to claim 7, wherein the polyol is sorbitol and wherein the concentration of sorbitol is between about 4 and about 6% (w/v).

9. The immunogenic composition according to any one of claims 1 to 8, comprising sucrose at a concentration between about 4 and about 6% (w/v).

10. The immunogenic composition according to any one of claims 1 to 9, further comprising one or more immunostimulants.

11. The immunogenic composition according to claim 10, wherein the immunogenic composition comprises QS21.

12. The immunogenic composition according to either claim 10 or claim 11, wherein the immunogenic composition comprises 3-de-O-acylated monophoshoryl lipid A.

13. The immunogenic composition according to any one of claims 1 to 12, which comprises QS21 and 3-de-O-acylated monophoshoryl lipid A.

14. The immunogenic composition according to claim 13, wherein QS21 and 3-de-O-acylated monophoshoryl lipid A are in the form of liposomes.

15. The immunogenic composition according to any one of claims 1 to 14, wherein the osmolality is 250 to 750 mOsm/kg.

16. The immunogenic composition according to any one of claims 1 to 15, wherein the composition is provided as a unit dose of between 50 ul and 1 ml and wherein the unit dose contains 1 to 100 ug of Rv1196 related protein.

17. The immunogenic composition according to any one of claims 1 to 16, wherein the pH of said composition is in the range 7.0 to 9.0.

18. The immunogenic composition according to claim 17, wherein the pH of said composition is in the range 7.5 to 8.5.

19. The immunogenic composition according to any one of claims 1 to 18, wherein the Rv1196 related antigen comprises a sequence having at least 90% identity to SEQ ID No: 1.

20. The immunogenic composition according to any one of claims 1 to 18, wherein the Rv1196 related antigen comprises a fragment of SEQ ID No: 1 which is at least 350 amino acids in length.

21. The immunogenic composition according to any one of claims 1 to 20, for use in medicine.

22. Use of an immunogenic composition according to any one of claims 1 to 20 in the manufacture of a medicament.

23. The immunogenic composition according to either claim 21 or 22, for administration to a human.