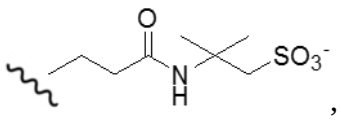
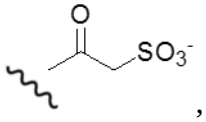
Claims

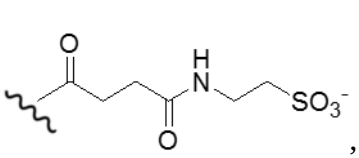
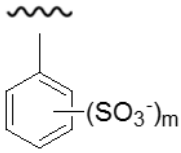
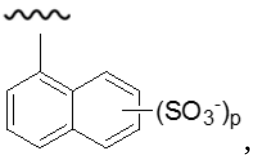
1. A method of preventing or reducing the likelihood of Coronavirus (CoV) infection in a human individual, or a method of preventing or reducing the likelihood or severity of a symptom of a CoV infection in a human individual, comprising:

administering to the individual an effective amount of a macromolecule or a pharmaceutically acceptable salt thereof, or a composition comprising the macromolecule or pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier,

wherein the macromolecule comprises a dendrimer of 3 to 5 generations with at least 15 sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer, and

wherein the sulfonic acid- or sulfonate-containing moiety is selected from the group consisting of:

$-NH-(CH_2)_nSO_3^-$, $-(CH_2)_nSO_3^-$, , ,

,  and ,

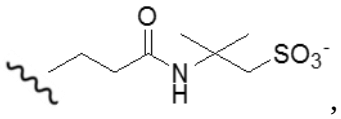
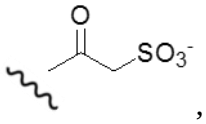
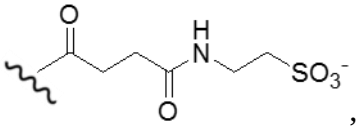
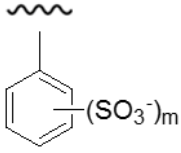
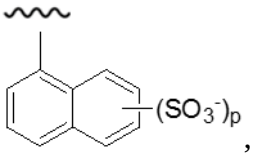
wherein n is zero or is an integer from 1 to 20, m is an integer 1 or 2 and p is an integer from 1 to 3.

2. A method of reducing the severity and/or duration of a Coronavirus (CoV) infection in a human individual, or a method of preventing or reducing viral shedding in a human individual infected with a CoV, comprising,

administering to the individual an effective amount of a macromolecule or a pharmaceutically acceptable salt thereof, or a composition comprising the macromolecule or pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier,

wherein the macromolecule comprises a dendrimer of 3 to 5 generations with at least 15 sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer, and

wherein the sulfonic acid- or sulfonate-containing moiety is selected from the group consisting of:

$-NH-(CH_2)_nSO_3^-$, $-(CH_2)_nSO_3^-$, , , ,  and ,

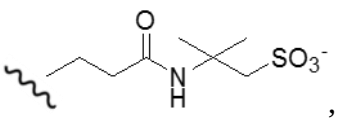
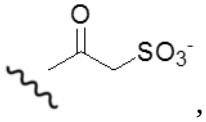
wherein n is zero or is an integer from 1 to 20, m is an integer 1 or 2 and p is an integer from 1 to 3.

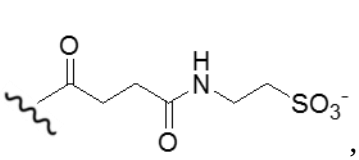
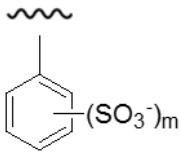
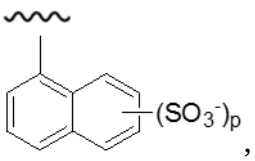
3. A method of treating a Coronavirus (CoV) infection in a human individual comprising:

administering to the individual an effective amount of a macromolecule or a pharmaceutically acceptable salt thereof, or a composition comprising the macromolecule or pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier,

wherein the macromolecule comprises a dendrimer of 3 to 5 generations with at least 15 sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer, and

wherein the sulfonic acid- or sulfonate-containing moiety is selected from the group consisting of:

-NH-$(CH_2)_nSO_3^-$, -$(CH_2)_nSO_3^-$, , ,

,  and ,

wherein n is zero or is an integer from 1to 20, m is an integer 1 or 2 and p is an integer from 1 to 3.

4. The method of claim 1, wherein the symptom of CoV infection is selected from one or more of: fever, cough, sore throat, shortness of breath, viral shedding, respiratory insufficiency, runny nose, nasal congestion, bronchitis, headache, muscle pain, dyspnea, moderate pneumonia, severe pneumonia, and acute respiratory distress syndrome (ARDS).

5. The method of any one of claims 1 to 4, wherein the CoV is selected from one or more of:

(a) an/a Alphacoronavirus, Betacoronavirus, Gammacoronavirus and Deltacoronavirus;

(b) severe acute respiratory syndrome-related coronavirus-2 (SARS-CoV-2), human coronavirus OC43 (HCoV-OC43), human coronavirus HKU1 (HCoV-HKU1), human coronavirus 229E (HCoV-229E), human coronavirus NL63 (HCoV-NL63), Severe acute respiratory syndrome-related coronavirus (SARS-CoV), and Middle-East respiratory syndrome-related coronavirus (MERS-CoV) or a subtype or a variant thereof; and

(c) SARS-CoV-2 or a subtype or variant thereof.

6. The method of any one of claims 1 to 5, wherein administering comprises administering topically or administering to the respiratory tract.

7. The method of claim 6, wherein administering to the respiratory tract comprises administering to one or more of: upper respiratory tract, lower respiratory tract, nasal mucosa, nasal cavity, oral cavity, sinuses, throat, pharynx, larynx, nasal turbinates, nasopharynx, oropharynx, trachea, primary bronchi and lungs.

8. The method of any one of claims 1 to 7, wherein the composition comprises one or more of the following features:

(a) about 0.5% to about 5% by weight of the macromolecule or pharmaceutically acceptable salt thereof;

(b) about 1% by weight of the macromolecule or pharmaceutically acceptable salt thereof;

(c) the effective amount is about 0.1 to about 5 mg per dose; and

(d) the effective amount is about is 1 mg per dose.

9. The method of any one of claims 1 to 8, wherein the macromolecule or a pharmaceutically acceptable salt thereof is administered in a nasal spray or an oral spray.

10. The method of any one of claims 1 to 9, wherein the macromolecule or a pharmaceutically acceptable salt thereof is administered 1 to 8 times daily.

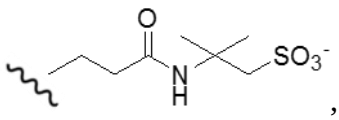
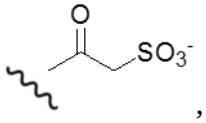
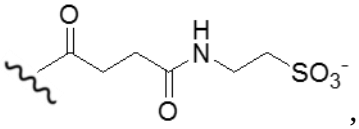
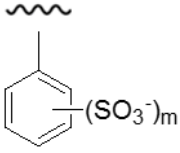
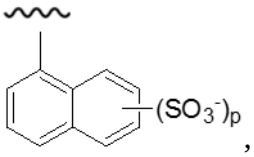
11. The method of any one of claims 1 to 10, wherein the macromolecule or a pharmaceutically acceptable salt thereof is administered for about 1 to about 2 weeks, or about 1 to about 3 weeks, or for less than 30 days.

12. A composition when used to prevent or reduce the likelihood of, or treat a Coronavirus (CoV) infection in an individual; reduce the severity and/or duration of CoV infection in an individual; prevent or reduce viral shedding in an individual infected with a CoV; or reduce transmission of a CoV in a population, comprising:

an effective amount of a macromolecule or a pharmaceutically acceptable salt thereof, or a composition comprising the macromolecule or pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier,

wherein the macromolecule comprises a dendrimer of 3 to 5 generations with at least 15 sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer, and

wherein the sulfonic acid- or sulfonate-containing moiety is selected from the group consisting of:

$-NH-(CH_2)_nSO_3^-$, $-(CH_2)_nSO_3^-$, , , ,  and ,

wherein n is zero or is an integer from 1-20, m is an integer 1 or 2 and p is an integer from 1 to 3.

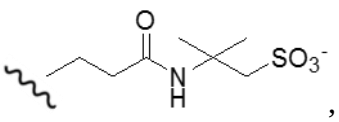
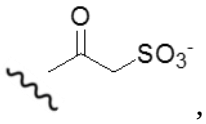
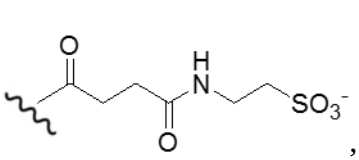
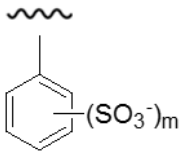
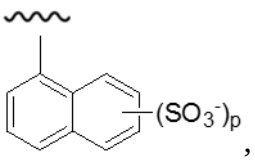
13. A composition comprising:

a macromolecule or a pharmaceutically acceptable salt thereof, or a composition comprising the macromolecule or pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier,

wherein the macromolecule comprises a dendrimer of 3 to 5 generations with at least 15 sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer and Carbopol 974 or Carbopol 971,

wherein the composition comprises a w/w ratio of about 1:20 to about 1:10 of Carpobol 974 or Carbopol 971 to the macromolecule, and

wherein the sulfonic acid- or sulfonate-containing moiety is selected from the group consisting of:

-NH-$(CH_2)_nSO_3^-$, -$(CH_2)_nSO_3^-$, , , ,  and ,

wherein n is zero or is an integer from 1 to 20, m is an integer 1 or 2 and p is an integer from 1 to 3.

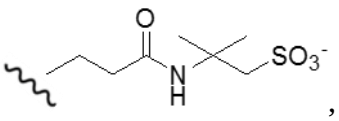
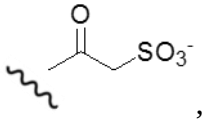
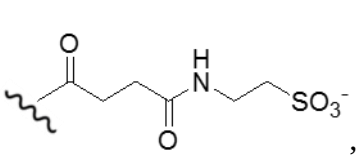
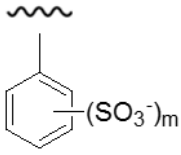
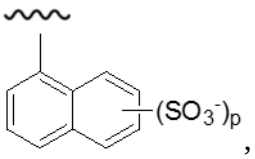
14. A composition comprising:

a macromolecule or a pharmaceutically acceptable salt thereof, or a composition comprising the macromolecule or pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier,

wherein the macromolecule comprises a dendrimer of 3 to 5 generations with at least or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer and Carbopol 974,

wherein the composition comprises about 0.01% w/w to about 5% w/w, or about 0.05% w/w to about 0.1%, or about 0.05% w/w Carbopol 974, and

wherein the sulfonic acid- or sulfonate-containing moiety is selected from the group consisting of:

-NH-$(CH_2)_nSO_3^-$, -$(CH_2)_nSO_3^-$, , , ,  and ,

wherein n is zero or is an integer from 1 to 20, m is an integer 1 or 2 and p is an integer from 1 to 3.

15. The composition of any one of claims 12 to 14, wherein the composition is a nasal bioadhesive composition.

16. The composition of any one of claims 12 to 15, wherein the composition additionally comprises one or more agents selected from one or more of:

a) an antiviral active agent, a vaccine, an immunomodulatory, an antibacterial agent, an anti-inflammatory agent and a nasal bioadhesive agent; and
b) an antiviral active agent selected from one or more of: i) an antibiotic or a further dendrimer; and ii) a carrageenan, GM-CSF, IL-6R, CCR5, S protein of MERS, and drugs including, ribavirin, tilorone, favipiravir, Kaletra (lopinavir/ritonavir), Prezcobix (darunavir/cobicistat), nelfinavir, mycophenolic acid, Galidesivir, Actemra, OYA1, BPI-002, Ifenprodil, APN01, EIDD-2801, baricitinib, camostat mesylate, lycorine, Brilacidin, BX-25, an interferon (e.g. IFNβ), chloroquine and azithromycin.

17. The composition of any one of claims 12 to 16, wherein the composition comprises one or more of: Carbopol 974, hydroxypropylmethyl-cellulose, microcrystalline cellulose /carboxy methyl cellulose, glycerine, propylene glycol, methyl paraben, propyl paraben, benzalkonium chloride, ethylenediamine tetraacetic acid and sodium hydroxide.

18. The composition of any one of claims 12 to 17, wherein the composition comprises:

a) a rheology modifier selected from one or more of: Carbopol 974, hydroxypropylmethyl-cellulose or microcrystalline cellulose /carboxy methyl cellulose;
b) a preservative selected from one or more of: methyl paraben, propyl paraben, and benzalkonium chloride
c) an excipient selected from one or more of: glycerine, propylene glycol, ethylenediamine tetraacetic acid; and
d) a pH modifier.

19. The composition of any one of claims 12 to 18, wherein the composition comprises one or more of the following features:

(a) a w/w ratio of about 1:20 to 1:10 of Carbopol 974 or Carbopol 971 to the macromolecule;

(b) about 0.05% w/w Carbopol 974 or Carbopol 971 and about 1% w/w of macromolecule;

(c) a pH of about 3.5 to about 7.5, or a pH of about 5.5. to about 6.5;

(d) a viscosity of about 1 to about 10cP;

(e) is suitable for administration in a device selected from the group consisting of: a nasal spray, an oral spray, an inhaler, a nebuliser, nasal wash or oral wash;

(f) is present in or applied to protective wear or a cleaning products; and

(g) the cleaning product of (f) wherein the cleaning produce is selected from a wipe, a surgical field preparation spray or a cleaning solution.

20. The composition of claim 19, wherein the spray, inhaler or nebuliser comprises a means for generating particles of a size of about 0.1 μm to about 100 μm and/or, wherein less than 6% of the particles are of a size of about 10 μm or less.

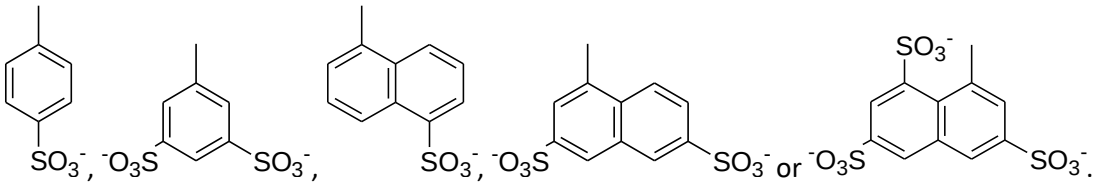
21. The composition of any one of claims 12 to 20, wherein the composition comprises: water, Carbopol 974, glycerin, propylene glycol, methyl paraben, propyl paraben, and EDTA.

22. The composition of any one of claims 12 to 21, wherein the composition inactivates more than 90%, or more than 92%, or more than 95%, or more than 99%, or more than 99.9% of SARS-CoV2 or a subtype or variant thereof.

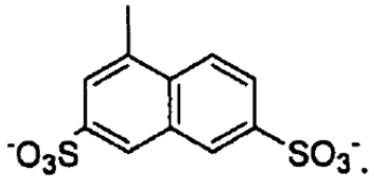
23. The composition of claim 22, wherein exposure to the composition for about a minute inactivates more than 90%, or more than 92%, or more than 95%, or more than 99% or more than 99.9% of SARS-CoV2 or a subtype or variant thereof.

24. The method of any one of claims 1 to 11, or the composition of any one of claims 12 to 23, wherein the macromolecule or pharmaceutically acceptable salt thereof is a dendrimer comprising lysine building units of from 3 to 5 generations, and the sulfonic acid- or sulfonate-containing moieties are napthyldisulfonate moieties.

25. The method or composition of any one of claims 1 to 24, wherein the sulfonic acid or sulfonate-containing moiety is selected from the group consisting of:



26. The method or composition of claim 24 or claim 25, wherein the sulfonic acid-containing moiety is



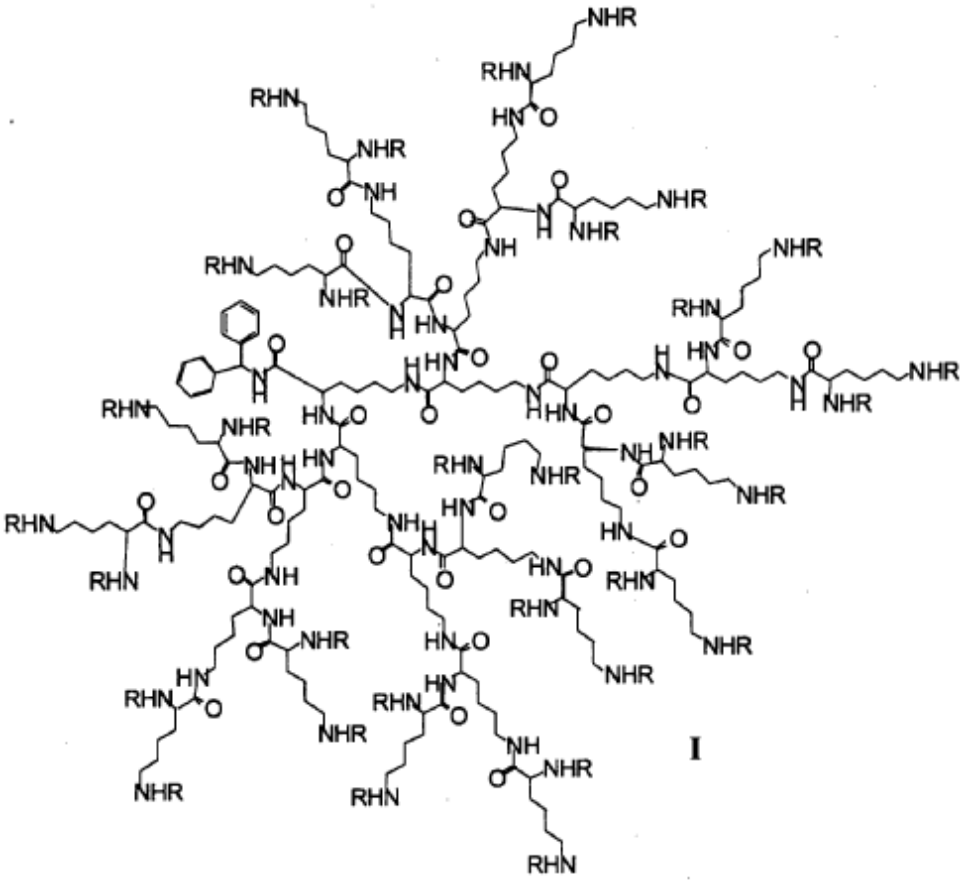
27. The method of any one of claims 1 to 11, or the composition of any one of claims 12 to 26, wherein the sulfonic acid- or sulfonate- containing moiety is attached to the dendrimer terminal amino group by a linker.

28. The method or composition of claim 27, wherein the linker is an alkylene or alkenylene group in which one or more non-adjacent carbon atoms is optionally replaced with an oxygen or sulfur atom, or a group $-X_1-(CH_2)_q-X_2-$ wherein X_1 and X_2 are independently selected from -NH-, -C(O)-, -O-, -S-, and -C(S) and q is 0 or an integer from 1 to 10, and in which one or more non-adjacent (CH_2) groups may be replaced with -O- or -S-.

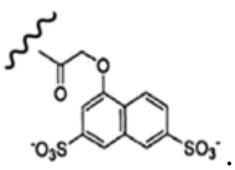
29. The method or composition of claim 28, wherein the linker is #-O-CH_2-C(O)-* in which # designates attachment to the sulfonic acid-containing moiety and * designates attachment to the terminal amino group of the dendrimer.

30. The method of any one of claims 1 to 11 or claims 24 to 29, or the composition of any one of claims 12 to 29, wherein the dendrimer is a polylysine dendrimer.

31. The method or composition of claim 30, wherein the dendrimer is



and wherein at least 50% of R is



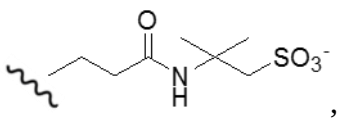
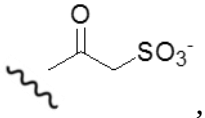
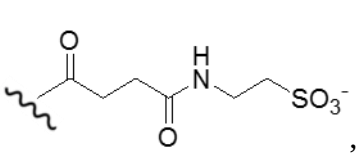
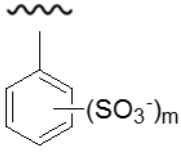
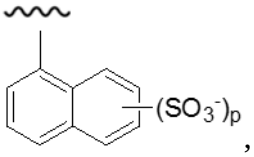
32. The method or composition of claim 31, wherein the pharmaceutically acceptable salt of the dendrimer is a sodium salt.

33. The composition of any one of claims 12 to 32, wherein the composition is a nasal moisture barrier dressing.

34. A device when used to deliver a nasal, oral or pulmonary composition comprising a macromolecule or a pharmaceutically acceptable salt thereof, or a composition comprising the macromolecule or pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier,

wherein the macromolecule comprises a dendrimer of 3 to 5 generations with at least 15 sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer, and

wherein the sulfonic acid- or sulfonate-containing moiety is selected from the group consisting of:

$-NH-(CH_2)_nSO_3^-$, $-(CH_2)_nSO_3^-$, , , ,  and ,

wherein n is zero or is an integer from 1-20, m is an integer 1 or 2 and p is an integer from 1 to 3.

35. The device of claim 34, wherein the device is a nasal delivery device or an oral delivery device for delivering a spray.

36. The device of claim 35, wherein the device is an inhaler or a nebuliser.