CLAIMS

1. An immunogenic composition comprising one or more GBS conjugates and one or more antigens selected from: a) cellular or acellular pertussis antigen, b) a tetanus toxoid, c) a diphtheria toxoid and d) an inactivated polio virus antigen, wherein each GBS conjugate is a group B streptococcus capsular saccharide conjugated to a carrier protein.

2. The immunogenic composition of claim 1, wherein the GBS conjugates comprise: i) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein; ii) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein; and/or iii) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein.

3. The immunogenic composition according to claim 1 or claim 2, comprising: i) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein, ii) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein, iii) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein and iv) a diphtheria toxoid.

4. The immunogenic composition according to claim 1 or claim 2, comprising: i) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein, ii) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein, iii) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein and iv) a tetanus toxoid.

5. The immunogenic composition according to claim 1 or claim 2, comprising: i) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein, ii) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein, iii) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein, iv) a diphtheria toxoid and v) a tetanus toxoid.

6. The immunogenic composition according to claim 1 or claim 2, comprising: i) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein, ii) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein, iii) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein, iv) a diphtheria toxoid, v) a tetanus toxoid and vi) acellular pertussis antigen.

7. The immunogenic composition according to claim 1 or claim 2, comprising: i) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein, ii) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein, iii) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein, iv) a diphtheria toxoid, v) a tetanus toxoid, vi) acellular pertussis antigen and vii) an inactivated polio virus antigen.

8. The immunogenic composition according to any one of the preceding claims, wherein the total quantity of GBS capsular saccharides is ≤70 μg.

9. The immunogenic composition according to any one of the preceding claims, wherein each GBS capsular saccharide is present at an amount from 0.1 to 30 μg per dose.

10. The immunogenic composition according to any one of claims 2-9, 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.

11. The immunogenic composition according to any one of claims 2-10, wherein the ratio of the masses of the GBS serotype Ia, Ib and III capsular saccharides is 1:1:1.

12. The immunogenic composition according to any one of claims 2-11, 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.

13. The immunogenic composition according to any one of claims 2-12, wherein the carrier protein in the GBS conjugate comprising a capsular saccharide from GBS serotype Ia capsular saccharide, the GBS conjugate comprising GBS serotype Ib capsular saccharide and/or the GBS conjugate comprising GBS serotype III capsular saccharide is a diphtheria toxoid, a tetanus toxoid or CRM197.

14. The immunogenic composition according to claim 13, wherein the carrier protein in the GBS conjugate comprising a capsular saccharide from GBS serotype Ia capsular saccharide, the GBS conjugate comprising GBS serotype Ib capsular saccharide and the GBS conjugate comprising GBS serotype III capsular saccharide is CRM197.

15. The immunogenic composition according to any one of claims 2-14, further comprising: a conjugate that is a capsular saccharide from GBS serotype II conjugated to a carrier protein; and/or a conjugate that is a capsular saccharide from GBS serotype V conjugated to a carrier protein.

16. The immunogenic composition according to claim 15, wherein the carrier protein in the GBS conjugate comprising GBS serotype II capsular saccharide and/or the GBS conjugate comprising GBS serotype V capsular saccharide is a diphtheria toxoid, a tetanus toxoid or CRM197.

17. The immunogenic composition according to claim 16, wherein the carrier protein in the GBS conjugate comprising GBS serotype II capsular saccharide and/or the GBS conjugate comprising GBS serotype V capsular saccharide is CRM197.

18. The immunogenic composition according to any one of the preceding claims, wherein the acellular pertussis antigen comprises detoxified pertussis toxin, filamentous hemagglutinin and pertactin.

19. The immunogenic composition according to claim 18, wherein inactivated pertussis toxin, filamentous hemagglutinin and pertactin are present at a ratio of 16:16:5 (measured by weight).

20. The immunogenic composition according to any one of the preceding claims, wherein the inactivated polio virus antigen comprises antigens from each of a poliovirus Type 1 strain, a poliovirus Type 2 strain and a poliovirus Type 3 strain.

21. The immunogenic composition according to claim 20, wherein the inactivated polio virus antigens are present at a Type 1:2:3 ratio of 5:1:4 (measured by D-antigen Unit).

22. The immunogenic composition according to any one of the preceding claims, wherein the diphtheria toxoid is present at a concentration of between 4 Lf/ml and 8 Lf/ml, for example, 4 Lf per 0.5 ml dose.

23. The immunogenic composition according to any one of claims 1-21, wherein the diphtheria toxoid is present at a concentration of between 20 and 50 Lf/ml, for example, 25 Lf per 0.5 ml dose.

24. The immunogenic composition according to any one of the preceding claims, wherein tetanus toxoid is present at a concentration of about 5 Lf per 0.5 ml dose.

25. The immunogenic composition according to any one of claims 1-23, wherein tetanus toxoid is present at a concentration of between 5 and 10 Lf per 0.5 ml dose.

26. The immunogenic composition according to any one of the preceding claims, wherein the immunogenic composition comprises diphtheria toxoid and tetanus toxoid, and they are present at a diphtheria toxoid:tetanus toxoid ratio that is greater than 1, for example, between 2:1 and 3:1 (measured in Lf units), such as 2.5:1.

27. The immunogenic composition according to any one of claims 1-25, wherein the immunogenic composition comprises tetanus toxoid and diphtheria toxoid, and they are present at a tetanus toxoid:diphtheria toxoid ratio that is greater than 1, for example, between 1.5:1 and 2.5:1 (measured in Lf units), such as 2:1.

28. The immunogenic composition according to any one of the preceding claims, wherein the immunogenic composition contains an adjuvant.

29. The immunogenic composition according to any one of the preceding claims, wherein the immunogenic composition contains an aluminium salt adjuvant.

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

31. The immunogenic composition according to any one of claims 1-29, wherein the composition is lyophilised.

32. The immunogenic composition according to claim 31, wherein the composition comprises mannitol to stabilise the conjugates.

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

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

35. The immunogenic compositions according to any one of the preceding claims, wherein the composition is preservative-free.

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

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

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

39. A method for raising an immune response in a patient, comprising the step of administering to the patient a composition according to any one of the preceding claims.

40. A process for preparing the immunogenic composition according to any one of the preceding claims, comprising mixing a first component comprising one or more GBS conjugates and a second component comprising one or more antigens selected from: a) cellular or acellular pertussis antigen, b) a tetanus toxoid, c) a diphtheria toxoid and d) an inactivated polio virus antigen.

41. The process according to claim 40, wherein the GBS conjugates in the first component are lyophilised.

42. The process according to clam 40 or claim 41, wherein the second component comprises aqueous antigens.

43. The process according to claim 42, comprising a further step of reconstituting the lyophilised GBS conjugates in the first component with the aqueous antigens of the second component.

44. The process according to any one of claims 40-43, wherein the first component does not comprise an adjuvant.

45. The process according to any of one claims 40-44, wherein the second component comprises an adjuvant, for example, an aluminium salt adjuvant.

46. A kit for preparing the immunogenic composition according to any one of the preceding claims, comprising a first component comprising one or more GBS conjugates; and a second component comprising one or more antigens selected from: a) cellular or acellular pertussis antigen, b) a tetanus toxoid, c) a diphtheria toxoid and d) an inactivated polio virus antigen; wherein the two components are in separate containers.

47. The kit of claim 46, wherein the GBS conjugates in the first component are lyophilised.

48. The kit according to claim 46 or claim 47, wherein the second component comprises aqueous antigens.

49. The kit according to any one of claims 46-48, wherein the first component does not comprise an adjuvant.

50. The kit according to any of one claims 46-49, wherein the second component comprises an adjuvant, for example, an aluminium salt adjuvant.

CLAIMS

1. A kit for preparing the immunogenic composition according to any one of the preceding claims, comprising a first component comprising one or more GBS conjugates; and a second component comprising one or more antigens selected from: a) cellular or acellular pertussis antigen, b) a tetanus toxoid, c) a diphtheria toxoid and d) an inactivated polio virus antigen; wherein the two components are in separate containers.

2. The kit of claim 1, wherein the GBS conjugates in the first component are lyophilised.

3. The kit according to claim 1 or claim 2, wherein the second component comprises aqueous antigens.

4. The kit according to any one of claims 1 - 3, wherein the first component does not comprise an adjuvant.

5. The kit according to any of one claims 1 - 4, wherein the second component comprises an adjuvant, for example, an aluminium salt adjuvant.