CLAIMS

1. An immunogenic composition comprising: a) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein; b) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein; and c) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein.

2. The immunogenic composition according to claim 1, wherein the total quantity of GBS capsular saccharides is ≤ 70 μg.

3. The immunogenic composition according to claim 1 or claim 2, wherein each GBS capsular saccharide is present at an amount from 1 to 30 μg per unit dose.

4. The immunogenic composition according to claim 3, wherein each GBS capsular saccharide is present at an amount of 5 μg, 10 μg or 20 μg per unit dose.

5. The immunogenic composition according to claim 4, wherein the amounts of the GBS serotype Ia, Ib and III capsular saccharides per unit dose correspond to one of the dosing options described in the second column of Table C.

6. The immunogenic composition according to claim 5, wherein the amounts of the GBS serotype Ia, Ib and III capsular saccharides per unit dose are selected from the group consisting of 20 μg, 20μg and 20μg; 10μg, 10μg and 10μg; and 5μg, 5μg and 5μg.

7. The immunogenic composition according to claim 6, wherein the amounts of the GBS serotype Ia, Ib and III capsular saccharides per unit dose are 5μg, 5μg and 5μg.

8. The immunogenic composition according to claim 1 or claim 2, wherein each GBS capsular saccharide is present at an amount from 0.1 to 5 μg per unit dose.

9. The immunogenic composition according to claim 8, wherein each GBS capsular saccharide is present at an amount of 0.5, 2.5 or 5 μg per unit dose.

10. The immunogenic composition according to claim 9, wherein the amounts of the GBS serotype Ia, Ib and III capsular saccharides per unit dose correspond to one of the dosing options described in Table C'.

11. The immunogenic composition according to any one of claims 1 to 10, wherein the ratio of the masses of the GBS serotype Ia, Ib and III capsular saccharides correspond to one of the ratio options described in the second column of Table F.

12. The immunogenic composition according to claim 11, wherein the ratio of the masses of the GBS serotype Ia, Ib and III capsular saccharides is 1:1:1.

13. The immunogenic composition according to any one of claims 1 to 12, wherein the composition is for administration in one unit dose followed by a second unit dose administered 3 months after the first unit dose.

14. The immunogenic composition according to any one of claims 1 to 12 further comprising: d) a conjugate that is a capsular saccharide from GBS serotype V conjugated to a carrier protein.

15. The immunogenic composition according to claim 14, wherein the composition is for administration in one unit dose followed by a second unit dose administered 1 month after the first unit dose.

16. The immunogenic composition according to any one of claims 1-12 and 14, wherein the composition is for administration in a single dose.

17. The immunogenic composition according to any one of the preceding claims, wherein the immunogenic composition does not contain an aluminium salt adjuvant.

18. The immunogenic composition according to any one of the preceding claims, wherein the immunogenic composition does not contain any adjuvant.

19. The immunogenic composition according to any one of the preceding claims, wherein the carrier protein in a), b) and/or c) is diphtheria toxoid, tetanus toxoid or CRM197.

20. The immunogenic composition according to claim 19, wherein the carrier protein in a), b) and c) is CRM197.

21. The immunogenic composition according to any one of the preceding claims, wherein the conjugate(s) are obtainable by reductive amination of aldehyde groups generated before conjugation by oxidation of between 10 and 30% of the saccharide(s)' sialic acid residues.

22. The immunogenic composition according to any one of the preceding claims, wherein the GBS capsular saccharide(s) have substantially no O-acetylation of sialic acid residues at positions 7, 8 and/or 9.

23. The immunogenic composition according to any one of the preceding claims, wherein the capsular saccharide from GBS serotype Ia has a MW in the range of 150-300kDa; the capsular saccharide from GBS serotype Ib has a MW in the range of 150-300kDa; and/or the capsular saccharide from GBS serotype III has a MW in the range of 50-200kDa.

24. The immunogenic composition according to any one of the preceding claims, wherein the conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein has a saccharide:protein ratio (w/w) between about 1:1 to 1:2; the conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein has a saccharide:protein ratio (w/w) between about 1:1 to 1:2; and/or the conjugate that is a capsular saccharide from GBS

serotype III conjugated to a carrier protein has a saccharide:protein ratio (w/w) between about 3:1 to 1:1.

25. The immunogenic composition according to any one of the preceding claims, wherein the composition is for administration intramuscularly.

26. The immunogenic composition according to any one of the preceding claims, wherein the composition further comprises: (a) a polypeptide comprising an amino acid sequence selected from SEQ ID NOs 1 to 3, and/or (b) a polypeptide comprising (i) an amino acid sequence that has sequence identity to one or more of SEQ ID NOs 1 to 3 and/or (ii) a fragment of SEQ ID NOs 1 to 3.

27. The immunogenic composition according to any one of the preceding claims, wherein the composition is an injectable liquid solution or suspension.

28. The immunogenic composition according to any one of claims 1-26, wherein the composition is lyophilised.

29. The immunogenic composition according to claim 28, wherein the composition comprises mannitol to stabilise the conjugate(s).

30. The immunogenic compositions according to any one of the preceding claims, wherein the composition comprises a potassium dihydrogen phosphate buffer.

31. The immunogenic compositions according to any one of the preceding claims, wherein the composition comprises sodium chloride.

32. The immunogenic composition according to any one of the preceding claims, wherein the composition is a vaccine.

33. The immunogenic composition according to any one of the preceding claims, wherein the composition is for administration to a human.

34. The immunogenic composition according to any one of the preceding claims, wherein the composition is for administration to humans selected from females of child-bearing age, pregnant females and elderly patients.

35. The immunogenic composition according to claim 34, wherein the composition is for administration to a pregnant female.

36. The immunogenic composition according to any one of claims 33-35, wherein prior to administration the human has undetectable levels of antibodies against capsular saccharide from GBS serotype Ia, capsular saccharide from GBS serotype Ib, and/or capsular saccharide from GBS serotype III.

37. The immunogenic composition according to any one of the preceding claims, wherein the composition is for use as a medicament.

38. The immunogenic composition according to claim 37, wherein the composition is for the prevention and/or treatment of a disease caused by *S.agalactiae*.

39. The immunogenic composition according to claim 38, wherein the disease is neonatal sepsis, bacteremia, neonatal pneumonia, neonatal meningitis, endometritis, osteomyelitis or septic arthritis.

40. The immunogenic composition according to any one of the preceding claims, wherein the composition is for administration to a patient that has been pre-immunised with a diphtheria toxoid or derivative thereof and at least one conjugate in the immunogenic composition is a capsular saccharide from GBS conjugated to a diphtheria toxoid or derivative thereof.

41. A method for immunising a patient against infection by GBS comprising the step of administering to the patient a conjugate that is a capsular saccharide from GBS conjugated to a diphtheria toxoid or derivative thereof, wherein the patient has been pre-immunised with a diphtheria toxoid or derivative thereof.

42. The method according to claim 41, wherein the conjugate is in an immunogenic composition comprising: a) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein; b) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein; and c) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein; and the capsular saccharide from GBS is the capsular saccharide from GBS serotype Ia, Ib or III.

43. The method according to claim 42, wherein the capsular saccharide from GBS is the capsular saccharide from GBS serotype III.

44. The method according to claim 42 or claim 43, wherein the immunogenic composition has the features of any one of claims 1-39.

45. A method for immunising a patient against infection by GBS comprising the step of administering to the patient a conjugate that is a capsular saccharide from GBS conjugated to a tetanus toxoid or derivative thereof, wherein the patient has been pre-immunised with a tetanus toxoid or derivative thereof.

46. The method according to claim 45, wherein the conjugate is in an immunogenic composition comprising: a) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein; b) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein; and c) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein; and the capsular saccharide from GBS is the capsular saccharide from GBS serotype Ia, Ib or III.

47. The method according to claim 46, wherein the capsular saccharide from GBS is the capsular saccharide from GBS serotype III.

48. The method according to claim 46 or claim 47, wherein the immunogenic composition has the features of any one of claims 1-39.

CLAIMS

1. An immunogenic composition comprising: a) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein; b) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein; and c) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein, wherein each GBS capsular saccharide is present in an amount of 5 μg, 10 μg or 20 μg per unit dose, (ii) the carrier protein in a), b) or c) is diphtheria toxoid or CRM197, and (iii) the immunogenic composition does not contain an aluminium salt.

2. The immunogenic composition according to claim 1, wherein each of the GBS serotype Ia, Ib and III capsular saccharides are present in amount of 5 μg per unit dose.

3. The immunogenic composition according to claim 1 or 2, wherein the GBS serotype Ia, Ib and III capsular saccharides have a ratio of masses of 1:1:1.

4. The immunogenic composition according to any one of claims 1 to 3 further comprising: d) a conjugate that is a capsular saccharide from GBS serotype V conjugated to a carrier protein.

5. The immunogenic composition according to any one of claims 1 to 4, wherein said composition is formulated as a single dose.

6. The immunogenic composition according to any one of claims 1 to 5, wherein the immunogenic composition does not contain any adjuvant.

7. The immunogenic composition according to any one of claims 1 to 6, wherein the conjugate(s) are obtained by reductive amination of aldehyde groups generated before conjugation by oxidation of between 10 and 30% of the saccharide(s)' sialic acid residues.

8. The immunogenic composition according to any one of claims 1 to 7, wherein the GBS capsular saccharide(s) have substantially no O-acetylation of sialic acid residues at positions 7,

9. The immunogenic composition according to any one of claims 1 to 8, wherein said composition further comprises one or more Group B Streptococcus (GBS) antigens or antigenic peptide thereof selected from:

(a) a GBS antigen or antigenic peptide having an amino acid sequence selected from: an amino acid sequence set forth in SEQ ID NO: 1; an amino acid sequence comprising at least 7 consecutive residues of SEQ ID NO: 1 that include a B-cell epitope thereof; and a variant of SEQ ID NO: 1 having at least 50% sequence identity to SEQ ID NO: 1 and comprising a B-cell epitope thereof;

(b) a GBS antigen or antigenic peptide having an amino acid sequence selected from: an amino acid sequence set forth in SEQ ID NO: 2; an amino acid sequence comprising at least 7 consecutive residues of SEQ ID NO: 2 that include a B-cell epitope thereof; and a variant of SEQ ID NO: 2 having at least 50% sequence identity to SEQ ID NO: 2 and comprising a B-cell epitope thereof; and

(c) a GBS antigen or antigenic peptide having an amino acid sequence selected from: an amino acid sequence set forth in SEQ ID NO: 3; an amino acid sequence comprising at least 7 consecutive residues of SEQ ID NO: 3 that include a B-cell epitope thereof; and a variant of SEQ ID NO: 3 having at least 50% sequence identity to SEQ ID NO: 3 and comprising a B-cell epitope thereof.

10. The immunogenic composition according to any one of claims 1 to 9, wherein the immunogenic composition comprises mannitol to stabilise the conjugate(s).

11. Use of the immunogenic composition according to any one of claims 1 to 10 in preparation of a medicament for immunising a subject against infection by Group B Streptococcus (GBS) and/or for treating or preventing a disease caused by GBS infection.

12. The use according to claim 11, wherein the GBS isStreptococcus agalactiae.

13. The use according to claim 12, wherein the disease caused by GBS infection is neonatal sepsis, bacteremia, neonatal pneumonia, neonatal meningitis, endometritis, osteomyelitis or septic arthritis.

14. The use according to any one of claims 11 to 13, wherein the subject is a human subject selected from a female of child-bearing age, a pregnant female and an elderly patient.

15. The use according to any one of claims 11 to 13, wherein the subject has been pre-immunised with a diphtheria toxoid or derivative thereof.