

Claims

1. A method of preventing or reducing the likelihood of Coronavirus (CoV) infection in a human individual, comprising:
administering to the individual an effective amount of a macromolecule or a
5 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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more
10 surface groups of the dendrimer.
2. A method of preventing or, reducing the likelihood or severity of a symptom associated with a Coronavirus (CoV) infection in a human individual comprising:
administering to the individual an effective amount of a macromolecule or a
15 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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more
20 surface groups of the dendrimer.
3. The method of claim 2, wherein the symptom associated with 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,
25 muscle pain, dyspnea, moderate pneumonia, severe pneumonia, and acute respiratory distress syndrome (ARDS).
4. A method of reducing the severity and/or duration of a Coronavirus (CoV) infection in a human individual, comprising,
30 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
35 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.

5. 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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.
6. A method of preventing or reducing viral shedding in a human individual infected with a Coronavirus (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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.
7. A method of reducing transmission of a Coronavirus (CoV) in a human population, comprising:
- administering to the respiratory tract of a portion of the population 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 1 to 8 generations with one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.
8. A method of preventing or reducing the likelihood of Respiratory syncytial virus (RSV) infection in an individual, comprising:
- administering to the respiratory tract of 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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.

9. A method of preventing or, reducing the likelihood or severity of a symptom associated with a Respiratory syncytial virus (RSV) infection in an individual comprising:

administering to the respiratory tract of 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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.

10. The method of claim 7, wherein the symptom associated with RSV infection is selected from one or more of: congested or runny nose, decrease in appetite, coughing, mucus when coughing (yellow, green, or gray mucus), sneezing, sore throat, mild headache, fever, wheezing, rapid breathing or difficulty breathing, bluish colour of the skin (cyanosis), severe asthma symptoms in individuals with asthma, acute bronchitis, severe bronchitis, airway inflammation, airway congestion, chronic obstructive pulmonary disease, heart congestion, bacteraemia, pneumonia, acute otitis media, and recurrent otitis media.

11. A method of reducing the severity and/or duration of a Respiratory syncytial virus (RSV) infection in an individual, comprising,

administering to the respiratory tract of 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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.

12. A method of treating a Respiratory syncytial virus (RSV) infection in an individual comprising:
administering to the respiratory tract of the individual an effective amount of a macromolecule or a pharmaceutically acceptable salt thereof, or a composition
5 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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.
- 10 13. A method of preventing or reducing viral shedding in an individual infected with a Respiratory syncytial virus (RSV), comprising,
administering to the respiratory tract of the individual an effective amount of a macromolecule or a pharmaceutically acceptable salt thereof, or a composition
15 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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.
- 20 14. A method of reducing transmission of a Respiratory syncytial virus (RSV) in a population, comprising:
administering to the respiratory tract of a portion of the population an effective amount of a macromolecule or a pharmaceutically acceptable salt thereof, or a
25 composition comprising the macromolecule or pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier,
wherein the macromolecule comprises a dendrimer of 1 to 8 generations with one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.
- 30 15. The method of any one of claims 1 to 7, wherein the CoV is selected from an/a Alphacoronavirus, Betacoronavirus, Gammacoronavirus and Deltacoronavirus.
- 35 16. The method of any one of claims 1 to 7 or 15, wherein the CoV is a Betacoronavirus.

17. The method of any one of claims 1 to 7 or 15 or 16, wherein the CoV is selected from: 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
5 acute respiratory syndrome-related coronavirus (SARS-CoV), and Middle-East respiratory syndrome-related coronavirus (MERS-CoV) or a subtype or a variant thereof.
18. The method of any one of claims 1 to 7 or 15 to 17, wherein the CoV is SARS-
10 CoV-2 or a subtype or variant thereof.
19. The method of any one of claims 8 to 14, wherein the RSV is selected from: RSV subtype A (RSVA) and RSV subtype B (RSVB).
20. The method of any one of claims 1 to 7 or 15 to 18, wherein administering comprises administering topically or administering to the respiratory tract.
21. The method of claim 20, wherein administering topically comprises administering to the hands and/or face.
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22. The method of any one of claims 8 to 14 or 20, wherein administering to the respiratory tract comprises administering to the upper respiratory tract and/or lower respiratory tract.
23. The method of claim 22, wherein administering to the upper respiratory tract comprises administering to one or more of the: nasal cavity, oral cavity, sinuses, throat, pharynx, larynx, nasal turbinates, nasopharynx, and oropharynx..
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24. The method of claim 22 or claim 23, wherein administering to the upper
30 respiratory tract comprises administering to the nasal mucosa.
25. The method of claim 22, wherein administering to the lower respiratory tract comprises administering to one or more of the: trachea, primary bronchi and lungs.
26. The method of any one of claims 8 to 14, wherein the individual is human.
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27. The method of any one of claims 1 to 26, wherein the composition comprises about 0.5% to about 5% by weight of the macromolecule or pharmaceutically acceptable salt thereof.
- 5 28. The method of any one of claims 1 to 27, wherein the composition comprises about 1% by weight of the macromolecule or pharmaceutically acceptable salt thereof
29. The method of any one of claims 1 to 28, wherein the effective amount is about 0.1 to about 5 mg per dose.
- 10 30. The method of any one of the claims 1 to 29, wherein the effective amount is about is 1 mg per dose.
31. The method of any one of claims 1 to 30, wherein the macromolecule or a
15 pharmaceutically acceptable salt thereof is administered in a nasal spray or an oral spray.
32. The method of any one of claims 1 to 31, wherein the macromolecule or a pharmaceutically acceptable salt thereof is administered 1 to 8 times daily.
- 20 33. The method of any one of claims 1 to 32, 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.
- 25 34. A composition for: preventing or reducing the likelihood of, or treating a Coronavirus (CoV) infection in an individual; reducing the severity and/or duration of CoV infection in an individual; preventing or reducing viral shedding in an individual infected with a CoV; or reducing 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
5 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer.

35. The composition of claim 34, wherein the composition is a nasal bioadhesive composition.

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36. The composition of claim 34 or claim 35, wherein the composition additionally comprises one or more agents selected from: an antiviral active agent, a vaccine, an immunomodulatory, an antibacterial agent, an anti-inflammatory agent and a nasal bioadhesive agent.

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37. The composition of claim 36, wherein the antiviral active agent is 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

20 including, ribavirin, tilorone, favipiravir, Kaletra (lopinavir/ritonavir), Prezcoibix (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. IFN β),
chloroquine and azithromycin.

38. The composition of any one of claims 34 to 37, wherein the composition
5 comprises one or more of: Carbopol 974, hydroxypropylmethyl-cellulose and
microcrystalline cellulose /carboxy methyl cellulose.
39. The composition of any one of claims 34 to 38, wherein the composition
comprises one or more of: glycerine, propylene glycol, methyl paraben, propyl paraben,
10 benzalkonium chloride, ethylenediamine tetraacetic acid and sodium hydroxide.
40. The composition of any one of claims 34 to 39, wherein the composition
comprises:
- (a) a rheology modifier selected from one or more of: Carbopol 974,
15 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,
20 ethylenediamine tetraacetic acid; and
 - (d) a pH modifier.
41. The composition of anyone of claims 38 to 40, wherein the composition
comprises a w/w ratio of about 1:20 to 1:10 of Carbopol 974 or Carbopol 971 to the
25 macromolecule.
42. The composition of anyone of claims 38 to 41, wherein the composition
comprises about 0.05% w/w Carbopol 974 or Carbopol 971 and about 1% w/w of
macromolecule.

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43. The composition of any one of claims 34 to 42, wherein the composition is in a form selected from: a liquid, semi-solid, solid, and powder composition.
44. The composition of any one of claims 34 to 43, wherein the composition has a
5 pH of about 3.5 to about 7.5, or a pH of about 5.5. to about 6.5.
45. The composition of any one of claims 34 to 44, wherein the composition has a viscosity of about 1 to about 10cP.
- 10 46. The composition of any one of claims 34 to 45, wherein the composition 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.
47. The composition of claim 46, wherein the spray, inhaler or nebuliser comprises
15 a means for generating particles of a size of about 0.1 μm to about 100 μm .
48. The composition of claim 47, wherein less than 6% of the particles are of a size of about 10 μm or less.
- 20 49. The composition of claim 47 or claim 48, wherein particle size is measured using an actuation of 60mm/s and a distance of 40 to 70mm from the means for generating particles.
50. The composition of any one of claims 34 to 49, wherein the composition
25 comprises: SPL7013, water, Carbopol 974 or Carbopol 971, hydroxypropylmethyl-cellulose, microcrystalline cellulose, glycerin, propylene glycol, methyl paraben, propyl paraben, benzalkonium chloride, and EDTA.
51. The composition of any one of claims 34 to 50, wherein the composition is
30 present in or applied to protective wear or cleaning products.
52. The composition of claim 51, wherein the protective wear is selected from a face mask, gloves and a gown.

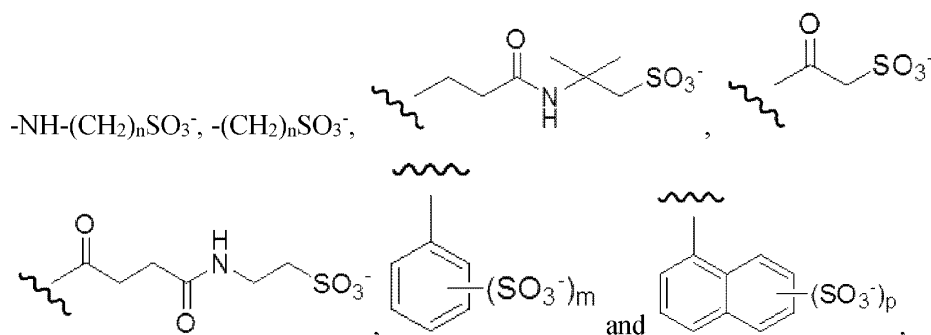
53. The composition of claim 51, wherein the cleaning product is selected from a wipe, a surgical field preparation spray or a cleaning solution.

5 54. The composition of any one of claims 34 to 53, 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.

55. The composition of claim 54, wherein the composition inactivates more than
10 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 after at least 1 minute of exposure to the virus.

56. The method of any one of claims 1 to 33, or the composition of any one of
15 claims 34 to 55, 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 naphthylsulfonate moieties.

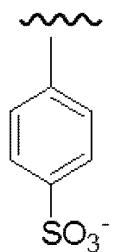
57. The method of any one of claims 1 to 33 or 54, or the composition of any one of
20 claims 34 to 56, wherein the sulfonic acid- or sulfonate-containing moiety is selected from the group consisting of:



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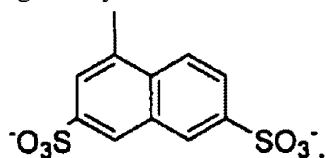
wherein n is zero or is an integer from 1-20, m is an integer 1 or 2 and p is an integer 1 to 3.

58. The method or composition of claim 57, wherein the sulfonic acid or sulfonate-containing moiety is selected from the group consisting of:



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59. The method or composition of claim 57 or claim 58, wherein the sulfonic acid-containing moiety is



10 60. The method of any one of claims 1 to 33 or claims 56 to 59, or the composition of any one of claims 34 to 59, wherein the sulfonic acid- or sulfonate- containing moiety is attached to the dendrimer terminal amino group by a linker.

15 61. The method or composition of claim 60, 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 $-S-$.

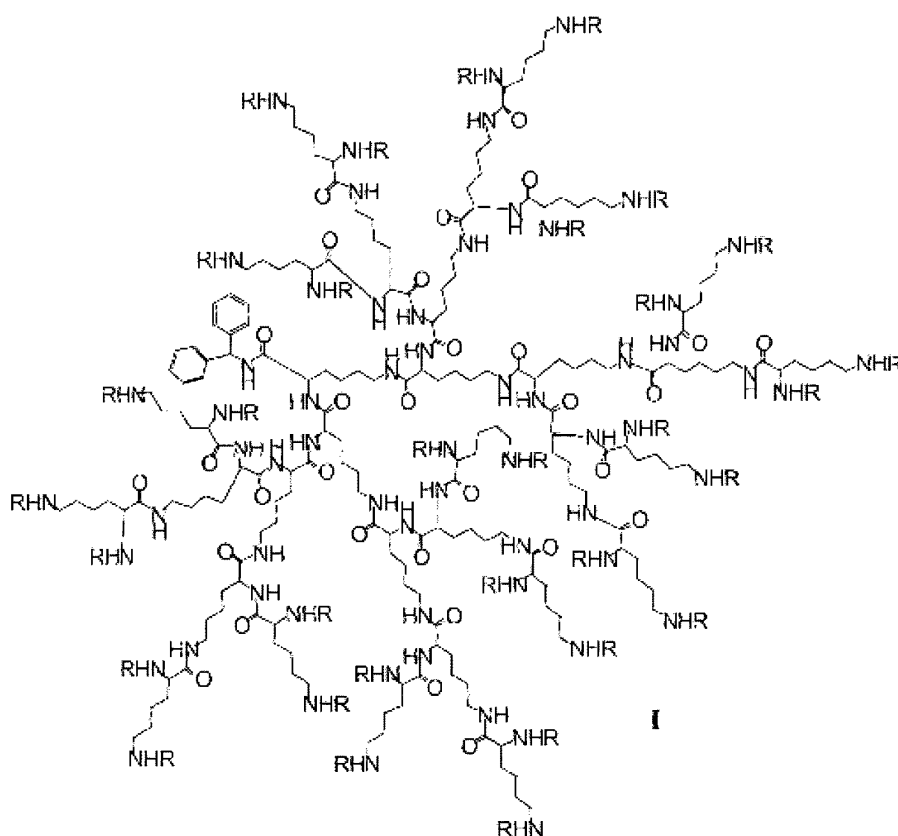
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62. The method or composition of claim 61, wherein the linker is $\#-O-CH_2-C(O)-^*$ in which $\#$ designates attachment to the sulfonic acid-containing moiety and * designates attachment to the terminal amino group of the dendrimer.

25 63. The method of any one of claims 1 to 33 or claims 56 to 62, or the composition of any one of claims 34 to 62, wherein the dendrimer has 3-4 generations.

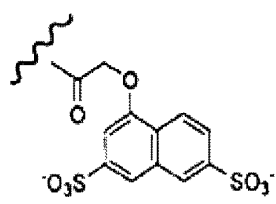
64. The method of any one of claims 1 to 33 or claims 56 to 63, or the composition of any one of claims 34 to 63, wherein the dendrimer is a polylysine dendrimer.

65. The method or composition of claim 64, wherein the dendrimer is



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and wherein at least 50% of R is



O_3S and SO_3^- , and wherein the pharmaceutically acceptable salt is a sodium salt.

10 66. A device for delivering 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,

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

67. The device of claim 66, wherein the device is a nasal delivery device or an oral delivery device for delivering a spray.

- 10 68. The device of claim 66, wherein the device is an inhaler or a nebuliser.

69. A nasal moisture barrier dressing 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,

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

- 20 70. A composition 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,

- 25 wherein the macromolecule comprises a dendrimer of 3 to 5 generations with one or more 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 Carbopol 974 or Carbopol 971 to the macromolecule.

- 30 71. A composition 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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer and Carbopol 974,

- 5 wherein the composition comprises about 0.05% w/w to about 5% w/w, or about 0.05% w/w to about 3% w/w, or about 0.05% w/w to about 2% w/w, or about 0.05% w/w to about 1% w/w, or about 0.05% w/w Carbopol 974.

72. A composition comprising:
 an effective amount of a macromolecule or a pharmaceutically acceptable salt
10 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 one or more sulfonic acid- or sulfonate-containing moieties attached to one or more surface groups of the dendrimer and Carbopol 971,
15 wherein the composition comprises about 0.05% w/w to about 1% w/w, or about 0.05% w/w to about 1.5% w/w, or about 0.05% w/w to about 1.8% w/w Carbopol 971.