

**DENTAL-BLEACHING COMPOSITIONS AND METHODS WITH REDUCED
PEROXIDE CONCENTRATION**

FIELD

[0001] This application relates generally to dental-whitening methods and compositions and, more particularly, to dental-bleaching methods and compositions based upon peroxide compounds.

BACKGROUND

[0002] Tooth whitening methods currently offered in dental practices often involve the use of take-home whitening kits containing a peroxide gel or paste. In one type of kit, the peroxide product is placed in a pre-fabricated tray and worn by the patient for 1-2 weeks in daily application times ranging from 30 minutes to overnight. In an attempt to obtain faster whitening, products containing high concentrations up to 22% carbamide peroxide are now available. Nevertheless, such products with high peroxide concentrations can often produce greater tooth and gingival irritation. Thus, there remains a continuing need for new peroxide-based tooth-whitening products.

SUMMARY

[0003] Accordingly, the present inventors have succeeded in developing methods and compositions for enhancing tooth-whitening with peroxide compounds that accelerate the tooth-whitening process, increase the whitening activity of the peroxide compounds and decrease oral irritation. The methods and compositions are based upon a tooth-whitening composition comprising a peroxide compound and one or more abrasive compounds, said composition having a pH of 9.0 or greater. Any one or more of an increased rate of tooth-whitening, increased effectiveness of tooth-whitening and decreased oral irritation are produced in comparison to that produced by a tooth-whitening composition containing the

same or greater concentration of the peroxide compound at a pH of 7.0 or less in absence of the one or more abrasive compounds. The methods can involve increasing the pH of the peroxide-containing tooth-whitening composition from a pH of 7.0 or less to a pH to 9.0 or greater by combining, in a dual component system, a first component comprising the peroxide compound in an aqueous vehicle at a pH of about 7 or less and adding a second component comprising an alkaline compound produce a mixture having a pH of about 9 or greater. It is also possible to initially preparing the composition containing both the peroxide compound and the alkaline compound such that the composition has a pH of about 9 or greater. The presence of the one or more abrasive compounds further increases the effectiveness of the composition. As a result, the whitening process is accelerated whitening at a lower concentration of the peroxide compound and with less oral irritation than that produced by a peroxide-containing composition having a pH of about 7 or less in absence of the one or more abrasive compounds.

[0004] Thus, in various embodiments, the present invention can involve a dual component dentifrice system comprising first and second components. The first component can comprise a peroxide compound and a peroxide-compatible abrasive compound. The second component can comprise an alkaline compound. Combining the first and second components in a mixture produces a dentifrice composition having a pH of about 9 or greater is produced. By combining the first and second components it is meant that the first and second components are mixed in their entireties or that predetermined portions of the first and second components are mixed, such as, for example, the first and second components can be combined in a 1:1 ratio by either weight or volume. The pH of the first component can be in a range of from about 4 to about 7 and the pH of the second component can be in a pH range of from at least about 9 to about 13. The peroxide compound in the dentifrice composition can

be at a hydrogen-peroxide-equivalent concentration of not greater than about 5% by weight or at a hydrogen-peroxide-equivalent concentration of not greater than about 3.5% by weight.

[0005] In various embodiments, the present invention can also include dentifrice compositions comprising a peroxide compound and a peroxide-compatible abrasive compound. The pH of the composition can be 9.0 or greater and the concentration of the peroxide compound can be at a hydrogen-peroxide-equivalent concentration of not greater than about 5% by weight or at a hydrogen-peroxide-equivalent concentration of not greater than about 3.5% by weight. The composition can produce a tooth-whitening effect equal to or greater than that of a comparative tooth-whitening composition having a hydrogen peroxide concentration of about 7% or greater by weight.

[0006] In various embodiments, the present invention can also include methods for whitening a tooth in a mammal. The methods can comprise contacting the tooth for an effective tooth-whitening period with a tooth-whitening composition. The tooth-whitening composition can comprise a peroxide compound and a peroxide-compatible abrasive compound. The pH of the tooth-whitening composition can be at least about 9 and the peroxide compound can be at a hydrogen-peroxide-equivalent concentration of not greater than about 5% by weight or at a hydrogen-peroxide-equivalent concentration of not greater than about 3.5% by weight. In various aspects, the composition can be prepared from a dual component system comprising a first component comprising a peroxide compound and a peroxide-compatible abrasive compound and a second component comprising an alkaline compound. The contacting is for a period of time which is effective in whitening the tooth, i.e. an effective tooth-whitening period, which is less than that required for a comparative composition comprising hydrogen peroxide at a concentration of about 7% by weight or greater and a pH of about 7.0 or less. Such effective tooth-whitening period of the tooth-whitening compositions of the present invention can be not more than about 15 minutes or

not more than about 20 minutes and that of comparative composition can be about 30 minutes or greater.

[0007] The present invention, in various embodiments, can also include methods for decreasing whitening time, increasing whitening effectiveness or decreasing oral irritation in a tooth-whitening process. The methods can comprise contacting a tooth for an effective tooth-whitening period with a tooth-whitening composition comprising a peroxide compound and a peroxide-compatible abrasive compound. The pH of the tooth-whitening composition can be at least about 9 and the peroxide compound can be present at a hydrogen-peroxide-equivalent concentration of not greater than about 5% by weight or at a hydrogen-peroxide-equivalent concentration of not greater than about 3.5% by weight. The tooth-whitening composition produces a decrease in whitening time, an increase in whitening effectiveness or a decrease in oral irritation or any combination thereof in comparison to a reference composition having a peroxide compound concentration of about 7% by weight or greater and a pH of about 7.0 or less. In various aspects of this embodiment, the contacting can be for an effective tooth-whitening period which is less than that required for a comparative composition comprising hydrogen peroxide at a concentration of about 7% by weight or greater and a pH of about 7.0 or less. For example, the effective tooth-whitening period of the tooth-whitening composition can be not more than about 15 minutes or not more than about 20 minutes and that of comparative composition can be about 30 minutes or greater. In various aspects of this embodiment, the tooth-whitening composition can be prepared from a dual component system comprising first and second components in which the first component can comprise a peroxide compound and a peroxide-compatible abrasive compound and the second component can comprise an alkaline compound.

[0008] In various aspects of the embodiments of the present invention involving a dual component system, the first and second components can combine not more than about

15 minutes, not more than about 10 minutes, not more than about 5 minutes or not more than about 2 minutes prior contacting a tooth with the composition to produce tooth whitening.

[0009] In various of the embodiments of the present invention, the peroxide compound can be hydrogen peroxide, an organic peroxide compound, a hydrogen peroxide generating compound or combinations thereof. Such organic peroxide compound can be, for example, urea hydrogen peroxide, glyceryl peroxide, benzoyl peroxide, monoperoxyphthalate or combinations thereof. The hydrogen peroxide generating compound can be, for example, sodium persulfate, sodium dipersulfate, sodium percarbonate, sodium perphosphate, sodium perborate, sodium persilicate, potassium persulfate, potassium dipersulfate, potassium percarbonate, potassium perphosphate, potassium perborate, potassium persilicate, calcium persulfate, calcium dipersulfate, calcium percarbonate, calcium perphosphate, calcium perborate, calcium persilicate, sodium peroxide, potassium peroxide and calcium peroxide or combinations thereof.

[0010] In various of the embodiments of the present invention the peroxide-compatible abrasive comprises one or more calcium phosphate salts including, for example calcium pyrophosphate. The peroxide-compatible abrasive can be present in the tooth-whitening composition or in the dentifrice composition at a concentration of at least about 10% by weight or at a concentration of at least about 20% by weight.

[0011] In various embodiments of the present invention, an alkaline compound can be present. Such alkaline compound can be, for example, sodium hydroxide, potassium hydroxide, ammonium hydroxide, calcium hydroxide, magnesium hydroxide, sodium carbonate, potassium carbonate, ammonium carbonate, calcium carbonate, magnesium carbonate, sodium bicarbonate, potassium bicarbonate, ammonium bicarbonate, calcium bicarbonate, magnesium bicarbonate, urea, monoethanolamine, diethanolamine, triethanolamine, mono(iso)propanolamine, di(iso)propanolamine, tri(iso)propanolamine, 2-

amino-2-methylpropanol, 2-amino-2-methyl-1,3-propanediol, 2-amino-2-ethyl-1,3-propanediol, tris(hydroxymethyl)aminomethane, N,N,N',N'-tetrakis(2-hydroxypropyl)ethylenediamine, di(2-ethylhexyl)amine, triamylamine, dodecylamine, morpholine or combinations thereof.

[0012] In various embodiments of the present invention involving a dual component system, the second component can also comprise an abrasive compound. The abrasive compound in the second component can be one or more peroxide-incompatible abrasive compounds, such as, for example a silica compound or an alumina compound or one or more peroxide-compatible abrasive compounds, such as, for example one or more calcium phosphate salts including calcium pyrophosphate as well as a combination of one or more peroxide-incompatible and/or peroxide-compatible abrasive compounds. The total concentration of abrasive compounds in the tooth-whitening compositions or the dentifrice compositions can be at least 10% by weight or at least 20% by weight.

[0013] In various embodiments of the present invention involving a dual component system, the second component can also comprise a color indicator such as, for example, group consisting of FD&C Red No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Green No. 3, FD&C Blue No. 1 and combinations thereof. In addition, either or both of the first or second components can further comprise a tooth-desensitizing compound such as, for example, a potassium salt of a weak acid or eugenol.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Figure 1 illustrates the *in vitro* treatment of extracted human teeth for 28 treatment periods using the composition of Example 1 for 20 minute treatment periods; comparative example C1 for 30 minute treatment periods; and comparative example C2 for 30 minute treatment periods.

[0015] Figure 2 illustrates the *in vitro* treatment of extracted human teeth for 14 or greater treatments using the compositions of Example 1 for 20 minute treatment periods; the composition of Example 5 for 15 minute treatment periods; comparative example C1 for 30 minute treatment periods; and comparative example C2 for 30 minute treatment periods.

DETAILED DESCRIPTION

[0016] The present invention, in various embodiments, can involve methods and compositions for enhancing tooth-whitening with compositions containing one or more peroxide compounds and one or more abrasive compounds, wherein the compositions can have a pH of at least about 9.0. Such compositions can accelerate the tooth-whitening process, increase the whitening activity of the peroxide compounds and decrease oral irritation.

[0017] Reference herein to “a tooth” is intended to include the singular (tooth) and the plural (teeth). The tooth-whitening effect of the compositions is detectable by visual observation or by measurement using any of various instruments following a given application period or following successive application periods of the same duration.

[0018] The enhanced whitening effect of the compositions of the present invention, can be achieved at a reduced concentration of peroxide compounds compared to concentrations normally used. Concentrations of peroxide compounds normally used can be, for example, 7% hydrogen peroxide by weight or 7.5% hydrogen peroxide by weight or an amount of a peroxide compound other than hydrogen peroxide in which the peroxide compound delivers a hydrogen peroxide ion or an organic peroxide ion in an amount equivalent to the hydrogen peroxide ion delivered by 7% by weight hydrogen peroxide or 7.5% by weight hydrogen peroxide under the same conditions of temperature, exposure to

light or other radiation, agitation and the like. Such equivalence is sometimes referenced herein as hydrogen-peroxide-equivalent concentration for a given peroxide compound.

[0019] Thus, concentrations of peroxide compounds as used herein refer concentrations that deliver the amount of bleaching activity equal to that delivered by hydrogen peroxide at the stated concentration. In various embodiments, the compounds deliver an amount of peroxide ion equal to that delivered by hydrogen peroxide at the stated concentration. For example, carbamide peroxide at a concentration of 10% by weight in an aqueous solution is generally considered to deliver the same amount of hydrogen peroxide ion as an aqueous solution of hydrogen peroxide at a concentration of about 3% by weight. Thus, for carbamide peroxide, a hydrogen-peroxide-equivalent concentration of 3.5% by weight is intended to mean a carbamide peroxide concentration of about 12% by weight, a hydrogen-peroxide-equivalent concentration of 5% by weight is intended to mean a carbamide peroxide concentration of about 17% by weight and a hydrogen-peroxide-equivalent concentration of 7% by weight is intended to mean a carbamide peroxide concentration of about 22% by weight.

[0020] All amounts in the specification and claims are by weight unless otherwise indicated. Reference herein to amounts by weight can also be expressed as (w/w) which intended to mean the ratio of the number of grams of a particular component of a composition to the total number of grams of that composition.

[0021] The terms “comparative composition” and “reference composition” are used interchangeably herein. Concentrations of the comparative or reference compositions as used herein is intended to mean the concentrations that deliver an amount of peroxide ion equal to that delivered by hydrogen peroxide at the stated concentration. In various embodiments, the reference or comparative composition can be hydrogen peroxide. Other comparative compositions can, however, be used and in such instances, the concentrations of the

comparative compositions are intended to mean the hydrogen-peroxide-equivalent concentrations of the comparative compositions. The comparative compositions can be at a hydrogen-peroxide-equivalent concentration of about 3.5% by weight or greater, about 5% by weight or greater, about 7% by weight or greater, about 7.5% by weight or greater, about 10% by weight or greater, or about 13% by weight or greater.

[0022] The hydrogen-peroxide-equivalent concentrations of the peroxide compounds of the present invention, show an enhanced whitening effect at hydrogen-peroxide-equivalent concentrations of not more than 3% by weight, not more than 3.5% by weight, not more than 4% by weight, not more than 4.5% by weight, not more than 5% by weight, not more than 5.5% by weight, not more than 6% by weight, and not more than 6.5% by weight.

[0023] In various embodiments of the present invention, the concentration of the peroxide compound can be viewed as a reduced concentration compared to the reference composition, i.e. the methods in certain embodiments, can involve a reduction in the concentration of the peroxide compound necessary to achieve the same whitening effect in duration of whitening period, effectiveness of whitening and degree of absence of oral irritation.

[0024] The peroxide compound can be any of a variety of peroxide-based bleaching agents, which deliver a hydrogen peroxide ion or an organic peroxide ion. Such compound include, for example, hydrogen peroxide, organic peroxide compounds, hydrogen peroxide generating compounds, organic peroxide generating compounds and combinations thereof.

[0025] Organic peroxide compounds include, for example, urea hydrogen peroxide (carbamide peroxide), glyceryl hydrogen peroxide as well as groups of peroxides classified according to the number and kind of organic functional groups attached to the oxygen atoms, such as, for example, alkyl hydrogen peroxide (R-O-O-H), dialkyl hydrogen peroxide (R-O-O-R') peroxy acids (RCO-O-O-H), peroxy esters (RCO-OOR'), and diacyl peroxides (R-CO-

O-O-CO-R'). Among such peroxides used in dental whitening are the diacyl peroxide, benzoyl peroxide and the peroxy acid monoperoxyphthalate.

[0026] The hydrogen peroxide generating compound can be, for example, alkali metal and alkaline-earth metal persulfate, dipersulfate, percarbonate, perphosphate, perborate, and persilicate salts such as, for example, sodium persulfate, sodium dipersulfate, sodium percarbonate, sodium perphosphate, sodium perborate, sodium persilicate, potassium persulfate, potassium dipersulfate, potassium percarbonate, potassium perphosphate, potassium perborate, potassium persilicate, calcium persulfate, calcium dipersulfate, calcium percarbonate, calcium perphosphate, calcium perborate, calcium persilicate salts as well as sodium peroxide, potassium peroxide and calcium peroxide and combinations of all of the above hydrogen peroxide generating compounds.

[0027] The enhanced whitening effect is achieved at least in part due to the high pH of the tooth-whitening composition which is, in turn achieved by the presence of at least one alkaline compound in the composition. In dual component systems, the alkaline compound can be present in one component and the peroxide compound, in the other component such that upon combination prior to use, the tooth-whitening mixture has a pH of at least about 9 or greater.

[0028] The alkaline compound can be, for example, an alkali metal, ammonium or alkaline earth metal compound such as, for example, sodium hydroxide, potassium hydroxide, ammonium hydroxide, calcium hydroxide, magnesium hydroxide, sodium carbonate, potassium carbonate, ammonium carbonate, calcium carbonate, magnesium carbonate, sodium bicarbonate, potassium bicarbonate, ammonium bicarbonate, calcium bicarbonate, magnesium bicarbonate or combinations thereof; an organic amine such as urea, alkanolamines such as monoethanolamine, diethanolamine, triethanolamine, mono(iso)propanolamine, di(iso)propanolamine, tri(iso)propanolamine or 2-amino-2-

methylpropanol; alkanediolamines such as 2-amino-2-methyl-1,3-propanediol or 2-amino-2-ethyl-1,3-propanediol; alkanepolyamines such as tris(hydroxymethyl)aminomethane or N,N,N'-tetrakis(2-hydroxypropyl)ethylenediamine; alkylamines such as di(2-ethylhexyl)amine, triamylamine or dodecylamine; or amino ethers such as morpholine.

[0029] The alkaline compound can be at a concentration of from about 0.1% by weight to about 30% by weight, from about 0.2% by weight to about 10% by weight, from about 0.5% by weight to about 2% by weight or from about 0.5% by weight to about 0.75% by weight.

[0030] One or more abrasive compounds can be included in the tooth-whitening compositions of the present invention. Such compounds impart cleaning and polishing functions to the composition. In addition to such actions, the abrasive compounds can enhance the whitening effect of peroxide compounds.

[0031] The method of incorporating the abrasive compound into the tooth-whitening composition can depend upon the type of abrasive compound. For example, certain abrasive compounds can be considered incompatible with peroxide based bleaching compounds because they tend to produce a decomposition of the peroxide compound. This can result not only in a reduced efficacy, but also in premature gas evolution resulting in swelling and/or bursting of tubes containing products made up of a peroxide compound and a peroxide-incompatible abrasive.

[0032] Peroxide-compatible abrasives, i.e. abrasive compounds not considered to cause substantial decomposition of peroxide compounds, include calcium phosphate abrasive compounds (see for example, U.S. Patent No. 5,171,564, which is incorporated in its entirety by reference). Examples of such peroxide compatible abrasives include dicalcium phosphate dihydrate, anhydrous dicalcium phosphate, calcium pyrophosphate and mixtures thereof.

[0033] Peroxide-incompatible abrasives include silica compounds and alumina compounds. Such silica compounds include for example, hydrated silica, such as Sorbosil AC-35, marketed by INEOS Silicas Ltd (Warrington, UK; formerly Crosfield Chemicals), or Zeodent 115 from Huber Company (Edison, N.J.). Alumina compounds can include, for example, alumina trihydrate, aluminum silicate, calcined alumina and mixtures thereof.

[0034] Other abrasives can also be included in the compositions of the present invention, such as, for example, hydroxyapatite, sodium metaphosphate, potassium metaphosphate, tricalcium phosphate, calcium carbonate, sodium bicarbonate, bentonite, and mixtures thereof.

[0035] Peroxide-incompatible abrasives can be combined with peroxide compounds immediately prior to use without producing substantial decomposition of the peroxide compounds. Such mixtures can produce an enhanced whitening activity of the peroxide compound (see for example, U.S. Patent No. 5,766,574 which is incorporated in its entirety by reference).

[0036] Thus, in various embodiments, the tooth-whitening compositions of the present invention can be in the form of a dual component system. The first component can comprise the peroxide compound and the second component can comprise the alkaline compound. In certain embodiments, the second component can also comprise a peroxide-incompatible abrasive compound. A peroxide-compatible abrasive compound can be incorporated into either or both of the first or second components. In particular, the first component of a two component system of the present invention can comprise a peroxide compound and a calcium phosphate abrasive compound such as calcium pyrophosphate and the second component can comprise an alkaline compound. In various embodiments, the second component can also contain either or both of a peroxide-incompatible abrasive compound and a peroxide-compatible abrasive compound.

[0037] The first and second components can, independently, be in the form of a liquid or a semi-solid liquid such as a gel or paste.

[0038] The dual component system can be in the form of a kit which includes the first and second components along with instructions for combining the first and second components and/or instructions as to the method of use of the first and second components and the a mixture thereof. Such instructions as to the method of use can include the amount to be used, time period for applying the compositions, schedule for repeated application and the like.

[0039] Typically, equal amounts of the first component and the second component are combined in such a manner to effect mixing. Such mixing results in an increase in the pH of the mixture to about 9 or greater, about 9.5 or greater, or about 10 or greater, or about 11 or greater, or about 12 or greater up to a pH of about 13 or greater.

[0040] The time period for applying the compositions of the present invention to achieve tooth-whitening is sometimes referenced herein as “effective tooth-whitening period.” This represents the time period during which the compositions contact the tooth during a single application. An “effective tooth-whitening period” can be about 10 minutes or less, about 15 minutes or less, about 20 minutes or less, about 25 minutes or less or about 30 minutes or less or more than about 30 minutes.

[0041] The tooth whitening composition can be applied in a single application or in repeated application. Such repeated or successive applications can be performed one or more times during the day such as, for example, once a day, twice a day or three times a day or less frequently such as, for example once every two days, once every three days or once a week. The application period can continue, for example for about one week, about two weeks, about three weeks, or about four weeks or longer.

[0042] The compositions of the present invention, including the tooth-whitening compositions and the first and second component compositions of two-component systems, can, in various embodiments, contain a thickening agent which imparts a high viscosity to the composition. Typically the compositions have a viscosity of from less than about 200 CPS up to about 10,000 or greater or from about 1000 cps up to about 9000 cps or from about 4000 to about 6000 cps. In certain embodiments, the thickening agent can be a hydrophilic block copolymer of polyethylene oxide and polypropylene oxide such as a Pluronic® compound, for example Pluronic® F127 which is a trade name of BASF obtained therefrom (BASF Corporation, Mount Olive, New Jersey). Pluronic® F127 has a molecular weight of about 4000. This substance can be present in the compositions at a concentration of about 5% by weight about 10% by weight, about 15% by weight, about 20% by weight, about 25% by weight, about 30% by weight or greater. In particular, the Pluronic® F127 concentration in the first component containing the peroxide compound can be about 20% by weight, in the second component containing the alkaline compound, the concentration can be about 17% by weight and in the tooth-whitening mixture of the two, the concentration can be about 18.5% by weight.

[0043] Polyethylene oxide of high molecular weight can also be used in the compositions of the present invention as thickening agents. Such polyethylene oxide thickeners have a number average molecular weight, a viscosity average molecular weight, a weight average molecular weight or a Z-average molecular weight of about 50,000 to about 5,000,000. One or more high molecular weight polyethylene oxide can be present in a concentration range of from about 0% to about 30% by weight, from about 10% by weight to about 25% by weight or from about 15% by weight to about 20% by weight.

[0044] One or more of glycerin, sorbitol and low molecular weight polyethylene glycol can also be included in the compositions as carrier materials which can also impart

effects on viscosity. The polyethylene glycol is a nonionic polymer of ethylene oxide. The polyethylene glycol when present in the compositions of the present invention can have a number average, weight average, or Z average molecular weight of from about 200 to about 1000, from about 400 to about 800 or about 600. The glycerin, sorbitol and polyethylene glycol can each independently be present in amounts of from about 0% to about 30% by weight, from about 5% by weight to about 25% by weight, from about 10% by weight to about 20% by weight, or from about 15% by weight to about 20% by weight. Typically, glycerin and polyethylene glycol (600) are present in amounts of about 5% by weight and about 15% by weight, respectively in the first component composition, in amounts of about 5% by weight and about 10% by weight, respectively in the second component composition and in amounts of about 5% by weight and about 12.5% by weight, respectively in the tooth-whitening composition.

[0045] The compositions of the present invention can also contain added water in an amount of from about 5% by weight to about 40% by weight, from about 10% by weight to about 30% by weight or from about 5% by weight to about 20% by weight.

[0046] Surfactants can also be included in the compositions of the present invention as solubilizing, dispersing and/or emulsifying agents. Such surfactants can include nonionic surfactants such as, for example, Tween 20 or anionic surfactants such as, for example, sodium lauryl sulfate or sodium dodecyl sulfate.

[0047] The compositions of the present invention can also contain flavoring substances at a concentration of from about 0.05% by weight to about 5% by weight. Such flavoring substances include, for example, an essential oil, extract or flavoring aldehyde, ester or alcohol that imparts a flavor of spearmint, peppermint, wintergreen, sassafras, clove, sage, eucalyptus, marjoram, cinnamon, lemon, lime, grapefruit, orange, apple, pear, peach,

strawberry, cherry, apricot, watermelon, banana, coffee, cocoa, menthol, carvone, anethole or combinations thereof.

[0048] One or more sweetening agents can also be included in the compositions of the present invention. Such sweetening agents can include sodium saccharin, sodium cyclamate, zylitol, aspartame and the like in a concentration of from about 0.01% by weight to about 1.0% by weight.

[0049] The compositions of the present invention can also be formulated to contain one or more desensitizing agents to reduce tissue sensitivity and irritation upon application of the tooth-whitening compositions. Such sensitizers include, for example, potassium salts of weak acids, such as potassium citrate, potassium chloride, potassium tartrate, potassium bicarbonate, potassium oxalate, potassium nitrate as well as strontium salts and eugenol (4-allyl-2-methoxyphenol). One or more of the sensitizers can be present in the compositions of the present invention at a concentration of from about 0.05% by weight to about 0.5% by weight or from about 0.1% by weight to about 0.25% by weight for eugenol and from about 1% by weight to about 10% by weight or from about 3% by weight to about 6% by weight for potassium salts of weak acids such as, for example potassium nitrate.

[0050] One or more redox color indicators that are oxidized by hydrogen peroxide, can also be included in the second component of the dual-component system. The color indicator can be a dye suitable for use in an tooth-bleaching composition such as, for food color additives certified under the Food Drug & Cosmetic Act for use in food and ingested drugs, including dyes such as FD&C Red No. 3 (sodium salt of tetraiodofluorescein), FD&C Yellow No. 5 (sodium salt of 4-p-sulfophenylazo-1-p-sulfophenyl-5-hydroxypyrazole-3-carboxylic acid), FD&C Yellow No. 6 (sodium salt of p-sulfophenylazo-B-naphtol-6-monosulfonate), FD&C Green No. 3 (disodium salt of 4-{[4-(N-ethyl-p-sulfobenzylamino)-phenyl]-(4-hydroxy-2-sulfoniumphenyl)-mewthylene }-[1-(N-ethyl-N-p-sulfobenzyl)-Δ-3,5-

cyclohexadienimine], FD&C Blue No. 1 (disodium salt of dibenzyl-diethyldiaminotriphenylcarbinol trisulfonic acid of indigotin). The dyes change colors upon contacting the peroxide compound, thereby signaling the user when the effective whitening period is completed. The second component composition can contain one or more dyes at a concentration of from about 0.005% by weight to about 0.5% by weight or from about 0.025% by weight to about 0.15% by weight.

[0051] Agents that chelate metal ions can also be present in the compositions of the present invention. Such chelating agents include sodium acid pyrophosphate, disodium calcium ethylene diamine tetraacetic acid, phosphoric acid, citric acid, sodium citrate, potassium citrate, sodium pyrophosphate, potassium pyrophosphate, disodium ethylenediamine tetraacetic acid and the like. The chelating agents can be incorporated into the compositions of the present invention in an amount of from about 0.1% by weight to about 8% by weight or from about 0.5% by weight to about 3.0% by weight.

[0052] Fluoride compounds having anti-caries activity can also be incorporated in the compositions of the present invention. These substances release fluoride ions in an aqueous environment. Such fluoride compounds include salts such as, for example, sodium fluoride, potassium fluoride, cuprous fluoride, stannous fluoride, stannous chlorofluoride, sodium fluorosilicate, ammonium fluorosilicate, sodium monofluorophosphate, alumina monofluorophosphate and alumina difluorophosphate. The fluoride compounds, when present, can be at a concentration sufficient to release fluoride ion in an amount of from about 15 to about 1500 ppm.

[0053] Anti-forming agents such as simethicone can also be present in the compositions of the present invention at a concentration of from about 0% by weight to about 0.1% by weight.

[0054] Tooth whiteness can be visually observed or measured by any of various instruments measured. One such instrument can be a colorimetry such as, for example, a Minolta portable Chroma-meter such as model CR-400 (Minolta Corp. Ramsey, New Jersey). This colorimeter can be programmed to measure Hunter lab values of "L", "a" and "b" in which "L" values represent lightness and "a" and "b" values represent the chromaticity coordinates. Lightness "L" values can represent dark to light color in which a value of 0 represents black and a value of 100 represents white. Green to red can be expressed by the "a" value, the more positive value represented more red, and the more negative value represented more green color (-80 represents green and 100 represents red). Blue to yellow can be expressed by the "b" value, a more positive value represented more yellow color in the sample (-80 represents blue and 70 represents yellow). Typically "L" values are used to measure tooth-whiteness.

[0055] The invention can be further understood by reference to the examples which follow.

EXAMPLE 1

[0056] This Example illustrates a two component tooth-whitening system in which the concentration of the peroxide compound in the tooth-whitening composition formed by combining the two components is about 3.5% by weight.

[0057] The composition of the first, peroxide component, and the second alkaline component are as shown in Table 1.

Table 1. Tooth-Whitening Composition having 3.5% H₂O₂.

Component	A	B
Ingredients	Peroxide Component Weight %	Alkaline Component Weight %
Deionized Water	14.3	31
Hydrogen peroxide	20 (35% solution)	--
Potassium Nitrate	--	6
Glycerin	5	5
Polyethylene glycol 600	15	10
Pluronic F-127	20	17
Saccharin	0.2	--
Sodium hydroxide	--	0.5-0.75
FD+C Yellow #6	--	0.025 – 0.15
Eugenol	0.25	--
Calcium pyrophosphate	25	30
Sodium lauryl sulfate	--	0.4
Flavor	0.25	--

[0058] Components A and B were prepared in a Ross mixer (Charles Ross & Son Company, Hauppauge, NY) as follows.

Component A: Water, saccharin and 30% of the total volume of 35% hydrogen peroxide were stirred in a beaker until the saccharin dissolves. PEG 600 and glycerin were added and the mixture was placed in the Ross mixer along with Pluronic F127 and stirred at high speed under vacuum until a clear gel formed (approximately 45 minutes). Calcium pyrophosphate was added and the mixture stirred at medium speed for another 10 minutes under vacuum. The remaining 70% of the peroxide volume was added and stirred 10 minutes at medium speed. Next, the flavor was added and the mixture was stirred 5 minutes at low speed. An extrudible paste having a pH of 6.0 was obtained.

Component B: Water, sodium hydroxide potassium nitrate and FD+C Green #3 dye were mixed in a beaker until the potassium nitrate dissolved. PEG 600 and glycerin were added to the aqueous phase and the mixture was placed in the Ross mixing pot along with Pluronic F127. The mixture was stirred at high speed under vacuum until a clear gel formed (approximately 45 minutes). Calcium pyrophosphate, sodium lauryl sulfate, sodium bicarbonate and sodium hydroxide were added and the mixture stirred at medium speed for another 10 minutes under vacuum. An extrudable paste having a pH of 9.6 was obtained.

EXAMPLE 2

[0059] This example illustrates the *in vitro* whitening effect of the tooth-whitening composition of Example 1 containing peroxide compound at a concentration of 3.5% by weight and calcium pyrophosphate at a concentration of 27.5%.

[0060] Three compositions were tested. The composition of Example 1 was prepared by mixing component A with component B in approximately equal proportions. Comparative composition designated "C" was a simple pluronic gel prepared at approximately the same pH and peroxide concentration as the composition of Example 1, but having water in place of the calcium pyrophosphate. Comparative composition designated "C1" was a commercially available whitening composition comprised of a thickened Pluronic gel containing about 7% hydrogen peroxide at a pH of about 5.8 in addition to calcium pyrophosphate and dicalcium phosphate.

[0061] Extracted, naturally-stained human teeth were pumiced and initial color determined using a Minolta Chromameter CR-241. Three teeth each were immersed for 15 minutes at 37 °C in each of the three tooth-whitening compositions. These 15 minute-treatments were repeated 8 times for a total contact time of 2 hours. Tooth shade was

measured midway and at the end of the total treatment period. The increase in tooth whiteness, represented as ΔE values was calculated using the following formula:

$$\Delta E = [\Delta L]^2 + (\Delta a)^2 + (\Delta b)^2]^{1/2}$$

wherein "L", "a" and "b" are Hunter lab values in which "L" values represent lightness and "a" and "b" values represent the chromaticity coordinates as described above. Higher values of ΔE , indicate higher levels of tooth whiteness achieved. Results are shown in Table 2 below.

Table 2. *In vitro* Immersion Study

Composition	pH	ΔE	
		<u>4 treatments</u>	<u>8 treatments</u>
Example 1	9.8	3.48 ± 1.28	5.21 ± 1.52
Comparative Example C	9.8	1.61 ± 0.50	2.17 ± 0.56
Comparative Example C1	5.8	2.60 ± 0.47	4.23 ± 0.97

[0062] As shown in the table, the tooth-whitening effect of the composition of Example 1 was greater than that of comparative composition C at both measurement points. The comparative composition C contained 3.5% by weight hydrogen peroxide as did the composition of Example 1, however, the composition of Example 1 also contained calcium pyrophosphate at a concentration 27.5%. This suggests that the calcium pyrophosphate contributed to the tooth-whitening effect of the composition of Example 1. Since the majority of the extrinsic staining was removed from the sample teeth with pumice, the improved whitening produced by calcium pyrophosphate is believed to result from removal of intrinsic tooth stain. Thus, the data above show that the calcium pyrophosphate provided a beneficial whitening benefit in addition to its effect on surface polishing and extrinsic stain removal.

[0063] The whitening effect produced by the composition of Example 1 was greater than that produced by comparative composition, C1, which contained hydrogen peroxide at a concentration of about 7% and a pH of about 9.

EXAMPLE 3

[0064] This example illustrates the long-term *in vitro* effectiveness of the tooth-whitening composition of Example 1 containing peroxide compound at a concentration of 3.5% by weight and calcium pyrophosphate at a concentration of 27.5%.

[0065] Three compositions were tested. The composition of Example 1 was prepared by mixing component A with component B in approximately equal proportions. Comparative composition designated "C1" was a commercially available whitening composition comprised of a thickened Pluronic gel containing about 7% hydrogen peroxide at a pH of about 5.8 in addition to calcium pyrophosphate and dicalcium phosphate. Comparative composition "C2" was a commercially available whitening composition comprising a thickened Pluronic gel which contained about 7.5% hydrogen peroxide at a pH of about 9 and no added abrasive compounds.

[0066] Five human extracted teeth each were repeatedly treated with comparative composition "C1" for a periods of 30 minutes per treatment; or comparative composition "C2" for periods of 30 minutes per treatment. Another five human extracted teeth were treated with the composition of Example 1 for periods of 20 minutes per treatment.

[0067] The study was carried out to 28 treatments, which is equivalent to 14 days of twice daily treatments (a typical treatment regimen for at-home whitening). Shade readings were taken at various intervals with the Minolta Chromameter. Results are shown in Figure 1. As seen in the Figure 1, the tooth-whitening composition of Example 1 achieved whitening comparable to that of comparative composition C1 in half the number of treatments compared to that of the composition of Example 1. In addition, the composition of Example

1 achieved whitening comparable to that of comparative composition C2 which contained more than twice the level of hydrogen peroxide at a concentration of 7.5% compared to 3.5% for the composition of Example 1.

EXAMPLE 4

[0068] This example illustrates the *in vivo* testing of the tooth-whitening composition of Example 1 containing peroxide compound at a concentration of 3.5% by weight and calcium pyrophosphate at a concentration of 27.5%.

[0069] The whitening efficacy of the composition of Example 1 was also compared to comparative composition C1 in a 2-week clinical study. One cell used comparative composition C1 30 minutes twice daily and the other cell used the composition of Example 1 for 20 minutes once daily. Tooth shade was evaluated after 14 days using a Vita shade guide. The results are summarized in the Table 2.

Table 3: Clinical Testing of Composition of Example 1

Composition	Hydrogen Peroxide Concentration	No. of Subjects	Total Wear Time	Shade Change
Example 1	3.5%	13	4.7 hrs.	4.85 $\pm$ 2.48
Comparative Example C1	7.5%	10	14.0 hrs.	4.56 $\pm$ 2.65

[0070] As shown in the Table, there was no significant difference between tooth shade changes. Thus the composition of Example 1 provides the same whitening effect as comparative example C1, but at half the peroxide level and 1/3 the total wear time. In addition, subjects using comparative composition C1 reported significantly ($p=0.038$) more gum irritation than those using the composition of Example 1.

EXAMPLE 5

[0071] This Example illustrates a two component tooth-whitening system in which the concentration of the peroxide compound in the tooth-whitening composition formed by combining the two components is about 5% by weight.

[0072] The composition of the first, peroxide component, and the second alkaline component are as shown in Table 4.

Table 4. Tooth-Whitening Composition having 5% H₂O₂

Component Ingredients	A	B
	Peroxide Component Weight %	Alkaline Component Weight %
Deionized Water	24	30.2
Hydrogen peroxide	10	--
Potassium Nitrate	--	10
Polyox (PEG 2M)	5	--
Glycerin	5	25
Polyethylene glycol 600	10	3
Xanthan	--	0.7
Na carboxymethyl cellulose	--	0.5
Pluronic F-127	20	2
Sodium saccharin	--	0.2
Titanium dioxide	--	1
Sodium hydroxide (50%)	--	1
TiO ₂	--	1
FD+C Green #3	--	0.025
Zeodent 115 (silica abrasive)	--	17.5
Zeodent 165 (silica thickener)	--	3
Sodium bicarbonate	--	5
Calcium pyrophosphate	25	--
Sodium lauryl sulfate	--	0.4
Flavor	0.5	0.5

Components A and B were prepared as described above in Example 1.

EXAMPLE 6

[0073] This example illustrates the *in vitro* whitening effect of the tooth-whitening composition of Example 5 containing peroxide compound at a concentration of 5% by weight and calcium pyrophosphate at a concentration of 12.5%.

[0074] *In Vitro* assessment of stain removal by the tooth-whitening composition of Example 5 was determined by an *in vitro* study procedure using human extracted teeth as described above in Example 2. The teeth were polished with a prophylaxis paste to remove any surface stain. The root portions of five teeth were placed in a row and immersed in an impression compound. To mimic *in vivo* use, a tray for the sample teeth was prepared by placing a piece of tray material in a tray former and heated until the material began to soften. The softened tray material was then pulled down over the five teeth using a vacuum and allowed to harden to entrap the teeth in the hardened tray material.

[0075] Baseline Chromameter readings were taken of the teeth using a Minolta Chromameter CR-241. Next, small dots of the tooth-whitening composition of Example 5 composed of equal weight amounts of component A and B, so that the peroxide content was 5% by weight, were placed in each tooth well in a dental tray. The tray was weighed and then placed over the teeth so that a thin film of the composition of Example 5 covered each tooth. The tray covered teeth were placed in a 37°C incubator for 15 minute intervals and thereafter removed, rinsed and measured with the Chromameter. This process was repeated for each time point. The ΔE values were determined for each time point as described above.

[0076] For purposes of comparison, the single component peroxide paste similar to component A alone but containing hydrogen peroxide at a concentration of 3.5% and designated composition "C1A" as described above was evaluated for tooth whitening efficacy following the procedure of the Example 3 above. The ΔE values of the tray covered teeth were measured at 30 minute intervals for composition C1A. For purposes of further

comparison, a commercially available professional tooth whitening composition was also evaluated for tooth whitening efficacy with chromameter measurements being performed also at 30 minute intervals. The commercial whitening composition, designated composition "C2" as described above was a thickened Pluronic gel which contained 7.5% peroxide at a of about pH 9. No abrasives were present in the gel. The whitening study was carried out to 14 treatments, which is equivalent to a typical home whitening regimen of twice daily treatments over a one week period. Results are shown in Table 5.

Table 5. Tooth Whitening Efficacy of Composition Containing 5% H₂O₂.

Composition	Number of Treatments			
	4	8	12	14
Example 5	6.98	7.82	8.07	8.23
Comparative Example C1A	2.71	4.26	5.55	5.84
Comparative Example C2	4.47	7.12	8.16	8.38

[0077] The results recorded in Table 5 indicate that although the treatment time (15 minutes) using the composition of Example 5 was half the treatment time (30 minutes) of comparative composition C2, the composition of Example 5 achieved faster maximum whitening in half the number of treatments and half the application time in spite of the fact that the composition C2 contained 33% more peroxide whitening agent than that of the composition of Example 5 (7.5% v. 5.0%).

[0078] These results are further illustrated in Figure 2 which shows the comparisons above and in addition, the whitening effects of the composition of Example 1.

[0079] While not intending to be bound by any theory, the unexpected enhancement in whitening efficacy produced by the compositions of Examples 1 and 5 in comparison to the comparative composition C2 may be due to the presence in the composition of calcium pyrophosphate and silica abrasives which serve to aid in extrinsic stain removal and, boost the effective peroxide concentration delivered inside the tooth by the increased density and

solid content of the compositions of Example 1 and 5 as compared to the comparative composition C2. Thus, larger amounts of peroxide are believed to have been delivered by the compositions of Examples 1 and 5 to the teeth per unit weight of paste. In addition, the peroxide ingredient in the compositions of Example 1 and 2 are believed to have been concentrated into the water soluble portion of the composition and it is believed that this concentrated portion may have diffused into the teeth to remove intrinsic stain.

EXAMPLE 7

[0080] This example illustrates the *in vivo* assessment of whitening efficacy of the composition of Example 5.

[0081] The composition of Example 5 was prepared by combining equal weight amounts of Components A and B. Whitening efficacy of the composition was also compared to that of comparative composition C2 in a two week human clinical study wherein one cell of 9 subjects used composition C2 thirty minutes twice daily according to the manufacturer's instruction. The other cell with 12 patients used the composition of Example 5 for fifteen minutes once daily. Tooth shade was evaluated after 0, 5, 7 and 14 days using a value-ordered Vita shade guide. The results are summarized in Table 6.

Table 6. *In vivo* Whitening Efficacy of Composition Containing 5% H₂O₂.

Composition	Average Shade at Baseline	Shade Guide Change			Average Shade Guide Change (Day)		
		Average Shade Guide (Day)			Average Shade Guide Change (Day)		
		5	7	14	5	7	14
Example 5	D3	7.67	6.15	4.88	3.58	4.92	6.19
Comparative Example C2	D3	8.06	6.11	4.22	2.28	3.92	5.66

[0082] The results recorded in Table 6 indicate that the overall whitening efficacy of the composition of Example 5 was directionally better than comparative composition C2 and statistically better at 5 days ($p=0.025$) evidencing faster whitening efficacy since both the application time and number of treatments using the composition of Example 5 was one quarter that of comparative composition C2 (15 minutes once daily versus 30 minutes twice daily).

[0083] In addition to enhanced efficacy, the patients in the tooth whitening study using the composition of Example 5 as described above reported less gingival irritation and tooth sensitivity than patients using comparative composition C2. The patients involved in the study rated their tooth sensitivity and gingival irritation on a scale of zero (none) to 5, the higher the number, the greater the tooth sensitivity and gingival irritation experienced by the patient involved in the study. Patient rated their perception of tooth sensitivity and gingival irritation using this scale before using the product (baseline) and after using the product for 7 days and 14 days. The patient ratings of gum irritation and tooth sensitivity minus the baseline ratings are recorded in Table 7 below.

Table 7. Sensitivity and Irritation Study with Composition of Example 5.

	Δ Gum Irritation*		Δ Tooth Sensitivity**	
	(Day)		(Day)	
Composition	7	14	7	14
Example 5	-0.08	0.00	-0.62	-0.46
Comparative Example C2	+1.11	+1.13	0.00	+0.33

* Change in gum irritation from baseline

** Change in tooth sensitivity from baseline

[0084] Ratings for gum irritation and tooth sensitivity were lower for the composition of Example 5 compared to that of comparative composition C2 at 7 and 14 days. The levels of tooth sensitivity reported for the composition of Example 5 at 7 and 14 days were negative (lower than the reported baseline values), suggesting that the desensitizing agent present in the composition reduced tooth sensitivity over the treatment period.

[0085] Copending Application No. 10/065,244 filed September 27, 2002 is hereby incorporated in its entirety by reference.

[0086] The description of the invention is merely exemplary in nature and, thus, variations that do not depart from the gist of the invention are intended to be within the scope of the invention. Such variations are not to be regarded as a departure from the spirit and scope of the invention.

CLAIMS

WHAT IS CLAIMED IS:

1. A dual component dentifrice system comprising a first component comprising a peroxide compound and a peroxide-compatible abrasive compound and a second component comprising an alkaline compound, wherein upon combining the first and second components, a dentifrice composition having a pH of about 9.0 or greater is produced.
2. A system according to claim 1, wherein the first component has a pH of from about 4 to about 7 and the second component has a pH of from about 9 to about 13.
3. A system according to claim 1, wherein the peroxide compound is selected from the group consisting of hydrogen peroxide, an organic peroxide compound, a hydrogen peroxide generating compound and combinations thereof.
4. A system according to claim 1, wherein the peroxide compound is an organic peroxide compound selected from the group consisting of urea hydrogen peroxide, glyceryl peroxide, benzoyl peroxide, monoperoxyphthalate and combinations thereof.
5. A system according to claim 1, wherein the peroxide compound is a hydrogen peroxide generating compound selected from the group consisting of sodium persulfate, sodium dipersulfate, sodium percarbonate, sodium perphosphate, sodium perborate, sodium persilicate, potassium persulfate, potassium dipersulfate, potassium percarbonate, potassium perphosphate, potassium perborate, potassium persilicate, calcium persulfate, calcium dipersulfate, calcium percarbonate, calcium perphosphate, calcium perborate, calcium

persilicate, sodium peroxide, potassium peroxide and calcium peroxide and combinations thereof.

6. A system according to claim 1 wherein, upon combining the first and second components the peroxide compound is present in the dentifrice composition at a hydrogen-peroxide-equivalent concentration of not greater than about 5.0% by weight.

7. A system according to claim 6, wherein upon combining the first and second components the peroxide compound is present in the dentifrice composition at a hydrogen-peroxide-equivalent concentration of not greater than about 3.5% by weight.

8. A system according to claim 1, wherein the peroxide-compatible abrasive comprises one or more calcium phosphate salts.

9. A system according to claim 8, wherein the peroxide-compatible abrasive comprises calcium pyrophosphate.

10. A system according to claim 1, wherein upon combining the first and second components, the peroxide-compatible abrasive is present in the dentifrice composition at a concentration of at least about 10% by weight.

11. A system according to claim 10, wherein upon combining the first and second components, the peroxide-compatible abrasive is present in the dentifrice composition at a concentration of at least about 20% by weight.

12. A system according to claim 1, wherein the alkaline compound is an alkali metal hydroxide or an alkali metal carbonate salt.

13. A system according to claim 1, wherein the alkaline compound is selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, calcium hydroxide, magnesium hydroxide, sodium carbonate, potassium carbonate, ammonium carbonate, calcium carbonate, magnesium carbonate, sodium bicarbonate, potassium bicarbonate, ammonium bicarbonate, calcium bicarbonate, magnesium bicarbonate, urea, monoethanolamine, diethanolamine, triethanolamine, mono(iso)propanolamine, di(iso)propanolamine, tri(iso)propanolamine, 2-amino-2-methylpropanol, 2-amino-2-methyl-1,3-propanediol, 2-amino-2-ethyl-1,3-propanediol, tris(hydroxymethyl)aminomethane, N,N,N',N'-tetrakis(2-hydroxypropyl)ethylenediamine, di(2-ethylhexyl)amine, triamylamine, dodecylamine, morpholine and combinations thereof.

14. A system according to claim 1, wherein the second component further comprises a second abrasive compound.

15. A system according to claim 14, wherein the second component comprises a peroxide-incompatible abrasive compound.

16. A system according to claim 15, wherein the peroxide-incompatible abrasive compound is a silica compound or an alumina compound.

17. A system according to claim 14, wherein the second abrasive compound comprises one or more calcium phosphate salts.

18. A system according to claim 17, wherein the second abrasive compound comprises calcium pyrophosphate.

19. A system according to claim 14, wherein upon combining the first and second components, the total concentration of abrasive compounds in the dentifrice composition is at least about 20% by weight.

20. A system according to claim 1, wherein the second component further comprises a color indicator.

21. A system according to claim 20, wherein the color indicator is selected from the group consisting of FD&C Red No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Green No. 3, FD&C Blue No. 1 and combinations thereof.

22. A system according to claim 1, wherein either or both of the first or second components further comprise a tooth-desensitizing compound.

23. A system according to claim 22, wherein the tooth-desensitizing compound is a potassium salt of a weak acid or eugenol.

24. A dentifrice composition comprising a peroxide compound at a hydrogen-peroxide-equivalent concentration of not greater than about 5.0% by weight and a peroxide-compatible abrasive compound, wherein said composition has a pH of about 9.0 or greater.

25. A composition according to claim 24, wherein the peroxide compound is at a hydrogen-peroxide-equivalent concentration of not more than about 3.5% by weight.

26. A composition according to claims 24 or 25, wherein the composition produces a tooth-whitening effect equal to or greater than that of a comparative tooth-whitening composition having a hydrogen peroxide concentration of 7% by weight or greater.

27. A composition according to claims 24 or 25, wherein the peroxide compound is selected from the group consisting of hydrogen peroxide, an organic peroxide compound, a hydrogen peroxide generating compound and combinations thereof.

28. A composition according to claims 27, wherein the peroxide compound is an organic peroxide compound selected from the group consisting of urea hydrogen peroxide, glyceryl peroxide, benzoyl peroxide, monoperoxyphthalate and combinations thereof.

29. A composition according to claim 27, wherein the peroxide compound is a hydrogen peroxide generating compound selected from the group consisting of sodium persulfate, sodium dipersulfate, sodium percarbonate, sodium perphosphate, sodium perborate, sodium persilicate, potassium persulfate, potassium dipersulfate, potassium percarbonate, potassium perphosphate, potassium perborate, potassium persilicate, calcium persulfate, calcium dipersulfate, calcium percarbonate, calcium perphosphate, calcium perborate, calcium persilicate, sodium peroxide, potassium peroxide and calcium peroxide and combinations thereof.

30. A composition according to claims 24 or 25, wherein the peroxide-compatible abrasive comprises one or more calcium phosphate salts.

31. A composition according to claim 30, wherein the peroxide-compatible abrasive comprises calcium pyrophosphate.

32. A composition according to claims 24 or 25, wherein the peroxide-compatible abrasive is present in the dentifrice composition at a concentration of at least about 10% by weight.

33. A composition according to claim 32, wherein the peroxide-compatible abrasive is present in the dentifrice composition at a concentration of at least about 20% by weight.

34. A composition according to claims 24 or 25, wherein the composition comprises an alkaline compound that is an alkali metal hydroxide or an alkali metal carbonate salt.

35. A composition according to claims 24 or 25, wherein the composition comprises an alkaline compound selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, calcium hydroxide, magnesium hydroxide, sodium carbonate, potassium carbonate, ammonium carbonate, calcium carbonate, magnesium carbonate, sodium bicarbonate, potassium bicarbonate, ammonium bicarbonate, calcium bicarbonate, magnesium bicarbonate, urea, monoethanolamine, diethanolamine, triethanolamine, mono(iso)propanolamine, di(iso)propanolamine, tri(iso)propanolamine, 2-amino-2-methylpropanol, 2-amino-2-methyl-1,3-propanediol, 2-amino-2-ethyl-1,3-propanediol, tris(hydroxymethyl)aminomethane, N,N,N',N'-tetrakis(2-

hydroxypropyl)ethylenediamine, di(2-ethylhexyl)amine, triamylamine, dodecylamine, morpholine and combinations thereof.

36. A composition according to claims 24 or 25, further comprising an abrasive which is a silica compound or an alumina compound.

37. A composition according to claim 36, wherein the total concentration of abrasive compounds is at least about 20% by weight.

38. A composition according to claims 24 or 25, wherein said composition is a tooth-whitening composition which is prepared not more than about 15 minutes prior to application to a tooth.

39. A composition according to claim 38, further comprising a color indicator.

40. A composition according to claim 39, wherein the color indicator is selected from the group consisting of FD&C Red No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Green No. 3, FD&C Blue No. 1 and combinations thereof.

41. A composition according to claims 24 or 25, further comprising a tooth-desensitizing compound.

42. A composition according to claim 41, wherein the tooth-desensitizing compound is a potassium salt of a weak acid or eugenol.

43. A method for whitening a tooth in a mammal, the method comprising contacting the tooth for an effective tooth-whitening period with a tooth-whitening composition that comprises a peroxide compound at a hydrogen-peroxide-equivalent concentration of not greater than about 5% by weight and a peroxide-compatible abrasive compound, said composition having a pH of at least about 9.

44. A method according to claim 43 wherein the peroxide compound is at a hydrogen-peroxide-equivalent concentration of not greater than about 3.5% by weight.

45. A method according to claims 43 or 44, wherein the composition is prepared from a dual component system comprising a first component comprising a peroxide compound and a peroxide-compatible abrasive compound and a second component comprising an alkaline compound.

46. A method according to claim 45, wherein the composition is prepared not more than 15 minutes prior said contacting.

47. A method according to claims 43 or 44, wherein the contacting is for an effective tooth-whitening period which is less than that required for a comparative composition comprising hydrogen peroxide at a concentration of 7% by weight or greater and a pH of 7.0 or less.

48. A method according to claim 47 wherein the effective tooth-whitening period of the tooth-whitening composition is not more than about 20 minutes and that of comparative composition is about 30 minutes or greater.

49. A method according to claims 43 or 44, wherein the peroxide compound is selected from the group consisting of hydrogen peroxide, an organic peroxide compound, a hydrogen peroxide generating compound and combinations thereof.

50. A method according to claims 49, wherein the peroxide compound is an organic peroxide compound selected from the group consisting of urea hydrogen peroxide, glyceryl peroxide, benzoyl peroxide, monoperoxyphthalate and combinations thereof.

51. A method according to claim 49, wherein the peroxide compound is a hydrogen peroxide generating compound selected from the group consisting of sodium persulfate, sodium dipersulfate, sodium percarbonate, sodium perphosphate, sodium perborate, sodium persilicate, potassium persulfate, potassium dipersulfate, potassium percarbonate, potassium perphosphate, potassium perborate, potassium persilicate, calcium persulfate, calcium dipersulfate, calcium percarbonate, calcium perphosphate, calcium perborate, calcium persilicate, sodium peroxide, potassium peroxide and calcium peroxide and combinations thereof.

52. A method according to claims 43 or 44, wherein the peroxide-compatible abrasive comprises one or more calcium phosphate salts.

53. A method according to claim 52, wherein the peroxide-compatible abrasive comprises calcium pyrophosphate.

54. A method according to claims 43 or 44, wherein the peroxide-compatible abrasive is present in the tooth-whitening composition at a concentration of at least about 10% by weight.

55. A method according to claim 54, the peroxide-compatible abrasive is present in the tooth-whitening composition at a concentration of at least about 20% by weight.

56. A method according to claim 45, wherein the alkaline compound is an alkali metal hydroxide or an alkali metal carbonate salt.

57. A method according to claim 45, wherein the alkaline compound is an alkaline compound selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, calcium hydroxide, magnesium hydroxide, sodium carbonate, potassium carbonate, ammonium carbonate, calcium carbonate, magnesium carbonate, sodium bicarbonate, potassium bicarbonate, ammonium bicarbonate, calcium bicarbonate, magnesium bicarbonate, urea, monoethanolamine, diethanolamine, triethanolamine, mono(iso)propanolamine, di(iso)propanolamine, tri(iso)propanolamine, 2-amino-2-methylpropanol, 2-amino-2-methyl-1,3-propanediol, 2-amino-2-ethyl-1,3-propanediol, tris(hydroxymethyl)aminomethane, N,N,N',N'-tetrakis(2-hydroxypropyl)ethylenediamine, di(2-ethylhexyl)amine, triamylamine, dodecylamine, morpholine and combinations thereof.

58. A method according to claim 45, wherein the second component of the two component system further comprises a second abrasive compound.

59. A method according to claim 58, wherein the second abrasive compound is a peroxide-incompatible abrasive compound.

60. A method according to claim 59, wherein the peroxide-incompatible abrasive compound comprises a silica compound or an alumina compound.

61. A method according to claim 58, wherein the second abrasive compound comprises one or more calcium phosphate salts.

62. A method according to claim 61, wherein the one or more calcium phosphate salts comprises calcium pyrophosphate.

63. A method according to claim 58, wherein the tooth-whitening composition has a total concentration of abrasive compounds in the dentifrice composition is at least about 20% by weight.

64. A method according to claim 45, wherein the second component further comprises a color indicator.

65. A method according to claim 64, wherein the color indicator is selected from the group consisting of FD&C Red No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Green No. 3, FD&C Blue No. 1 and combinations thereof.

66. A method according to claim 45, wherein either or both of the first or second components further comprise a tooth-desensitizing compound.

67. A method according to claim 66, wherein the tooth-desensitizing compound is a potassium salt of a weak acid or eugenol.

68. A method for decreasing whitening time, increasing whitening effectiveness or decreasing oral irritation in a tooth-whitening process, the method comprising contacting a tooth for an effective tooth-whitening period with a tooth-whitening composition comprising a peroxide compound at a hydrogen-peroxide-equivalent concentration of not greater than about 5% by weight and a peroxide-compatible abrasive compound, said tooth-whitening composition having a pH of at least about 9.0.

69. A method according to claim 68, wherein the tooth-whitening composition comprises the peroxide compound at a concentration of not more than about 3.5% by weight.

70. A method according to claims 68 or 69, wherein the tooth-whitening composition produces a decrease in whitening time, an increase in whitening effectiveness or a decrease in oral irritation or any combination thereof in comparison to a reference composition having a peroxide compound concentration of about 7% by weight or greater and a pH of 7.0 or less.

71. A method according to claims 68 or 69, wherein the tooth-whitening composition is prepared from a dual component system comprising a first component comprising a peroxide compound and a peroxide-compatible abrasive compound and a second component comprising an alkaline compound.

72. A method according to claim 71, wherein the tooth-whitening composition is prepared not more than 15 minutes prior said contacting.

73. A method according to claims 68 or 69, wherein the contacting is for an effective tooth-whitening period which is less than that required for a comparative composition comprising hydrogen peroxide at a concentration of 7% by weight or greater and a pH of 7.0 or less.

74. A method according to claim 73 wherein the effective tooth-whitening period of the tooth-whitening composition is not more than about 20 minutes and that of comparative composition is about 30 minutes or greater.

75. A method according to claims 68 or 69, wherein the peroxide compound is selected from the group consisting of hydrogen peroxide, an organic peroxide compound, a hydrogen peroxide generating compound and combinations thereof.

76. A method according to claims 75, wherein the peroxide compound is an organic peroxide compound selected from the group consisting of urea hydrogen peroxide, glyceryl peroxide, benzoyl peroxide, monoperoxyphthalate and combinations thereof.

77. A method according to claim 75, wherein the peroxide compound is a hydrogen peroxide generating compound selected from the group consisting of sodium persulfate, sodium dipersulfate, sodium percarbonate, sodium perphosphate, sodium perborate, sodium persilicate, potassium persulfate, potassium dipersulfate, potassium percarbonate, potassium perphosphate, potassium perborate, potassium persilicate, calcium persulfate, calcium

dipersulfate, calcium percarbonate, calcium perphosphate, calcium perborate, calcium persilicate, sodium peroxide, potassium peroxide and calcium peroxide and combinations thereof.

78. A method according to claims 68 or 69, wherein the peroxide-compatible abrasive comprises one or more calcium phosphate salts.

79. A method according to claim 78, wherein the one or more calcium phosphate salts comprise calcium pyrophosphate.

80. A method according to claims 68 or 69, wherein the peroxide-compatible abrasive is present in the tooth-whitening composition at a concentration of at least about 10% by weight.

81. A method according to claim 80, wherein the peroxide-compatible abrasive is present in the tooth-whitening composition at a concentration of at least about 20% by weight.

82. A method according to claim 71, wherein the alkaline compound is an alkali metal hydroxide or an alkali metal carbonate salt.

83. A method according to claim 71, wherein the alkaline compound is an alkaline compound selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, calcium hydroxide, magnesium hydroxide, sodium carbonate, potassium carbonate, ammonium carbonate, calcium carbonate, magnesium carbonate,

sodium bicarbonate, potassium bicarbonate, ammonium bicarbonate, calcium bicarbonate, magnesium bicarbonate, urea, monoethanolamine, diethanolamine, triethanolamine, mono(iso)propanolamine, di(iso)propanolamine, tri(iso)propanolamine, 2-amino-2-methylpropanol, 2-amino-2-methyl-1,3-propanediol, 2-amino-2-ethyl-1,3-propanediol, tris(hydroxymethyl)aminomethane, N,N,N',N'-tetrakis(2-hydroxypropyl)ethylenediamine, di(2-ethylhexyl)amine, triamylamine, dodecylamine, morpholine and combinations thereof.

84. A method according to claim 71, wherein the second component of the two component system further comprises a second abrasive compound.

85. A method according to claim 84, wherein the second abrasive comprises a peroxide-incompatible abrasive compound.

86. A method according to claim 85, wherein the peroxide-incompatible abrasive comprises a silica compound or an alumina compound.

87. A method according to claim 84, wherein the second abrasive compound comprises one or more calcium phosphate salts.

88. A method according to claim 87, wherein the one or more calcium phosphate salts comprise calcium pyrophosphate.

89. A method according to claim 84, wherein the tooth-whitening composition has a total concentration of abrasive compounds in the dentifrice composition is at least about 20% by weight.

90. A method according to claim 71, wherein the second component further comprises a color indicator.

91. A method according to claim 90, wherein the color indicator is selected from the group consisting of FD&C Red No. 3, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Green No. 3, FD&C Blue No. 1 and combinations thereof.

92. A method according to claim 71, wherein either or both of the first or second components further comprise a tooth-desensitizing compound.

93. A method according to claim 92, wherein the tooth-desensitizing compound is a potassium salt of a weak acid or eugenol.