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(54) Titre : COMPOSITIONS DE SOIN BUCCAL RENFERMANT UN ACIDE AMINE, DES SOURCES D'IONDE ZINC MELANGEES ET UN SYSTEME D'EPAISSISSANT CELLULOSE/POLYSACCHARIDE

(54) Title: ORAL CARE COMPOSITIONS COMPRISING AN AMINO ACID, MIXED ZINC ION SOURCES, AND A CELLULOSE/POLYSACCHARIDE THICKENING SYSTEM

(57) Abrégé/Abstract:
There is provided an oral care composition comprising: a basic amino acid in free or salt form, the basic amino acid being selected from the group consisting of arginine, lysine, and combinations thereof; a combination of zinc ion sources, the combination comprising zinc oxide and zinc citrate; and a thickening system comprising: from about 0.25 wt.% to about 1 wt.% of a nonionic cellulose ether having a molecular weight of about 300,000 to about 350,000; and from about 0.4 wt.% to about1 wt.% of a polysaccharide gum. The nonionic cellulose may comprise hydroxyethylcellulose, and the polysaccharide gum may be xanthan gum. Additionally, the oral care compositions may exhibit increased stability, corresponding to a reduced loss in viscosity over time.

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ABSTRACT

There is provided an oral care composition comprising: a basic amino acid in free or salt form, the basic amino acid being selected from the group consisting of arginine, lysine, and combinations thereof; a combination of zinc ion sources, the combination comprising zinc oxide and zinc citrate; and a thickening system comprising: from about 0.25 wt.% to about 1 wt.% of a nonionic cellulose ether having a molecular weight of about 300,000 to about 350,000; and from about 0.4 wt.% to about1 wt.% of a polysaccharide gum. The nonionic cellulose may comprise hydroxyethylcellulose, and the polysaccharide gum may be xanthan gum. Additionally, the oral care compositions may exhibit increased stability, corresponding to a reduced loss in viscosity over time.

ORAL CARE COMPOSITIONS COMPRISING AN AMINO ACID, MIXED ZINC ION SOURCES, AND A CELLULOSE/POLYSACCHARIDE THICKENING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the priority from PCT/CN2016/086994, filed June 24, 2016.

BACKGROUND

[0002] Arginine-based oral care compositions generally include some combination of polymers, abrasive(s); and in some instances, additional active ingredients. In those instances where additional active ingredients are included and comprise cationic metal ions, e.g. zinc, maintaining the physical stability of the composition is a challenge because of the interaction between these cationic metal ions and certain polymeric components and abrasive systems.

[0003] The use of certain abrasives or specific concentrations of particular polymers are two ways in which the stability issues have been addressed. However, these methods have generally been individually focused on stand-up (i.e., appearance on the brush) and squeezability from packaging (toothpaste tubes). As such, there remains a need to reconcile these physical stability concerns and processability. Certain embodiments of the present invention are designed to address this need.

BRIEF SUMMARY

[0004] Some embodiments of the present invention provide oral care compositions comprising a basic amino acid in free or salt wherein the amino acid is selected from arginine, lysine, and a combination thereof; a combination of zinc ion sources; and a thickening system comprising from about 0.5 wt.% to about 2 wt.% of a nonionic cellulose ether; and from about 0.1 wt.% to about 1 wt.% of a polysaccharide gum. In some embodiments, the nonionic cellulose ether is hydroxyethylcellulose and the polysaccharide gum is xanthan gum.

[0005] Other embodiments provide compositions further comprising a silica abrasive which exhibits an approximately neutral pH when measured in an aqueous medium. Still

further embodiments provide oral care compositions comprising a basic amino acid in free or salt wherein the amino acid is selected from arginine, lysine, and a combination thereof; a combination of zinc ion sources; a thickening system comprising from about 0.5 wt.% to about 2 wt.% of a nonionic cellulose ether; and from about 0.1 wt.% to about 1 wt.% of a polysaccharide gum; and a silica abrasive which exhibits an approximately neutral pH when measured in an aqueous medium.

[0006] In some embodiments, the oral care compositions of the present invention demonstrate the ability to avoid viscosity loss and maintain static yield stress over an extended period of time, e.g. after one year.

[0007] In one aspect the invention is an oral care composition (Composition 1.0) comprising:

a. A basic amino acid in free or salt from, wherein the amino acid is selected from arginine, lysine, and combinations thereof; (e.g., free form arginine);
b. zinc oxide and zinc citrate;
c. a fluoride source (e.g., sodium fluoride); and
d. a silica abrasive which exhibits an acid pH when measured as an aqueous slurry (e.g., prophy silica).

[0008] For example, the invention contemplates any of the following compositions (unless otherwise indicated, values are given as percentage of the overall weight of the composition):

1.01 Composition 1.0 wherein the silica abrasive which exhibits an acid pH when measured as an aqueous slurry is prophy silica.

1.02 Any of the preceding compositions wherein the silica abrasive which exhibits an acid pH when measured as an aqueous slurry is Sylodent 783.

1.03 Any of the preceding compositions wherein the silica abrasive exhibits a pH of 3.5-4.5 in an aqueous slurry of the abrasive.

1.04 Any of the preceding compositions wherein the silica abrasive which exhibits an acid pH when measured as an aqueous slurry is present in an amount from 2 to 35 weight percent.

1.05 Any of the preceding compositions wherein the silica abrasive which exhibits an acid pH when measured as an aqueous slurry is present in an amount from 3 to 15 weight percent.

1.06 Any of the preceding compositions wherein the silica abrasive which exhibits an acid pH when measured as an aqueous slurry is present in an amount selected from 2 wt.%, 3 wt.%, 4% wt.%, 5 wt.%, 6 wt.%, 7 wt.%, 8 wt.%, 9 wt.%, 10 wt.%, 11 wt.%, 12 wt.%, 13 wt.%, 14 wt.%, 15 wt.%, 16 wt.%, 17 wt.%, 18 wt.%, 19 wt.%, 20 wt.%.

1.07 Any of the preceding compositions wherein the basic amino acid has the L-configuration (e.g., L-arginine).

1.08 Any of the preceding compositions wherein the basic amino acid is arginine or lysine is in free form.

1.09 Any of the preceding compositions wherein the basic amino acid is provided in the form of a di- or tri-peptide comprising arginine or lysine, or salts thereof.

1.10 Any of the preceding compositions wherein the basic amino acid is arginine or lysine, and wherein the arginine or lysine is present in an amount corresponding to 1% to 15%, e.g., 3 wt. % to 10 wt. % of the total composition weight, about e.g., 1.5%, 4%, 5%, or 8%, wherein the weight of the basic amino acid is calculated as free form.

1.11 Any of the preceding compositions wherein the amino acid is arginine from 0.1 wt. % - 6.0 wt. %. (e.g., about 1.5 wt.%).

1.12 Any of the preceding compositions wherein the amino acid is arginine from about 1.5 wt. %.

1.13 Any of the preceding compositions wherein the amino acid is arginine from 4.5 wt. % – 8.5 wt. % (e.g., 5.0 wt.%).

1.14 Any of the preceding compositions wherein the amino acid is arginine from about 5.0 wt.%.

1.15 Any of the preceding compositions wherein the amino acid is arginine from 3.5 wt. % – 9 wt.%.

1.16 Any of the preceding compositions wherein the amino acid is arginine from about 8.0 wt.%.

1.17 Any of the preceding compositions wherein the amino acid is L-arginine.

1.18 Any of the preceding compositions wherein the amino acid is a free form arginine.

1.19 Any of the preceding compositions wherein the basic amino acid is lysine (e.g., 2 wt.%, 3 wt.%, 4 wt.%, 5 wt.%, 6 wt.%), (e.g., 4 wt.%).

1.20 Any of the preceding compositions wherein the amino acid is lysine from 1.0 wt. % - 6.0 wt. %.

1.21 Any of the preceding compositions wherein the amino acid is lysine from about 1.5 wt. %.

1.22 Any of the preceding compositions wherein the amino acid is lysine from about 4.0 wt. %.

1.23 Any of the preceding compositions wherein the amino acid is L-lysine.

1.24 Any of the preceding compositions wherein the amino acid is free form lysine.

1.25 Any of the preceding compositions wherein the amino acid is arginine or lysine in partially or wholly in salt form.

1.26 Composition 1.25 wherein the amino acid is arginine phosphate.

1.27 Composition 1.25 wherein the amino acid is arginine hydrochloride.

1.28 Composition 1.25 wherein the amino acid is arginine bicarbonate.

1.29 Composition 1.25 wherein the amino acid is lysine phosphate.

1.30 Composition 1.25 wherein the amino acid is lysine hydrochloride.

1.31 Composition 1.25 wherein the amino acid is lysine bicarbonate.

1.32 Any of the preceding compositions wherein the amino acid is arginine or lysine ionized by neutralization with an acid or a salt of an acid.

1.33 Any of preceding compositions wherein the composition is ethanol-free.

1.34 Any of the preceding compositions further comprising a fluoride source selected from: stannous fluoride, sodium fluoride, potassium fluoride, sodium monofluorophosphate, sodium fluorosilicate, ammonium fluorosilicate, amine fluoride (e.g., N'-octadecyltrimethylendiamine-N,N,N'- tris(2-ethanol)-dihydrofluoride), ammonium fluoride, titanium fluoride, hexafluorosulfate, and combinations thereof.

1.35 The composition of 1.34, wherein the fluoride source is stannous fluoride.

1.36 Any of the preceding compositions wherein the fluoride source is a fluorophosphate.

1.37 Any of the preceding compositions wherein the fluoride source is sodium monofluorophosphate.

1.38 The composition of 1.34, wherein the fluoride source is sodium fluoride.

1.39 Any of the preceding compositions wherein the fluoride source is a fluoride salt present in an amount of 0.1 wt. % to 2 wt. % (0.1 wt% - 0.6 wt.%) of the total composition weight (e.g., sodium fluoride (e.g., about 0.32 wt.%) or sodium monofluorophosphate).

1.40 Any of the preceding compositions wherein the fluoride source is sodium fluoride in an amount about 0.32 wt.% based on the weight of the composition.

1.41 Any of the preceding compositions wherein the fluoride source is a soluble fluoride salt which provides fluoride ion in an amount of from 50 to 25,000 ppm (e.g., 750 -2000ppm, e.g., 1000-1500ppm, e.g., about 1000 ppm, e.g., about 1450ppm)

1.42 Any of the preceding compositions wherein the fluoride source is sodium fluoride which provides fluoride in an amount from 750 – 2000ppm (e.g., about 1450ppm).

1.43 Any of the preceding compositions wherein the fluoride source is selected from sodium fluoride and sodium monofluorophosphate and which provides fluoride in an amount from 1000ppm -1500ppm.

1.44 Any of the preceding compositions wherein the fluoride source is sodium fluoride or sodium monofluorophosphate and which provides fluoride in an amount of about 1450ppm.

1.45 Any of the preceding compositions wherein the pH is between 6.0 and 10.5, e.g., 7.0 to 9.0, e.g., about 8.0.

1.46 Any of the preceding compositions further comprising calcium carbonate.

1.47 The composition of 1.46, wherein the calcium carbonate is a precipitated calcium carbonate high absorption (e.g., 20% to 30% by weight of the composition) (e.g., 25% precipitated calcium carbonate high absorption).

1.48 The composition of 1.47, further comprising a precipitated calcium carbonate – light (e.g., about 10% precipitated calcium carbonate – light) (e.g., about 10% natural calcium carbonate).

1.49 Any of the preceding compositions further comprising an effective amount of one or more alkali phosphate salts, e.g., sodium, potassium or calcium salts, e.g., selected from alkali dibasic phosphate and alkali pyrophosphate salts, e.g., alkali phosphate salts selected from sodium phosphate dibasic, potassium phosphate dibasic, dicalcium phosphate dihydrate, calcium pyrophosphate, tetrasodium pyrophosphate, tetrapotassium pyrophosphate, sodium tripolyphosphate, disodium hydrogenorthophoshpate, monosodium phosphate, pentapotassium triphosphate and mixtures of any of two or more of these, in an amount of 0.1-20%, e.g., 0.1-8%, e.g., e.g., 0.2 to 5%, e.g., 0.3 to 2%, e.g., 0.3 to 1%, e.g about 0.5%, about 1%, about 2%, about 5%, about 6%, by weight of the composition.

1.50 Any of the preceding compositions comprising tetrapotassium pyrophosphate, disodium hydrogenorthophosphate, monosodium phosphate, and pentapotassium triphosphate.

1.51 Any of the preceding compositions, wherein the composition further comprises stannous pyrophosphate, wherein the stannous pyrophosphate is from 0.1% - 3% by wt. of the composition. (e.g., about 1% by wt. of the composition).

1.52 Any of the preceding compositions comprising a polyphosphate.

1.53 The composition of 1.49, wherein the polyphosphate is tetrasodium pyrophosphate.

1.54 The composition of 1.53, wherein the tetrasodium pyrophosphate is from .1 – 1.0 wt% (e.g., about .5 wt%).

1.55 Any of the preceding compositions further comprising a second abrasive or particulate (e.g., silica).

1.56 Any of the preceding compositions wherein the second abrasive silica is synthetic amorphous silica. (e.g., 1% - 28% by wt.) (e.g., 8% - 25% by wt.)

1.57 Any of the preceding composition wherein the silica abrasives are silica gels or precipitated amorphous silicas, e.g. silicas having an average particle size ranging from 2.5 microns to 12 microns.

1.58 Any of the preceding compositions further comprising a small particle silica having a median particle size (d50) of 1- 5 microns (e.g., 3 - 4 microns) (e.g., about 5 wt. % Sorbosil AC43 from PQ Chemicals, Warrington, United Kingdom).

1.59 Any of the preceding compositions wherein 20-30 wt% of the total silica in the composition is small particle silica (e.g., having a median particle size (d50) of 3 - 4 microns) and wherein the small particle silica is about 5 wt.% of the oral care composition.

1.60 Any of the preceding compositions comprising silica wherein the silica is used as a thickening agent, e.g., particle silica.

1.61 Any of the preceding compositions further comprising a nonionic surfactant, wherein the nonionic surfactant is in an amount of from 0.5 -5%, e.g, 1-2%, selected from poloxamers (e.g., poloxamer 407), polysorbates (e.g., polysorbate 20), polyoxyl hydrogenated castor oil (e.g., polyoxyl 40 hydrogenated castor oil), and mixtures thereof.

1.62 Any of the preceding compositions, wherein the poloxamer nonionic surfactant has an average polyoxypropylene molecular mass (Mw) of from 3000 to 5000g/mol and a polyoxyethylene content of from 60 to 80 mol%, e.g., the poloxamer nonionic surfactant comprises poloxamer 407.

1.63 Any of the preceding compositions further comprising glycerin, wherein the glycerin is in a total amount of 25- 40% (e.g., about 35%).

1.64 The composition of 1.63, wherein the glycerin is in an amount of about 35% by wt. of the composition.

1.65 The composition of 1.63, wherein the glycerin is in an amount of about 26% by wt. of the composition.

1.66 Any of the preceding compositions further comprising sorbitol, wherein the sorbitol is in a total amount of 10- 40% (e.g., about 23%).

1.67 The composition of 1.66, wherein the sorbitol is in an amount of about 13% by wt. of the composition.

1.68 The composition of any of 1.63 – 1.67, wherein the glycerin is an amount of about 26% by wt., and the sorbitol is in an amount of about 13% by wt.

1.69 Any of the preceding compositions, wherein the ratio of the amount of zinc oxide (e.g., wt.%) to zinc citrate (e.g., wt%) is from 1.5:1 to 4.5:1 (e.g., 2:1, 2.5:1, 3:1, 3.5:1, or 4:1).

1.70 Any of the preceding compositions, wherein the zinc citrate is in an amount of from 0.25 to 1.0 wt% (e.g., 0.5 wt. %) and zinc oxide may be present in an amount of from 0.75 to 1.25 wt% (e.g., 1.0 wt. %) based on the weight of the oral care composition.

1.71 Any of the preceding compositions wherein the zinc citrate is about 0.5 wt%.

1.72 Any of the preceding compositions wherein the zinc oxide is about 1.0 wt%.

1.73 Any of the preceding compositions where the zinc citrate is about 0.5 wt% and the zinc oxide is about 1.0 wt%.

1.74 Any of the preceding compositions further comprising an additional ingredient selected from: benzyl alcohol, Methylisothizolinone ("MIT"), Sodium bicarbonate, sodium methyl cocoyl taurate (tauranol), lauryl alcohol, and polyphosphate.

1.75 Any of the preceding compositions wherein the benzyl alcohol is present from 0.1 - 0.6 wt %., (e.g., 0.1 – 0.4 wt %) e.g. about 0.1 wt. %, about 0.2 wt. %, or about 0.3 wt. %.

1.76 Any of the preceding compositions wherein the benzyl alcohol is about 0.1 wt%.

1.77 Any of the preceding compositions wherein the benzyl alcohol is considered a preservative.

1.78 Any of the preceding compositions comprising polymer films.

1.79 Any of the preceding compositions comprising flavoring, fragrance and/or coloring.

1.80 The composition of 1.65, wherein the flavoring agent is sodium saccharin, sucralose, or a mixture thereof.

1.81 Any of the preceding compositions, wherein the composition comprises a thickening agents selected from the group consisting of carboxyvinyl polymers, xanthan gum, carrageenan, hydroxyethyl cellulose and water soluble salts of cellulose ethers (e.g., sodium carboxymethyl cellulose and sodium carboxymethyl hydroxyethyl cellulose).

1.82 Any of the preceding compositions, wherein the compositions comprises sodium carboxymethyl cellulose (e.g., from 0.5 wt.% – 1.5 wt.%).

1.83 Any of the preceding compositions comprising from 5% – 40%, e.g., 10% – 35%, e.g., about 15%, 25%, 30%, and 35% water.

1.84 Any of the preceding compositions comprising an additional antibacterial agent selected from halogenated diphenyl ether (e.g. triclosan), herbal extracts and essential oils (e.g., rosemary extract, tea extract, magnolia extract, thymol, menthol, eucalyptol, geraniol, carvacrol, citral, honokiol, catechol, methyl salicylate, epigallocatechin gallate, epigallocatechin, gallic acid, miswak extract, sea-buckthorn extract), bisguanide antiseptics (e.g., chlorhexidine, alexidine or octenidine), quaternary ammonium compounds (e.g., cetylpyridinium chloride (CPC), benzalkonium chloride, tetradecylpyridinium chloride (TPC), N-tetradecyl-4-ethylpyridinium chloride (TDEPC)), phenolic antiseptics, hexetidine, octenidine, sanguinarine, povidone iodine, delmopinol, salifluor, metal ions (e.g., zinc salts and zinc compounds, for example, Zinc Chloride, Zinc Lactate, Zinc Sulfate, Zinc Oxide, stannous salts, copper salts, iron salts), sanguinarine, propolis and oxygenating agents (e.g., hydrogen peroxide, buffered sodium peroxyborate or peroxycarbonate), phthalic acid and its salts, monoperthalic acid and its salts and esters, ascorbyl stearate, oleoyl sarcosine, alkyl sulfate, dioctyl sulfosuccinate, salicylanilide, domiphen bromide, delmopinol, octapinol and other piperidino derivatives, nicin preparations, chlorite salts; and mixtures of any of the foregoing.

1.85 Any of the preceding compositions comprising an antioxidant, e.g., selected from the group consisting of Co-enzyme Q10, PQQ, Vitamin C, Vitamin E, Vitamin A, BHT, anethole-dithiothione, and mixtures thereof.

1.86 Any of the preceding compositions comprising a whitening agent.

1.87 Any of the preceding compositions comprising a whitening agent selected from a whitening active selected from the group consisting of peroxides, metal chlorites, perborates, percarbonates, peroxyacids, hypochlorites, and combinations thereof.

1.88 Any of the preceding compositions further comprising hydrogen peroxide or a hydrogen peroxide source, e.g., urea peroxide or a peroxide salt or complex (e.g.,

such as peroxyphosphate, peroxycarbonate, perborate, peroxysilicate, or persulphate salts; for example calcium peroxyphosphate, sodium perborate, sodium carbonate peroxide, sodium peroxyphosphate, and potassium persulfate), or hydrogen peroxide polymer complexes such as hydrogen peroxide-polyvinyl pyrrolidone polymer complexes.

1.89 Any of the preceding compositions further comprising an agent that interferes with or prevents bacterial attachment, e.g., ethyl lauryl arginate (ELA) or chitosan.

1.90 Any of the preceding compositions comprising:

a. about 1.0% zinc oxide

b. about 0.5% zinc citrate

c. about 1.5% L-arginine

d. about 0.32% sodium fluoride;

e. about 3 wt.% to 15 wt.% silica abrasive which exhibits an acid pH when measured as an aqueous slurry (e.g., prophy silica) (e.g., Sylodent 783)

1.91 Any of the preceding compositions comprising:

a. about 1.0% zinc oxide

b. about 0.5% zinc citrate

c. about 5% L-arginine

d. about 0.32% sodium fluoride

e. about 10 wt.% to 15 wt.% silica abrasive which exhibits an acid pH when measured as an aqueous slurry (e.g., prophy silica) (e.g., Sylodent 783), and

1.92 Any of the preceding compositions comprising:

a. about 1.0% zinc oxide

b. about 0.5% zinc citrate

c. about 5% L-arginine

d. about 0.32% sodium fluoride;

e. about 3 wt.% to 15 wt.% silica abrasive which exhibits an acid pH when measured as an aqueous slurry. (e.g., prophy silica) (e.g., Sylodent 783)

1.93 Any of the preceding compositions comprising a silica, wherein the silica is Zeodent 114.

1.94 Any of the preceding compositions effective upon application to the oral cavity, e.g., by rinsing, optionally in conjunction with brushing, to (i) reduce or inhibit formation of dental caries, (ii) reduce, repair or inhibit pre-carious lesions of the enamel, e.g., as detected by quantitative light-induced fluorescence (QLF) or electrical caries measurement (ECM), (iii) reduce or inhibit demineralization and promote remineralization of the teeth, (iv) reduce hypersensitivity of the teeth, (v) reduce or inhibit gingivitis, (vi) promote healing of sores or cuts in the mouth, (vii) reduce levels of acid producing bacteria, (viii) to increase relative levels of arginolytic bacteria, (ix) inhibit microbial biofilm formation in the oral cavity, (x) raise and/or maintain plaque pH at levels of at least pH 5.5 following sugar challenge, (xi) reduce plaque accumulation, (xii) treat, relieve or reduce dry mouth, (xiii) clean the teeth and oral cavity (xiv) reduce erosion, (xv) prevents stains and/or whiten teeth, (xvi) immunize the teeth against cariogenic bacteria; and/or (xvii) promote systemic health, including cardiovascular health, e.g., by reducing potential for systemic infection via the oral tissues.

1.95 Any of the preceding oral compositions, wherein the oral composition may be any of the following oral compositions selected from the group consisting of: a toothpaste or a dentifrice, a mouthwash or a mouth rinse, a topical oral gel, and a denture cleanser.

1.96 A composition obtained or obtainable by combining the ingredients as set forth in any of the preceding compositions.

1.97 A composition obtained or obtainable by combining the ingredients as set forth in any of the preceding compositions.

1.98 A composition for use as set for in any of the preceding compositions.

[0009] In another embodiment, the invention encompasses a method to improve oral health comprising applying an effective amount of the oral composition of any of the embodiments set forth above (e.g., any of Composition 1.0 *et seq*) to the oral cavity of a subject in need thereof, e.g.,

i. a method to reduce or inhibit formation of dental caries, reduce, repair or inhibit early enamel lesions, e.g., as detected by quantitative light- induced fluorescence (QLF) or electrical caries measurement(ECM),

ii. reduce or inhibit demineralization and promote remineralization of the teeth,

iii. reduce hypersensitivity of the teeth,

iv. reduce or inhibit gingivitis,

v. promote healing of sores or cuts in the mouth,

vi. reduce levels of acid producing bacteria,

vii. to increase relative levels of arginolytic bacteria,

viii. inhibit microbial bio film formation in the oral cavity,

ix. raise and/or maintain plaque pH at levels of at least pH 5.5 following sugar challenge,

x. reduce plaque accumulation,

xi. treat dry mouth,

xii. enhance systemic health, including cardiovascular health, e.g., by reducing potential for systemic infection via the oral tissues,

xiii. whiten teeth,

xiv. reduce erosion of the teeth,

xv. immunize (or protect) the teeth against cariogenic bacteria and their effects, and/or

xvi. clean the teeth and oral cavity.

[00010] In some embodiments, the present invention further comprises the use of sodium bicarbonate, sodium methyl cocoyl taurate (tauranol), methylisothiazolinone, and benzyl alcohol and combinations thereof in the manufacture of a Composition of the Invention, e.g., for use in any of the indications set forth in the above method of Composition 1.0, et seq. In further embodiments, the nonionic cellulose ether and the polysaccharide gum are present in a weight ratio of 3:1, 2.5:1, 1.5:1 or 1:1; the amino acid is arginine, and is present at about 1.5 wt. %, about 5 wt. %, or about 8 wt. %, of the oral care composition; the weight ratio of zinc oxide to zinc citrate is about 2:1; the zinc citrate is in an amount of about 0.5 wt. % and zinc oxide is present in an amount of about 1.0 wt. % based on the total weight of the oral care composition; the fluoride ion source provides soluble fluoride in an amount of about 1450ppm; and/or the composition i) has a static yield stress greater than about 20 Pa, about 25 Pa, about 30 Pa, about 35 Pa, or about 40 Pa; ii) has a drainage time of less than

10 minutes; iii) demonstrates less than 225 grams of leftovers; iv) loses no more than about 25% of its initial viscosity after one year; or combinations thereof.

[00010a] In a further aspect, there is provided an oral care composition comprising: a. a basic amino acid in free or salt form wherein the basic amino acid is selected from the group consisting of arginine, lysine, and a combination thereof; b. a combination of zinc ion sources, wherein the combination comprises zinc oxide and zinc citrate; and c. a thickening system comprising: i. from about 0.25 wt.% to about 1 wt.% of a nonionic cellulose ether having a molecular weight of about 300,000 to about 350,000; and ii. from about 0.4 wt.% to about 1 wt.% of a polysaccharide gum.

[00010b] In a further aspect, there is provided use of the oral care composition described herein for:

i. reducing or inhibiting formation of dental caries,
ii. reducing, repairing or inhibiting early enamel lesions,
iii. reducing or inhibiting demineralization and promote remineralization of teeth,
iv. reducing hypersensitivity of teeth,
v. reducing or inhibit gingivitis,
vi. promoting healing of sores or cuts in the mouth,
vii. reducing levels of acid producing bacteria,
viii. increasing relative levels of arginolytic bacteria,
ix. inhibiting microbial bio film formation in the oral cavity,
x. raising and/or maintaining plaque pH at levels of at least pH 5.5 following sugar challenge,
xi. reducing plaque accumulation,
xii. treating dry mouth,
xiii. enhancing systemic health, including cardiovascular health,
xiv. whitening teeth,
xv. reducing erosion of the teeth,
xvi. immunizing or protecting teeth against cariogenic bacteria and their effects, and/or
xvii. cleaning teeth and oral cavities.

DETAILED DESCRIPTION

[00011] As used herein, the terms "oral composition" and "oral care composition" mean the total composition that is delivered to the oral surfaces. The composition is further defined as a product which, during the normal course of usage, is not, intended for systemic administration of particular therapeutic agents or intentionally swallowed; but rather, is retained in the oral cavity for a time sufficient to contact substantially all of the

dental surfaces and/or oral tissues for the purposes of oral activity. Examples of such compositions include, but are not limited to, toothpaste or a dentifrice, a mouthwash or a mouth rinse, a topical oral gel, a denture cleanser, and the like.

[00012] As used herein, the term "dentifrice" means paste, gel, or liquid formulations unless otherwise specified. The dentifrice composition can be in any desired form such as deep striped, surface striped, multi-layered, having the gel surrounding the paste, or any combination thereof. Alternatively the oral composition is provided as a dual phase composition, wherein individual compositions are combined when dispensed from a separated compartment dispenser.

Basic Amino Acids

[00013] The basic amino acids which can be used in the compositions and methods of the invention include not only naturally occurring basic amino acids, such as arginine, lysine, and histidine, but also any basic amino acids having a carboxyl group and an amino group in the molecule, which are water-soluble and provide an aqueous solution with a pH of 7 or greater.

[00014] Accordingly, basic amino acids include, but are not limited to, arginine, lysine, serine, citrullene, ornithine, creatine, histidine, diaminobutanoic acid, diaminoproprionic acid, salts thereof or combinations thereof. In a particular embodiment, the basic amino acids are selected from arginine, citrullene, and ornithine.

[00015] In certain embodiments, the basic amino acid is arginine, for example, L-arginine, or a salt thereof.

[00016] The compositions of the invention are intended for topical use in the mouth and so salts for use in the present invention should be safe for such use, in the amounts and concentrations provided. Suitable salts include salts known in the art to be pharmaceutically acceptable salts which are generally considered to be physiologically acceptable in the amounts and concentrations provided. Physiologically acceptable salts include those derived from pharmaceutically acceptable inorganic or organic acids or bases, for example acid addition salts formed by acids which form a physiological acceptable anion, e.g., hydrochloride or bromide salt, and base addition salts formed by bases which form a physiologically acceptable cation, for example those derived from alkali metals such as potassium and sodium or alkaline earth metals such as calcium and

magnesium. Physiologically acceptable salts may be obtained using standard procedures known in the art, for example, by reacting a sufficiently basic compound such as an amine with a suitable acid affording a physiologically acceptable anion.

Fluoride Ion Source

[00017] The oral care compositions may further include one or more fluoride ion sources, e.g., soluble fluoride salts. A wide variety of fluoride ion-yielding materials can be employed as sources of soluble fluoride in the present compositions. Examples of suitable fluoride ion-yielding materials are found in U.S. Pat. No. 3,535,421, to Briner et al.; U.S. Pat. No. 4,885,155, to Parran, Jr. et al. and U.S. Pat. No. 3,678,154, to Widder et al. Representative fluoride ion sources used with the present invention (e.g., Composition 1.0 *et seq.*) include, but are not limited to, stannous fluoride, sodium fluoride, potassium fluoride, sodium monofluorophosphate, sodium fluorosilicate, ammonium fluorosilicate, amine fluoride, ammonium fluoride, and combinations thereof. In certain embodiments the fluoride ion source includes stannous fluoride, sodium fluoride, sodium monofluorophosphate as well as mixtures thereof. Where the formulation comprises calcium salts, the fluoride salts are preferably salts wherein the fluoride is covalently bound to another atom, e.g., as in sodium monofluorophosphate, rather than merely ionically bound, e.g., as in sodium fluoride.

Surfactants

[00018] The invention may in some embodiments contain anionic surfactants, e.g., the Compositions of Composition 1.0, *et seq.*, for example, water-soluble salts of higher fatty acid monoglyceride monosulfates, such as the sodium salt of the monosulfated monoglyceride of hydrogenated coconut oil fatty acids such as sodium N- methyl N-cocoyl taurate, sodium coco-glyceride sulfate; higher alkyl sulfates, such as sodium lauryl sulfate; higher alkyl-ether sulfates, e.g., of formula $CH_3(CH_2)_mCH_2(OCH_2CH_2)_nOSO_3X$, wherein m is 6-16, e.g., 10, n is 1-6, e.g., 2, 3 or 4, and X is Na or , for example sodium laureth-2 sulfate ($CH_3(CH2)_{10}CH_2(OCH_2CH_2)_2OSO_3Na$); higher alkyl aryl sulfonates such as sodium dodecyl benzene sulfonate (sodium lauryl benzene sulfonate); higher alkyl sulfoacetates, such as sodium lauryl sulfoacetate (dodecyl sodium sulfoacetate), higher fatty acid esters

of 1,2 dihydroxy propane sulfonate, sulfocolaurate (N-2- ethyl laurate potassium sulfoacetamide) and sodium lauryl sarcosinate. By "higher alkyl" is meant, e.g., C_{6-30} alkyl. In particular embodiments, the anionic surfactant (where present) is selected from sodium lauryl sulfate and sodium ether lauryl sulfate. When present, the anionic surfactant is present in an amount which is effective, e.g., > 0.001% by weight of the formulation, but not at a concentration which would be irritating to the oral tissue, e.g., 1 %, and optimal concentrations depend on the particular formulation and the particular surfactant. In one embodiment, the anionic surfactant is present at from 0.03% to 5% by weight, e.g., 1.5%.

[00019] Cationic surfactants useful in the present invention can be broadly defined as derivatives of aliphatic quaternary ammonium compounds having one long alkyl chain containing 8 to 18 carbon atoms such as lauryl trimethylammonium chloride, cetyl pyridinium chloride, cetyl trimethylammonium bromide, di-isobutylphenoxyethyldimethylbenzylammonium chloride, coconut alkyltrimethylammonium nitrite, cetyl pyridinium fluoride, and mixtures thereof. Illustrative cationic surfactants are the quaternary ammonium fluorides described in U.S. Pat. No. 3,535,421, to Briner et al. Certain cationic surfactants can also act as germicides in the compositions.

[00020] Illustrative nonionic surfactants of Composition 1.0, *et seq.*, that can be used in the compositions of the invention can be broadly defined as compounds produced by the condensation of alkylene oxide groups (hydrophilic in nature) with an organic hydrophobic compound which may be aliphatic or alkylaromatic in nature. Examples of suitable nonionic surfactants include, but are not limited to, the Pluronics, polyethylene oxide condensates of alkyl phenols, products derived from the condensation of ethylene oxide with the reaction product of propylene oxide and ethylene diamine, ethylene oxide condensates of aliphatic alcohols, long chain tertiary amine oxides, long chain tertiary phosphine oxides, long chain dialkyl sulfoxides and mixtures of such materials. In a particular embodiment, the composition of the invention comprises a nonionic surfactant selected from polaxamers (e.g., polaxamer 407), polysorbates (e.g., polysorbate 20), polyoxyl hydrogenated castor oils (e.g., polyoxyl 40 hydrogenated castor oil), and mixtures thereof.

[00021] Illustrative amphoteric surfactants of Composition 1.0, *et seq.*, that can be used in the compositions of the invention include betaines (such as cocamidopropylbetaine), derivatives of aliphatic secondary and tertiary amines in which the aliphatic radical can be a straight or branched chain and wherein one of the aliphatic substituents contains about 8-18 carbon atoms and one contains an anionic water-solubilizing group (such as carboxylate, sulfonate, sulfate, phosphate or phosphonate), and mixtures of such materials.

[00022] Illustrative zwitterionic surfactants of Composition 1.0, *et seq.*, that can be used in the compositions of the invention include derivatives of aliphatic quaternary ammonium, phosphonium and sulfonium compounds in which the aliphatic radical can be a straight or branched chain and wherein one of the aliphatic substituents contains about 8-18 carbon atoms and one contains an anionic water-solubilizing group (such as carboxy, sulfonate, sulfate, phosphate or phosphonate). The surfactant or mixtures of compatible surfactants can be present in the compositions of the present invention in 0.1% to 5%, in another embodiment 0.3% to 3% and in another embodiment 0.5% to 2% by weight of the total composition.

Flavoring Agents

[00023] The oral care compositions of the invention may also include a flavoring agent. Flavoring agents which are used in the practice of the present invention include, but are not limited to, essential oils and various flavoring aldehydes, esters, alcohols, and similar materials, as well as sweeteners such as sodium saccharin. Examples of the essential oils include oils of spearmint, peppermint, wintergreen, sassafras, clove, sage, eucalyptus, marjoram, cinnamon, lemon, lime, grapefruit, and orange. Also useful are such chemicals as menthol, carvone, and anethole. Certain embodiments employ the oils of peppermint and spearmint.

[00024] The flavoring agent is incorporated in the oral composition at a concentration of 0.01 to 1% by weight.

Chelating and anti-calculus agents

[00025] The oral care compositions of the invention (e.g., Composition 1.0 *et seq*) also may include one or more chelating agents able to complex calcium found in the cell walls

of the bacteria. Binding of this calcium weakens the bacterial cell wall and augments bacterial lysis.

[00026] Another group of agents suitable for use as chelating or anti-calculus agents in the present invention are the soluble pyrophosphates. The pyrophosphate salts used in the present compositions can be any of the alkali metal pyrophosphate salts. In certain embodiments, salts include tetra alkali metal pyrophosphate, dialkali metal diacid pyrophosphate, trialkali metal monoacid pyrophosphate and mixtures thereof, wherein the alkali metals are sodium or potassium. The salts are useful in both their hydrated and unhydrated forms. An effective amount of pyrophosphate salt useful in the present composition is generally enough to provide least 0.1 wt. % pyrophosphate ions, e.g., 0.1 to 3 wt.%, e.g., 0.1 to 2 wt.%, e.g., 0.1 to 1 wt.%, e.g., 0.2 to 0.5 wt.%. The pyrophosphates also contribute to preservation of the compositions by lowering the effect of water activity.

Polymers

[00027] The oral care compositions of the invention (e.g., Composition 1.0, *et seq*) also optionally include one or more polymers, such as polyethylene glycols, polyvinyl methyl ether maleic acid copolymers, polysaccharides (e.g., cellulose derivatives, for example carboxymethyl cellulose, or polysaccharide gums, for example xanthan gum or carrageenan gum). Acidic polymers, for example polyacrylate gels, may be provided in the form of their free acids or partially or fully neutralized water soluble alkali metal (e.g., potassium and sodium) or ammonium salts. Certain embodiments include 1 :4 to 4: 1 copolymers of maleic anhydride or acid with another polymerizable ethylenically unsaturated monomer, for example, methyl vinyl ether (methoxyethylene) having a molecular weight (M.W.) of about 30,000 to about 1,000,000. These copolymers are available for example as Gantrez AN 139(M.W. 500,000), AN 1 19 (M.W. 250,000) and S-97 Pharmaceutical Grade (M.W. 70,000), of GAF Chemicals Corporation.

[00028] Other operative polymers include those such as the 1:1 copolymers of maleic anhydride with ethyl acrylate, hydroxyethyl methacrylate, N-vinyl-2-pyrollidone, or ethylene, the latter being available for example as Monsanto EMA No. 1 103, M.W. 10,000 and EMA Grade 61, and 1 : 1 copolymers of acrylic acid with methyl or

hydroxyethyl methacrylate, methyl or ethyl acrylate, isobutyl vinyl ether or N-vinyl-2-pyrrolidone.

[00029] Suitable generally, are polymerized olefinically or ethylenically unsaturated carboxylic acids containing an activated carbon-to-carbon olefinic double bond and at least one carboxyl group, that is, an acid containing an olefinic double bond which readily functions in polymerization because of its presence in the monomer molecule either in the alpha-beta position with respect to a carboxyl group or as part of a terminal methylene grouping. Illustrative of such acids are acrylic, methacrylic, ethacrylic, alpha-chloroacrylic, crotonic, beta-acryloxy propionic, sorbic, alpha-chlorosorbic, cinnamic, beta-styrylacrylic, muconic, itaconic, citraconic, mesaconic, glutaconic, aconitic, alpha-phenylacrylic, 2-benzyl acrylic, 2-cyclohexylacrylic, angelic, umbellic, fumaric, maleic acids and anhydrides. Other different olefinic monomers copolymerizable with such carboxylic monomers include vinylacetate, vinyl chloride, dimethyl maleate and the like. Copolymers contain sufficient carboxylic salt groups for water-solubility.

[00030] A further class of polymeric agents includes a composition containing homopolymers of substituted acrylamides and/or homopolymers of unsaturated sulfonic acids and salts thereof, in particular where polymers are based on unsaturated sulfonic acids selected from acrylamidoalykane sulfonic acids such as 2-acrylamide 2 methylpropane sulfonic acid having a molecular weight of about 1,000 to about 2,000,000, described in U.S. Pat. No. 4,842,847, Jun. 27, 1989 to Zahid.

[00031] Another useful class of polymeric agents includes polyamino acids, particularly those containing proportions of anionic surface-active amino acids such as aspartic acid, glutamic acid and phosphoserine, as disclosed in U.S. Pat. No. 4,866,161 Sikes et al.

[00032] In preparing oral care compositions, it is sometimes necessary to add some thickening material to provide a desirable consistency or to stabilize or enhance the performance of the formulation. In certain embodiments, the thickening agents are carboxyvinyl polymers, carrageenan, xanthan gum, hydroxyethyl cellulose and water soluble salts of cellulose ethers such as sodium carboxymethyl cellulose and sodium carboxymethyl hydroxyethyl cellulose. Natural gums such as karaya, gum arabic, and

gum tragacanth can also be incorporated. Colloidal magnesium aluminum silicate or finely divided silica can be used as component of the thickening composition to further improve the composition's texture. In certain embodiments, thickening agents in an amount of about 0.5% to about 5.0% by weight of the total composition are used.

Abrasives

[00033] Generally, the inclusion of abrasives in dentifrice formulations is necessary for effective cleaning of teeth by brushing. It has been determined that by including an abrasive silica having an acid pH in the composition, compositions of enhanced viscosity stability are obtained. Prophy silica available from Grace, offered as Sylodent™, can be used with various embodiments of the present invention (e.g., Composition 1.0 *et seq*).

[00034] The acidic silica abrasive is included in the dentifrice components at a concentration of about 2 to about 35% by weight; about 3 to about 20 % by weight, about 3 to about 15% by weight, about 10 to about 15 % by weight. For example, the acidic silica abrasive may be present in an amount selected from 2 wt.%, 3 wt.%, 4 wt.%, 5 wt.%, 6 wt.%, 7 wt.%, 8 wt.%, 9 wt.%, 10 wt.%, 11 wt.%, 12 wt.%, 13 wt.%, 14 wt.%, 15 wt.%, 16 wt.%, 17 wt.%, 18 wt.%, 19 wt.%, 20 wt.%.

[00035] A commercially available acidic silica abrasive is Sylodent 783 available from W. R. Grace & Company, Baltimore, Md. Sylodent 783 has a pH of 3.4-4.2 when measured as a 5% by weight slurry in water. For use in the present invention, the silica material has an average particle size of less than 10 microns, e.g., 3-7 microns, e.g. about 5.5 microns. For example a small particle silica may have an average particle size (D50) of 2.5 – 4.5 microns.

[00036] The composition may also include any silica suitable for oral care compositions, such as precipitated silicas or silica gels. For example synthetic amorphous silica. Silica may also be available as a thickening agent, e.g., particle silica. For example, the silica can also be small particle silica (e.g., Sorbosil AC43 from PQ Corporation, Warrington, United Kingdom). However the additional abrasives are preferably not present in a type or amount so as to increase the RDA of the dentifrice to levels which could damage sensitive teeth, e.g., greater than 130.

[00037] The invention may also comprise a commercially available cleaning silica in certain embodiments of the invention (e.g., any of Composition 1.0, *et seq*). Zeodent 114

offered by J.M. Huber Finland Oy Telakkatie 5 FIN-49460 Hamina, is one such commercially available silica.

Water

[00038] Water is present in the oral compositions of the invention. Water, employed in the preparation of commercial oral compositions should be deionized and free of organic impurities. Water commonly makes up the balance of the compositions and includes 5% to 45%, e.g., 10% to 20%, e.g., 25 – 35%, by weight of the oral compositions. This amount of water includes the free water which is added plus that amount which is introduced with other materials such as with sorbitol or silica or any components of the invention. The Karl Fischer method is a one measure of calculating free water.

Humectants

[00039] Within certain embodiments of the oral compositions (e.g., Composition 1.0 *et seq*), it is also desirable to incorporate a humectant to reduce evaporation and also contribute towards preservation by lowering water activity. Certain humectants can also impart desirable sweetness or flavor to the compositions. The humectant, on a pure humectant basis, generally includes 15% to 70% in one embodiment or 30% to 65% in another embodiment by weight of the composition.

[00040] Suitable humectants include edible polyhydric alcohols such as glycerin, sorbitol, xylitol, propylene glycol as well as other polyols and mixtures of these humectants. Mixtures of glycerin and sorbitol may be used in certain embodiments as the humectant component of the compositions herein.

[00041] The present invention in its method aspect involves applying to the oral cavity a safe and effective amount of the compositions described herein.

[00042] The compositions and methods according to the invention (e.g., Composition 1.0 *et seq*) can be incorporated into oral compositions for the care of the mouth and teeth such as toothpastes, transparent pastes, gels, mouth rinses, sprays and chewing gum.

[00043] In some embodiments, the present invention provides an oral care composition comprising: a basic amino acid in free or salt wherein the amino acid is selected from arginine, lysine, and a combination thereof; a combination of zinc ion sources; and a thickening system comprising: from about 0.5 wt.% to about 2 wt.% of a nonionic cellulose ether; and from about 0.1 wt.% to about 1 wt.% of a polysaccharide gum. In

some embodiments, the present invention provides an oral care composition comprising: a basic amino acid in free or salt wherein the amino acid is selected from arginine, lysine, and a combination thereof; a combination of zinc ion sources; and a thickening system comprising: from about 0.5 wt.% to about 1 wt.% of a nonionic cellulose ether; and from about 0.25 wt.% to about 0.75 wt.% of a polysaccharide gum.

[00044] Some embodiments provide compositions comprising a nonionic cellulose ether having a molecular weight of about 300,000 to about 350,000. Other embodiments provide compositions comprising a nonionic cellulose ether having a molecular weight of about 300,000. While other embodiments provide compositions comprising a nonionic cellulose ether having a molecular weight of about 350,000 (e.g. such as Tylose variants available SE Tylose GmbH & Co. KG).

[00045] In some embodiments, the nonionic cellulose ether comprises hydroxyethylcellulose. In further embodiments, the oral care composition comprises from about 0.5 wt.% to about 1 wt.% of hydroxyethylcellulose. Still further embodiments provide oral care compositions comprising from about 0.6 wt.% to about 0.8 wt.% of hydroxyethylcellulose. Yet other embodiments provide oral care compositions comprising about 0.5 wt.%, about 0.6 wt.%, about 0.7 wt.%, about 0.8 wt.%, about 0.9 wt.% or about 1 wt.% of hydroxyethylcellulose. Some embodiments provide oral care compositions comprising 0.5 wt.%, 0.6 wt.%, 0.7 wt.%, 0.8 wt.%, 0.9 wt.% or 1 wt.% of hydroxyethylcellulose.

[00046] In some embodiments, the hydroxyethylcellulose has a viscosity, measured at 2% in water at 25 °C, of about 150 to about 400 cps. In some embodiments, the hydroxyethylcellulose having a viscosity, measured at 2% in water at 25 °C, of about 150 to about 400 cps at 25 °C is present in an amount of from about 0.5 wt.% to about 1 wt.%. Some embodiments provide oral care compositions comprising 0.5 wt.%, 0.6 wt.%, 0.7 wt.%, 0.8 wt.%, 0.9 wt.% or 1 wt.% of a hydroxyethylcellulose having a viscosity, measured at 2% in water at 25 °C, of about 150 to about 400 cps.

[00047] Some embodiments provide oral care compositions comprising hydroxyethylcellulose having a molecular weight of about 300,000 or about 350,000, in the amount of from about 0.5 wt.% to about 1 wt.%. Other embodiments provide oral care compositions comprising 0.5 wt.%, 0.6 wt.%, 0.7 wt.%, 0.8 wt.%, 0.9 wt.% or 1

wt.% of a hydroxyethylcellulose having a molecular weight of about 300,000. Certain embodiments provide oral care compositions comprising 0.5 wt.%, 0.6 wt.%, 0.7 wt.%, 0.8 wt.%, 0.9 wt.% or 1 wt.% of a hydroxyethylcellulose having a molecular weight of about 350,000.

[00048] In some embodiments, the polysaccharide gum is xanthan gum. In some embodiments, the oral care composition comprises from about 0.1 wt.% to about 1 wt.% of xanthan gum. In some embodiments, the oral care composition comprises from about 0.2 wt.% to about 0.9 wt.% of xanthan gum. In some embodiments, the oral care composition comprises from about 0.25 wt.% to about 0.75 wt.% of xanthan gum. In some embodiments, the oral care composition comprises from about 0.3 wt.% to about 0.7 wt.% of xanthan gum. In some embodiments, the oral care composition comprises about 0.3 wt.% about 0.4 wt.%, about 0.5 wt.%, about 0.6 wt.% or about 0.7 wt.% of xanthan gum.

[00049] In some embodiments, the present invention provides an oral care composition comprising: a basic amino acid in free or salt wherein the amino acid is selected from arginine, lysine, and a combination thereof; a combination of zinc ion sources; and a thickening system comprising: from about 0.5 wt.% to about 1 wt.% of a nonionic cellulose ether; and from about 0.25 wt.% to about 0.75 wt.% of a polysaccharide gum. In some embodiments, the present invention provides an oral care composition comprising: a basic amino acid in free or salt wherein the amino acid is selected from arginine, lysine, and a combination thereof; a combination of zinc ion sources; and a thickening system comprising: from about 0.6 wt.% to about 0.8 wt.% of a nonionic cellulose ether; and from about 0.7 wt.% to about 0.8 wt.% of a polysaccharide gum.

[00050] In some embodiments, the thickening system further comprises from about 5 wt.% to about 10 wt.% silica. In some embodiments, the thickening system comprises from about 0.5 wt.% to about 15 wt.% of the oral care composition.

[00051] In certain embodiments, the hydroxyethylcellulose and the polysaccharide gum are present in a weight ratio of from about 8:1 to about 1:10. In other embodiments, the hydroxyethylcellulose and the polysaccharide gum are present in a weight ratio of from about 4:1 to about 1:2. Yet other embodiments provide compositions wherein the

hydroxyethylcellulose and the polysaccharide gum are present in a weight ratio of from about 3:1 to about 1:1.

[00052] In some embodiments, the oral care composition further comprises a fluoride ion source selected from sodium fluoride, sodium monofluorophosphate, and stannous fluoride.

[00053] In some embodiments, the oral care composition comprises about 1.0 wt.% zinc oxide; about 0.5 wt.% zinc citrate; about 1.5 wt.% L-arginine; from about 0.3 wt.% to about 0.8 wt.% of xanthan gum; and from about 0.5 wt.% to about 1 wt.% of hydroxyethylcellulose. Some embodiments comprise from about 0.3 wt.% to about 0.6 wt.% of xanthan gum.

[00054] In further embodiments, the oral care composition loses no more than about 45% of its initial viscosity after one year. In some embodiments, the oral care composition loses no more than about 40% of its initial viscosity after one year. In other embodiments, the oral care composition loses no more than about 35% of its initial viscosity after one year. In yet other embodiments, the oral care composition loses no more than about 30% of its initial viscosity after one year. In some embodiments, the oral care composition loses no more than about 25%, 24%, 23%, 22%, 21% or 20% of its initial viscosity after one year.

[00055] In some embodiments, the oral care composition has a G'/G" ratio of greater than 0.5. In some embodiments, the oral care composition has a G'/G" ratio of greater than 0.75. In some embodiments, the oral care composition has a G'/G" ratio of greater than 1. In some embodiments, the oral care composition has a G'/G" ratio of greater than 1.5. In some embodiments, the oral care composition has a G'/G" ratio of less than 2. In some embodiments, the oral care composition has a G'/G" ratio of less than 1.5. In some embodiments, the oral care composition has a G'/G" ratio of less than 1. Methods of quantifying the elastic modulus (G'), the loss modulus (G") and G'/G" ratios are described, for example, in WO 2013/089734 A1.

[00056] In some embodiments, the compositions of the present invention provide a consistency, K, less than 30 $Pa*s^n$. In some embodiments, the compositions of the present invention provide a flow index, n, of greater than 0.3. In some embodiments, the

compositions of the present invention provide a consistency, K, less than 30 $Pa*s^n$ and a flow index, n, of greater than 0.3. In some embodiments, the compositions of the present invention provide a consistency, K, less than 30 $Pa*s^n$; a flow index, n, of greater than 0.3; and a G'/G" ratio of less than 2. In some embodiments, the compositions of the present invention provide a flow index, n, of greater than 0.3; and a G'/G" ratio of less than 2. In some embodiments, the compositions of the present invention provide a consistency, K, less than 30 $Pa*s^n$; and a G'/G" ratio of less than 2.

[00057] In some embodiments, the oral care compositions of the present invention provide a yield stress greater than 25 Pa. In other embodiments, the oral care compositions of the present invention provide a yield stress greater than 30 Pa. Yet further embodiments, provide oral care compositions that demonstrate a yield stress greater than 35 Pa.

[00058] As used throughout, ranges are used as shorthand for describing each and every value that is within the range. Any value within the range can be selected as the terminus of the range. In the event of a conflict in a definition in the present disclosure and that of a cited reference, the present disclosure controls. It is understood that when formulations are described, they may be described in terms of their ingredients, as is common in the art, notwithstanding that these ingredients may react with one another in the actual formulation as it is made, stored and used, and such products are intended to be covered by the formulations described.

[00059] The following examples further describe and demonstrate illustrative embodiments within the scope of the present invention. The examples are given solely for illustration and are not to be construed as limitations of this invention as many variations are possible without departing from the spirit and scope thereof.

EXAMPLES

Example 1

[00060] The examples herein detail how the viscosity over time for a composition which exhibits a problem of rapid reduction in viscosity (Run A), is compared to five

compositions which show the stabilized viscosity provided by the invention (Compositions 1-5 in Table 1).

[00061] Viscosity is measured on a Brookfield HADV2 viscometer using a V74 vane spindle. This viscometer applies a user-controlled angular velocity to the spindle, typically measured in rotations per second (RPM), and reports torque on the shaft of the spindle. Viscosity is then calculated from RPM and torque as explained in the Brookfield Manual (Operating Instructions) using too conversion parameters SRC (shear rate constant) and SMC (spindle multiplier constant). The conversion parameters are defined as follows: SMC=290, SRC=0.2723. The test is performed at room temperature, and varies between 22 and 25 °C. During the test, RPM of the spindle is swept from 200 to 0.5 in 12 steps, 10 seconds per step. The viscosity reading reported is taken at RPM=1.

[00062] Compositions containing zinc oxide, zinc citrate, arginine and a fluoride source are prepared as described in Table 1, below. All compositions are formulated to provide a 10% pH of 8 - 8.5 using 0 - 0.35% phosphoric acid. The composition identified as Run A does not contain a silica abrasive which exhibits an acid pH when measured as an aqueous slurry. The compositions identified as Compositions 1-5 in Table 1 (below) contain a silica abrasive which exhibits an acid pH (Prophy Silica – Sylodent 783) when measured as an aqueous slurry in varying amounts, as detailed below.

Table 1. Dentifrice Formulations

Experiment ID	Run A	Composition 1	Composition 2	Composition 3	Composition 4	Composition 5
INGREDIENTS						
99.0% - 101.0% GLYCERIN - USP,EP VEG	35	35	35	35	35	35
DEMINERALIZED WATER	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.
PROPHY SILICA (SYLODENT 783)	0	15	10	5	5	3
ABRASIVES (e.g., includes Abrasive silcas, High Cleaning Silicas)	20	5	10	15	15	17
SILICA-THICKENER	6.5	7	7	7	7	7
ANIONIC SURFACTANT	2	2	2	2	2	2

L-ARGININE	1.5	1.5	1.5	1.5	1.5	1.5
AMPHOTERIC SURFACTANT	1.25	1.25	1.25	1.25	1.25	1.25
NON-IONIC SURFACTANT	0.75	0.75	0.75	0.75	0.75	0.75
ZINC OXIDE	1	1	1	1	1	1
POLYMER	1	1.3	1.3	1.3	1.3	1.3
COLORANT	0.75	0.75	0.75	0.75	0.75	0.75
ALKALI PHOSPHATE SALT	0.5	0.5	0.5	0.5	0.5	0.5
ZINC CITRATE TRIHYDRATE	0.5	0.5	0.5	0.5	0.5	0.5
PRESERVATIVE	0.4	0.4	0.4	0.4	0.4	0.4
SODIUM FLUORIDE - USP, EP	0.32	0.32	0.32	0.32	0.32	0.32
85% SYRUPY PHOSPHORIC ACID - FOOD GRADE	0.35	0	0	0	0	0
FLAVORING AGENT	2	2	2	2	1.82	1.52
TOTAL COMPONENTS	100	100	100	100	100	100

[00063] The composition identified as Run A displays an initial viscosity which is initially 500,000 cps to 600,000 cps high, but decreases to under 400,000 cps in 2 weeks, and under 200,000 cps at 6 weeks. Surprisingly, the compositions containing a silica abrasive which exhibits an acid pH (Prophy Silica – Sylodent 783) when measured as an aqueous slurry, Compositions 1 to 5 in Table 1 (above), eliminate this undesirable characteristic and instead produce viscosities that are stable or increase over time (See, Table 2 below).

Table 2. Viscosity data

Experiment ID	**Run A**	**Composition 1**	**Composition 2**	**Composition 3**	**Composition 4**	**Composition 5**
Time	**Viscosity (cps)**					
0					491040	363489
1 d	539119	211912	300155	272475		
5 d	601597			309816		
1 wk	627362		288561		383245	371651
2 wk	433485	340733		328495	403212	364565
3 wk		343310	314325	334292		
4 wk	224794	395483	304019		430909	423823
5 wk		375515	338801	322698		

6 wk	193233	376804	344598	334292	406432	442503
7 wk			334292			
9 wk			387753			
10 wk		351039		364565		
11 wk	158451		373583	381956		
12 wk		405788	357480			
13 wk		405788	398059	393550		

[00064] Upon further investigation, it was found that the silica abrasive which exhibits an acid pH when measured as an aqueous slurry silica is acidic (pH 3.4 - 4.2) does not require phosphoric acid to adjust the product pH. Other abrasive silicas and high cleaning silicas are about neutral in pH (pH 7 – 8) and thus, require phosphoric acid for pH adjustment.

Table 3

	Composition 6	**Composition 7**	**Composition 8**
Demineralized Water	Q.S.	Q.S.	Q.S.
Glycerin - 99.5%	35	35	35
Polymer	1.2	1.2	1.2
Zinc Oxide	1	1	1
Zinc Citrate	0.5	0.5	0.5
Alkali Phosphate Salt	0.5	0.5	0.5
Flavoring agent	1.82	1.82	1.82
Sodium Fluoride	0.32	0.32	0.32
Colorant	0.75	0.75	0.75
L-Arginine	1.5	1.5	1.5
Non-Ionic Surfactant	0.5	0.5	0.5
Abrasives (e.g., includes Abrasive Silcas, High Cleaning Silicas)	8	10	12
Prophy silica (Sylodent 783)	7	5	3
Silica - thickener	7	7	8.5
Preservative	0.4	0.4	0.4
Anionic Surfactant	5.7	5.7	5.7
Amphoteric Surfactant	1.25	1.25	1.25
Total Components	100	100	100

[00065] Upon further investigation, when phosphoric acid is removed from further formulations (Compositions 6-8 in Table 3, above), they demonstrate improvement in viscosity stability, and this viscosity trend remained relatively stable from day 1 to 4 weeks when tested at: room temperature, 40 °C and 49 °C. The data is further detailed in Table 4 below.

Table 4

	Composition 6			Composition 7			Composition 8		
	Viscosity, 10^3 cps			Viscosity, 10^3 cps			Viscosity, 10^3 cps		
	RT	40 °C	49 °C	RT	40 °C	49 °C	RT	40 °C	49 °C
0	471			324			336		
0.14	370			197			268		
1	363	418	390	200	227	258	230	256	263
2	360	430	440	201	243	269	220	250	258
3	325			205	246	245	228	277	274
4	314	412	385	224	253	253	227	268	272
6	327			218			233		

Example 2

[00066] Table 5 (below) describes the formulas of three exemplary compositions of the present invention (Compositions 9, 10 and 11) and a comparative example (Comparative Example I).

Table 5

	Composition 9	Composition 10	Composition 11		Comparative Example I
Ingredient	**Wt%**				
GLYCERIN	35.00000	26.00000	26.00000		35.00000
SORBITOL - NON-CRYSTAL - 70% SOLN	--	13.00000	13.00000		--
EP PURIFIED WATER	30.90474	27.82474	27.62474		30.84874
STANDARD ABRASIVE SILICA	10.00000	10.00000	10.00000		10.00000
SILICA-THICKENER	7.00000	6.00000	6.00000		7.00000
SMALL PARTICLE SILICA	5.00000	5.00000	5.00000		5.00000
LAURYL SULFATE GRANULES	2.10526	2.10526	2.10526		2.10526
Flavor	1.50000	1.50000	1.50000		1.50000
L-ARGININE	1.50000	1.50000	1.50000		1.50000
COCAMIDOPROPYL BETAINE	1.25000	1.25000	1.25000		1.25000
ZINC OXIDE	1.00000	1.00000	1.00000		1.00000
TITANIUM DIOXIDE	0.75000	0.75000	0.75000		--
XANTHAN GUM	0.60000	0.30000	0.30000		0.40000
SODIUM CMC - TYPE 12	--	--	--		1.10000
HYDROXYETHYL-	0.50000	0.80000	1.00000		--

CELLULOSE (HEC)*					
TETRASODIUM PYROPHOSPHATE	0.50000	0.50000	0.50000		0.50000
ZINC CITRATE TRIHYDRATE	0.50000	0.50000	0.50000		0.50000
POLOXAMER 407	0.50000	0.50000	0.50000		0.50000
BENZYL ALCOHOL	0.40000	0.40000	0.40000		0.40000
85% PHOSPHORIC ACID	0.35000	0.35000	0.35000		0.35000
SODIUM FLUORIDE - USP, EP	0.32000	0.32000	0.32000		0.32000
Sweeteners	0.32000	0.40000	0.40000		0.42000
Additional Colorants	--	--	--		0.30600

*HEC having a molecular weight of about 350,000

Example 3

[00067] Table 6 (below) describes the results of viscosity and static yield stress evaluations performed on an exemplary composition of the present invention and a reference formula.

[00068] Viscosity and Yield Stress are measured on a Brookfield HADV2 viscometer using V74 vane spindle 1.176 cm in length and 0.589 cm in diameter. This viscometer applies a user-controlled angular velocity to the spindle, typically measured in rotations per second (RPM), and reports torque, T%, measured in the percentage of the maximum total torque on the shaft of the spindle. The torque, T, measured in SI units, N*m, is related to T% as reported by the above mentioned viscometer as $T=1.437*10^{-5}*T\%$.

[00069] The tests are performed at room temperature (22 to 25 °C). During the test 0.5 RPM of the spindle is first rotated for 400 sec and then RPM is swept from 0.5 to 200 and back to 0.5 in 12 logarithmical steps each way, 10 seconds per step. The viscosity reading is taken at RPM=1 on the decreasing RPM sweep. Viscosity is then calculated from RPM and T as explained in the Brookfield Manual (Operating Instructions) using two conversion parameters SRC (shear rate constant) and SMC (spindle multiplier constant). In this case, the conversion parameters are defined as follows: SMC=290, SRC=0.27.

[00070] Static Yield Stress (YS) is calculated as a fitting parameter by fitting experimental T(RPM) dependence on increasing RPM sweep with the theoretical one which was calculated assuming the so-called Casson constitutive equation and is implicitly given by the following equation:

$$RPM = \frac{15}{\pi}\int_{YS}^{SW}\frac{\left(S^n - YS^n\right)^{1/n}}{HSV * S}dS$$

where HSV (high-shear viscosity limit) is another fitting parameter, n=0.3, and SW is the stress on the imaginary wall encompassing the vane which is estimated as follows:

$$SW = \frac{2T}{\pi LD^2\left(1+\frac{D}{3L}\right)}$$

T(RPM) is calculated from these two equations numerically. Only data points with RPM from 5 to 200 and T% between 3 and 100 are fitted.

Table 6

Comparative Example I			
Days after Manufacturing		Viscosity at 1 RPM (cP)	Static Yield Stress (Pa)
1		442984	152
21		277573	161
30		202798	133
37		203931	99
90		167110	94
365		226817	40
Composition 11			
Days after Manufacturing		Viscosity at 1 RPM (cP)	Static Yield Stress (Pa)
1		609528	161
14		527956	184
44		425990	187
75		431088	199
290		493401	250

[00071] The data described in Table 6 (above) demonstrates the unexpected stabilizing effects provided by the inventive thickening systems of the present invention. Importantly, these effects are observed over an extended period of time, rather than being transient in nature.

Example 4

[00072] Table 7 (below) describes the formulas of two additional compositions of the present invention (Compositions 12 and 13) and another comparative formula (Comparative Example II).

Table 7

	Composition 12	Composition 13		Comparative Example II
Ingredient	**Wt%**			
GLYCERIN	--	26.000000		35.000000
SORBITOL	39.000000	13.000000		--
SUCRALOSE	--	--		0.020000
EP PURIFIED WATER	27.824737	28.244737		30.848737
SODIUM SACCHARIN	0.400000	0.400000		0.400000
STANDARD ABRASIVE SILICA	10.000000	10.000000		10.000000
SILICA-THICKENER	6.000000	6.000000		7.000000
AMORPHOUS SILICA	5.000000	5.000000		5.000000
Na-LAURYL SULFATE GRANULES	2.105263	2.105263		2.105263
Flavor	1.500000	1.500000		1.500000
L-ARGININE	1.500000	1.500000		1.500000
COCAMIDOPROPYL BETAINE	1.250000	1.250000		1.250000
ZINC OXIDE	1.000000	1.000000		1.000000
TITANIUM DIOXIDE	0.750000	--		0.300000
XANTHAN GUM	0.300000	0.300000		0.400000
SODIUM CMC - TYPE 12	--	--		1.100000
HYDROXYETHYL CELLULOSE (HEC)*	0.800000	1.000000		--
TETRASODIUM PYROPHOSPHATE	0.500000	0.500000		0.500000
ZINC CITRATE TRIHYDRATE	0.500000	0.500000		0.500000
POLOXAMER 407	0.500000	0.500000		0.500000
BENZYL ALCOHOL	0.400000	0.400000		0.400000
85% PHOSPHORIC ACID	0.350000	0.350000		0.350000
SODIUM FLUORIDE - USP, EP	0.320000	0.320000		0.320000
Additional Colorants	--	0.130000		0.006000

*HEC having a molecular weight of about 350,000

Example 5

[00073] Table 8 (below) describes the percentage change in viscosity loss and loss of static yield stress for two exemplary compositions of the present invention (Compositions 12 and 13) and a comparative composition (Comparative Example II). Viscosity and Static Yield Stress were calculated in accordance with the methods described in Example 3 herein.

Table 8

Composition	Viscosity Loss	Loss of Static Yield Stress

	(1 Year)	(After 1 Year)
Composition 12	19 %	Stable
Composition 13	21 %	Stable
Comparative Example II	49 %	73 %

[00074] The data described in Table 8 (above) not only shows that compositions of the present invention demonstrate less viscosity loss and static yield stress loss than a comparative composition, but it also demonstrates that the benefits are reproducible.

Example 6

[00075] Table 9 (below) describes an exemplary backbone for oral care compositions of the present invention comprising – inter alia – a basic amino acid in free or salt form (e.g. L-arginine); and a combination of zinc ion sources.

Table 9

L-Arginine	1.5
Glycerin	33.8
Zn Citrate Trihydrate	0.5
Sodium Fluoride	0.32
Non-ionic surfactant	0.5
Alkali Phosphate salt	0.5
Zinc Oxide	1
Saccharin	0.4
Colorant	0.75
Silica Abrasive(s)	15
Silica thickener	7.5
Anionic surfactant	2
Flavoring agent	1.5
Preservative	0.4
Amphoteric surfactant	1.25

[00076] Added to this backbone were the various combinations of water, a nonionic cellulose ether (hydroxyethylcellulose [HEC]); and a polysaccharide gum (xanthan gum), described in Table 10 (below).

Table 10

Composition	**Water**	**Xanthan Gum**	**HEC****
	Wt.%		
14	32.18	0.20	0.70

15	32.18	0.70	0.20
16	32.18	0.70	0.20
17	32.18	0.52	0.38
18	32.05	0.70	0.33
19	31.84	0.52	0.72
20	31.78	0.70	0.60
21	31.78	0.40	0.90
22	31.98	0.20	0.90
23	31.94	0.65	0.49
24	32.18	0.35	0.55
25	32.02	0.48	0.57

**HEC having a molecular weight of about 300,000

[00077] Toothpastes were prepared from each of these combinations by first creating a gel comprising water, xanthan gum and hydroxyethylcellulose (HEC); and then combining each gel with the remaining components (see Table 9) in a Ross double planetary mixer. The rheological profiles of both the gel pre-mixes and the toothpaste end products are evaluated.

Example 7

[00078] Gels are tested in ARES G2 rheometer by TA Instruments using Couette geometry (standard DIN cell). Two tests are performed: shear rate sweep between 1 and 100 sec^{-1} and frequency sweeps under small-amplitude oscillations. The data of the shear rate sweeps are fitted with power law, i.e.

$$\text{Shear stress} = K * \text{shear rate}^n$$

[00079] where consistency, K, and flow index, n, are listed in Table 11 (below). Consistency can be as well thought of as viscosity at shear rate 1 sec^{-1}. Flow index $n = 1$ corresponds to Newtonian fluid, lower values indicate shear thinning with an extreme case of n = 0 corresponding to yield stress fluid. From frequency sweeps only viscoelastic moduli at 1 Hz are reported below in Table 11, elastic modulus G' and viscous modulus G", as well as their ratio.

Table 11

Composition	**Gel Parameters**				
	K ($Pa*s^n$)	n	G' (Pa)	G" (Pa)	G'/G"
14	3.53	0.5866	7.1	8.77	0.81

15	20.88	0.245	48.3	18.7	2.58
16	23.16	0.243	45.7	17.5	2.61
17	13.72	0.3298	28.3	14.6	1.94
18	23.59	0.269	49	20.5	2.39
19	17.48	0.4125	32.5	23.2	1.40
20	22.88	0.3409	48.6	26.9	1.81
21	12.29	0.4938	22.9	22.4	1.02
22	4.79	0.6171	8.3	12.15	0.68
23	20.97	0.3278	43.3	22.4	1.93
24	7.11	0.4536	14.2	11.3	1.26
25	13.63	0.3918	26.7	17.4	1.53

[00080] Easy processability of the gel requires low viscosity, less shear thinning and less elasticity, which generally correlates with low values of K, G' and G'/G", but higher values of *n*. The exact limits on these parameters depend on the actual design of the mixer.

Example 8

[00081] Static yield stress (YS) and viscosity at 0.25 s^{-1} for the finished toothpaste end-products prepared based on the combinations described in Tables 9 and 10, are evaluated. Measurements are performed on ARG2 rheometer by TA Instrument using a cylindrical cup and vane upper geometry. The measurements were performed in the same containers, in which the samples were aged. Those were standard 50 cc centrifuge tubes, available from VWR, into which the samples were placed at the time of preparation. Then the samples were consolidated by centrifuging at low rotations in the centrifuge so as to remove air pockets and aged directly in these tubes at room temperature (RT) or at 49 °C for up to 2 months. Before the measurements the heated tubes were allowed to cool for 2 hours at room temperature and then inserted directly into the cup of the rheometer. To avoid the tubes mobility in the cup, they were wrapped with a thin layer of tape. The vane was inserted into the tubes and samples measured directly inside them. The measurement procedure closely mimicked the one described above for Brookfield viscometer, i.e., a constant shear rate of 0.05 sec^{-1} was applied for 400 sec and followed by shear rate sweeps up and down from 0.1 to 30 sec^{-1}. Here shear rate is calculated from angular velocity of the vane, Ω, following TA Instruments conventions as follows:

$$S = \frac{1+k^2}{1-k^2}\Omega$$

where k is the ratio of the diameter of the vane to the diameter of the tube. Torque, T, on the shaft of the vane was measured. Yield stress was calculated by fitting T(Ω) with the theoretical function calculated assuming Casson constitutive equation and implicitly given by the following equation:

$$\Omega = \frac{1}{2}\int_{SW0}^{SW} \frac{\left(S^n - YS^n\right)^{1/n}}{HSV * S} dS$$

where HSV (high-shear viscosity limit) is another fitting parameter, n=0.2, and SW is the stress on the imaginary wall encompassing the vane which is estimated as follows:

$$SW = \frac{2T}{\pi LD^2\left(1+\frac{D}{3L}\right)}$$

and SW0 is the largest of the two values: YS and k^2SW. Viscosity, V, at S=0.25 sec^{-1} was calculated according to Casson equation as follows

$$V = \left(\left(\frac{YS}{S}\right)^n + HSV^n\right)^{1/n}$$

Note that the exponent n used to process these data is different from the one used to process Brookfield data above (0.2 instead of 0.3) to accommodate a wide range of shear rates as measured by a rheometer.

[00082] The results of these evaluations are described in Table 12 (below).

Table 12

Composition	Paste aged at RT for 1 wk		Paste aged at 49C for 1 month		Paste aged at RT for 2 month	
	YS (Pa)	Viscosity at 0.25 s^{-1} (cP)	YS (Pa)	Viscosity at 0.25 s^{-1} (cP)	YS (Pa)	Viscosity at 0.25 s^{-1} (cP)
14	1.7	50,232	17.4	85,022	2.2	55,034
15	25.2	173,848	48.3	222,280	29.0	183,000
16	24.8	167,895	42.6	204,157	26.8	176,172
17	11.9	102,691	42.6	204,157	13.4	106,199
18	26.0	180,787	52.1	214,586	27.6	188,500
19	12.1	161,077	26.0	168,495	13.4	161,060

20	23.4	210,000	50.5	241,336	30.7	236,770
21	7.7	138,867	26.0	164,016	10.8	146,088
22	4.6	87,257	14.9	106,338	8.4	110,207
23	31.2	231,467	53.7	250,236	44.7	249,000
24	5.8	81,449	24.2	111,160	N/a	N/a
25	9.0	120,471	34.1	155,823	13.0	133,262

[00083] The data described in Table 12 (above) demonstrates that exemplary compositions of the present invention will maintain their shape on the brush, while also being easily squeezed from a toothpaste tube.

[00084] As used throughout, ranges are used as shorthand for describing each and every value that is within the range. Any value within the range can be selected as the terminus of the range. In the event of a conflict in a definition in the present disclosure and that of a cited reference, the present disclosure controls.

[00085] Unless otherwise specified, all percentages and amounts expressed herein and elsewhere in the specification should be understood to refer to percentages by weight. The amounts given are based on the active weight of the material.

[00086] While the present invention has been described with reference to embodiments, it will be understood by those skilled in the art that various modifications and variations may be made therein without departing from the scope of the present invention as defined by the appended claims.

CLAIMS:

1. An oral care composition comprising:
    a. a basic amino acid in free or salt form wherein the basic amino acid is selected from the group consisting of arginine, lysine, and a combination thereof;
    b. a combination of zinc ion sources, wherein the combination comprises zinc oxide and zinc citrate; and
    c. a thickening system comprising:
        i. from about 0.25 wt.% to about 1 wt.% of a nonionic cellulose ether having a molecular weight of about 300,000 to about 350,000; and
        ii. from about 0.4 wt.% to about 1 wt.% of a polysaccharide gum.

2. The oral care composition according to claim 1, wherein the nonionic cellulose ether has a viscosity, measured at 2% in water at 25 °C, of from about 150 to about 400 cps.

3. The oral care composition according to claim 1 or 2, comprising from about 0.5 wt.% to about 1 wt.% of the nonionic cellulose ether.

4. The oral care composition according to claim 1 or 2 comprising from about 0.6 wt.% to about 0.9 wt.% of the nonionic cellulose ether.

5. The oral care composition according to claim 1 or 2, comprising 0.5 wt%, 0.6 wt.%, 0.7 wt%, 0.8 wt%, 0.9 wt.% or 1 wt.% of the nonionic cellulose ether.

6. The oral care composition according to any one of claims 1 to 5, wherein the nonionic cellulose ether comprises hydroxyethylcellulose.

7. The oral care composition according to any one of claims 1 to 6, comprising from about 0.4 wt.% to about 0.9 wt.% of the polysaccharide gum.

8. The oral care composition according to any one of claims 1 to 6, comprising from about 0.5 wt.% to about 0.9 wt.% of the polysaccharide gum.

9. The oral care composition according to any one of claims 1 to 6, comprising from about 0.6 wt.% to about 0.9 wt.% of the polysaccharide gum.

10. The oral care composition according to any one of claims 1 to 6, comprising about 0.3 wt.%, about 0.4 wt.%, about 0.5 wt.%, about 0.6 wt.%, about 0.7 wt.%, about 0.8 wt.% or about 0.9 wt.% of the polysaccharide gum.

11. The oral care composition according to any one of claims 1 to 10, wherein the polysaccharide gum is xanthan gum.

12. The oral care composition according to claim 1 to 11, wherein the thickening system further comprises from about 5 wt.% to about 10 wt.% silica.

13. The oral care composition according to any one of claims 1 to 12, wherein the thickening system comprises from about 0.5 wt% to about 15 wt% of the oral care composition.

14. The oral care composition according to any one of claims 1 to 13, wherein the nonionic cellulose ether and the polysaccharide gum are present in a weight ratio of from about 3:1 to about 1:2.

15. The oral care composition according to any one of claims 1 to 13, wherein the nonionic cellulose ether and the polysaccharide gum are present in a weight ratio of from about 2:1 to about 1:1.

16. The oral care composition according to any one of claims 1 to 13, wherein the nonionic cellulose ether and the polysaccharide gum are present in a weight ratio of about 1:1.

17. The oral care composition according to any one of claims 1 to 13, wherein the nonionic cellulose ether and the polysaccharide gum are present in a weight ratio of 3:1, 2.5:1, 1.5:1 or 1:1.

18. The oral care composition according to any one of claims 1 to 17, wherein the amino acid is arginine, and is present at about 1.5 wt.%, 5 wt.%, or about 8 wt.%, of the oral care composition.

19. The oral care composition according to any one of claims 1 to 18, wherein the weight ratio of zinc oxide to zinc citrate is about 2:1.

20. The oral care composition according to any one of claims 1 to 19, wherein the zinc citrate is in an amount of about 0.5 wt% and zinc oxide is present in an amount of about 1.0 wt% based on the total weight of the oral care composition.

21. The oral care composition according to any one of claims 1 to 20, further comprising a fluoride ion source selected from the group consisting of sodium fluoride, sodium monofluorophosphate, and stannous fluoride.

22. The oral care composition according to claim 21, wherein the fluoride ion source provides soluble fluoride in an amount of about 1450 ppm.

23. The oral care composition according to claim 21 or 22, wherein the fluoride ion source comprises stannous fluoride.

24. The oral care composition according to claim 1, comprising:
    a. about 1.0 wt.% zinc oxide;
    b. about 0.5 wt.% zinc citrate;
    c. about 1.5 wt.% L-arginine;
    d. from about 0.5 wt.% to about 1 wt.% of hydroxyethylcellulose; and
    e. from about 0.3 wt.% to about 0.8 wt.% of xanthan gum.

25. The oral care composition according to claim 24, comprising from about 0.3 wt.% to about 0.6 wt.% of xanthan gum.

26. The oral care composition according to claim 24, comprising from about 0.7 wt% to about 0.8 wt% of xanthan gum.

27. The oral care composition according to any one of claims 1 to 26, wherein the oral care composition is in a form selected from the group consisting of: a toothpaste, a mouthwash, and a gel.

28. The oral care composition according to any one of claims 1 to 27, having a static yield stress greater than 20 Pa, 25 Pa, 30 Pa, 35 Pa, or 40 Pa.

29. The oral care composition according to any one of claims 1 to 28, having a drainage time of less than 10 minutes.

30. The oral care composition according to any one of claims 1 to 29, demonstrating less than 225 grams of left-overs.

31. The oral care composition according to any one of claims 1 to 30, wherein the oral care composition loses no more than 25% of the initial viscosity thereof after one year.

32. The oral care composition according to any one of claims 1 to 31 for use in:

i. reducing or inhibiting formation of dental caries,
ii. reducing, repairing or inhibiting early enamel lesions,
iii. reducing or inhibiting demineralization and promote remineralization of teeth,
iv. reducing hypersensitivity of teeth,
v. reducing or inhibit gingivitis,
vi. promoting healing of sores or cuts in the mouth,
vii. reducing levels of acid producing bacteria,
viii. increasing relative levels of arginolytic bacteria,
ix. inhibiting microbial bio film formation in the oral cavity,
x. raising and/or maintaining plaque pH at levels of at least pH 5.5 following sugar challenge,
xi. reducing plaque accumulation,
xii. treating dry mouth,
xiii. enhancing systemic health, including cardiovascular health,
xiv. whitening teeth,
xv. reducing erosion of the teeth,
xvi. immunizing or protecting teeth against cariogenic bacteria and their effects, and/or
xvii. cleaning teeth and oral cavities.

33. The oral care composition for use according to claim 32, wherein the reducing, repairing or inhibiting early enamel lesions is as detected by quantitative light-induced fluorescence (QLF) or electrical caries measurement (ECM).

34. Use of the oral care composition as defined in any one of claims 1 to 31 for:

i. reducing or inhibiting formation of dental caries,
ii. reducing, repairing or inhibiting early enamel lesions,
iii. reducing or inhibiting demineralization and promote remineralization of teeth,
iv. reducing hypersensitivity of teeth,

v. reducing or inhibit gingivitis,

vi. promoting healing of sores or cuts in the mouth,

vii. reducing levels of acid producing bacteria,

viii. increasing relative levels of arginolytic bacteria,

ix. inhibiting microbial bio film formation in the oral cavity,

x. raising and/or maintaining plaque pH at levels of at least pH 5.5 following sugar challenge,

xi. reducing plaque accumulation,

xii. treating dry mouth,

xiii. enhancing systemic health, including cardiovascular health,

xiv. whitening teeth,

xv. reducing erosion of the teeth,

xvi. immunizing or protecting teeth against cariogenic bacteria and their effects, and/or

xvii. cleaning teeth and oral cavities.

35. The use according to claim 34, wherein the reducing, repairing or inhibiting early enamel lesions is as detected by quantitative light- induced fluorescence (QLF) or electrical caries measurement (ECM).