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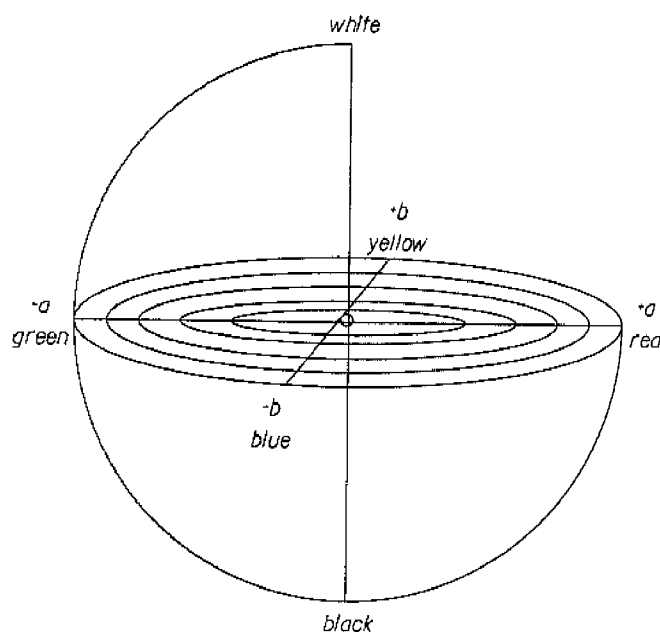
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(54) Title: CHOCOLATE FLAVORED DENTIFRICE WITH NEW VISUALS



(57) Abstract: A multi-phase dentifrice composition is provided, comprising an orally acceptable carrier and a chocolate flavoring, wherein, using the CIE L*a*b* color scale, a first phase of the composition has an L* value of at least about 75, an a* value from about -8 to about 8, and a b* value from about 0 to about 5, and a second phase of the composition has an L* value of at most about 65, an a* value from about 0 to about 12, and a b* value from about 0 to about 15.

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CHOCOLATE FLAVORED DENTIFRICE WITH NEW VISUALS

FIELD OF THE INVENTION

The present invention relates to a multi-phase dentifrice composition.

BACKGROUND OF THE INVENTION

Aesthetics are known to play an important role in consumer choice and use of dentifrice. Unique flavors and sensations are often sought by consumers. Similarly, a unique visual appearance for a dentifrice provides an aesthetic effect that the user finds pleasing and promotes the use of the dentifrice.

Various flavors and visuals have been used to distinguish and market new dentifrice products. But there remains a continuous need for new and attractive visual variations for dentifrices. The present invention meets this need by providing a chocolate-flavored dentifrice with at least two visually distinct phases, comprising the colors green, brown, and white.

SUMMARY OF THE INVENTION

The present invention is a multi-phase dentifrice composition comprising an orally acceptable carrier and a chocolate flavoring wherein, using the CIE L*a*b* color scale, a first phase of the composition has an L* value of at least about 75, an a* value from about -8 to about 8, and a b* value from about 0 to about 5, and a second phase of the composition has an L* value of at most about 65, an a* value from about 0 to about 12, and a b* value from about 0 to about 15.

In some embodiments, the chocolate-flavored dentifrice appears striped and/or has specks. In other embodiments, the chocolate-flavored dentifrice provides at least one cooling sensation. In still other embodiments, a third phase provides more variation of the visual appearance of the chocolate-flavored dentifrice.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a schematic illustration of the 1976 CIE LAB color space.

DETAILED DESCRIPTION OF THE INVENTION

While the specification concludes with claims that particularly point out and distinctly claim the invention, it is believed the present invention will be better understood from the following description.

Definitions

The term “orally acceptable carrier” as used herein means a suitable vehicle, which can be used to apply the present compositions to the oral cavity in a safe and effective manner. Such vehicle may include materials such as fluoride ion sources, additional anticalculus agents, buffers, other abrasive materials, peroxide sources, alkali metal bicarbonate salts, thickening materials, humectants, water, surfactants, titanium dioxide, flavor system, sweetening agents, cooling agents, xylitol, coloring agents, and mixtures thereof.

The term “comprising” as used herein means that other steps and other ingredients which do not affect the end result can be added. This term encompasses the terms “consisting of” and “consisting essentially of.” The compositions of the present invention can comprise, consist of, and consist essentially of the essential elements and limitations of the invention described herein, as well as any of the additional or optional ingredients, components, steps, or limitations described herein.

The term “effective amount” as used herein means an amount of a compound or composition sufficient to significantly induce a positive benefit, preferably an oral health benefit, but low enough to avoid serious side effects, i.e., to provide a reasonable benefit to risk ratio, within the sound judgment of a skilled artisan.

The term “oral composition” as used herein means a product that in the ordinary course of usage is not intentionally swallowed for purposes of systemic administration of particular therapeutic agents, but is rather retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces and/or oral tissues for purposes of oral activity. The oral composition of the present invention may be in various forms including toothpaste, dentifrice, tooth gel, subgingival gel, foam, mouse, or denture product. The oral composition may also be incorporated onto strips or films for direct application or attachment to oral surfaces.

The term “dentifrice” as used herein means paste, gel, powder, or liquid formulations, unless otherwise specified, that are used to clean the surfaces of the oral cavity.

The term “teeth” as used herein refers to natural teeth as well as artificial teeth or dental prosthesis.

The term “polymer” as used herein shall include materials whether made by polymerization of one type of monomer or made by two (*i.e.*, copolymers) or more types of monomers.

The term “water soluble” as used herein means that the material is soluble in water in the present composition. In general, the material should be soluble at 25° C at a concentration of 0.1% by weight of the water solvent, preferably at 1%, more preferably at 5%, more preferably at 15%.

The term “phase” as used herein means a mechanically separate, homogeneous part of a heterogeneous system.

The term “multi-phase” as used herein means that at least two phases herein occupy separate but distinct physical spaces inside the container in which they are stored, but are in direct contact with one another.

The term “speck” as used herein means a small particle differing in color or substance from that of its surrounding material.

The term “sensation” as used herein means a perception or awareness through the senses.

The term “striped” as used herein means alternating bands.

The term “visually distinct” as used herein means a difference clearly perceived by sight.

The term “pattern” as used herein means a decorative or distinctive design, not necessarily repeating or imitative, including but not limited to the following: marbled, check, mottled, veined, clustered, geometric, spotted, helical, swirl, arrayed, variegated, textured, spiral, cycle, contoured, laced, tessellated, starburst, lobed, lightning, blocks, textured, pleated, cupped, concave, convex, braided, tapered, and combinations thereof.

The term “marbled” as used herein means a mottled or variegated appearance that could include swirls, spots, or blotches of different colors or shades.

The term “blocks” as used herein means a series of segments laid end-to-end, each segment being generally shaped as a square or rectangular. Each segment appears visually distinct from the segment preceding it, but the same visually distinct segment may appear more than once.

The term “coil” as used herein means a series of spirals or rings.

The term “coolant” as used herein means an agent that produces a cooling sensation.

All percentages, parts and ratios are based upon the total weight of the compositions of the present invention, unless otherwise specified. All such weights as they pertain to listed ingredients are based on the active level and, therefore, do not include solvents or by-products

that may be included in commercially available materials, unless otherwise specified. The term “weight percent” may be denoted as “wt.%” herein.

All molecular weights as used herein are weight average molecular weights expressed as grams/mole, unless otherwise specified.

CIE LAB and embodiments

The present invention is directed to a dentifrice comprising an orally acceptable carrier and a chocolate flavoring, wherein there are at least two visually distinct phases, comprising the colors green, brown, and white. These colors can be more specifically described using the CIE $L^*a^*b^*$ (CIE LAB) color space.

CIE LAB is a color model used to describe all the colors visible to the human eye. Fig. 1 illustrates a model of the 1976 CIE LAB color space. The L^* value measures brightness and varies from a value of one hundred for perfect white to zero for black assuming a^* and b^* are zero. The a^* value is a measure of redness when positive and greenness when negative. The b^* value is a measure of yellowness when positive and blueness when negative. The a^* and b^* axes have no specific numerical limits.

In one preferred embodiment, a first phase is white to light green, with an L^* value of at least about 75, an a^* value from about -8 to about 8, and a b^* value from about 0 to about 5, and a second phase is brown, having an L^* value of at most about 65, an a^* value from about 0 to about 12, and a b^* value from about 0 to about 15.

In another preferred embodiment, a first phase is a light green, with an L^* value of at least about 80, an a^* value from about -8 to about 0, and a b^* value from about 0 to 5, with a second phase having an L^* value of at most about 60, an a^* value from about 5 to about 12, and a b^* value from about 0 to 15.

In other more preferred embodiments, the composition's first phase has an L^* value from about 80 to about 90, an a^* value from about -8 to -5, and a b^* value from about 0 to about 5, and the second phase has an L^* value of at most about 60, an a^* value from about 7 to about 11, and a b^* value from about 0 to about 8.

In still other embodiments, there may be a third phase. For example, in some embodiments, the third phase may be dark green in color, having an L^* value from about 20 to 50, an a^* value of at most about -18, and a b^* value from about 5 to 15. In other embodiments, the third phase may be dark brown, having an L^* value of at most 30, an a^* value from about 6 to 12, and a b^* value from about 0 to about 9.

In some embodiments described, the first phase may comprise at least about 50%, by weight, of the composition. In other embodiments, the first phase may comprise at least about 60%, by weight, of the composition.

In all embodiments described, various appearances may be formed by the arrangement of the at least two phases. For example, in some embodiments, the first and second phases may be arranged in a striped formation. In some embodiments, the second phase may be arranged as specks within the first phase. Such specks may be made of polyethylene or other similar materials. When there are three phases, any two phases may be arranged in a striped formation with the remaining phase arranged as specks within either or both of the two striped phases. In some embodiments, two, three, or more phases may be arranged to form patterns, including, but not limited to, stripes, swirls, spirals, coils, marbled, geometric, petals, starburst, lightning, blocks, and combinations thereof. Patterns may appear two-dimensional or three-dimensional, depending on whether the phases are opaque or transparent; as long as at least one phase is generally transparent, the pattern appears three-dimensional. Some embodiments may have more than one pattern.

The dentifrice phases may be packaged in a generally transparent container. In one aspect, at least 5%, 10%, 20%, 30%, 40%, 50%, 60 %, 70%, 80%, 90%, or even 100% of the container's surface area may be generally transparent. Materials from which said generally transparent portion may be made include, but are not limited to: polypropylene (PP), polyethylene (PE), polycarbonate (PC), polyamides (PA), polyethylene terephthalate (PETE), polyvinylchloride (PVC), general purpose polystyrene (GPPS), and polystyrene (PS). The generally transparent portion of said container may have a transmittance of more than 25%, 30%, 40%, 50%, 60% or even more than 70% in the visible part of the spectrum (approx. 410-800 nm). For purposes of the invention, as long as one wavelength in the visible light range has greater than 25% transmittance, it is considered to be generally transparent.

A portion of the container or the entire container may be tinted, shaded, colored, frosted, patterned, or striped. Such container appearances may be achieved, for example, by including colorant in the resin during manufacture of the container. The appearances may also be attained by adding decorations to a finished container, or by printing on, embossing, or stamping an already-manufactured container. Shrink-wrapping or stretch-wrapping the container or portion of the container may also create the described appearances for the container.

In still other embodiments of the present invention, the combination of the dentifrice plus the container may create the appearance of a pattern. In other embodiments, the combination of

the dentifrice, the container, and at least one packaging layer may form a pattern. A packaging layer is any further bundling or wrapping of the dentifrice beyond the container, including but not limited to a label, shrink wrap, stretch wrap, or a box. In still other embodiments, the combination of the dentifrice and at least one packaging layer may create the appearance of a pattern.

In the embodiments in which the container and/or packaging layer help form a pattern, the patterns that may be formed include but are not limited to stripes, marbled, spiral, geometric, starburst, lightning, blocks, and combinations thereof. In embodiments in which the container and/or packaging layer help form a pattern, the container or packaging layer appearance may be striped, colored, tinted, shaded, frosted, or patterned.

The container of the present invention may be of any form, shape, or size suitable for storing and packaging dentifrice. Examples of forms include tubes, bottles, tottles, thermoforms, or pouches. The shape of the container may be, for example, cylindrical, which is defined as a tube with a consistent cross-sectional area and two equally-sized circles on either end. Any container shape that does not have two equally-sized circles on the ends is non-cylindrical. For example, the container may be oval-shaped at the ends, wherein the two ovals may be the same size or different sizes, and the body of the container has a generally oval-shaped cross-section at all points. The shape of the container may affect the visual appearance of the phases, for example, by affecting the colors or by creating the appearance of layers. The size of the container may range from a single dose up to 30 oz., preferably up to 20 oz., and more preferably up to 14 oz. Ways that the phases may be dispensed from the container include, for example, squeezing the container, by a pump mechanism, or by gravity.

The container may have a label adhered to it. The label may be transparent, generally transparent, or opaque. The label may be colored, shaded, tinted, patterned, or striped. The label may be in any shape, including simple shapes such as bands, squares, rectangles, rectangles with round corners, circles, or ovals, or more complicated shapes, for example, shapes such as letters. The label may cover up to 100% of the container. The label may contain multiple pages. The label may be printed inside out so as to be read through a transparent product. All or part of the label may be shrink-wrapped or stretch-wrapped onto the container. Labeling of the container may be etched into the mold of the container or embossed on the container, and, in some embodiments, then printed on.

Any packaging layer, such as shrink wrap, stretch wrap, or a box, for the dentifrice may be patterned, colored, shaded, tinted, or striped.

Various embodiments of the present invention include a flavor composition that comprises chocolate flavoring. A purely artificial chocolate flavoring may comprise vanillin and derivatives of vanillin, such as ethyl vanillin, esters, most notably phenyl esters (prevalent in honey), pyrazines, which are common in nuts, and a variety of acids, such as butyric acid. Additionally, the aforementioned components may be used together with a "cocoa base" which comes from the roasted cocoa bean and contains many of the minute flavor components that give chocolate its particular character. The flavor may also be changed from dark to milk chocolate depending on the degree of dairy components that are added, such as acetoin, diacetyl, and various lactones.

Other suitable flavoring components include oil of wintergreen, clove bud oil, menthol, anethole, methyl salicylate, eucalyptol, cassia, 1-menthyl acetate, sage, eugenol, parsley oil, oxanone, alpha-irisone, marjoram, lemon, orange, propenyl guaethol, cinnamon, vanillin, ethyl vanillin, vanilla custard, heliotropine, 4-cis-heptenal, diacetyl, methyl-para-tert-butyl phenyl acetate, cranberry, green tea, and mixtures thereof.

Optionally, some embodiments may comprise a coolant, or more than one coolant as part of the flavor composition. Coolants suitable for the present compositions include the paramenthan carboxamide agents such as N-ethyl-p-menthan-3-carboxamide (known commercially as WS-3, WS-23, WS-5), MGA, TK-10, Physcool, and mixtures thereof. More than one coolant may be added in a single embodiment, creating numerous cooling sensations. In some embodiments, the cooling sensations may be successive. For example, the user of the dentifrice may notice one cooling sensation, then, as the first cooling sensation goes away, notice a second and different cooling sensation, and so on. Though mint oils may be used in the present invention, in some embodiments, there may be at least one cooling sensation even though the flavor composition does not comprise mint oil. Mint oils are essential oils used in flavoring and obtained through steam distillation of the leaves of the mint plants. These mint plants could be peppermint (*mentha piperita*), spearmint, both Native and Scotch varieties (*mentha spicata*), as well as cornmint (*mentha arvensis*).

Salivating agents, warming agents, numbing agents, and other optional materials can be used to deliver a signal while the dentifrice is being used.

A flavor composition is generally used in the dentifrice at levels of from about 0.001% to about 5%, by weight of the dentifrice. The flavor composition will preferably be present in an amount of from about 0.01% to about 4%, more preferably from about 0.1% to about 3%, and more preferably from about 0.5% to about 2% by weight.

Dentifrice Compositions

The dentifrice compositions of the present invention may be typical dentifrice formulations. Each of the multi-phases may be a separate composition or may be generally the same except for something that makes it visually distinguishable. The material that changes the visual appearance of a phase may be added at the very end of production so that the two or more compositions can be formed in one batch and then differentiated at the last point in the process before or as filling occurs. The material added to distinguish a phase may be a colorant, dye, titanium dioxide, opacifying agent, brightening agent, pearlescent, photosensitive material, or a type of particle. The actual material added may be visible itself or it may cause an effect that is visible in the final composition. A material itself may be the separate phase. For example, during filling, a layer of sparkles may be added that is visible. This would create a visually distinct phase. Each of the visually distinct phases may have the same viscosity or different viscosities.

Dentifrice compositions are well known. The selection of a particular composition will depend on the visual appearance desired and on secondary considerations like taste, cost, stability, benefits desired, etc. The following includes examples of suitable materials in dentifrice compositions.

The dentifrice composition may comprise suitable cosmetic and/or therapeutic actives. Such actives include any material that is generally considered safe for use in the oral cavity and that provides changes to the overall appearance and/or health of the oral cavity, including, but not limited to, anti-calculus agents, fluoride ion sources, stannous ion sources, whitening agents, anti-microbial, anti-plaque agents, anti-inflammatory agents, nutrients, antioxidants, anti-viral agents, analgesic and anesthetic agents, H-2 antagonists, and mixtures thereof. When present, the level of cosmetic and/or therapeutic active in the dentifrice is, in one embodiment from about 0.001% to about 90%, in another embodiment from about 0.01% to about 50%, and in another embodiment from about 0.1% to about 30%, by weight of the dentifrice.

The following is a non-limiting list of actives that may be used in the present invention.

a) Fluoride Ion

The present invention may comprise a safe and effective amount of a fluoride compound (e.g. water soluble). The fluoride ion may be present in an amount sufficient to give a fluoride ion concentration in the composition at 25°C, and/or in one embodiment can be used at levels of from about 0.0025% to about 5.0% by weight, in another embodiment from about 0.005% to

about 2.0% by weight, to provide anticaries effectiveness. 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 disclosed in U.S. Patent Nos. 3,535,421, and 3,678,154. Representative fluoride ion sources include: stannous fluoride, sodium fluoride, potassium fluoride, amine fluoride, sodium monofluorophosphate and many others. In one embodiment the dentifrice composition comprises stannous fluoride or sodium fluoride, as well as mixtures thereof.

b) Anticalculus Agent

Dentifrice compositions of the present invention may also comprise an anti-calculus agent, which in one embodiment may be present from about 0.05% to about 50%, by weight of the dentifrice composition, in another embodiment is from about 0.05% to about 25%, and in another embodiment is from about 0.1% to about 15%. The anti-calculus agent may be selected from the group consisting of polyphosphates (including pyrophosphates) and salts thereof; polyamino propane sulfonic acid (AMPS) and salts thereof; polyolefin sulfonates and salts thereof; polyvinyl phosphates and salts thereof; polyolefin phosphates and salts thereof; diposphonates and salts thereof; phosphonoalkane carboxylic acid and salts thereof; polyphosphonates and salts thereof; polyvinyl phosphonates and salts thereof; polyolefin phosphonates and salts thereof; polypeptides; and mixtures thereof. In one embodiment, the salts are alkali metal salts. Polyphosphates are generally employed as their wholly or partially neutralized water-soluble alkali metal salts such as potassium, sodium, ammonium salts, and mixtures thereof. The inorganic polyphosphate salts include alkali metal (e.g. sodium) tripolyphosphate, tetrapolyphosphate, dialkyl metal (e.g. disodium) diacid, trialkyl metal (e.g. trisodium) monoacid, potassium hydrogen phosphate, sodium hydrogen phosphate, and alkali metal (e.g. sodium) hexametaphosphate, and mixtures thereof. Polyphosphates larger than tetrapolyphosphate usually occur as amorphous glassy materials. In one embodiment the polyphosphates are those manufactured by FMC Corporation, which are commercially known as Sodaphos ($n \approx 6$), Hexaphos ($n \approx 13$), and Glass H ($n \approx 21$, sodium hexametaphosphate), and mixtures thereof. The pyrophosphate salts useful in the present invention include, alkali metal pyrophosphates, di-, tri-, and mono-potassium or sodium pyrophosphates, dialkali metal pyrophosphate salts, tetraalkali metal pyrophosphate salts, and mixtures thereof. In one embodiment the pyrophosphate salt is selected from the group consisting of trisodium pyrophosphate, disodium dihydrogen pyrophosphate ($\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$), dipotassium pyrophosphate, tetrasodium pyrophosphate ($\text{Na}_4\text{P}_2\text{O}_7$), tetrapotassium pyrophosphate ($\text{K}_4\text{P}_2\text{O}_7$), and mixtures

thereof. Polyolefin sulfonates include those wherein the olefin group contains 2 or more carbon atoms, and salts thereof. Polyolefin phosphonates include those wherein the olefin group contains 2 or more carbon atoms. Polyvinylphosphonates include polyvinylphosphonic acid. Diphosphonates and salts thereof include azocycloalkane-2,2-diphosphonic acids and salts thereof, ions of azocycloalkane-2,2-diphosphonic acids and salts thereof, azacyclohexane-2,2-diphosphonic acid, azacyclopentane-2,2-diphosphonic acid, N-methyl-azacyclopentane-2,3-diphosphonic acid, EHDP (ethane-1-hydroxy-1,1-diphosphonic acid), AHP (azacycloheptane-2,2-diphosphonic acid), ethane-1-amino-1,1-diphosphonate, dichloromethane-diphosphonate, etc. Phosphonoalkane carboxylic acid or their alkali metal salts include PPTA (phosphonopropane tricarboxylic acid), PBTA (phosphonobutane-1,2,4-tricarboxylic acid), each as acid or alkali metal salts. Polyolefin phosphates include those wherein the olefin group contains 2 or more carbon atoms. Polypeptides include polyaspartic and polyglutamic acids.

c) Stannous Ion

The dentifrice compositions of the present invention may include a stannous ion source. The stannous ions may be provided from stannous fluoride and/or other stannous salts. Stannous fluoride has been found to help in the reduction of gingivitis, plaque, sensitivity, and in improved breath benefits. The stannous ions provided in a dentifrice composition will provide efficacy to a subject using the dentifrice composition. Although efficacy could include benefits other than the reduction in gingivitis, efficacy is defined as a noticeable amount of reduction in *in situ* plaque metabolism. Formulations providing such efficacy typically include stannous levels provided by stannous fluoride and/or other stannous salts ranging from about 3,000 ppm to about 15,000 ppm stannous ions in the total dentifrice composition. The stannous ion is present in an amount of from about 4,000 ppm to about 12,000 ppm, in one embodiment from about 5,000 ppm to about 10,000 ppm. Other stannous salts include organic stannous carboxylates, such as stannous acetate, stannous gluconate, stannous oxalate, stannous malonate, stannous citrate, stannous ethylene glycoxide, stannous formate, stannous sulfate, stannous lactate, stannous tartrate, and the like. Other stannous ion sources include, stannous halides such as stannous chlorides, stannous bromide, stannous iodide and stannous chloride dihydride. In one embodiment the stannous ion source is stannous fluoride in another embodiment, stannous chloride dihydrate. The combined stannous salts may be present in an amount of from about 0.001% to about 11%, by weight of the dentifrice compositions. The stannous salts may, in one embodiment, be present in an amount of from about 0.01% to about 7%, in another embodiment from about 0.1% to about 5%, and in another embodiment from about 1.5% to about 3%, by weight of the dentifrice composition.

d) Whitening Agent

A whitening agent may be included as an active in the present dentifrice compositions. The actives suitable for whitening are selected from the group consisting of alkali metal and alkaline earth metal peroxides, metal chlorites, perborates inclusive of mono and tetrahydrates, perphosphates, percarbonates, peroxyacids, and persulfates, such as ammonium, potassium, sodium and lithium persulfates, and combinations thereof. Suitable peroxide compounds include hydrogen peroxide, urea peroxide, calcium peroxide, carbamide peroxide, magnesium peroxide, zinc peroxide, strontium peroxide and mixtures thereof. In one embodiment the peroxide compound is carbamide peroxide. Suitable metal chlorites include calcium chlorite, barium chlorite, magnesium chlorite, lithium chlorite, sodium chlorite, and potassium chlorite. Additional whitening actives may be hypochlorite and chlorine dioxide. In one embodiment the chlorite is sodium chlorite. In another embodiment the percarbonate is sodium percarbonate. In one embodiment the persulfates are oxones. The level of these substances is dependent on the available oxygen or chlorine, respectively, that the molecule is capable of providing to bleach the stain. In one embodiment the whitening agents may be present at levels from about 0.01% to about 40%, in another embodiment from about 0.1% to about 20%, in another embodiment from about 0.5% to about 10%, and in another embodiment from about 4% to about 7%, by weight of the dentifrice composition.

e) Anti-Microbial Agent

Anti-microbial agents may be included in the dentifrice compositions of the present invention. Such agents may include, but are not limited to: 5-chloro-2-(2,4-dichlorophenoxy)-phenol, commonly referred to as triclosan; 8-hydroxyquinoline and its salts; copper II compounds, including, but not limited to, copper(II) chloride, copper(II) sulfate, copper(II) acetate, copper(II) fluoride and copper(II) hydroxide; phthalic acid and its salts including, but not limited to those disclosed in U.S. Pat. 4,994,262, including magnesium monopotassium phthalate; chlorhexidine; alexidine; hexetidine; sanguinarine; benzalkonium chloride; salicylanilide; domiphen bromide; cetylpyridinium chloride (CPC); tetradecylpyridinium chloride (TPC); N-tetradecyl-4-ethylpyridinium chloride (TDEPC); octenidine; iodine; sulfonamides; bisbiguanides; phenolics; delmopinol, octapinol, and other piperidino derivatives; niacin preparations; zinc or stannous ion agents; nystatin; grapefruit extract; apple extract; thyme oil; thymol; antibiotics such as augmentin, amoxicillin, tetracycline, doxycycline, minocycline, metronidazole, neomycin, kanamycin, cetylpyridinium chloride, and clindamycin; analogs and salts of the above; methyl salicylate; hydrogen peroxide; metal salts of chlorite; and mixtures of all of the above. Anti-

microbial components may be present from about 0.001% to about 20% by weight of the dentifrice composition. In another embodiment the antimicrobial agents generally comprise from about 0.1% to about 5% by weight of the dentifrice compositions of the present invention.

f) Anti-Plaque Agent

The dentifrice compositions of the present invention may include an anti-plaque agent such as stannous salts, copper salts, strontium salts, magnesium salts or a dimethicone copolyol. The dimethicone copolyol is selected from C12 to C20 alkyl dimethicone copolyols and mixtures thereof. In one embodiment the dimethicone copolyol is cetyl dimethicone copolyol marketed under the Trade Name Abil EM90. The dimethicone copolyol in one embodiment can be present in a level of from about 0.001% to about 25%, in another embodiment from about 0.01% to about 5%, and in another embodiment from about 0.1% to about 1.5% by weight of the dentifrice composition.

g) Anti-Inflammatory Agent

Anti-inflammatory agents can also be present in the dentifrice compositions of the present invention. Such agents may include, but are not limited to, non-steroidal anti-inflammatory (NSAID) agents oxicams, salicylates, propionic acids, acetic acids and fenamates. Such NSAIDs include but are not limited to ketorolac, flurbiprofen, ibuprofen, naproxen, indomethacin, diclofenac, etodolac, indomethacin, sulindac, tolmetin, ketoprofen, fenoprofen, piroxicam, nabumetone, aspirin, diflunisal, meclofenamate, mefenamic acid, oxyphenbutazone, phenylbutazone and acetaminophen. Use of NSAIDs such as ketorolac are claimed in U.S. Patent 5,626,838. Disclosed therein are methods of preventing and/or treating primary and reoccurring squamous cell carcinoma of the oral cavity or oropharynx by topical administration to the oral cavity or oropharynx of an effective amount of an NSAID. Suitable steroidal anti-inflammatory agents include corticosteroids, such as fluccinolone, and hydrocortisone.

h) Nutrients

Nutrients may improve the condition of the oral cavity and can be included in the dentifrice compositions of the present invention. Nutrients include minerals, vitamins, oral nutritional supplements, enteral nutritional supplements, and mixtures thereof. Useful minerals include calcium, phosphorus, zinc, manganese, potassium and mixtures thereof. Vitamins can be included with minerals or used independently. Suitable vitamins include Vitamins C and D, thiamine, riboflavin, calcium pantothenate, niacin, folic acid, nicotinamide, pyridoxine, cyanocobalamin, para-aminobenzoic acid, bioflavonoids, and mixtures thereof. Oral nutritional supplements include amino acids, lipotropics, fish oil, and mixtures thereof. Amino acids

include, but are not limited to L-Tryptophan, L-Lysine, Methionine, Threonine, Levocarnitine or L- carnitine and mixtures thereof. Lipotropics include, but are not limited to, choline, inositol, betaine, linoleic acid, linolenic acid, and mixtures thereof. Fish oil contains large amounts of Omega-3 (N-3) polyunsaturated fatty acids, eicosapentaenoic acid and docosahexaenoic acid. Enteral nutritional supplements include, but are not limited to, protein products, glucose polymers, corn oil, safflower oil, medium chain triglycerides. Minerals, vitamins, oral nutritional supplements and enteral nutritional supplements are described in more detail in Drug Facts and Comparisons (loose leaf drug information service), Wolters Kluwer Company, St. Louis, Mo., © 1997, pps. 3-17 and 54-57.

i) Antioxidants

Antioxidants are generally recognized as useful in dentifrice compositions. Antioxidants are disclosed in texts such as Cadenas and Packer, *The Handbook of Antioxidants*, © 1996 by Marcel Dekker, Inc. Antioxidants useful in the present invention include, but are not limited to, Vitamin E, ascorbic acid, Uric acid, carotenoids, Vitamin A, flavonoids and polyphenols, herbal antioxidants, melatonin, aminoindoles, lipoic acids and mixtures thereof.

j) Analgesic and Anesthetic Agents

Anti-pain or desensitizing agents can also be present in the dentifrice compositions of the present invention. Analgesics are agents that relieve pain by acting centrally to elevate pain threshold without disturbing consciousness or altering other sensory modalities. Such agents may include, but are not limited to: strontium chloride; potassium nitrate; sodium fluoride; sodium nitrate; acetanilide; phenacetin; acetophan; thiorphan; spiradoline; aspirin; codeine; thebaine; levorphenol; hydromorphone; oxymorphone; phenazocine; fentanyl; buprenorphine; butaphanol; nalbuphine; pentazocine; natural herbs, such as gall nut; Asarum; Cubebin; Galanga; scutellaria; Liangmianzhen; and Baizhi. Anesthetic agents, or topical analgesics, such as acetaminophen, sodium salicylate, trolamine salicylate, lidocaine and benzocaine may also be present. These analgesic actives are described in detail in *Kirk-Othmer, Encyclopedia of Chemical Technology*, Fourth Edition, Volume 2, Wiley-Interscience Publishers (1992), pp. 729-737.

k) H-1 and H-2 Antagonists

The present invention may also optionally comprise selective H-1 and H-2 antagonists including compounds disclosed in U.S. Patent 5,294,433.

l) Antiviral Actives

Antiviral actives useful in the present composition include any known actives that are routinely used to treat viral infections. Such anti-viral actives are disclosed in *Drug Facts and*

Comparisons, Wolters Kluwer Company, ©1997, pp. 402(a)-407(z). Specific examples include anti-viral actives disclosed in U.S. Patent 5,747,070, issued May 5, 1998. Said Patent discloses the use of stannous salts to control viruses. Stannous salts and other anti-viral actives are described in detail in Kirk & Othmer, *Encyclopedia of Chemical Technology*, Third Edition, Volume 23, Wiley-Interscience Publishers (1982), pp. 42-71. The stannous salts that may be used in the present invention would include organic stannous carboxylates and inorganic stannous halides. While stannous fluoride may be used, it is typically used only in combination with another stannous halide or one or more stannous carboxylates or another therapeutic agent.

m) Chelant

Chelating agents are able to complex calcium found in the cell walls of bacteria and can help to disrupt plaque by removing calcium from the calcium bridges which help hold this biomass intact. Suitable chelating agents include tartaric acid and salts thereof, citric acid and alkali metal citrates, soluble pyrophosphates, anionic polymeric polycarboxylates, and combinations thereof.

n) Additional actives

Additional actives suitable for use in the present invention may include, but are not limited to, insulin, steroids, herbal and other plant derived remedies. Additionally, anti-gingivitis or gum care agents known in the art may also be included. Components which impart a clean feel to the teeth may optionally be included. These components may include, for example, baking soda or Glass-H. Also, it is recognized that in certain forms of therapy, combinations of these above-named agents may be useful in order to obtain an optimal effect. Thus, for example, an anti-microbial and an anti-inflammatory agent may be combined in a single dentifrice composition to provide combined effectiveness.

Optional agents to be used include such known materials as synthetic anionic polymers, including polyacrylates and copolymers of maleic anhydride or acid and methyl vinyl ether (e.g., Gantrez), as described, for example, in U.S. Patent 4,627,977, as well as, e.g., polyamino propoane sulfonic acid (AMPS), zinc citrate trihydrate, polyphosphates (e.g., tripolyphosphate; hexametaphosphate), diphosphonates (e.g., EHDP; AHP), polypeptides (such as polyaspartic and polyglutamic acids), and mixtures thereof. Additionally, the dentifrice composition can include a polymer carrier, such as those described in U.S. Patent Nos. 6,682,722 and 6,589,512 and U.S. Application Nos. 10/424,640 and 10/430,617.

o) Buffering agents

The dentifrice compositions may contain a buffering agent. Buffering agents, as used herein, refer to agents that can be used to adjust the pH of the dentifrice compositions to a range of about pH 3.0 to about pH 10. The buffering agents include alkali metal hydroxides, ammonium hydroxide, organic ammonium compounds, carbonates, sesquicarbonates, borates, silicates, phosphates, imidazole, and mixtures thereof. Specific buffering agents include monosodium phosphate, trisodium phosphate, sodium benzoate, benzoic acid, sodium hydroxide, potassium hydroxide, alkali metal carbonate salts, sodium carbonate, imidazole, pyrophosphate salts, citric acid, and sodium citrate. Buffering agents are used at a level of from about 0.1% to about 30%, preferably from about 0.1% to about 10%, and more preferably from about 0.3% to about 3%, by weight of the dentifrice compositions.

p) Abrasive Polishing Materials

An abrasive polishing material may also be included in the dentifrice compositions. The abrasive polishing material contemplated for use in the compositions of the present invention can be any material that does not excessively abrade dentin. Typical abrasive polishing materials include silicas including gels and precipitates; aluminas; phosphates including orthophosphates, polymetaphosphates, and pyrophosphates; and mixtures thereof. Specific examples include dicalcium orthophosphate dihydrate, calcium pyrophosphate, tricalcium phosphate, calcium polymetaphosphate, insoluble sodium polymetaphosphate, hydrated alumina, beta calcium pyrophosphate, calcium carbonate, and resinous abrasive materials such as particulate condensation products of urea and formaldehyde, and others such as disclosed by Cooley et al in U.S. Patent 3,070,510, issued Dec. 25, 1962. Mixtures of abrasives may also be used. If the dentifrice composition or particular phase comprises a polyphosphate having an average chain length of about 4 or more, calcium containing abrasives and alumina are not preferred abrasives. The most preferred abrasive is silica.

Silica dental abrasives of various types are preferred because of their unique benefits of exceptional dental cleaning and polishing performance without unduly abrading tooth enamel or dentine. The silica abrasive polishing materials herein, as well as other abrasives, generally have an average particle size ranging between about 0.1 to about 30 microns, and preferably from about 5 to about 15 microns. The abrasive can be precipitated silica or silica gels such as the silica xerogels described in Pader et al., U.S. Patent 3,538,230, issued Mar. 2, 1970, and DiGiulio, U.S. Patent 3,862,307, issued Jan. 21, 1975. Preferred are the silica xerogels marketed under the trade name "Syloid" by the W.R. Grace & Company, Davison Chemical Division. Also

preferred are the precipitated silica materials such as those marketed by the J. M. Huber Corporation under the trade name, "Zeodent", particularly the silica carrying the designation "Zeodent 119." The types of silica dental abrasives useful in the toothpastes of the present invention are described in more detail in Wason, U.S. Patent 4,340,583, issued July 29, 1982. Silica abrasives are also described in Rice, U.S. Patents 5,589,160; 5,603,920; 5,651,958; 5,658,553; and 5,716,601. The abrasive in the dentifrice compositions described herein is generally present at a level of from about 6% to about 70% by weight of the composition. Preferably, dentifrice compositions contain from about 10% to about 50% of abrasive, by weight of the dentifrice composition.

q) Titanium dioxide may also be added to the present composition. Titanium dioxide is a white powder which adds opacity to the compositions. Titanium dioxide generally comprises from about 0.25% to about 5%, by weight of the composition.

r) Coloring agents may also be added to the present composition. The coloring agent may be in the form of an aqueous solution, preferably 1% coloring agent in a solution of water. Pigments, peeling agents, filler powders, talc, mica, magnesium carbonate, calcium carbonate, bismuth oxychloride, zinc oxide, and other materials capable of creating a visual change to the dentifrice compositions may also be used. Color solutions and other agents generally comprise from about 0.01% to about 5%, by weight of the composition.

s) Sweetening agents can be added to the compositions. These include saccharin, dextrose, sucrose, lactose, xylitol, maltose, levulose, aspartame, sodium cyclamate, D-tryptophan, dihydrochalcones, acesulfame, sucralose, neotame, and mixtures thereof. Various coloring agents may also be incorporated in the present invention. Sweetening agents are generally used in toothpastes at levels of from about 0.005% to about 5%, by weight of the composition.

t) Thickening agents

Additional thickening agents, such as polymeric thickeners, may be utilized. Suitable thickening agents are carboxyvinyl polymers, carrageenan, hydroxyethyl cellulose, laponite and water soluble salts of cellulose ethers such as sodium carboxymethylcellulose and sodium carboxymethyl hydroxyethyl cellulose. Natural gums such as gum karaya, xanthan gum, gum arabic, and gum tragacanth can also be used. Colloidal magnesium aluminum silicate or finely divided silica can be used as part of the thickening agent to further improve texture. Thickening agents can include polymeric polyether compounds, e.g., polyethylene or polypropylene oxide (M.W. 300 to 1,000,000), capped with alkyl or acyl groups containing 1 to about 18 carbon atoms.

A suitable class of thickening or gelling agents includes a class of homopolymers of acrylic acid crosslinked with an alkyl ether of pentaerythritol or an alkyl ether of sucrose, or carbomers. Carbomers are commercially available from B.F. Goodrich as the Carbopol® series. Particularly the carbopols include Carbopol 934, 940, 941, 956, and mixtures thereof.

Copolymers of lactide and glycolide monomers, the copolymer having the molecular weight in the range of from about 1,000 to about 120,000 (number average), are useful for delivery of actives into the periodontal pockets or around the periodontal pockets as a "subgingival gel carrier." These polymers are described in U.S. Pat. Nos. 5,198,220; 5,242,910; and 4,443,430.

Thickening agents in an amount from about 0% to about 15%, or from about 0.01% to about 6%, in another embodiment from about 0.1% to about 5%, by weight of the total dentifrice composition, can be used.

u) Humectant

A humectant can help to keep the dentifrice composition from hardening upon exposure to air and provide a moist feel in the mouth. A humectant or additional solvent may be added to the oral carrier phase. Suitable humectants for the present invention include water, edible polyhydric alcohols such as glycerin, sorbitol, xylitol, butylene glycol, polyethylene glycol, propylene glycol, and combinations thereof. Sorbitol, glycerin, water, and combinations thereof are preferred humectants. The humectant may be present in an amount of from about 0.1% to about 99%, from about 0.5% to about 95%, and from about 1% to about 90%.

v) Surfactants

A surfactant may be added to the dentifrice composition. Surfactants, also commonly referred to as sudsing agents, may aid in the cleaning or foaming of the dentifrice composition. Suitable surfactants are those which are reasonably stable and foam throughout a wide pH range. The surfactant may be anionic, nonionic, amphoteric, zwitterionic, cationic, or mixtures thereof.

Examples of anionic surfactants useful herein include the water-soluble salts of alkyl sulfates having from 8 to 20 carbon atoms in the alkyl radical (e.g., sodium alkyl sulfate) and the water-soluble salts of sulfonated monoglycerides of fatty acids having from 8 to 20 carbon atoms. Sodium lauryl sulfate (SLS) and sodium coconut monoglyceride sulfonates are examples of anionic surfactants of this type. Examples of other suitable anionic surfactants are sarcosinates, such as sodium lauroyl sarcosinate, taurates, sodium lauryl sulfoacetate, sodium lauroyl isethionate, sodium laureth carboxylate, and sodium dodecyl benzenesulfonate. Mixtures of anionic surfactants can also be employed. Many suitable anionic surfactants are disclosed by

Agricola et al., U.S. Patent 3,959,458, issued May 25, 1976. In some embodiments, the dentifrice composition may comprise an anionic surfactant at a level of from about 0.025% to about 9%, from about 0.05% to about 5% in some embodiments, and from about 0.1% to about 1% in other embodiments.

Another suitable surfactant is one selected from the group consisting of sarcosinate surfactants, isethionate surfactants and taurate surfactants. Preferred for use herein are alkali metal or ammonium salts of these surfactants, such as the sodium and potassium salts of the following: lauroyl sarcosinate, myristoyl sarcosinate, palmitoyl sarcosinate, stearyl sarcosinate and oleoyl sarcosinate. The sarcosinate surfactant may be present in the compositions of the present invention from about 0.1% to about 2.5%, or from about 0.5% to about 2% by weight of the total composition.

Cationic surfactants useful in the present invention include derivatives of aliphatic quaternary ammonium compounds having one long alkyl chain containing from about 8 to 18 carbon atoms such as lauryl trimethylammonium chloride; cetyl pyridinium chloride; cetyl trimethylammonium bromide; di-isobutylphenoxyethyl-dimethylbenzylammonium chloride; coconut alkyltrimethylammonium nitrite; cetyl pyridinium fluoride; etc. Preferred compounds are the quaternary ammonium fluorides described in U.S. Patent 3,535,421, October 20, 1970, to Briner et al., where said quaternary ammonium fluorides have detergent properties. Certain cationic surfactants can also act as germicides in the compositions disclosed herein. Cationic surfactants such as chlorhexidine, although suitable for use in the current invention, are not preferred due to their capacity to stain the oral cavity's hard tissues. Persons skilled in the art are aware of this possibility and should incorporate cationic surfactants only with this limitation in mind.

Nonionic surfactants that can be used in the compositions of the present invention include 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 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.

Zwitterionic synthetic surfactants useful in the present invention include derivatives of aliphatic quaternary ammonium, phosphonium, and sulfonium compounds, in which the aliphatic

radicals can be straight chain or branched, and wherein one of the aliphatic substituents contains from about 8 to 18 carbon atoms and one contains an anionic water-solubilizing group, e.g., carboxy, sulfonate, sulfate, phosphate or phosphonate.

Suitable betaine surfactants are disclosed in U.S. Patent 5,180,577 to Polefka et al., issued January 19, 1993. Typical alkyl dimethyl betaines include decyl betaine or 2-(N-decyl-N,N-dimethylammonio) acetate, coco betaine or 2-(N-coc-N, N-dimethyl ammonio) acetate, myristyl betaine, palmityl betaine, lauryl betaine, cetyl betaine, cetyl betaine, stearyl betaine, etc. The amidobetaines are exemplified by cocoamidoethyl betaine, cocoamidopropyl betaine, lauramidopropyl betaine and the like. The betaines of choice are preferably the cocoamidopropyl betaine and, more preferably, the lauramidopropyl betaine.

Non-limiting Examples

The dentifrice compositions illustrated in the following examples illustrate specific embodiments of the dentifrice compositions of the present invention, but are not intended to be limiting thereof. Other modifications can be undertaken by the skilled artisan without departing from the spirit and scope of this invention.

Examples 1-3:

Ingredient	Example #1	Example #2	Example #3
	Lt Green Paste, Brown Specks	Lt Brown Paste, Green Specks	White Paste, Brown Specks
Sodium Fluoride	0.243	0.243	0.243
Sorbitol Sol'n (70%)	62.741	61.000	52.057
Water	5.900	6.677	7.000
Sodium Saccharin	0.330	0.330	0.400
Sodium Acid Pyrophosphate	0.556	1.600	4.250
Xanthan Gum	0.630	0.550	0.400
Carbopol 956	0.250	0.300	0.200
Sodium Carboxymethyl Cellulose	0.200		0.200
Precipitated Silica	22.000	23.000	25.000
Chocolate Flavor	1.200	1.000	1.500
Titanium Dioxide	1.000	0.050	1.000
Green Color Solution	0.050		
Polyethylene Microbrown Specks	0.500		0.500

Polyethylene Microgreen Specks		0.500	
Sodium Lauryl Sulfate sol'n (28%)	4.000	4.000	5.000
Sodium Hydroxide (50% sol'n)	0.400	0.750	2.250
	100.000	100.000	100.000

Examples 4-7:

Ingredient	Example #4a	Example #4b	Example #5a	Example #5b
	Lt Green paste stripe	Dark Brown Gel Stripe	Chocolate Brown paste stripe	Dark Green Gel stripe
Sodium Fluoride	0.243	0.243	0.243	0.243
Sorbitol Sol'n (70%)	48.050	47.600	62.902	63.200
Glycerin	8.000	8.000		
Water	13.907	13.907	5.699	5.651
Sodium Saccharin	0.450	0.450	0.400	0.400
Sodium Acid Pyrophosphate	1.500	1.500	0.556	0.556
Xanthan Gum	0.400	0.400	0.450	0.450
Carbopol 956	0.300	0.300	0.300	0.300
Sodium Carboxymethyl Cellulose	0.200	0.200	0.200	0.200
Precipitated Silica Zeodent 119	20.000	20.000	22.500	22.500
Chocolate Flavor	0.900	0.900	1.200	1.200
Titanium Dioxide	1.000		0.050	
Green Color Solution	0.050		0.100	
Polyethylene Microbrown Specks		1.500		
Polyethylene Microgreen Specks				0.800
Red Color Solution			0.250	
Yellow Color Solution			0.650	
Sodium Lauryl Sulfate sol'n (28%)	4.000	4.000	4.000	4.000
Sodium Hydroxide (50% sol'n)	1.000	1.000	0.500	0.500
	100.000	100.000	100.000	100.000

The CIE LAB measurements may be made using a BYK Gardner Color View Model 9000. To make the measurements, such as in the following examples, the instrument is turned on

and calibrated using the BYK standard black and white tiles. The same white tile is then used as the color standard and the L*, a*, and b* values are recorded. The various samples are then tested, and their L*, a*, and b* values are recorded.

Examples 6-11:

Material	L*	a*	b*
White tile control	98.79	-0.14	0.03
White paste (Example 3)	89.82	0.03	3.09
Light Brown Paste (Examples 2 and 5a)	61.38	9.15	10.46
Polyethylene Microbrown Specks (Examples 1, 3, and 4b)	27.13	10.13	7.69
Polyethylene Microgreen Specks (Examples 2 and 5b)	46.76	-27.00	12.94
Light green paste (Examples 1 and 4a)	86.51	-6.24	2.29

All documents cited in the Detailed Description of the Invention are, in relevant part, incorporated herein by reference; the citation of any document is not to be construed as an admission that it is prior art with respect to the present invention. To the extent that any meaning or definition of a term in this written document conflicts with any meaning or definition of the term in a document incorporated by reference, the meaning or definition assigned to the term in this written document shall govern.

The dimensions and values disclosed herein are not to be understood as being strictly limited to the exact numerical values recited. Instead, unless otherwise specified, each such dimension is intended to mean both the recited value and a functionally equivalent range surrounding that value. For example, a dimension disclosed as “40 mm” is intended to mean “about 40 mm.”

While particular embodiments of the present invention have been illustrated and described, it would be obvious to those skilled in the art that various other changes and modifications can be made without departing from the spirit and scope of the invention. It is therefore intended to cover in the appended claims all such changes and modifications that are within the scope of this invention.

CLAIMS

What is claimed is:

1. A multi-phase dentifrice composition comprising:
an orally acceptable carrier and a chocolate flavoring;
wherein, using the CIE L*a*b* color scale, a first phase of the composition has an L* value of at least 75, an a* value from -8 to 8, and a b* value from 0 to 5, and
a second phase of the composition has an L* value of at most 65, an a* value from 0 to 12, and a b* value from 0 to 15.
2. The composition of claim 1, wherein the first phase comprises at least 50%, by weight, of the composition.
3. The composition of claim 1, wherein the first phase and second phase are arranged in a striped formation.
4. The composition of claim 1, wherein the second phase is arranged as specks within the first phase.
5. The composition of claim 1, wherein the flavoring does not comprise mint oil.
6. The composition of claim 1, wherein the composition further comprises at least two coolants.
7. The composition of claim 1, wherein, using the CIE L*a*b* color scale, the first phase has an L* value from 80 to 90, an a* value from -8 to -5, and a b* value from 0 to 5; and
the second phase has an L* value of at most 60, an a* value from 7 to 11, and a b* value from 0 to 8.
8. The composition of claim 1, further comprising a third phase, wherein, using the CIE L*a*b* color scale, the third phase of the composition has an L* value from 20 to 50, an a* value of at most -18, and a b* value from 5 to 15.

9. The composition of claim 10, wherein the first and second phases are arranged in a striped formation and the third phase is arranged as specks within the first and second phases.

10. The composition of claim 1, further comprising a third phase, wherein, using the CIE $L^*a^*b^*$ color scale, the third phase of the composition has an L^* value of at most 30, an a^* value from 6 to 12, and a b^* value from 0 to 9;
wherein the first and second phases are arranged in a striped formation, and the third phase is arranged as specks within the first and second phases.

1/1

