CLAIMS

1. An aqueous adjuvant composition comprising: (a) a TLR-4 agonist and a saponin in a liposomal formulation; and (b) a non-ionic isotonicity agent, wherein the concentration of sodium chloride or the ionic strength in the adjuvant composition is less than 100mM.
2. An aqueous adjuvant composition as claimed in claim 1 wherein the concentration of sodium chloride or ionic strength is less than 80mM.
3. An aqueous adjuvant composition as claimed in claim 2 wherein the concentration of sodium chloride or ionic strength is less than 30mM.
4. An aqueous adjuvant composition as claimed in claim 3 wherein the concentration of sodium chloride or ionic strength is less than 10mM.
5. An aqueous adjuvant composition as claimed in claim 4 wherein the concentration of sodium chloride or ionic strength is less than 5mM.
6. An aqueous adjuvant composition as claimed in claim 5 which contains essentially no sodium chloride.
7. An aqueous adjuvant composition according to any preceding claim wherein the non-ionic isotonicity agent is a polyol.
8. An aqueous adjuvant composition according to claim 7 wherein the polyol is sorbitol.
9. The aqueous adjuvant composition of claim 8 wherein the concentration of sorbitol is between about 3% and about 15% (w/v).
10. An aqueous adjuvant composition of claim 9 wherein the concentration of sorbitol is between about 4% and about 10% (w/v).
11. The aqueous adjuvant composition of any preceding claim wherein said TLR-4 agonist is 3D-MPL.
12. An aqueous adjuvant composition according to any preceding wherein said saponin is QuilA or a derivative thereof.
13. An aqueous adjuvant composition according to claim 12 wherein the derivative of QuilA is QS21.
14. An aqueous adjuvant composition according to any preceding claim comprising about 5mM sodium chloride and between 5% and 6% w/v sorbitol.
15. An immunogenic composition comprising an antigen or antigenic preparation and an aqueous adjuvant composition of any one of claims 1 to 14.
16. An immunogenic composition according to claim 15 wherein said antigen or antigenic preparation is not soluble in salt concentrations or in solutions wherein the ionic strength is higher than 5mM, 10mM, 20mm, 30mM, 40mM, 50mM, 60mM, 70mM, 80mM, 90mM or 100mM.
17. An immunogenic composition of claim 15 or 16 wherein the antigen or antigenic preparation is derived from HIV, *Neisseria meningitidis,* or is a tumour associated antigen.

18. An immunogenic composition according to claim 17 wherein the antigen is selected from either PRAME or NY-ESO-1 or a fragment or derivative thereof.

19. An immunogenic composition according to any one of claims 15 to 18 further comprising a CpG oligonucleotide.

20. A process for preparing an immunogenic composition of any of claims 15 to 19 comprising the step of reconstituting a lyophilised composition comprising at least one antigen or antigenic preparation with an aqueous adjuvant composition as defined in any of claims 1 to 14.

21. A kit comprising (i) a lyophilised composition comprising an antigen or antigenic preparation and (ii) an aqueous adjuvant composition of any one of claims 1 to 14.

22. The process of claim 20 or the kit of claim 21 wherein said lyophilised composition further comprises a TLR9 agonist.

23. The process or kit of claim 22 wherein said TLR9 agonist is a CpG immunostimulatory oligonucleotide.

24. The process or kit of claims 20 to 23 wherein the antigen or antigenic preparation is not soluble in salt concentrations or in solutions wherein the ionic strength is greater than 10mM, 20mm, 30mM, 40mM, 50mM, 60mM, 70mM, 80mM, 90mM or 100mM.

CLAIMS

1. An aqueous adjuvant composition comprising: (a) a TLR-4 agonist and a saponin in a liposomal formulation; and (b) a non-ionic isotonicity agent, wherein the concentration of sodium chloride or the ionic strength in the adjuvant composition is less than 100mM.
2. An aqueous adjuvant composition according to any preceding claim wherein the non-ionic isotonicity agent is a polyol.
3. An aqueous adjuvant composition according to claim 2 wherein the polyol is sorbitol.
4. An aqueous adjuvant composition of claim 3 wherein the concentration of sorbitol is between about 4% and about 10% (w/v).
5. The aqueous adjuvant composition of any preceding claim wherein said TLR-4 agonist is 3D-MPL.
6. An aqueous adjuvant composition according to any preceding wherein said saponin is QuilA or a derivative thereof.
7. An aqueous adjuvant composition according to claim 6 wherein the derivative of QuilA is QS21.
8. An aqueous adjuvant composition according to any preceding claim comprising about 5mM sodium chloride and between 5% and 6% w/v sorbitol.
9. An immunogenic composition comprising an antigen or antigenic preparation and an aqueous adjuvant composition of any one of claims 1 to 8.
10. An immunogenic composition according to claim 9 wherein said antigen or antigenic preparation is not soluble in salt concentrations or in solutions wherein the ionic strength is higher than 5mM, 10mM, 20mM, 30mM, 40mM, 50mM, 60mM, 70mM, 80mM, 90mM or 100mM.
11. A process for preparing an immunogenic composition of either claim 9 or 10 comprising the step of reconstituting a lyophilised composition comprising at least one antigen or antigenic preparation with an aqueous adjuvant composition as defined in any of claims 1 to 8.
12. A kit comprising (i) a lyophilised composition comprising an antigen or antigenic preparation and (ii) an aqueous adjuvant composition of any one of claims 1 to 8.
13. The process or kit of claims 11 or 12 wherein the antigen or antigenic preparation is not soluble in salt concentrations or in solutions wherein the ionic strength is greater than 10mM, 20mM, 30mM, 40mM, 50mM, 60mM, 70mM, 80mM, 90mM or 100mM.
14. An immunogenic composition according to claims 9 or 10 for use in medicine.