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(54) **Title:** SINGLE PHASE WHITENING DENTIFRICE

(57) **Abstract:** A single phase whitening dentifrice that includes (i) a whitening agent selected from the group consisting of hydrogen peroxide, a bound peroxide and a solid peroxide (ii) an abrasive and (iii) a substantially anhydrous orally acceptable carrier, for example, polyethylene glycol. The bound peroxide may be hydrogen peroxide and a polymer and/or any peroxide compound and a porous cross-linked polymer, such as polymers of polyvinyl pyrrolidone, polyacrylates, a polymethacrylates, and a polyitaconates. The solid peroxide may be sodium perborate or urea peroxide. The invention also provides methods of whitening the tooth surfaces by contacting the surface with the composition.

SINGLE PHASE WHITENING DENTIFRICE

BACKGROUND OF THE INVENTION

[0001] Many individuals desire a "bright" smile and white teeth, and consider dull and stained teeth cosmetically unattractive. Unfortunately, without preventive or remedial measures, stained teeth are almost inevitable due to the absorbent nature of dental material. Everyday activities such as smoking or other oral use of tobacco products, and eating, chewing or drinking certain foods and beverages (in particular coffee, tea and red wine), cause undesirable staining of surfaces of teeth. Staining can also result from microbial activity, including that associated with dental plaque. The chromogens or color causing substances in these materials become part of the pellicle layer and can permeate the enamel layer. Even with regular brushing and flossing, years of chromogen accumulation can impart noticeable tooth discoloration.

[0002] There are a variety of compositions described in the art for preventing or treating the discoloration of teeth. In particular, to combat staining and brighten or restore the natural enamel color, a variety of products containing bleaching materials are commercially available for professional and consumer use. The materials most commonly used in teeth whitening today are peroxides. Peroxides are generally deemed safe from a physiological standpoint, and can be effective to whiten teeth.

[0003] Professional dental treatments frequently include a tooth surface preparation such as acid etching followed by the application of highly concentrated bleaching solutions (*e.g.*, up to 37% hydrogen peroxide) and/or the application of heat or light. These procedures provide rapid results, but are expensive, and often require several trips to the dentist. Alternatively, at-home bleaching systems can be used. These systems have gained significant popularity in the past decade because of reduced cost, and increased convenience. Instead of time consuming and frequent trips to the dentist, the tooth whitener is purchased at a consumer retail store and may be easily integrated into the daily hygiene program. At-home treatment methods include whitening strips, abrasive toothpastes, and toothpastes that contain peroxides. These peroxide toothpastes require the use of a dual chamber system that separates the peroxide from other ingredients. If the contents of the two chambers are mixed prematurely, the oxidation activity and whitening benefits are lost.

[0004] It would be desirable to provide a whitening oral care composition which promotes consumer compliance and utilizes a single chamber or tube to deliver sufficient

amounts of whitening ingredients and other oral care actives without adverse reaction between the ingredients.

BRIEF SUMMARY OF THE INVENTION

[0005] The invention provides a single phase whitening dentifrice that includes (i) a whitening agent selected from the group consisting of hydrogen peroxide, a bound peroxide and a solid peroxide (ii) an abrasive and (iii) a substantially anhydrous orally acceptable carrier, for example, polyethylene glycol. The bound peroxide may be hydrogen peroxide and a polymer and/or any peroxide compound and a porous cross-linked polymer, such as polymers of polyvinylpyrrolidone, polyacrylates, a polymethacrylates, and a polyitaconates. The solid peroxide may be sodium perborate or urea hydroxide.

[0006] The invention also provides methods of whitening the tooth surfaces by contacting the surface with the composition.

DETAILED DESCRIPTION OF THE INVENTION

[0007] The present invention provides single phase whitening oral care compositions, comprising a peroxide whitening agent; a peroxide incompatible abrasive; and a substantially anhydrous orally acceptable carrier. In various embodiments, the substantially anhydrous orally acceptable carrier and the particular peroxides employed allow for a shelf-stable single tube oral care composition where the peroxide and the peroxide incompatible ingredients, such as abrasives, may be combined. The oral care composition provides highly efficacious whitening and cleaning.

[0008] The single phase oral care composition has a "low water" content, meaning that a total concentration of water, including any free water and all water contained in any ingredients, is less than about 4%, about 7% or les than about 10% water. The selection of the whitening agent in conjunction with the low water carrier provides stabilized delivery of the whitening agent. The whitening activity is maintained for application to the tooth or oral surface and is maintained through storage.

[0009] Any whitening agent known or developed in the art may be used. Preferably, the whitening agent includes solid whitening agents and bound whitening agents which are substantially anhydrous oxygen generating compounds. Solid whitening agents useful herein include peroxides, metal chlorites, persulfate. Exemplary peroxide phases include hydroperoxides, hydrogen peroxide, peroxides of alkali and alkaline earth metals, organic peroxy compounds, peroxy acids, pharmaceutically-acceptable salts thereof, and mixtures thereof. Peroxides of alkali and alkaline earth metals include lithium peroxide, potassium

peroxide, sodium peroxide, magnesium peroxide, calcium peroxide, barium peroxide, and mixtures thereof. Organic peroxy compounds include urea peroxide, glyceryl hydrogen peroxide, alkyl hydrogen peroxides, dialkyl peroxides, alkyl peroxy acids, peroxy esters, diacyl peroxides, benzoyl peroxide, and monoperoxyphthalate, and mixtures thereof. Peroxy acids and their salts include organic peroxy acids such as alkyl peroxy acids, and monoperoxyphthalate and mixtures thereof, as well as inorganic peroxy acid salts such as and perborate salts of alkali and alkaline earth metals such as lithium, potassium, sodium, magnesium, calcium and barium, and mixtures thereof. Preferred solid peroxides are sodium perborate, urea peroxide, and mixtures thereof. Suitable metal chlorites include calcium chlorite, barium chlorite, magnesium chlorite, lithium chlorite, sodium chlorite, and potassium chlorite. The whitening agent may be preferably bound. For example, peroxide may be bound to a polymer such as PVP (poly(N-vinylpyrrolidone). Suitable PVP complexes are disclosed, for example, in United States Patent No. 5,122,370, the contents of which are incorporated herein by reference. In some embodiments, it may be desirable to use any known whitening agent except sodium percarbonate and/or any of the percarbonate salts.

[0010] The compositions of the present invention may include any dental abrasive or combination of dental abrasive agents known or to be developed in the art. "Abrasive" is as used herein is meant to include materials commonly referred to as "polishing agents" as well. Suitable abrasive may include those previously considered to be incompatible in a peroxide containing formulation ("a peroxide-incompatible abrasive"). Such abrasive is one which, in an aqueous solution with hydrogen peroxide, substantially reacts with the hydrogen peroxide so as to reduce whitening efficacy of the solution.

[0011] Any orally acceptable abrasive can be used, but preferably, type, fineness (particle size) and amount of abrasive should be selected so that tooth enamel is not excessively abraded in normal use of the composition. Suitable abrasives include without limitation silica, for example in the form of silica gel, hydrated silica or precipitated silica, alumina, insoluble phosphates, calcium carbonate, resinous abrasives such as urea-formaldehyde condensation products and the like. Among insoluble phosphates useful as abrasives are orthophosphates, polymetaphosphates and pyrophosphates. Illustrative examples are dicalcium orthophosphate dihydrate, calcium pyrophosphate, β-calcium pyrophosphate, tricalcium phosphate, calcium polymetaphosphate and insoluble sodium polymetaphosphate. Average particle size of an abrasive, if present, is generally about 0.1 to about 30 μm, for example about 1 to about 20 μm or about 5 to about 15 μm. One

or more abrasives are present in an abrasive effective total amount, typically about 0.1% to about 40%.

[0012] In various embodiments of the present invention, the oral composition comprises an anticalculus agent. Generally, tartar control agents are categorized as being incompatible with some whitening agents, but embodiments of the present invention incorporate tartar control agents and whitening agents in a single phase whitening composition. Suitable anticalculus agents include without limitation phosphates and polyphosphates (for example pyrophosphates), polyaminopropanesulfonic acid (AMPS), hexametaphosphate salts, zinc citrate trihydrate, polypeptides, polyolefin sulfonates, polyolefin phosphates, diphosphonates. The anticalculus agent is present at about 0.1% to about 30%. The oral composition may include a mixture of different anticalculus agents. In one preferred embodiment, tetrasodium pyrophosphate (TSPP) and sodium tripolyphosphate (STPP) are used. The anticalculus agent comprises TSPP at about 1% and STPP at about 7% to about 10%.

[0013] The oral care composition can optionally include at least one orally acceptable source of fluoride ions. Any known or to be developed in the art may be used. Suitable sources of fluoride ions include fluoride, monofluorophosphate and fluorosilicate salts. One or more fluoride ion-releasing compound is optionally present in an amount providing a total of about 100 to about 20,000 ppm, about 200 to about 5,000 ppm, or about 500 to about 2,500 ppm, fluoride ions.

[0014] The carrier is preferably low water content orally acceptable carrier and may include any known ingredients or additives.

[0015] In preferred embodiments of this invention, the oral composition is a dentifrice. Such dentifrices may include toothpowder, a dental tablet, toothpaste (dental cream), tooth powders, or gel, or any other known form known to one of skill in the art.

[0016] The substantially anhydrous carrier may also comprise various dentifrice ingredients to adjust the rheology and feel of the composition such as humectants, surface active agents, thickening or gelling agents, etc.

[0017] The compositions of the present invention preferably comprise a surface active agent. Suitable surfactants include without limitation water-soluble salts of C_{8-20} alkyl sulfates, sulfonated monoglycerides of C_{8-20} fatty acids, sarcosinates, taurates, sodium lauryl sulfate, sodium cocoyl monoglyceride sulfonate, sodium lauryl sarcosinate, sodium lauryl isoethionate, sodium laureth carboxylate and sodium dodecyl benzenesulfonate, and cocoamidopropyl betaine.

[0018] The compositions of the present invention optionally comprise a thickener. Any orally acceptable thickening agent can be used, including without limitation carbomers, also known as carboxyvinyl polymers, carrageenans, also known as Irish moss and more particularly ι-carrageenan (iota-carrageenan), high molecular weight polyethylene glycols (such as CARBOWAX®, available from The Dow Chemical Company), cellulosic polymers such as hydroxyethylcellulose, carboxymethylcellulose (CMC) and salts thereof, *e.g.*, CMC sodium, natural gums such as karaya, xanthan, gum arabic and tragacanth, colloidal magnesium aluminum silicate, and colloidal and/or fumed silica and mixtures of the same. One or more thickening agents are optionally present in a total amount of about 0.1% to about 90%, for example about 1% to about 50% or about 5% to about 35%.

[0019] In various preferred embodiments, the carrier may comprise polymers and/or copolymers of polyethylene glycol, of ethylene oxide propylene oxide, and of silicone. IF such copolymers/polymers are used, they may be selected from the commercially available materials PLURAFLO® L4370 and PLURAFLO® L1220 (available from BASF, Wyandotte, Michigan, United States of America). It is preferred that the carrier(s) provide a dentifrice with a viscosity of about 10,000 CPS to about 700,000 CPS, preferably about 30,000 CPS to about 300,000 CPS.

[0020] As recognized by one of skill in the art, the oral compositions of the present invention optionally include other materials, such as for example, anti-caries agents, desensitizing agents, viscosity modifiers, diluents, surface active agents, such as surfactants, emulsifiers, and foam modulators, pH modifying agents, abrasives, in addition to those listed above, humectants, mouth feel agents, sweetening agents, flavor agents, colorants, preservatives, and combinations thereof. It is understood that while general attributes of each of the above categories of materials may differ, there may be some common attributes and any given material may serve multiple purposes within two or more of such categories of materials. Preferably, the carrier is selected for compatibility with other ingredients of the composition.

[0021] Flavorants, sweeteners, colorants, foam modulators, mouth-feel agents and others additively may be included if desired, in the composition.

[0022] The compositions of the present invention optionally comprise one or more further active material(s), which is operable for the prevention or treatment of a condition or disorder of hard or soft tissue of the oral cavity, the prevention or treatment of a physiological disorder or condition, or to provide a cosmetic benefit.

[0023] The compositions may include a stannous ion or a stannous ion source. Suitable stannous ion sources include without limitation stannous fluoride, other stannous halides such as stannous chloride dihydrate, stannous pyrophosphate, organic stannous carboxylate salts such as stannous formate, acetate, gluconate, lactate, tartrate, oxalate, malonate and citrate, stannous ethylene glyoxide and the like. One or more stannous ion sources are optionally and illustratively present in a total amount of about 0.01% to about 10%, for example about 0.1% to about 7% or about 1% to about 5%.

[0024] The compositions of the present invention optionally comprise an antimicrobial (*e.g.*, antibacterial) agent. A further illustrative list of useful antibacterial agents is provided in such as those listed in U.S. Patent No. 5,776,435 to Gaffar *et al.*, the contents of which are incorporated herein by reference. One or more antimicrobial agents are optionally present in an antimicrobial effective total amount, typically about 0.05% to about 10%, for example about 0.1% to about 3%.

[0025] The compositions of the present invention optionally comprise an antioxidant. Any orally acceptable antioxidant can be used, including butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), vitamin A, carotenoids, vitamin E, flavonoids, polyphenols, ascorbic acid, herbal antioxidants, chlorophyll, melatonin, and mixtures thereof.

[0026] The compositions of the present invention optionally comprise a sialagogue or saliva-stimulating agent, an antiplaque agent, an anti-inflammatory agent, a desensitizing.

[0027] Methods are provided to whiten an oral surface in a human or animal subject comprising storing in stable form a whitening oral care composition comprising a peroxide whitening agent, a peroxide incompatible abrasive, and a substantially anhydrous and a substantially anhydrous orally acceptable carrier; and contacting said composition with the oral surface. As used herein "animal subject" includes higher order non-human mammals such as canines, felines, and horses. The oral care composition is contacted with an oral surface of the mammalian subject to thereby whiten teeth in a highly efficacious manner, without any negative interaction between the whitening agent, the peroxide incompatible abrasive, and other ingredients.

[0028] In various embodiments, it is preferred that the oral care composition is applied and contacted with the oral surface. The dentifrice, prepared in accordance with the present invention is preferably applied regularly to an oral surface, preferably on a daily basis, at least one time daily for multiple days, but alternately every second or third day. Preferably the oral composition is applied to the oral surfaces from 1 to 3 times

daily, for at least 2 weeks up to 8 weeks, from four months to three years, or more up to lifetime.

[0029] The invention is illustrated in the following non-limiting examples.

Examples

Comparative Example I

[0030] A comparative, non-abrasive containing single phase dentifrice is prepared by mixing the ingredients of Table 1. After aging the dentifrice for two weeks at approximately 49°C, the peroxide recovery was 89% of the initially present amount.

Table 1

Ingredients	**Weight Percentage**
Cross-linked polyvinyl pyrrolidone – hydrogen peroxide complex	16.50
Polyethylene Glycol/Ethylene Oxide Block Copolymer (PLURAFLO® L4370)	42.44
Ethylene Oxide/Propylene Oxide Block Copolymer (PLURAFLO® L1220)	25.00
Silicone fluid	5.00
Saccharin	0.42
Flavor	1.20
Tetrasodium pyrophosphate	1.00
Sodium tripolyphosphate	7.00
Sodium fluoride	0.24
Sodium lauryl sulfate	1.20
TOTAL	100.00

Example 1

[0031] A single phase dentifrice was prepared by mixing the ingredients of Table 2. A peroxide incompatible silica abrasive is included at 12.44% and increases the cleaning and whitening benefits of the dentifrice. After aging the dentifrice for two weeks at approximately 49°C, the peroxide recovery was 77% of the initially present amount.

Table 2

Ingredients	Weight Percentage
Cross-linked polyvinyl pyrrolidone – hydrogen peroxide complex	16.50
Polyethylene Glycol/Ethylene Oxide Block Copolymer (PLURAFLO® L4370)	30.00
Ethylene Oxide/Propylene Oxide Block Copolymer (PLURAFLO® L1220)	25.00
Silicone fluid	5.00
Saccharin	0.42
Flavor	1.20
Tetrasodium pyrophosphate	1.00
Sodium tripolyphosphate	7.00
Sodium fluoride	0.24
Silica abrasive	12.44
Sodium lauryl sulfate	1.20
TOTAL	100.00

[0032] The examples and other embodiments described herein are exemplary and not intended to be limiting in describing the full scope of compositions and methods of this invention. Equivalent changes, modifications and variations of specific embodiments, materials, compositions and methods may be made within the scope of the present invention, with substantially similar results.

CLAIMS

We claim:

1. A single phase whitening dentifrice comprising:
a whitening agent selected from the group consisting of hydrogen peroxide, a bound peroxide and a solid peroxide;
an abrasive; and
a substantially anhydrous orally acceptable carrier.

2. The composition according to claim 1, wherein the whitening agent is not sodium percarbonate.

3. The composition according to claim 1, wherein the bound peroxide comprises hydrogen peroxide and a polymer.

4. The composition according to claim 1, wherein the bound peroxide comprises a peroxide compound and a cross-linked polymer.

5. The composition according to claim 4, wherein the monomer is selected from the group consisting of a polyvinyl pyrrolidone, polyacrylate, a polymethacrylate, and polyitaconates.

6. The composition according to claim 1, wherein the solid peroxide is selected from the group consisting of sodium perborate and urea peroxide.

7. The composition according to claim 1, comprising about 0.1% to about 30% of the whitening agent.

8. The composition according to claim 1, wherein the water content of the composition is less than about 10%.

9. The composition according to claim 1, wherein the substantially anhydrous carrier comprises polymers and copolymers of polyethylene glycol, of ethylene oxide and of propylene oxide.

10. The composition according to claim 1, wherein the substantially anhydrous carrier further comprises a surfactant, a silicone fluid, a fumed silica, a high molecular weight PEG, a carbomer, a gum and a synthetic gum.

11. The composition according to claim 1, further comprising a surfactant.

12. The composition according to claim 11, wherein the surfactant is anionic.

13. The composition according to claim 11, wherein the surfactant is sodium lauryl sulfate.

14. The composition according to claim 1, further comprising a fluoride salt.

15. A single phase whitening oral care composition, comprising:
    a. a substantially anhydrous agent selected from the a N-vinyl heterocyclic polymer cross-linked with hydrogen peroxide, a cross-linked polymer comprising a peroxide, and a solid peroxide;
    b. an anticalculus agent; and
    c. a substantially anhydrous carrier.

16. The composition according to claim 15, further comprising a peroxide incompatible silica abrasive.

17. The composition according to claim 15, further comprising a surfactant.

18. The composition according to claim 15, additionally comprising a fluoride salt.

19. The composition according to claim 15, further comprising an active agent selected from an antimicrobial agent, an anti-inflammatory agent, a zinc salt, a stannous salt, and triclosan.

20. The composition according to claim 15, wherein the abrasive is selected from calcium pyrophosphate and dicalcium phosphate.

21. A method of whitening a tooth surface, the method comprising contacting the tooth surface with a single phase whitening dentifrice comprising a whitening agent selected from the group consisting of a bound peroxide and a solid peroxide; an abrasive; and a substantially anhydrous orally acceptable carrier.

INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
INV. A61Q11/00 A61K8/22 A61K8/88 A61K8/81 A61K8/86
A61K8/25 A61K8/89 A61K8/73 A61K8/46 A61K8/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	WO 91/07184 A (GAF CHEMICALS) 30 May 1991 (1991-05-30) page 14 - page 16	1-21
X	US 2005/063923 A1 (PRENCIPE, MICHAEL ET AL) 24 March 2005 (2005-03-24) paragraph [0020] - paragraph [0025] claims	1-5,7,8, 15,18,21

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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