US 20220401321A1

(19) **United States**

(12) **Patent Application Publication**

KOCINSKA et al.

(10) **Pub. No.: US 2022/0401321 A1**

(43) **Pub. Date: Dec. 22, 2022**

(54) **ORAL CARE COMPOSITIONS**

(71) Applicant: **Colgate-Palmolive Company**, New York, NY (US)

(72) Inventors: **Agnieszka KOCINSKA**, Basel (CH); **Lauren EVANS**, Highland Park, NJ (US); **Tilo POTH**, Weinheim (DE)

(73) Assignee: **Colgate-Palmolive Company**, New York, NY (US)

(21) Appl. No.: **17/752,533**

(22) Filed: **May 24, 2022**

Related U.S. Application Data

(60) Provisional application No. 63/192,876, filed on May 25, 2021, provisional application No. 63/221,703, filed on Jul. 14, 2021.

Publication Classification

(51) **Int. Cl.**

A61K 8/27	(2006.01)
A61Q 11/00	(2006.01)
A61K 8/21	(2006.01)
A61K 8/46	(2006.01)

(52) **U.S. Cl.**

CPC ***A61K 8/27*** (2013.01); ***A61Q 11/00*** (2013.01); ***A61K 8/21*** (2013.01); ***A61K 8/466*** (2013.01)

(57) **ABSTRACT**

The present disclosure relates to oral care compositions comprising zinc phosphate, a fluoride source and a taurate surfactant. In one aspect the compositions of the disclosure can be used for the treatment or reduction of erosive tooth demineralization, gingivitis, plaque, and dental caries.

ORAL CARE COMPOSITIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application Ser. No. 63/192,876, filed May 25, 2021 and U.S. Provisional Patent Application Ser. No. 63/221,703 filed Jul. 14, 2021, the contents of each of which are incorporated herein by reference in their entireties.

FIELD

[0002] The present disclosure relates to oral care compositions comprising zinc phosphate, a fluoride source and a taurate surfactant. In one aspect the compositions of the disclosure can be used for the treatment or reduction of erosive tooth demineralization, gingivitis, plaque, and dental caries. In one aspect the oral care composition includes zinc phosphate, sodium fluoride and at least one taurate surfactant.

BACKGROUND

[0003] Dental erosion involves demineralization and damage to the tooth structure due to acid attack from nonbacterial sources. Erosion is found initially in the enamel and, if unchecked, may proceed to the underlying dentin.

[0004] Dental plaque is a sticky biofilm or mass of bacteria that is commonly found between the teeth, along the gum line, and below the gum line margins. Dental plaque can give rise to dental caries and periodontal problems such as gingivitis and periodontitis. Dental caries tooth decay or tooth demineralization caused by acid produced from the bacterial degradation of fermentable sugar.

[0005] Soluble zinc salts, such as zinc citrate, have been used in dentifrice compositions, but have several disadvantages. Zinc ions in solution impart an unpleasant, astringent mouthfeel, so formulations that provide effective levels of zinc, and also have acceptable organoleptic properties, have been difficult to achieve. Moreover, free zinc ions may react with fluoride ions to produce zinc fluoride, which is insoluble and so reduces the availability of both the zinc and the fluoride. Finally, the zinc ions will react with anionic surfactants such as sodium lauryl sulfate, thus interfering with foaming and cleaning.

[0006] Zinc phosphate ($Zn_3(PO_4)_2$) is insoluble in water, although soluble in acidic or basic solutions, e.g., solutions of mineral acids, acetic acid, ammonia, or alkali hydroxides. See, e.g., Merck Index, 13th Ed. (2001) p. 1812, monograph number 10205. Partly because it is viewed in the art as a generally inert material, zinc phosphate is commonly used in dental cements, for example in cementation of inlays, crowns, bridges, and orthodontic appliances, which are intended to endure in the mouth for many years. Zinc phosphate dental cements are generally prepared by mixing zinc oxide and magnesium oxide powders with a liquid consisting principally of phosphoric acid, water, and buffers, so the cement comprising zinc phosphate is formed in situ by reaction with phosphoric acid.

[0007] Sodium lauryl sulfate (SLS) is widely used in dentifrice formulations surfactant. SLS has the benefits, for example, of being neutral with respect to product taste and often does not impact active ingredients stability. However, there has been recent consumer interest in developing various oral care products that do not contain sodium lauryl sulfate. However, one of the drawbacks of developing formulations without SLS is that using new surfactant combinations in various oral care compositions (e.g., toothpaste) may lead to product separation because of the change of the ingredients balance in the formula. In some cases a surfactant substitution—e.g., substituting a surfactant for SLS— may have a negative impact on the taste or active ingredients stability. Moreover, microbiological stability of the formulation can be negatively impacted by the absence of sodium lauryl sulfate. There are also production benefits to having SLS in a given formulation. By removing SLS it may lead to a product being aerated during production and it may be more difficult to clean the equipment after the manufacturing process.

[0008] Thus, there is a need for providing improved zinc and fluoride containing products for treating or preventing erosion of tooth enamel, that do not contain sodium lauryl sulfate, but nevertheless are still have adequate stability, antimicrobial effectiveness and reduce plaque and treat or control gingivitis as traditional products that contain a sodium lauryl sulfate surfactant.

BRIEF SUMMARY

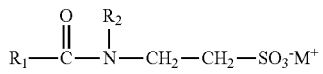
[0009] The Applicants have surprisingly discovered how to formulate oral care compositions with zinc phosphate, a taurate surfactant and a fluoride ion source wherein the compositions are free, or substantially free, of sodium lauryl sulfate. Formulas of the disclosure comprising a taurate surfactant as defined by Formula (1) (e.g., sodium methyl cocoyl taurate) are surprisingly physically stable and do not separate. Formulas of the disclosure (e.g., any of Composition 1.0 et seq) despite not containing an sodium lauryl sulfate can still maintain acceptable fluoride and zinc stability, as well as acceptable taste.

[0010] Disclosed herein are oral care compositions comprising:

[0011] zinc phosphate,

[0012] a fluoride source; and

[0013] a taurate surfactant represented by Formula (1):



[0014] wherein R_1 is a saturated or unsaturated, straight or branched alkyl chain with 6 to 18 C atoms R_2 is H or methyl, and M^+ is H, sodium, or potassium.

[0015] Methods and uses for this composition are also described throughout. The compositions disclosed herein provide improved protection from demineralization and enhanced antibacterial activity compared to the art. In some embodiments, the zinc phosphate is added to the dentifrice as a preformed salt. In some embodiments, the oral care composition is a toothpaste or oral gel composition.

[0016] Further areas of applicability of the present disclosure will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating the preferred embodiment of the disclosure, are intended for purposes of illustration only and are not intended to limit the scope of the disclosure.

DETAILED DESCRIPTION

[0017] The following description of the preferred embodiment(s) is merely exemplary in nature and is in no way intended to limit the disclosure, its application, or uses.

[0018] 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 addition, all references cited herein are hereby incorporated by referenced in their entireties. In the event of a conflict in a definition in the present disclosure and that of a cited reference, the present disclosure controls.

[0019] Unless otherwise specified, all percentages and amounts expressed herein and elsewhere in the specification should be understood to refer to percentages by weight of the entire composition. The amounts given are based on the active weight of the material.

[0020] It has been surprisingly found that an oral care composition comprising zinc phosphate, stannous fluoride, and a taurate surfactant, selected at certain concentrations and amounts, provides efficacious anti-erosion and anti-microbial properties when compared to similar oral care formulations that contain an anionic surfactant in lieu of a taurate surfactant. Moreover, the compositions of the present disclosure provide stable zinc and fluoride ions containing formulations when compared to similar formulations in the art that contain sodium lauryl sulfate in lieu of a taurate surfactant.

[0021] Compositions 1.0 et seq, which can include a toothpaste or oral gel, can comprises from 10% to 99% water, by weight of the composition. For example, the composition may comprise at least 10%, 15%, 20%, 25%, 30%, 35% or 40% water, up to a maximum of, for example, 60%, 70%, 80%, 90%, 95% or 99% water, by weight of the composition. As used herein, amounts of water refer to water added directly to the composition, as well as water added as part of ingredients or components which are added as aqueous solutions. In some embodiments, the composition comprises 10-60% water, or 10-50% water, or 10-40% water, or 10-30% water, or 15-30% water, or 20-30% water, or about 25% water, by weight of the composition.

[0022] As used herein, the term "preformed salt"—when used in reference to zinc phosphate—means that the zinc phosphate is not formed in situ in the oral care composition, e.g., through the reaction of phosphoric acid and another zinc salt.

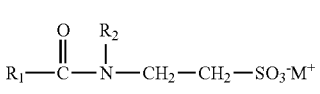
[0023] In one aspect, the present disclosure therefore provides an oral care composition (Composition 1.0) wherein the oral care composition comprises:

[0024] a.) an orally acceptable carrier,

[0025] b.) zinc phosphate (e.g., zinc phosphate)

[0026] c.) fluoride ion source, and

[0027] d.) a taurate surfactant represented by Formula (1):



[0028] wherein R_1 is a saturated or unsaturated, straight or branched alkyl chain with 6 to 18 C atoms R_2 is H or methyl, and M^+ is H, sodium, or potassium (e.g., sodium methyl cocoyl taurate).

[0029] For example, Composition 1.0 also includes the following:

[0030] 1.1 The oral care composition of Composition 1.0, wherein the R_1 is a saturated or unsaturated, straight or branched alkyl chain with 8 to 14 C atoms.

[0031] 1.2 The oral care composition of 1.0 or 11, wherein the taurate surfactant comprises one or more surfactant selected from the group consisting of: potassium cocoyl taurate, potassium methyl cocoyl taurate, sodium caproyl methyl taurate, sodium cocoyl taurate, sodium lauroyl taurate, sodium methyl cocoyl taurate, sodium methyl lauroyl taurate, sodium methyl myristoyl taurate, sodium methyl oleoyl taurate, sodium methyl palmitoyl taurate, sodium methyl stearoyl taurate, and combinations thereof.

[0032] 1.3 Any of the preceding oral care compositions, wherein the taurate surfactant comprises one or more surfactant selected from the group consisting of: sodium lauroyl methyl taurate (or sodium methyl lauroyl taurate), sodium methyl cocoyl taurate, and combinations thereof.

[0033] 1.4 Any of the preceding oral care compositions, wherein the taurate surfactant comprises sodium methyl cocoyl taurate (e.g., 1%-3% by wt. of sodium methyl cocoyl taurate) (e.g., from 1.75%-1.95% by wt. sodium methyl cocoyl taurate) (e.g., about 2% by wt. sodium methyl cocoyl taurate).

[0034] 1.5 Any of the preceding oral care compositions, wherein the taurate surfactant is present in an amount of from 0.4% to 3%, e.g., from 0.4% to 2.5%, from 0.4% to 2%, from 0.4% to 1.5%, from 0.5% to 3%, from 0.8% to 3%, from 1% to 3%, from 1.2% to 2.7%, from 1.5% to 3%, from 2% to 3%, from 1% to 2.8%, from 1% to 2.7%, from 1% to 2.5%, from 1.5% to 2.8%, from 1.5% to 2.5%, from 1.8% to 3%, from 1.8% to 2.8%, from 1.8% to 2.7%, from 1.8% to 2.5%, e.g., about 2% by weight of the composition.

[0035] 1.6 Any of the preceding oral care compositions, wherein the zinc phosphate is a preformed salt of zinc phosphate (e.g., zinc phosphate hydrate).

[0036] 1.7 Any preceding oral care composition, wherein the amount of zinc phosphate is from 0.05 to 10% by weight, relative to the weight of the oral care composition, for example, from 0.1% to 8% by weight, or from 0.5% to 5% by weight, or from 0.5% to 4% by weight, or from 1% to 4%, or from 1% to 3% by weight, or from 2% to 3% by weight, or about 1% or about 2%, or about 2.25% or about 2.5%, by weight.

[0037] 1.8 Any preceding oral care composition, wherein the amount of the fluoride ion source is in an amount from 0.01% to 5% by weight, relative to the weight of the oral care composition, for example, from 0.05 to 4% by weight, or from 0.1% to 3% by weight, or from 0.2% to 2% by weight, or from 0.3 to 1% by weight (e.g., about 0.53% by wt.), or from 0.3 to 0.5% by weight, or about 0.32% by weight (e.g., 0.32% by weight).

[0038] 1.9 Any of the preceding oral care compositions, wherein the fluoride source is selected from the group consisting of: sodium fluoride, potassium fluoride, calcium fluoride, zinc fluoride, zinc ammonium fluoride, lithium fluoride, ammonium fluoride, stannous fluoride, stannous fluorozirconate, sodium monofluorophosphate, potassium monofluorophosphate, laurylamine hydrofluoride, diethylaminoethyloctoylamide hydrofluoride, didecyldimethylammonium fluoride, cetylpyridinium fluoride, dilaurylmorpholinium fluoride, sarcosine stan-

nous fluoride, glycine potassium fluoride, glycine hydrofluoride, amine fluorides, and combinations thereof

[0039] 1.10 The preceding oral care composition, wherein the fluoride ion source comprises sodium fluoride (e.g., from 0.2%-2% by wt. of sodium fluoride)

[0040] 1.11 The oral care composition of 1.9, wherein the fluoride ion source comprises stannous fluoride.

[0041] 1.12 The oral care composition of 1.9, wherein the fluoride ion source comprises sodium monofluorophosphate.

[0042] 1.13 The oral care composition of 1.9, wherein the fluoride ion source comprises sodium fluoride and stannous fluoride (e.g., wherein the combination is present from 0.1%-2% by wt., relative to the total weight of the composition).

[0043] 1.14 Any preceding oral care composition, wherein the composition comprises water in the amount of 10% by weight or more, relative to the weight of the oral care composition, for example, 10-90%, or 10-80%, or 10-70%, or 10-60%, or 10-50%, or 10-40%, or 10-30%, or 15-30%, 15%-40% 20%-40%, 20-35%, or 20-50%, 25-35% or 30-35% or about 25% by wt., or about 27% by wt., or about 30% by wt., or about 34%, by weight of the composition.

[0044] 1.15 Any preceding oral care composition, further comprising an organic buffer system, wherein the buffer system comprises a carboxylic acid and one or more conjugate base salts thereof, for example, alkali metal salts thereof (e.g., citric acid and sodium citrate).

[0045] 1.16 Any preceding oral care composition, wherein the composition comprises the organic acid buffer system in an amount of 0.1 to 5.0% by weight of the composition, measured as the combined amount of organic acid and any conjugate base salts (e.g., citric acid and sodium citrate); for example, from 0.5 to 4.0%, or from 1.0 to 3.0%, or from 1.5 to 3.0%, or from 1.0 to 2.4%, or from 1.0% to 2.0%, or from 1.0% to 1.5%, or about 1.2%, by weight of the composition.

[0046] 1.17 Any preceding oral care composition, wherein the oral care composition further comprises an abrasive, for example, silica abrasives, calcium abrasives, and other abrasives as disclosed herein.

[0047] 1.18 Any preceding oral care composition, further comprising one or more humectants, as described herein, e.g., selected from sorbitol, glycerol, xylitol and propylene glycol, or combinations thereof, e.g., a combination of sorbitol and glycerin.

[0048] 1.19 The oral care composition of 1.18, wherein the humectant comprises sorbitol (e.g., from 20%-55% by wt. of sorbitol) (e.g., 25%-35% by wt.).

[0049] 1.20 The oral care composition of 1.18, wherein the humectant comprises glycerin (e.g., from 1%-10% by wt. of glycerin) (e.g., from 7%-10% by wt. of glycerin).

[0050] 1.21 The oral care composition of 1.18, wherein the humectant comprises sorbitol and glycerin.

[0051] 1.22 Any preceding oral care composition, further comprising a zwitterionic surfactant.

[0052] 1.23 The preceding oral care composition, wherein the zwitterionic surfactant comprises cocamidopropyl betaine ("CAPB"), (e.g., in an amount of 0.5-5% by weight) (e.g., about 0.45% by wt.) (e.g., about 0.6% by wt.) (e.g., about 1.5%) (e.g., about 2% by wt.).

[0053] 1.24 Any preceding oral care composition, further comprising an effective amount of one or more alkali phosphate salts for example orthophosphates, pyrophosphates, tripolyphosphates, tetraphosphates or higher polyphosphates.

[0054] 1.25 The oral care composition of 1.24, wherein the alkali phosphate salts comprise tetrasodium pyrophosphate or tetrapotassium pyrophosphate, for example, in an amount of 0.5 to 5% by weight of the composition, e.g., 1-4%, or about 2-4%, or about 1-2% or about 1.5% or about 2% or about 4%, by weight.

[0055] 1.26 The oral care composition 1.24 or 1.25, wherein the alkali phosphate salts comprise sodium tripolyphosphate or potassium tripolyphosphate, for example, in an amount of 0.5 to 6% by weight of the composition, e.g., 1-4%, or 2-3% or about 3% by weight.

[0056] 1.27 Any preceding oral care composition, further comprising a whitening agent.

[0057] 1.28 Any preceding oral care composition, further comprising one or more sources of zinc ions in addition to the zinc phosphate, for example a zinc salt selected from zinc citrate, zinc oxide, zinc lactate, zinc pyrophosphate, zinc sulfate, zinc chloride, and combinations thereof.

[0058] 1.29 Any preceding oral care composition, wherein the oral care composition is in the form selected from: a dentifrice (e.g., a toothpaste or oral gel), powder (e.g., tooth powder), cream, mouthwash, mousse, foam, mouth spray, oral tablet, strip, or gum (e.g., chewing gum).

[0059] 1.30 Any preceding oral care composition, wherein the pH of the composition is from 6 to 9, such as from 6.5 to 8, or from 6.5 to 7.5, or about 7.0.

[0060] 1.31 Any preceding oral care composition, wherein the composition is a single-phase composition (e.g., not a dual-phase composition).

[0061] 1.32 Any preceding oral care composition, wherein the composition does not comprise one or more of zinc oxide, zinc citrate, or zinc lactate.

[0062] 1.33 Any preceding oral care composition, wherein the zinc phosphate is the only zinc ion source.

[0063] 1.34 Any preceding oral care composition, wherein the composition is essentially free or free of phosphates of more than four phosphate groups.

[0064] 1.35 Any preceding oral care composition, wherein the composition is essentially free or free of phosphates of more than three phosphate groups.

[0065] 1.36 Any preceding oral care composition, wherein the composition is essentially free or free of hexametaphosphate salts (e.g., sodium hexametaphosphate).

[0066] 1.37 Any of the preceding oral care compositions, wherein the composition is 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.

[0067] 1.38 Any preceding oral care compositions, wherein the composition further comprises a polymer selected from the group consisting of: carboxymethyl cellulose (free form or a salt, e.g., sodium salt), a gum (e.g., xanthan gum, carrageenan gum, or gum arabic), polyethylene glycol (e.g., polyethylene glycol 200, 400, 600 or 800, or a mixture thereof), and a combination thereof, for example, a mixture of sodium carboxy methyl cellulose, xanthan gum, polyethylene glycol 600.

[0068] 1.39 Composition 1.38, wherein the polymer comprises sodium carboxy methyl cellulose.

[0069] 1.40 Composition 1.38, wherein the polymer comprises xanthan gum.

[0070] 1.41 Composition 1.38, wherein the polymer comprises polyethylene glycol 600.

[0071] 1.42 Any preceding oral care composition further comprising a silica thickener and/or a silica abrasive.

[0072] 1.43 Any preceding composition, wherein the oral care composition comprises an additional anionic surfactant that is not sodium lauryl sulfate, wherein the additional anionic surfactant is selected from the group consisting of: water-soluble salts of higher fatty acid monoglyceride monosulfates (such as the sodium salt of the monosulfated monoglyceride of hydrogenated coconut oil fatty acids), sodium cocomonoglyceride 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 K, for example sodium laureth-2 sulfate ($CH_3(CH_2)_{10}CH_2(OCH_2CH_2)_2OSO_3Na$)), 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.

[0073] 1.44 Any preceding oral care composition, wherein the oral care composition is free of sodium lauryl sulfate.

[0074] 1.45 Any preceding oral care composition, wherein the composition comprises:

[0075] Zinc phosphate;

[0076] Sodium fluoride;

[0077] Sodium methyl cocoyl taurate; and

[0078] An orally acceptable carrier.

[0079] 1.46 Any preceding oral care composition, wherein the composition comprises:

[0080] Zinc phosphate from 0.5%-4% by wt. of the total composition;

[0081] Sodium fluoride;

[0082] Sodium methyl cocoyl taurate from 0.5% to 3% (e.g., about 2% SMCT),

[0083] Water in the amount of 10%-40% by wt. of the total composition; and

[0084] An orally acceptable carrier.

[0085] 1.47 Any preceding oral care composition, wherein the composition comprises:

[0086] Zinc phosphate;

[0087] Sodium fluoride;

[0088] Sodium methyl cocoyl taurate from 0.5% to 3% (e.g., about 2% SMCT),

[0089] Water in the amount of 10%-40% by wt. of the total composition;

[0090] An orally acceptable carrier; and

[0091] wherein the composition is free of sodium lauryl sulfate.

[0092] 1.48 Any preceding oral care composition, wherein the composition comprises:

[0093] Zinc phosphate;

[0094] Stannous fluoride;

[0095] Sodium methyl cocoyl taurate (e.g., from 0.5% to 3%) (e.g., about 2% SMCT)

[0096] Water in the amount of 10%-50% by wt. of the total composition;

[0097] An orally acceptable carrier.

[0098] 1.49 Any preceding oral care composition, wherein the composition comprises:

[0099] Zinc phosphate;

[0100] Stannous fluoride;

[0101] Sodium methyl cocoyl taurate (e.g., from 0.5% to 3%) (e.g., about 2% SMCT)

[0102] Water in the amount of 10%-50% by wt. of the total composition;

[0103] An orally acceptable carrier; and

[0104] Wherein the composition is free of any sodium lauryl sulfate. 1.50 Any preceding oral care composition, wherein the composition comprises:

[0105] Zinc phosphate;

[0106] Stannous fluoride;

[0107] Sodium methyl cocoyl taurate (e.g., from 0.5% to 3%) (e.g., about 2% SMCT);

[0108] A zwitterionic surfactant (e.g., cocamidopropyl betaine)

[0109] Water in the amount of 10%-50% by wt. of the total composition; and

[0110] an orally acceptable carrier.

[0111] 1.51 Any preceding oral care composition, wherein the composition comprises:

[0112] Zinc phosphate;

[0113] Stannous fluoride;

[0114] Sodium methyl cocoyl taurate (e.g., from 0.5% to 3%) (e.g., about 2% SMCT);

[0115] A zwitterionic surfactant (e.g., cocamidopropyl betaine)

[0116] Water in the amount of 10%-50% by wt. of the total composition; and

[0117] an orally acceptable carrier.

[0118] Wherein the composition is free of any sodium lauryl sulfate.

[0119] 1.52 Any preceding composition comprising the following ingredients:

Ingredient	% by wt. of total composition
Zinc phosphate (e.g., zinc phosphate hydrate)	0.05-2.5%, e.g., about 1%
Sodium methyl cocoyl taurate	1%-3% (e.g., about 2% by wt.)

-continued

Ingredient	% by wt. of total composition
Sodium fluoride	0.2-2%, e.g., about 0.32%
Alkali metal pyrophosphate (e.g., tetrasodium or tetrapotassium pyrophosphate)	1-5%, e.g., about 2%
Zwitterionic Surfactant (e.g., CAPB)	1-3%, e.g., about 1.5%
Sorbitol (e.g., 70 wt.% solution)	20-50%, e.g., about 40% or about 50%
Glycerin	1-8%, e.g., about 4%
Gum polymer (e.g., xanthan gum)	0.05-2%, e.g., about 0.3%
Polyethylene glycol (e.g., PEG 600)	1-5%, e.g., about 2%
Carboxymethyl cellulose (e.g., Sodium CMC)	0.5-3%, e.g., about 2%
Water (e.g., purified water)	10-30%, e.g., 15-20%, e.g., about 20%
Abrasive	10%-30% (e.g., about 20%)
Flavor, Sweetener, Colors	0.5-5 (e.g., about 1.7%)
Total Water	20-50%, e.g., about 26% or about 34%
Total Components	100%

[0120] 1.53 Any of the preceding oral care compositions comprising an amount of zinc phosphate that is effective for protecting against enamel erosion and/or providing any of the other benefits described herein can be employed. Examples of suitable amounts of zinc phosphate can range from 0.05 to 5% by weight, such as from 0.1 to 4% by weight, or from 0.5 to 3% by weight, or from 0.5 to 2% by weight, or from 0.8 to 1.5% by weight, or from 0.9 to 1.1% by weight, or about 1% by weight, relative to the weight of the oral care composition.

[0121] 1.54 Any preceding composition wherein the composition does not contain any sodium lauryl sulfate.

[0122] 1.55 Any preceding oral care composition, wherein the composition comprises:

[0123] Zinc phosphate from 0.5%-4% by wt.;

[0124] Stannous fluoride from 0.2%-2% by wt. (e.g., about 0.45% by wt.);

[0125] Sodium fluoride from 0.05-2% by wt., (e.g., about 0.78% by wt.);

[0126] Sodium methyl cocoyl taurate (e.g., from 0.5% to 3%) (e.g., about 2% SMCT)

[0127] Water in the amount of 10%-50% by wt. of the total composition (e.g., about 25% by wt.) (e.g., about 30% by wt.); and

[0128] An orally acceptable carrier.

[0129] 1.56 Any preceding oral care composition, wherein the composition comprises:

[0130] Zinc phosphate from 0.5%-4% by wt.;

[0131] Stannous fluoride from 0.2%-2% by wt. (e.g., about 0.45% by wt.);

[0132] Sodium fluoride from 0.05-2% by wt., (e.g., about 0.78% by wt.);

[0133] Sodium methyl cocoyl taurate (e.g., from 0.5% to 3%) (e.g., about 2% SMCT)

[0134] Water in the amount of 10%-50% by wt. of the total composition (e.g., about 25% by wt.) (e.g., about 30% by wt.);

[0135] An orally acceptable vehicle; and

[0136] Wherein the composition is free of any sodium lauryl sulfate.

[0137] 1.57 Any preceding oral care composition, wherein the composition comprises:

[0138] Zinc phosphate from 0.5%-4% by wt.;

[0139] Stannous fluoride from 0.2%-2% by wt. (e.g., about 0.45% by wt.);

[0140] Sodium fluoride from 0.05-2% by wt., (e.g., about 0.78% by wt.);

[0141] Sodium methyl cocoyl taurate (e.g., from 0.5% to 3%) (e.g., about 2% SMCT);

[0142] A zwitterionic surfactant (e.g., cocamidopropyl betaine);

[0143] Water in the amount of 10%-50% by wt. of the total composition (e.g., about 25% by wt.) (e.g., about 30% by wt.); and

[0144] Wherein the composition is free of any sodium lauryl sulfate.

[0145] 1.58 Any of the preceding oral care compositions, wherein the composition is free of sodium lauryl sulfate.

[0146] 1.59 Any of the preceding oral care compositions, wherein the composition comprises sodium fluoride in an amount from 0.05%-2% by wt. of the composition (e.g., about 0.07% by wt.).

[0147] 1.60 Any of the preceding oral care compositions comprising hyaluronic acid.

[0148] The formulations of the disclosure, e.g., any of Composition 1.0 et seq., containing zinc phosphate and a taurate surfactant do not exhibit the poor taste and mouthfeel, poor fluoride delivery, and poor foaming and cleaning associated with conventional zinc-based oral care products, which use more soluble zinc salts. And the formulations of the disclosure can provide acceptable taste, mouthfeel, foaming and fluoride delivery that consumers expect from similar oral care compositions that contain sodium lauryl sulfate as a primary surfactant.

[0149] In one aspect in the compositions of the disclosure, e.g., any of Composition 1.0 et seq., the combination of zinc and a taurate surfactant (e.g., sodium methyl cocoyl taurate) in the oral care composition does not impact product stability of a silica toothpaste containing zinc phosphate, tetrasodium pyrophosphate and sodium fluoride, where the impact on stability is measured relative to a similar oral care composition using sodium lauryl sulfate as the primary surfactant. In another aspect, the compositions of the disclosure, e.g., any of the Composition 1.0 et seq, does not contain sodium lauryl sulfate but can be formulated as a single-phase composition that does not separate.

[0150] The compositions of the disclosure, e.g., any of Composition 1.0 et seq, may optionally comprise additional ingredients suitable for use in oral care compositions. Examples of such ingredients include active agents, such as a fluoride source and/or a phosphate source in addition to zinc phosphate. The compositions may be formulated in a suitable dentifrice base, e.g., comprising abrasives, e.g., silica abrasives, surfactants, foaming agents, vitamins, polymers, enzymes, humectants, thickeners, additional antimicrobial agents, preservatives, flavorings, colorings, and/or combinations thereof. Examples of suitable dentifrice bases are known in the art. Alternatively, the compositions may be formulated as a gel (e.g., for use in a tray), chewing gum, lozenge or mint. Examples of suitable additional ingredients that can be employed in the compositions of the present disclosure are discussed in more detail below.

[0151] As used herein, an "oral care composition" refers to a composition for which the intended use includes oral care,

oral hygiene, and/or oral appearance, or for which the intended method of use comprises administration to the oral cavity, and refers to compositions that are palatable and safe for topical administration to the oral cavity, and for providing a benefit to the teeth and/or oral cavity. The term "oral care composition" thus specifically excludes compositions which are highly toxic, unpalatable, or otherwise unsuitable for administration to the oral cavity. In some embodiments, an oral care composition is not intentionally swallowed, but is rather retained in the oral cavity for a time sufficient to affect the intended utility. The oral care compositions as disclosed herein may be used in nonhuman mammals such as companion animals (e.g., dogs and cats), as well as by humans. In some embodiments, the oral care compositions as disclosed herein are used by humans. Oral care compositions include, for example, dentifrice and mouthwash. In some embodiments, the disclosure provides mouthwash formulations.

[0152] As used herein, "orally acceptable" refers to a material that is safe and palatable at the relevant concentrations for use in an oral care formulation, such as a mouthwash or dentifrice.

[0153] As used herein, "orally acceptable carrier" refers to any vehicle useful in formulating the oral care compositions disclosed herein. The orally acceptable carrier is not harmful to a mammal in amounts disclosed herein when retained in the mouth, without swallowing, for a period sufficient to permit effective contact with a dental surface as required herein. In general, the orally acceptable carrier is not harmful even if unintentionally swallowed. Suitable orally acceptable carriers include, for example, one or more of the following: water, a thickener, a buffer, a humectant, a surfactant, an abrasive, a sweetener, a flavorant, a pigment, a dye, an anti-caries agent, an anti-bacterial, a whitening agent, a desensitizing agent, a vitamin, a preservative, an enzyme, and mixtures thereof.

[0154] Active Agents: The compositions of the disclosure, e.g., any of Composition 1.0 et seq, may comprise various other agents that are active to protect and enhance the strength and integrity of the enamel and tooth structure and/or to reduce bacteria and associated tooth decay and/or gum disease or to provide other desired benefits. Effective concentration of the active ingredients used herein will depend on the particular agent and the delivery system used. The concentration will also depend on the exact salt or polymer selected. For example, where the active agent is provided in salt form, the counterion will affect the weight of the salt, so that if the counterion is heavier, more salt by weight will be required to provide the same concentration of active ion in the final product.

[0155] Compositions of the disclosure may contain from 0.1 to 1 wt. % of an antibacterial agent, such as about 0.3 wt. %. Any suitable antimicrobial actives can be employed.

[0156] Fluoride Ion Source: The oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, can comprise one or more additional 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, the disclosure of each of which is hereby incorporated by reference in their entirety. Representative fluoride ion sources include, but are not limited to, 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 sodium fluoride, sodium monofluorophosphate as well as mixtures thereof. In certain embodiments, the oral care composition of the disclosure may contain stannous fluoride and any additional source of fluoride ions or fluorine-providing agents in amounts sufficient to supply, in total, from 25 ppm to 25,000 ppm (mass fraction) of fluoride ions, generally at least 500 ppm, e.g., from 500 to 2000 ppm, e.g., from 1000 to 1600 ppm, e.g., about 1450 ppm. The appropriate level of fluoride will depend on the particular application. A toothpaste for general consumer use would typically have from 1000 to about 1500 ppm, with pediatric toothpaste having somewhat less. A dentifrice or coating for professional application could have as much as 5,000 or even about 25,000 ppm fluoride. Additional fluoride ion sources may be added to the compositions of the disclosure at a level of from 0.01 wt. % to 10 wt. % in one embodiment or from 0.03 wt. % to 5 wt. %, and in another embodiment from 0.1 wt. % to 1 wt. % by weight of the composition. As discussed above, weights of fluoride salts to provide the appropriate level of fluoride ion will vary based on the weight of the counterion in the salt.

[0157] Abrasives: The oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, can comprise abrasives. Examples of suitable abrasives include silica abrasives, such as standard cleaning silicas, high cleaning silicas or any other suitable abrasive silicas. Additional examples of abrasives that can be used in addition to or in place of the silica abrasives include, for example, a calcium phosphate abrasive, e.g., tricalcium phosphate ($Ca_3(PO_4)_2$), hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$), or dicalcium phosphate dihydrate ($CaHPO_4.2H_2O$, also sometimes referred to herein as DiCal) or calcium pyrophosphate; calcium carbonate abrasive; or abrasives such as sodium metaphosphate, potassium metaphosphate, aluminum silicate, calcined alumina, bentonite or other siliceous materials, or combinations thereof.

[0158] Silica abrasive polishing materials useful herein, as well as the other abrasives, generally have an average particle size ranging between 0.1 and 30 microns, such as between 5 and 15 microns. The silica abrasives can be from precipitated silica or silica gels, such as the silica xerogels described in U.S. Pat. No. 3,538,230, to Pader et al. and U.S. Pat. No. 3,862,307, to Digiulio, the disclosures of which are incorporated herein by reference in their entireties. Particular silica xerogels are marketed under the trade name Syloid® by the W. R. Grace & Co., Davison Chemical Division. The precipitated silica materials include those marketed by the J. M. Huber Corp. under the trade name Zeodent®, including the silica carrying the designation Zeodent 115 and 119. These silica abrasives are described in U.S. Pat. No. 4,340,583, to Wason, the disclosure of which is incorporated herein by reference in its entirety. In certain embodiments, abrasive materials useful in the practice of the oral care compositions in accordance with the disclosure include silica gels and precipitated amorphous silica having an oil absorption value of less than 100 cc/100 g silica, such as from 45 cc/100 g to 70 cc/100 g silica. Oil absorption values are measured using the ASTA Rub-Out Method D281. In certain embodiments, the silicas are colloidal particles having an average particle size of from 3 microns

to 12 microns, and from 5 to 10 microns. Examples of low oil absorption silica abrasives useful in the practice of the disclosure are marketed under the trade designation Sylodent XWA® by Davison Chemical Division of W. R. Grace & Co., Baltimore, Md. 21203. Sylodent 650 XWA®, a silica hydrogel composed of particles of colloidal silica having a water content of 29% by weight averaging from 7 to 10 microns in diameter, and an oil absorption of less than 70 cc/100 g of silica is an example of a low oil absorption silica abrasive useful in the practice of the present disclosure. In some aspects, the compositions of the disclosure comprise a synthetic amorphous silica e.g., Sylodent VP5 (Davison Chemical Division of W. R. Grace & Co. (Baltimore, Md., USA)) as described in United States Patent Application 2012/0100193 (the contents of which are incorporated herein by reference).

[0159] Any suitable amount of silica abrasive can be employed. Examples of suitable amounts include 10 wt. % or more dry weight of silica particles, such as from 15 wt. % to 30 wt. % or from 15 wt. % to 25 wt. %, based on the total weight of the composition.

[0160] Foaming agents: The oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, can comprise an agent to increase the amount of foam that is produced when the oral cavity is brushed. Illustrative examples of agents that increase the amount of foam include, but are not limited to polyoxyethylene and certain polymers including, but not limited to, alginate polymers. The polyoxyethylene may increase the amount of foam and the thickness of the foam generated by the oral care compositions of the present disclosure. Polyoxyethylene is also commonly known as polyethylene glycol ("PEG") or polyethylene oxide. The polyoxyethylenes suitable for compositions of the present disclosure may have a molecular weight of from 200,000 to 7,000,000. In one embodiment the molecular weight may be from 600,000 to 2,000,000 and in another embodiment from 800,000 to 1,000,000. Polyox® is the trade name for the high molecular weight polyoxyethylene produced by Union Carbide. The foaming agent, (e.g., polyoxyethylene) may be present in an amount of from 0.1% to 50%, in one embodiment from 0.5% to 20% and in another embodiment from 1% to 10%, or from 2% to 5% by weight of the oral care compositions of the present disclosure.

[0161] Surfactants: The oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, may comprise an anionic surfactant that is not sodium lauryl sulfate. In one aspect, the taurate surfactant of Formula 1 (e.g., any of Composition 1.0 et seq) can be an anionic surfactant. For example, any of Composition 1.0 et seq can additionally comprise any of the following surfactants:

[0162] i. water-soluble salts of higher fatty acid monoglyceride monosulfates, such as the sodium salt of the monosulfated monoglyceride of hydrogenated coconut oil fatty acids, sodium cocomonoglyceride sulfate,

[0163] ii. 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 K, for example sodium laureth-2 sulfate ($CH_3(CH_2)_{10}CH_2(OCH_2CH_2)_2OSO_3Na$),

[0164] iii. higher alkyl aryl sulfonates such as sodium dodecyl benzene sulfonate (sodium lauryl benzene sulfonate),

[0165] iv. 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.

[0166] By "higher alkyl" is meant, e.g., C_{6-30} alkyl. In certain embodiments, the anionic surfactants useful herein include the water-soluble salts of alkyl sulfates having from 10 to 18 carbon atoms in the alkyl radical and the water-soluble salts of sulfonated monoglycerides of fatty acids having from 10 to 18 carbon atoms. Sodium lauroyl sarcosinate and sodium coconut monoglyceride sulfonates are examples of anionic surfactants of this type. The anionic surfactant may be present in an amount which is effective, e.g., >0.01% by weight of the formulation, but not at a concentration which would be irritating to the oral tissue, e.g., <10%, and optimal concentrations depend on the particular formulation and the particular surfactant. In one embodiment, the anionic surfactant is present in a toothpaste at from 0.3% to 4.5% by weight, e.g., about 1.5%. The compositions of the disclosure may optionally contain mixtures of surfactants, e.g., comprising anionic surfactants and other surfactants that may be anionic, cationic, zwitterionic or nonionic. Generally, suitable surfactants are those which are reasonably stable throughout a wide pH range. Surfactants are described more fully, for example, in U.S. Pat. No. 3,959,458, to Agricola et al.; U.S. Pat. No. 3,937,807, to Haefele; and U.S. Pat. No. 4,051,234, to Gieske et al, the disclosures of which are incorporated herein by reference in their entireties.

[0167] The surfactant or mixtures of compatible surfactants that are included in addition to the anionic surfactants can be present in the compositions of the present disclosure in from 0.1% to 5.0%, in another embodiment from 0.3% to 3.0% and in another embodiment from 0.5% to 2.0% by weight of the total composition. These ranges do not include the anionic surfactant amounts.

[0168] In some embodiments the oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, can comprise a zwitterionic surfactant, for example a betaine surfactant, for example cocamidopropylbetaine, e.g., in an amount of from 0.1% to 4.5% by weight (e.g., about 0.45% by wt.), e.g., from 0.5 to 2% by weight cocamidopropyl betaine (e.g., about 0.6% by wt.).

[0169] Tartar control agents: In various embodiments of the present disclosure, the oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, can comprise an anticalculus agent. Suitable anticalculus agents include, without limitation, phosphates and polyphosphates (for example pyrophosphates and tripolyphosphates), polyaminopropanesulfonic acid (AMPS), hexametaphosphate salts, zinc citrate trihydrate, polypeptides, polyolefin sulfonates, polyolefin phosphates, and diphosphonates. The compositions of the disclosure thus may comprise phosphate salts in addition to the zinc phosphate. In particular embodiments, these salts are alkali phosphate salts, e.g., salts of alkali metal hydroxides or alkaline earth hydroxides, for example, sodium, potassium or calcium salts. "Phosphate" as used herein encompasses orally acceptable mono- and polyphosphates, for example, P_{1-6} phosphates, for example monomeric phosphates such as monobasic, dibasic or tribasic phosphate; and dimeric phosphates such as pyrophosphates; and multimeric phosphates, such as tripolyphosphates, tetraphosphates, hexaphosphates and

hexametaphosphates (e.g., sodium hexametaphosphate). In particular examples, the selected phosphate is selected from alkali dibasic phosphate and alkali pyrophosphate salts, e.g., selected from sodium phosphate dibasic, potassium phosphate dibasic, dicalcium phosphate dihydrate, calcium pyrophosphate, tetrasodium pyrophosphate, tetrapotassium pyrophosphate, sodium tripolyphosphate, and mixtures of any of two or more of these. In a particular embodiment, for example the compositions may comprise tetrasodium pyrophosphate in an amount of from 0.5 to 5% by weight, e.g., 1-3%, or 1-4%, or 2-4%, or 1-2% or about 2%, or about 4% by weight of the composition. In another embodiment, the compositions may comprise a mixture of tetrasodium pyrophosphate (TSPP) and sodium tripolyphosphate (STPP), e.g., in proportions of TSPP at from 0.5 to 5 wt. %, such as from 1 to 2 wt. % or 1 to 4 wt. % and STPP at from 0.5% to 6 wt. %, such as 1 to 4%, or 2 to 3% by weight of the composition. Such phosphates are provided in an amount effective to reduce erosion of the enamel, to aid in cleaning the teeth, and/or to reduce tartar buildup on the teeth, for example in an amount of from 0.2 to 20 wt. %, e.g., from 1 to 15 wt. %, by weight of the composition.

[0170] Flavoring Agents: In certain aspects the oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, can comprise a flavoring agent. Flavoring agents which are used in the practice of the present disclosure include, but are not limited to, essential oils as well as various flavoring aldehydes, esters, alcohols, and similar materials. 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. The flavoring agent may be incorporated in the oral composition at a concentration of from 0.1 to 5% by weight e.g., from 0.5 to 1.5% by weight.

[0171] Polymers: In certain aspects the oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, can comprise additional polymers to adjust the viscosity of the formulation or enhance the solubility of other ingredients. Such additional polymers include polyethylene glycols, polysaccharides (e.g., cellulose derivatives, for example carboxymethyl cellulose, hydroxymethyl cellulose, ethyl cellulose, microcrystalline cellulose or polysaccharide gums, for example xanthan gum, guar 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. In one embodiment, the oral care composition may contain PVP. PVP generally refers to a polymer containing vinylpyrrolidone (also referred to as N-vinylpyrrolidone, N-vinyl-2-pyrrolidone and N-vinyl-2-pyrrolidinone) as a monomeric unit. The monomeric unit consists of a polar imide group, four non-polar methylene groups and a non-polar methane group.

[0172] In some embodiments, the compositions of the disclosure, e.g., any of Composition 1.0 et seq, can comprise one or more polyethylene glycols, for example, polyethylene glycols in a molecular weight range from 200 to 800. For example, the compositions may comprise one or more of polyethylene glycol 200, polyethylene glycol 300, polyethylene glycol 400, polyethylene glycol, 600 or polyethylene glycol 800.

[0173] Silica thickeners, which form polymeric structures or gels in aqueous media, may be present. Note that these silica thickeners are physically and functionally distinct from the particulate silica abrasives also present in the compositions, as the silica thickeners are very finely divided and provide little or no abrasive action. Other thickening agents are carboxyvinyl polymers, carrageenan, 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 can also be used as component of the thickening composition to further improve the composition's texture. In certain embodiments, thickening agents in an amount of from 0.5% to 5.0% by weight of the total composition are used.

[0174] In some embodiments, the oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, can comprise an anionic polymer, for example in an amount of from 0.05 to 5%. Examples of such agents generally known for use in dentifrice are disclosed in U.S. Pat. Nos. 5,188,821 and 5,192,531, both of which are incorporated herein by reference in their entirety; and include synthetic anionic polymeric polycarboxylates, such as 1:4 to 4:1 copolymers of maleic anhydride or acid with another polymerizable ethylenically unsaturated monomer, preferably methyl vinyl ether/maleic anhydride having a molecular weight (M.W.) of from 30,000 to 1,000,000, such as from 300,000 to 800,000. These copolymers are available for example as Gantrez, e.g., AN 139 (M.W. 500,000), AN 119 (M.W. 250,000) and preferably S-97 Pharmaceutical Grade (M.W. 700,000) available from ISP Technologies, Inc., Bound Brook, N.J. 08805. The enhancing agents when present are present in amounts ranging from 0.05 to 3% by weight. Other operative polymers include those such as the 1:1 copolymers of maleic anhydride with ethyl acrylate, hydroxyethyl methacrylate, N-vinyl-2-pyrrolidone, or ethylene, the latter being available for example as Monsanto EMA No. 1103, 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. 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-chlorsorbic, 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. 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 from 1,000 to 2,000,000. Another useful class of polymeric agents includes polyamino acids containing proportions of anionic surface-active amino acids such as aspartic acid, glutamic acid and phosphoserine, e.g. as disclosed in U.S. Pat. No. 4,866,161, issued to Sikes et al., which is also incorporated herein by reference in its entirety.

[0175] In some embodiments, there are no anionic polymers present in the composition. In other embodiments, there may be anionic polymers present, but they do not include copolymers of methyl vinyl ether and maleic acid or anhydride.

[0176] Humectants: Within certain embodiments of the disclosure, e.g., any of Composition 1.0 et seq, the composition comprise one or more humectants. Certain humectants can also impart desirable sweetness or flavor to dentifrice compositions. Suitable humectants include edible polyhydric alcohols such as glycerin, sorbitol, xylitol, propylene glycol as well as other polyols and mixtures of these humectants. In one embodiment of the disclosure, the principal humectant is one of glycerin, sorbitol or a combination thereof. The humectant may be present at levels of greater than 15 wt. %, such as from 15 wt. % to 55 wt. %, or from 20 wt. % to 50 wt. %, or from 20 wt. % to 40 wt. %, or about 20% or about 30% or about 40%, based on the total weight of the composition.

[0177] Other optional ingredients: In addition to the above-described components, in certain aspects the oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, can comprise a variety of optional oral care ingredients some of which are described below. Optional ingredients include, for example, but are not limited to, adhesives, sudsing agents, flavoring agents, sweetening agents such as sodium saccharin, additional antiplaque agents, abrasives, aesthetics such as TiO_2 coated mica or other coloring agents, such as dyes and/or pigments.

[0178] In some embodiments, the compositions of the present disclosure, e.g., any of Composition 1.0 et seq, can have any pH suitable for in a product for use in oral care. Examples of suitable pH ranges are from 6 to 9, such as from 6.5 to 8, or 6.5 to 7.5, or about 7.0.

[0179] In some embodiments, the oral care compositions of the disclosure, e.g., of any of Composition 1.0 et seq, are either essentially free of, free of, or do not include any sodium hexametaphosphate. In some embodiments, the oral care compositions of the present disclosure are either essentially free of, free of, or do not include any halogenated diphenyl ethers (e.g., triclosan).

[0180] In at least one aspect, the oral care compositions of the disclosure, e.g., any of Composition 1.0 et seq, are either essentially free of, free of, or do not include any sodium lauryl sulfate.

[0181] By "essentially free" is meant that the compositions have no more than 0.01% by weight of these compounds.

[0182] In some embodiments, the compositions of the present disclosure, e.g., any of Composition 1.0 et seq, are either essentially free of, free of or do not include any complexing agents for increasing solubility of zinc phosphate. Examples of known complexing agents that can be excluded from the compositions of the present disclosure include the chelating agents taught in U.S. Patent Application No. 2007/0025928, the disclosure of which is hereby incorporated by reference in its entirety. Such chelating agents include mineral surface-active agents, including mineral surface-active agents that are polymeric and/or polyelectrolytes and that are selected from phosphorylated polymers, wherein if the phosphorylated polymer is a polyphosphate, the polyphosphate has average chain length of 3.5 or more, such as 4 or more; polyphosphonates; polycarboxylates; carboxy-substituted polymers; copolymers of phosphate- or phosphonate-containing monomers or polymers with ethylenically unsaturated monomers, amino acids, proteins, polypeptides, polysaccharides, poly(acrylate), poly(acrylamide), poly(methacrylate), poly(ethacrylate), poly(hydroxyalkylmethacrylate), poly(vinyl alcohol), poly(maleic anhydride), poly(maleate) poly(amide), poly (ethylene amine), poly(ethylene glycol), poly(propylene glycol), poly(vinyl acetate) and poly(vinyl benzyl chloride); and mixtures thereof. Other known complexing agents that can be excluded from the compositions of the present disclosure include those taught in CA 2634758, the disclosure of which is incorporated here by reference in its entirety. Examples include polyphosphorylated inositol compounds such as phytic acid, myo-inositol pentakis(dihydrogen phosphate); myo-inositol tetrakis(dihydrogen phosphate), myo-inositol trikis(dihydrogen phosphate), and alkali metal, alkaline earth metal or ammonium salts of any of the above inositol compounds. Phytic acid is also known as myo-inositol 1,2,3,4,5,6-hexakis (dihydrogen phosphate) or inositol hexaphosphoric acid.

[0183] In another aspect, the present disclosure provides a method of treatment or prevention of erosive tooth demineralization, gingivitis, plaque, and/or dental caries, the method comprising the application to the oral cavity of a person in need thereof a composition according to the invention (e.g., Composition 1.0 et seq), e.g., by brushing, for example, one or more times per day.

[0184] In another aspect, the present disclosure provides a method of using the compositions described herein (e.g., any of Compositions 1.0 et seq) to increase zinc levels in the enamel and to treat, reduce or control the incidence of enamel erosion. The methods comprise applying any of the compositions as described herein to the teeth, e.g., by brushing, or otherwise administering the compositions to the oral cavity of a subject in need thereof. The compositions can be administered regularly, such as, for example, one or more times per day. In various embodiments, administering the compositions of the present disclosure to a patient can provide one or more of the following benefits: (i) reduce hypersensitivity of the teeth, (ii) reduce plaque accumulation, (iii) reduce or inhibit demineralization and promote remineralization of the teeth, (iv) inhibit microbial biofilm formation in the oral cavity, (v) reduce or inhibit gingivitis, (vi) promote healing of sores or cuts in the mouth, (vii) reduce levels of acid producing bacteria, (viii) increase relative levels of non-cariogenic and/or non-plaque forming bacteria, (ix) reduce or inhibit formation of dental caries, (x) 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), (xi) treat, relieve or reduce dry mouth, (xii) clean the teeth and oral cavity, (xiii) reduce erosion, (xiv) whiten teeth; (xv) reduce tartar build-up, and/or (xvi) promote systemic health, including cardiovascular health, e.g., by reducing potential for systemic infection via the oral tissues. The disclosure further provides compositions for use in any of the above methods.

Further embodiments provide methods wherein at least one tooth is remineralized after administration of a composition as described herein.

[0185] The present application further discloses a method of making any of the compositions of the present disclosure, e.g., any of Composition 1.0 et seq. The method comprises combining zinc phosphate, sodium fluoride and a taurate surfactant in water to form an aqueous zinc phosphate mixture. In some embodiments, the zinc phosphate is added to the dentifrice composition as a preformed salt and remains essentially insoluble in the aqueous mixture. The amount of water employed in the mixture can be any of the amounts recited herein for the compositions of the present disclosure. Any standard mixing techniques can be employed to combine the ingredients and form a stable composition. In one aspect, the method comprises combining zinc phosphate and sorbitol, wherein the combination of zinc phosphate and sorbitol creates a dispersion. Subsequently, the dispersion of zinc phosphate and stannous fluoride is added to a water solution an aqueous mixture. Finally, sodium methyl cocoyl taurate is added a final ingredient to the aqueous mixture comprising zinc phosphate and stannous fluoride.

EXAMPLES

Example 1—Dentifrice Formulation

[0186] Representative Dentifrice Formulations according to the present disclosure are prepared according to Table 1 below:

TABLE 1

Ingredient	Weight % (by wt.)
Water	Q.S. (e.g., 15%-40%)
Humectants	15-55 (e.g., 30%-40%)
Polymers	1%-5% (e.g., 3.8%)
Abrasives	10%-30% (e.g., 20%)
Thickeners	0.5%-5% (e.g., 1.5%)
Zinc Phosphate	0.05%-5% (e.g., 1%)
Flavor, Sweetener, Colors	0.5%-5% (e.g., 1.7%)
Alkali Phosphate Salts	0.5%-5% (e.g., 2%)
Sodium Methyl Cocoyl Taurate	0.01%-10% (e.g., 2%)
Zwitterionic Surfactant	0.1%-4.5% (e.g., 1.5%)
Sodium Fluoride	0.5-11% (e.g., 0.32%)
Total Components	100%

Example 2—Stability, Taste and Formula Production

[0187] Compositions detailed in Table 2 below are studied for stability and taste over a span of six weeks to six months:

TABLE 2

	(% by wt.)	
	Formula A	Formula B
Zinc phosphate	1%	1%
Sodium methyl cocoyl taurate	2%	2%
Sodium fluoride	0.32%	0.32%
Alkali phosphate salt	2%	2%
Zwitterionic surfactant	1.5%	1.5%
Sorbitol (70% solution)	40%	50%
Glycerin	4%	4%

TABLE 2-continued

	(% by wt.)	
	Formula A	Formula B
Xanthan gum	0.3%	0.3%
PEG 600	2%	2%
Sodium CMC	2%	2%
Abrasive	20%	20%
Flavor, Sweetener, Colors	1.7%	1.7%
Added water (e.g., demineralized water)	q. s. (e.g., about 21%)	q. s. (e.g., about 11%)
Total Water	About 36%	About 26%
Total Components	100%	100%

[0188] Formula A is stable at 6 months during aging assays at 40 C. Formula A is also stable including 6 weeks in tests involving taste and meets acceptable microbial standards.

TABLE 3

Ageing Stability Study for Formula A

	Time (mos)	pH. (10% Sol.).	Viscosity (cps)	ionic Fluoride (ppm)	Zinc
30° C./65% RH	0	8.3	272,282	1435	0.42%
30° C./65% RH	1				
30° C./65% RH	2				
30° C./65% RH	3	8.3	322,053	1430	
30° C./65% RH	6	8.2	409,984	1410	
40° C./75% RH	1	8.1	410,000	1439	
40° C./75% RH	2				
40° C./75% RH	3	8.3	328,637	1408	0.48%
40° C./75% RH	6	8.2	405,140	1448	

[0189] Formula B with 10% less water is also stable at 3 months during aging assays at 40 C. Moreover, Formula B is stable in recyclable tubes as well as in aluminum laminate tubes.

TABLE 4

Ageing Stability Study for Formula B

	Time (mos)	pH. (10% Sol.)	Viscosity (cps)	Ionic Fluoride (ppm)	Zinc
−10° C.	2	8.3	475,228	1467	
−30° C.	2	8.3	472,610	1464	
30° C./65% RH	0	8.4	388,389	1454	0.43%
30° C./65% RH	1				
30° C./65% RH	2				
30° C./65% RH	3	8.3	578,715	1413	
30° C./65% RH	6	8.5	522,050	1406	
40° C./75% RH	1	8.3	612,657	1488	
40° C./75% RH	2				
40° C./75% RH	3	8.3	629,431	1544	0.45%
49° C.	2	8.4	555,542	1406	

[0190] Additionally, the surfactant system of Formula B—which includes sodium methyl cocoyl taurate—does not have an influence on cleaning procedure. Coupon studies demonstrate that toothpaste containing SLS and containing taurate (Formula B) can be cleaned with the same method.

[0191] Accordingly, Formulas A and B—both which contain taurate—are shown to be physically stable and do not

separate. Formulas A and B are also acceptable from the taste perspective and provide acceptable fluoride and zinc stability.

Example 3—Dentifrice Formulations

[0192] Representative Dentifrice Formulations according to the present disclosure are prepared according to Table 5 below:

TABLE 5

Ingredient	Formula C Wt. %	Formula D Wt. %	Formula E Wt. %
Water	Q.S.	Q. S.	Q.S.
Sorbitol (70% Solution)	39	39	39
Glycerin	8	9.8	9.8
Polymers	2.1	1.9	1.9
Abrasives	20	20	24
Thickeners	1.5	—	—
Zinc Phosphate Hydrate	1	1	1
Trisodium citrate	1	1	1
Citric Acid	0.2	0.2	0.2
Flavor, Sweetener, Colors	2.01	1.81	2.04
Alkali Phosphate Salts	2	2	2
Sodium Methyl Cocoyl Taurate	2	2	2
Cocamidopropyl Betaine	2	2	2
Sodium Fluoride	0.774	0.774	0.774
Stannous Fluoride	0.454	0.454	0.454
Total Components	100.0%	100.0%	100.0%

[0193] While the disclosure has been described with respect to specific examples including presently preferred modes of carrying out the disclosure, those skilled in the art will appreciate that there are numerous variations and permutations of the above-described systems and techniques. It is to be understood that other embodiments may be utilized and structural and functional modifications may be made without departing from the scope of the present disclosure.

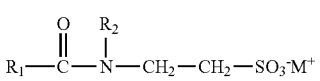
1. An oral care composition comprising:

a.) an orally acceptable carrier,

b.) zinc phosphate

c.) fluoride ion source, and

d.) a taurate surfactant represented by Formula (1):



(1)

wherein R_1 is a saturated or unsaturated, straight or branched alkyl chain with 6 to 18 C atoms R_2 is H or methyl, and M^+ is H, sodium, or potassium.

2. The oral care composition of claim **1**, wherein the taurate surfactant comprises one or more surfactant selected from the group consisting of: potassium cocoyl taurate, potassium methyl cocoyl taurate, sodium caproyl methyl taurate, sodium cocoyl taurate, sodium lauroyl taurate, sodium methyl cocoyl taurate, sodium methyl lauroyl taurate, sodium methyl myristoyl taurate, sodium methyl oleoyl taurate, sodium methyl palmitoyl taurate, sodium methyl stearoyl taurate, and combinations thereof.

3. The oral care composition of claim **1**, wherein the taurate surfactant comprises sodium methyl cocoyl taurate.

4. The oral care composition of claim **1**, wherein the taurate surfactant is present in an amount of from 0.4% to 3%.

5. The oral care composition of claim **1**, wherein the amount of zinc phosphate is from 0.05 to 10% by weight, relative to the weight of the oral care composition.

6. The oral care composition of claim **1**, wherein the amount of the fluoride ion source is in an amount from 0.01% to 5% by weight.

7. The oral care composition of claim **1**, wherein the fluoride source is selected from the group consisting of: sodium fluoride, potassium fluoride, calcium fluoride, zinc fluoride, zinc ammonium fluoride, lithium fluoride, ammonium fluoride, stannous fluoride, stannous fluorozirconate, sodium monofluorophosphate, potassium monofluorophosphate, laurylamine hydrofluoride, diethylaminoethyloctoylamide hydrofluoride, didecyldimethylammonium fluoride, cetylpyridinium fluoride, dilaurylmorpholinium fluoride, sarcosine stannous fluoride, glycine potassium fluoride, glycine hydrofluoride, amine fluorides, and combinations thereof.

8. The oral care composition of claim **1**, wherein the fluoride ion source comprises sodium fluoride.

9. The oral care composition of claim **1**, wherein the fluoride ion source comprises sodium fluoride and stannous fluoride.

10. The oral care composition of claim **1**, wherein the composition comprises water in the amount of 10% by weight or more, relative to the weight of the oral care composition.

11. The oral care composition of claim **1**, wherein the oral care composition further comprises an abrasive.

12. The oral care composition of claim **1**, further comprising one or more humectants selected from sorbitol, glycerol, xylitol and propylene glycol, and combinations thereof.

13. The oral care composition of claim **1** further comprising a zwitterionic surfactant.

14. The oral care composition of claim **13**, wherein the zwitterionic surfactant comprises cocamidopropyl betaine.

15. (canceled)

16. The oral care composition of claim **1**, wherein the oral care composition is selected from: a dentifrice, powder, cream, mouthwash, mousse, strip or chewing gum.

17. (canceled)

18. The oral care composition of claim **1**, wherein the composition comprises:

Zinc phosphate;

Sodium fluoride;

Sodium methyl cocoyl taurate from 0.5% to 3%,

Water in the amount of 10%-40% by wt. of the total composition; and

an orally acceptable carrier.

19. The oral care composition of claim **1**, wherein the composition comprises:

Zinc phosphate from 0.5%-4% by wt.;

Stannous fluoride from 0.2%-2% by wt.;

Sodium fluoride from 0.05-2% by wt.;

Sodium methyl cocoyl taurate;

An orally acceptable vehicle; and

Water in the amount of 10%-50% by wt. of the total composition.

20. The oral care composition of claim **1**, wherein the oral care composition is free, or substantially free, of sodium lauryl sulfate.

21. A method of treatment or prevention of erosive tooth demineralization, gingivitis, plaque, and/or dental caries, the method comprising the application to the oral cavity of a person in need thereof a composition according to claim **1**.

22. (canceled)

* * * * *