CLAIMS

[Claim 1]

A vaccine adjuvant agent comprising a polymer in which a constitutional unit is derived from acrylic acid, wherein the polymer has a carboxyl group content of 60.0 to 62.5 % by mass.

[Claim 2]

The vaccine adjuvant agent according to Claim 1, wherein the polymer is polyacrylic acid and/or a salt thereof.

[Claim 3]

The vaccine adjuvant agent according to Claim 1 or 2, wherein the polymer is a crosslinked polyacrylic acid and/or a salt thereof; the carboxyl group content is 60.0 to 62.0 % by mass as calculated for the free form of the polyacrylic acid; and a number-based mode diameter of particles of the polymer is 0.05 to 10 μm.

[Claim 4]

The vaccine adjuvant agent according to any one of Claims 1 to 3, wherein the polymer is a crosslinked polyacrylic acid and/or a salt thereof; the carboxyl group content is 60.0 to 62.0 % by mass as calculated for the free form of the polyacrylic acid; and a number-based mode diameter of particles of the polymer is adjusted to 0.05 to 10 μm by applying a mechanical shear force.

[Claim 5]

The vaccine adjuvant agent according to Claim 4, wherein the carboxyl group content is 60.0 to 61.0 % by mass as calculated for the free form of the polyacrylic acid.

[Claim 6]

The vaccine adjuvant agent according to Claim 5, wherein a number-based mode diameter of particles of the polymer is adjusted to 0.1 to 2.0 μm by applying a mechanical shear force.

[Claim 7]

The vaccine adjuvant agent according to Claim 4, wherein the carboxyl group content is more than 61.0 % by mass and less than or equal to 62.0% by mass as calculated for the free form of the polyacrylic acid.

[Claim 8]

The vaccine adjuvant agent according to Claim 7, wherein a number-based mode diameter of particles of the polymer is adjusted to 0.05 to 0.1 μm by applying a mechanical shear force.

[Claim 9]

The vaccine adjuvant agent according to Claim 1 or 2, wherein the polymer is a crosslinked polyacrylic acid and/or a salt thereof; the carboxyl group content is 60.0 to 62.0 % by mass as calculated for the free form of the polyacrylic acid; and a number-based mode diameter of particles of the polymer is 0.1 to 50 μm.

[Claim 10]

The vaccine adjuvant agent according to Claim 9, wherein the polymer has not been subjected to a mechanical shear force.

[Claim 11]

The vaccine adjuvant agent according to Claim 1 or 2, wherein the polymer is a non-crosslinked polyacrylic acid and/or a salt thereof, and, the polymer has a mass-average molecular weight ranging from 50,000 to 300,000.

[Claim 12]

The vaccine adjuvant agent according to Claim 11, wherein the carboxyl group content is 62.0 to 62.5 % by mass as calculated for the free form of the polyacrylic acid.

[Claim 13]

The vaccine adjuvant agent according to any one of Claims 1 to 12, further comprising water.

[Claim 14]

The vaccine adjuvant agent according to any one of Claims 3 to 9 and 13, wherein

the vaccine adjuvant agent comprises the polymer and water, and optionally comprises at least one additive selected from the group consisting of sodium chloride, sodium hydroxide, and L-arginine, and

the number-based mode diameter of particles of the polymer is adjusted by applying a mechanical shear force to a composition consisting of the polymer and the water, provided that, when the vaccine adjuvant agent comprises the at least one additive, the composition may comprise the at least one additive.

[Claim 15]

The vaccine adjuvant agent according to any one of Claims 1 to 14, wherein sodium chloride is comprised in an amount of 0.1 to 1.5 % by mass based on the total mass of the vaccine adjuvant agent.

[Claim 16]

The vaccine adjuvant agent according to any one of Claims 1 to 15, wherein the vaccine adjuvant agent further comprises sodium hydroxide and/or L-arginine

[Claim 17]

The vaccine adjuvant agent according to any one of Claims 1 to 16, wherein the vaccine adjuvant agent further comprises L-arginine

[Claim 18]

The vaccine adjuvant agent according to any one of Claims 1 to 17, wherein the vaccine adjuvant agent has pH of 6 to 8.

[Claim 19]

The vaccine adjuvant agent according to any one of Claims 1 to 18, wherein the polymer is comprised in an amount of 0.01 to 50 % by mass based on the total mass of the vaccine adjuvant agent.

[Claim 20]

The vaccine adjuvant agent according to any one of Claims 1 to 19, wherein the vaccine adjuvant agent further comprises at least one nonionic surfactant selected from the group consisting of an ether-type nonionic surfactant and an ester-ether type nonionic surfactant.

[Claim 21]

The vaccine composition according to Claim 20, wherein the nonionic surfactant

is polysorbate 80.

[Claim 22]

The vaccine adjuvant agent according to any one of Claims 1 to 21, wherein the vaccine adjuvant agent further comprises at least one polyhydric alcohol selected from the group consisting of polyethylene glycol, glycerin, propylene glycol, and 1,3-butylene glycol.

[Claim 23]

The vaccine adjuvant agent according to Claim 22, wherein the polyhydric alcohol is polyethylene glycol.

[Claim 24]

Use of the vaccine adjuvant agent according to any one of Claims 1 to 23, for the manufacture of a medicament for enhancing an immune response to an antigen.

[Claim 25]

Use of the vaccine adjuvant agent according to any one of Claims 1 to 23 in combination with an antigen in the manufacture of a medicament for inducing an immune response to the antigen.

[Claim 26]

Use of the vaccine adjuvant agent according to any one of Claims 1 to 23 in combination with an antigen derived from a pathogen in the manufacture of a vaccine composition for preventing a disease caused by the pathogen.

[Claim 27]

A vaccine composition comprising (i) the vaccine adjuvant agent according to any one of Claims 1 to 23, and (ii) an antigen.

[Claim 28]

A vaccine composition comprising:

(i) a polymer in an amount effective as a vaccine adjuvant, wherein a constitutional unit of the polymer is derived from acrylic acid, and the polymer has a carboxyl group content of 60.0 to 62.5 % by mass, and

(ii) an antigen.

[Claim 29]

The vaccine composition according to any one of Claims 27 or 28, wherein the polymer is comprised in a mass ratio of the antigen: the polymer = 1:0.1 to 1:1000.

[Claim 30]

The vaccine adjuvant agent according to any one of Claims 1 to 23 or the vaccine composition according to Claim 28 or 29 for use as a medicament.

[Claim 31]

Use according to any one of Claims 24 to 26 or the vaccine composition according to Claim 27 or 28, wherein the antigen comprises an antigen derived from an enveloped virus.

[Claim 32]

The use according to any one of Claims 24 to 26 or the vaccine composition according to Claim 28 or 29, wherein the antigen comprises an antigen derived from at least one virus selected from the group consisting of coronavirus and influenza virus.

[Claim 33]

The use according to claim 26, wherein the disease caused by the pathogen is a respiratory disease.

[Claim 34]

The use according to any one of Claims 24 to 26 and 30 to 33, wherein the medicament or the vaccine composition is to be administered via an injection route or a mucosal route.

[Claim 35]

The use according to any one of Claims 24 to 26 and 31 to 34, wherein the dosage of the polymer to be administered per administration is 1 μg to 100 mg.