

CLAIMS

1. An immunogenic composition comprising an antigen component and an adjuvant component, wherein
- 5 a) the adjuvant component comprises an emulsion containing oil, an immunostimulatory oligonucleotide, and at least one of:
- i) a polycationic polymer; or
- ii) a source of aluminum; and
- b) the antigen component comprises 0.5 - 10 µg of FMD (Foot-and-Mouth Disease) virus composition per dose.
- 10 2. The immunogenic composition of claim 1, wherein:
- a) said adjuvant component comprises the polycationic polymer,
- b) said polycationic polymer is diethylaminoethyl (DEAE) Dextran.
3. The immunogenic composition of claim 1 or claim 2, wherein the
- 15 immunostimulatory oligonucleotide comprises CpG.
4. The immunogenic composition of any one of claims 1-3, wherein the immunostimulatory oligonucleotide comprises at least 15 contiguous nucleotides of SEQ ID NO: 8.
- 20 5. The immunogenic composition of any one of claims 1-4, wherein said oily phase is present in the amount of up to 80% v/v of the composition.
6. The immunogenic composition of any one of claims 1-5, wherein the oily phase
- 25 comprises 50.01%-55% v/v of the composition.
7. The immunogenic composition of any one of claims 1-6 further comprising one or more emulsifiers.
- 30 8. The immunogenic composition of any one of claims 1-7, wherein the adjuvant component comprises SEQ ID NO: 8 and diethylaminoethyl (DEAE) Dextran.
9. The immunogenic composition of any one of claims 1-8, wherein the DEAE Dextran is present in the amount of 6-200 mg per dose.
- 35 10. The immunogenic composition of any one of claims 1-8, wherein the immunostimulatory oligonucleotide is present in the amount of 6-200 µg per dose.
11. The immunogenic composition of any one of claims 1-10, wherein said FMD virus
- 40 composition is a preparation of FMD virus Cruzeiro strain.

12. The immunogenic composition of claim 11, wherein said FMD virus Cruzeiro strain is genetically engineered.
- 5 13. The immunogenic composition of claim 12, wherein said FMD virus Cruzeiro strain contains a deletion of the leader coding region (LL).
14. The immunogenic composition of claim 12 or 13, wherein said FMD virus Cruzeiro strain contains negative antigenic markers introduced in one or both of the viral non-structural
10 3D^{pol} and 3B proteins.
15. The immunogenic composition of any one of claims 12-14, wherein said FMD virus Cruzeiro strain contains a heterologous capsid protein.
- 15 16. The immunogenic composition of claim 15, wherein the strain other than Cruzeiro is selected from Asia1, Turkey06, O1Campos, C3Indaial, and A2001-Argentina.
17. The immunogenic composition of any one of claims 1-16, wherein the antigen component comprises a 0.5 - 6 µg of FMD virus per dose.
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18. The immunogenic composition of any one of claims 1-16, wherein the antigen component comprises a 0.5 - 4 µg of FMD virus per dose.
19. The immunogenic composition of any one of claims 1-16, wherein the antigen
25 component comprises 0.5 - 2 µg of FMD virus per dose.
20. The immunogenic composition of any one of claims 1-16, wherein the antigen component comprises 0.5 - 1.5 µg of FMD virus per dose.
- 30 21. The immunogenic composition of any one of claims 1-20, wherein the FMD virus composition comprises both structural and non-structural FMD proteins.
22. A method of treating or preventing FMD in an animal in need thereof, comprising administering to said animal the immunogenic composition according to any one of claims
35 1-21.
23. A method of herd management, comprising administering to each member in said herd the immunogenic composition of any one of claims 1-16 wherein, in said composition,
40 a) the antigen component comprises 6 - 10 µg of FMD (Foot-and-Mouth Disease) virus composition per dose;
b) the immunostimulatory oligonucleotide comprises 75-200 µg per dose;

c) the polycationic carrier comprises 75-200 mg per dose.
and wherein further, upon suspected contact with FMD infection, the vaccinated members of said herd are not slaughtered.

- 5 24. A method of herd management, comprising administering to each member in said
herd the immunogenic composition of any one of claims 1-16 wherein, in said composition,
a) the antigen component comprises 6 - 10 µg of FMD (Foot-and-Mouth Disease) virus
composition per dose;
b) the immunostimulatory oligonucleotide comprises 75-200 µg per dose;
10 c) the polycationic carrier comprises 75-200 mg per dose.
and wherein further, upon suspected contact with FMD infection, the vaccinated members
of said herd are quarantined for 0-30 days.
- 15 25. A method of herd management, comprising administering to each member in said
herd the immunogenic composition of any one of claims 1-16 wherein, in said composition,
a) the antigen component comprises 6 - 10 µg of FMD (Foot-and-Mouth Disease) virus
composition per dose;
b) the immunostimulatory oligonucleotide comprises 75-200 µg per dose;
c) the polycationic carrier comprises 75-200 mg per dose.
20 and wherein further, upon suspected contact with FMD infection, the vaccinated members
of said herd are moved beyond the infected premises.
- 25 26. The method of reducing frequency of FMD persistence in a ruminant infected with
FMD comprising administering to said ruminant prior to the infection the immunogenic
composition of any one of claims 1-16 wherein, in said composition,
a) the antigen component comprises 6 - 10 µg of FMD (Foot-and-Mouth Disease) virus
composition per dose;
b) the immunostimulatory oligonucleotide comprises 75-200 µg per dose;
c) the polycationic carrier comprises 75-200 mg per dose.
30 27. The method according to any one of claims 23-26, wherein the vaccinated members
of the herd are not slaughtered and are quarantined for 0-30 days.
- 35 28. The method according to any one of claims 23-27, wherein the herd is a bovine herd.
29. The method according to any one of claims 22-28, wherein the FMD virus
composition is prepared by hollow fiber filtration.