BRIGARD& CASTRO
PROPIEDAD INTELECTUAL

Calle 70 A No. 4 – 41
BOGOTÁ – COLOMBIA
TEL: (571) 744 22 00
FAX: (571) 742 22 (
www.bc.com.co

As. 103.030

Señor
DIRECTOR DIVISIÓN DE NUEVAS CREACIONES
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
E. S. D.

REF: Expediente No. **07.007.211**– solicitud de patente de invención a favor de **COLGATE PALMOLIVE-COMPANY.** Título **COMPOSICIONES PARA EL CUIDADO ORAL CON POLÍMEROS FORMADORES DE PELÍCULA.**

JUAN PABLO CADENA SARMIENTO, portador de la tarjeta profesional No. 57.492 del C.S.J., obrando como apoderado de la sociedad solicitante, manifiesto a usted que debidamente notificado de la Resolución No. 15536 notificada del 20 de marzo de 2012, interpongo contra ella en debido término, RECURSO DE REPOSICIÓN, para que sea revocada en su totalidad, y en su lugar se conceda el Privilegio de Patente, para el objeto de la solicitud en referencia

Respaldo el RECURSO en los siguientes

HECHOS:

1. La resolución arriba citada No. 15536 niega el Privilegio exclusivo de Patente de Invención para el objeto de la solicitud de la referencia considerando que el capítulo reivindicatorio carece novedad. Lo anterior, de acuerdo con las siguientes consideraciones:

i. Determinación del Estado de la Técnica

Consultadas las fuentes de información con que se cuenta se encontraron los siguientes documentos, anteriores a la fecha de prioridad invocada y relacionados con la materia de la solicitud en estudio.

BRIGARD& CASTRO
PROPIEDAD INTELECTUAL

Calle 70 A No. 4 – 41
BOGOTÁ – COLOMBIA
TEL: (571) 744 22 00
FAX: (571) 742 22 00
www.bc.com.co

N°	Documento	Título	Fecha de Publicación
D2	US2003235549	Hydrogel compositions demonstrating phase separation on contact with aqueous media	2003-12-25
D3	Solicitud Colombiana 07-1970	Película para cuidado oral	Presentación en oficina Nacional: 2007-01-10 Fecha de prioridad: 2004-06-17

Novedad

Considera el señor Examinador que la presente invención no cumple con el requisito de novedad, ya que las características técnicas esenciales ya se encontraban divulgadas en las anterioridades D2 y D3 y por tanto se

RESUELVE:

ARTÍCULO PRIMERO: Denegar la patente de invención a la creación titulada **COMPOSICIONES PARA EL CUIDADO ORAL CON POLÍMEROS FORMADORES DE PELÍCULA.**

FUNDAMENTOS:

En primer lugar manifestamos que, contrario a lo expresado por el señor Examinador, el estado de la técnica no enseña todas y cada una de las características esenciales de la presente invención. Particularmente la reivindicación 1, única reivindicación independiente de producto, divulga:

Una composición para el cuidado oral que comprende:

(a) un agente blanqueador; y

(b) un polímero acrílico formador de película, en donde dicho polímero acrílico formador de película consta de un copolímero que comprende
una primera unidad monomérica seleccionada del grupo que consiste de ácido acrílico y ácido metácrilico, y
con una segunda unidad monomérica seleccionada del grupo que consiste de acrilatos, acrilamidas, acetatos de vinilo;

en donde el polímero es un terpolímero que comprende una combinación de dichas segundas unidades monoméricas.

BRIGARD& CASTRO
PROPIEDAD INTELECTUAL

Calle 70 A No. 4 – 41
BOGOTÁ – COLOMBIA
TEL: (571) 744 22 00
FAX: (571) 742 22 00
www.bc.com.co

Ahora bien, notamos que el señor Examinador no ha considerado todas características esenciales de la reivindicación 1 en su examen de novedad, concretamente la característica según la cual el polímero es un terpolímero que comprende una combinación de dichas segundas unidades monoméricas.

Los terpolímeros son moléculas completamente diferentes a los polímeros y copolímeros, como se puede apreciar en sus estructuras químicas:

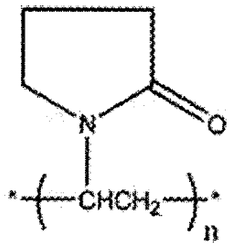

Fig. 1. Polímero, una sola unidad monomérica (n)

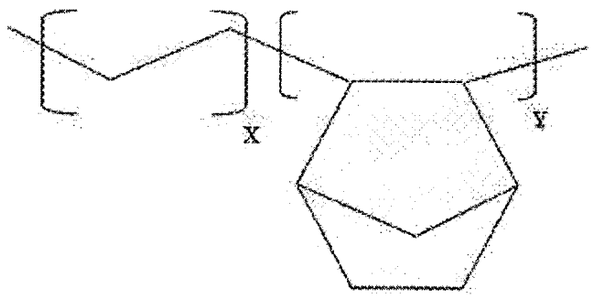

Fig. 2. Copolímero, dos unidades monoméricas (x, y)

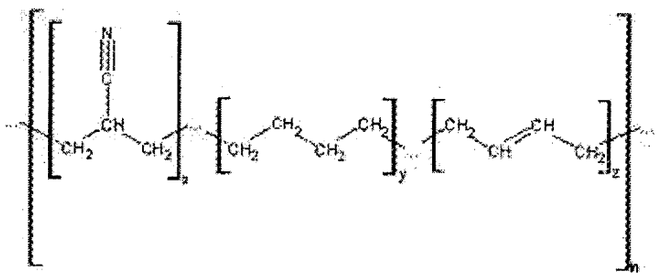

Fig. 3. Terpolímero, tres unidades monoméricas (x, y, z)

Notamos que ninguna de las anterioridades citadas por el señor Examinador en su examen de patentabilidad enseña composiciones que comprenden terpolímeros.

BRIGARD& CASTRO
PROPIEDAD INTELECTUAL

Calle 70 A No. 4 – 41
BOGOTÁ – COLOMBIA
TEL: (571) 744 22 00
FAX: (571) 742 22 00
www.bc.com.co

En efecto la anterioridad **US2003235549** (D2) únicamente enseña polímeros de una unidad monomérica, copolímeros de dos unidades poliméricas, o a lo sumo, combinaciones de dichos polímeros y copolímeros, pero nunca enseña un terpolímero. Para demostrar lo anterior, nos referimos a los ejemplos 10 y 11 de D2, citados por el señor Examinador en su análisis de novedad.

Dichos ejemplos contienen los siguientes elementos:

- Eudragit L 100-55, nombre comercial de un copolímero que comprende dos monómeros: ácido metacrílico y acrilato de etilo;
- PVP 30, PVP 90, polímeros también conocido como polivinilpirrolidona, formado por un solo monómero: vinilpirrolidonas (el PVP 30 y el PVP 90 difieren en su peso molecular);
- Agua;
- Etanol;
- PEG, también conocido como polietilenglicol un polímero de una única unidad monomérica: óxido de etileno;
- Eudragit RL 100, nombre comercial de un copolimero que comprende dos monómeros: acrilato de etilo y metacrilato de metilo:
- Citrato de sodio; y
- Peróxido de hidrógeno

Claramente ninguno de los elementos anteriormente mencionados es un terpolímero, como se requiere en la reivindicación 1 de la presente solicitud. Esta observación también resulta clara de las reivindicaciones de D2 en donde se reclaman exclusivamente polímeros (una unidad) y copolímeros (dos unidades) caracterizados a partir de sus unidades monoméricas específicas.

Sin embargo, afirma el señor Examinador que el estado de la técnica, representado por D2, enseña películas poliméricas que comprenden un primer polímero y un segundo polímero "*los cuales combinados proveen un polímero (terpolimero)* (sic) *formador de película*". Al respecto es necesario mencionar que los polímeros, incluyendo los terpolímeros, se forman por el proceso químico de la polimerización, el cual involucra reacciones químicas.

En este orden de ideas el Examinador está completamente equivocado al afirmar que durante la mezcla de ingredientes de una composición oral se produce un nuevo polímero por la simple combinación de elementos. Los terpolímeros requieren la agrupación química de los monómeros que lo constituyen, bajo condiciones altamente específicas que de ninguna manera se obtendrían al preparar la composición oral de D2.

BRIGARD& CASTRO
PROPIEDAD INTELECTUAL

Calle 70 A No. 4 – 41
BOGOTÁ – COLOMBIA
TEL: (571) 744 22 00
FAX: (571) 742 22 00
www.bc.com.co

En conclusión, el documento D2 enseña composiciones que, a lo sumo, contienen un polímero (una sola unidad monomérica), un copolímero (dos unidades monoméricas) y un agente blanqueador, lo que es sustancialmente diferente de las composiciones reivindicadas en la presente solicitud: un terpolímero (tres unidades monoméricas en la misma molécula) y un agente blanqueador. Por lo tanto, D2 no enseña todas y cada una de las características esenciales de las composiciones de la presente solicitud y no afecta la novedad de la misma.

Por otra parte, evalúa el señor Examinador la novedad de la reivindicación dependiente 2 en vista del documento 07-1970 (D3) y considera que no es novedosa en vista de las enseñanzas contenidas en la dicha anterioridad.

Hacemos notar que al igual que el documento D2, la publicación D3 no revela la presencia de terpolímeros en sus composiciones. De hecho, el análisis presentado anteriormente se aplica en su totalidad a las composiciones de D3. Para demostrar lo anterior, nos permitimos analizar cada uno de los ingredientes presentes en el ejemplo 1 de D3, referenciado por el señor Examinador, a continuación:

La composición del ejemplo 1 de D1 comprende:

- Etanol;
- Etilacetato;
- Agua
- Copolímero PVP/VA, el cual comprende dos unidades monoméricas: polivinilpirrolidona y vinil acetato;
- Polivinilpirrolidona, polímero de una sola unidad monomérica;
- Óxido de polietileno;
- PEG 600, también conocido como polietilenglicol un polímero de una única unidad monomérica: óxido de etileno;
- Colofonia, resina natural;
- Almáciga, resina natural;
- Goma laca, resina natural;
- Hidroxiapatita;
- PVP-H_2O_2, polivinilpirrolidona con peróxido de hidrogeno;
- Percarbonato de sodio;
- Sacarina de sodio.

BRIGARD& CASTRO
PROPIEDAD INTELECTUAL

Calle 70 A No. 4 – 41
BOGOTÁ – COLOMBIA
TEL: (571) 744 22 00
FAX: (571) 742 22 00
www.bc.com.co

Es claro entonces, que D3 no divulga composiciones orales que comprenden un terpolímero como se requiere en las reivindicaciones de la presente invención, razón por la cual dicha anterioridad no afecta la novedad de la presente solicitud.

Por otra parte, notamos que su despacho ha llevado a cabo un examen de novedad sobre la reivindicación **dependiente** 2. Al respecto, deseamos resaltar que el examen de novedad debe realizarse sobre las reivindicaciones independientes ya que estas son las que contienen las **características esenciales** de la invención.

No obstante lo anterior, habiendo demostrado la novedad de la reivindicación 1, la reivindicación 2 y demás dependientes, en virtud de su dependencia de la reivindicación 1, también son novedosas.

Dice su Despacho que una persone versada en la materia podrá a través de experimentación de rutina seleccionar adecuados monómeros hidrofilicos e hidrófobos con una relación de peso adecuado (... para proveer una sustancia activa para cuidado oral.

Respecto a esta afirmación del señor examinador consideramos que si todo es experimentación de rutina simplemente ningún compuesto químico o composición sería novedoso e inventivo ya que según su Despacho todo sería experimentación de rutina lo cual consideramos una posición sumamente arbitraria de su Despacho.

Cabe anotar que el señor examinador es quien debe probar con base en las enseñanzas del estado de la técnica que la invención es o no obvia. El examinador debe analizar si el estado de la técnica induce al versado en la materia a realizar la invención sin que hubiese requerido de su parte investigación alguna (ver instructivo de patentes, pág. 71). Es más dicha persona versada en la materia no es especializada, simplemente tiene los conocimientos medios en la materia.

De acuerdo a lo anterior, no es simplemente llevar a cabo experimentación de rutina como lo sugiere su Despacho. El examinador simplemente falla en su análisis.

En conclusión, el estado de la técnica citado no revela de forma idéntica todas y cada una de las características de la invención tal como lo requiere un examen minucioso de novedad y como se establece en el instructivo de examen de solicitudes de patente en su página 62.

BRIGARD& CASTRO
PROPIEDAD INTELECTUAL

Calle 70 A No. 4 – 41
BOGOTÁ – COLOMBIA
TEL: (571) 744 22 00
FAX: (571) 742 22 00
www.bc.com.co

Finalmente, teniendo en cuenta la autonomía con que cuenta su Despacho para el estudio de solicitudes de patente, deseamos resaltar que la oficina Europea de patentes concedió la respectiva patente a la solicitud equivalente Europea.

Cabe anotar que en el estudio de novedad y nivel inventivo, el examinador europeo tuvo en cuenta el documento citado por su despacho **US 2003/0235549**. Adjuntamos copia de la primera página de dicho reporte para claridad del señor Examinador. Así mismo, adjuntamos copia de la Decisión de conceder la patente Europea para referencia de su Despacho así como copia de la patente concedida.

Por otra parte deseamos resaltar lo que establece la legislación Europea respecto a la novedad de una invención según el artículo 54 de su legislación:

> *"Una invención se considerará novedosa si no hace parte del estado de la técnica"*
>
> *"El estado de la técnica comprende todo lo que se ha puesto a disposición del público por medio escrito u oral, uso o cualquier otro medio antes de la fecha de presentación de la solicitud europea".*

Puede notar el señor Examinador que el concepto de novedad es similar sino idéntico al establecido en la Decisión 486.

Lo anterior, solamente para resaltar que se reconoció novedad para la invención en vista del mismo documento citado por el señor Examinador, razón por la cual la decisión del señor Examinador no puede apartarse drásticamente del concepto de otras oficinas reconocidas a nivel mundial y donde los conceptos de patentabilidad son realizados por profesionales igualmente idóneos en el examen de solicitudes de patente.

PETICION

Por las razones anteriormente expuestas, solicito a ese despacho REVOCAR la decisión tomada mediante la Resolución No. 15536 notificada del 20 de marzo de 2012, y tendiente a obtener la concesión del Privilegio de Patente de conformidad con los artículos 14 y 48 de la Decisión 486 de la comunidad Andina.

BRIGARD& CASTRO
PROPIEDAD INTELECTUAL

Calle 70 A No. 4 – 41
BOGOTÁ – COLOMBIA
TEL: (571) 744 22 00
FAX: (571) 742 22 00
www.bc.com.co

NOTIFICACIONES

Recibiré notificaciones en la Secretaria General de la Superintendencia de Industria y Comercio, o en su defecto, en mi Oficina de Abogado, situada en la Calle 70A No. 4-41 de esta ciudad de Bogotá.

Del Señor Director

JUAN PABLO CADENA SARMIENTO
T.P. No. 57.492 del C.S.J.
C.C. 80.410.337 de Usaquén
Calle 70 A No. 4 - 41

DILIGENCIA DE PRESENTACIÓN PERSONAL

El anterior escrito dirigido a: Superintendencia de Industria y Comercio

fue presentado personalmente por su signatario Cadena Sarmiento Juan Pablo

quien se identificó con C.C. No: 80410774

de Usaquén-1057492

en la Notaría Cuarenta del Círculo de Bogotá D.C.,

hoy 17 ABR. 2012

EL NOTARIO CUARENTA DE BOGOTÁ D.C.

AGUSTÍN CASTILLO BARATE

NOTARIO

40

BOGOTÁ

EPA/EPO/OEB
D-80298 München
+49 89 2399-0
TX 523 656 epmu d
FAX +49 89 2399-4465

Europäisches Patentamt
Generaldirektion 2

European Patent Office
Directorate General 2

Office européen des brevets
Direction Générale 2

Telephone numbers:
Primary Examiner (substantive examination) +49 89 2399-8442
Formalities Officer / Assistant (Formalities and other matters) +49 89 2399-7736

Jenkins, Peter David
Page White & Farrer
Bedford House
John Street
London, WC1N 2BF
ROYAUME-UNI

Application No.	Ref.	Date
05 774 938.4 - 2108	314046EP/PDJ	04.05.2007
Applicant: Colgate-Palmolive Company		

Communication pursuant to Article 96(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 36(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).

Europäisches Patentamt • European Patent Office • Office européen des brevets

Diebold, Alain
Primary Examiner
for the Examining Division

Enclosure(s): 4 page/s reasons (Form 2906)

En la Notaría Cuarenta de este Círculo se cotejó la presente fotocopia que coincide con el original que me fue tenido a la vista.
17 ABR. 2012
NOTARIO CUARENTA
Bogotá, D.C., Colombia
Agustín Castillo Zárate

Registered Letter
EPO Form 2001 07.02CSX

Bescheid/Protokoll (Anlage)	Communication/Minutes (Annex)	Notification/Procès-verbal (Annexe)
Datum Date Date 04.05.2007	Blatt Sheet Feuille 1	Anmelde-Nr.: Application No.: Demande n°: 05 774 938.4

The examination is being carried out on the **following application documents**:

Description, Pages

1-48 as published

Claims, Numbers

1-35 as published

****

1) An International Preliminary Report on Patentability has already been drawn up for the present application in accordance with the PCT. The deficiencies mentioned in that report give rise to the following objections under the corresponding provisions of the EPC.

2) The following documents D1-D4 from the international search report are referred to in this communication. The numbering will be adhered to in the rest of the procedure:

D1 = US-A-2003/0152528
D2 = US-A-2003/0235549
D3 = US-A-4,032,627
D4 = WO-A-2004/071323

3) The present application does not meet the requirements of Article 52(1) EPC, because the subject-matter of the present independent claims 1, 18 and 26 is not new in the sense of Article 54(1) and (2) EPC, the reasons being as follows:

Documents D1 and D2 pertain to hydrogel compositions for tooth whitening comprising a water-swellable, water-insoluble polymer, a hydrophilic polymer, and a whitening agent, preferably a peroxide (see relevant passages in the international search report). These tooth whitening dental care products form a film when dry. The water-swellable, water-insoluble polymer is an acrylate-based polymer or copolymer (formed from acrylic acid, methacrylic acid, methyl acrylate, ethyl acrylate, methyl

11

Europäisches Patentamt
European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY
Tel. +49 (0)89 2399 - 0
Fax +49 (0)89 2399 - 4465

For any questions about this communication:
Tel.:+31 (0)70 340 45 00

Jenkins, Peter David
Page White & Farrer
Bedford House
John Street
London WC1N 2BF
ROYAUME UNI

Date
28.07.11

Reference	Application No./Patent No.
314046EP/PDJ	05774938.4 - 2108 / 1771227
Applicant/Proprietor	
Colgate-Palmolive Company	

Decision to grant a European patent pursuant to Article 97(1) EPC

Following examination of European patent application No. 05774938.4 a European patent with the title and the supporting documents indicated in the communication pursuant to Rule 71(3) EPC dated 14.03.11 is hereby granted in respect of the designated Contracting States.

Patent No. : 1771227
Date of filing : 21.07.05
Priority claimed : 29.07.04/USA 902720

Designated Contracting States and Proprietor(s) : AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR
Colgate-Palmolive Company
300 Park Avenue
New York NY 10022-7499/US

This decision will take effect on the date on which the European Patent Bulletin mentions the grant (Art. 97(3) EPC).

The mention of the grant will be published in European Patent Bulletin 11[illegible]4 of 24.08.11.

Examining Division

Diebold A Irwin L [illegible]

Europäisches Patentamt • European Patent Office • Office européen des brevets

En la Notaría Cuarenta de este Círculo se cotejó la presente fotocopia que corresponde con el original que se me mostró a la vista.
17 ABR. 2012
NOTARIO CUARENTA
Bogotá, D.C. Colombia
Agustín Castillo Zárate

Registered letter
EPO Form 2006A 12.07 (21/07/11)

to EPO postal service: 22.07.11

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 771 227 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
24.08.2011 Bulletin 2011/34

(21) Application number: **05774938.4**

(22) Date of filing: **21.07.2005**

(51) Int Cl.:
A61Q 11/00 *(2006.01)* ***A61K 8/02*** *(2006.01)*
A61K 8/22 *(2006.01)* ***A61K 8/34*** *(2006.01)*
A61K 8/38 *(2006.01)* ***A61K 8/81*** *(2006.01)*

(86) International application number:
PCT/US2005/025866

(87) International publication number:
WO 2006/014775 (09.02.2006 Gazette 2006/06)

(54) **ORAL CARE COMPOSITIONS WITH FILM FORMING POLYMERS**

MUNDPFLEGEZUSAMMENSETZUNGEN MIT FILMBILDENDEN POLYMEREN

COMPOSITIONS POUR SOINS BUCCAUX À BASE DE POLYMÈRES FILMOGÈNES

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR

(30) Priority: **29.07.2004 US 902720**

(43) Date of publication of application:
11.04.2007 Bulletin 2007/15

(73) Proprietor: **Colgate-Palmolive Company**
New York NY 10022-7499 (US)

(72) Inventors:
- **MAITRA, Prithwiraj**
  Morristown, NJ 07960 (US)
- **ZAIDEL, Lynette**
  Cranford, NJ 07016 (US)
- **CHOPRA, Suman**
  Monroe, NJ 08831 (US)
- **PAN, Guisheng**
  Philadelphia, PA 19114 (US)
- **PRENCIPE, Michael**
  West Windsor, NJ 08550 (US)
- **IBRAHIM, Sayed**
  Somerset, NJ 00873 (US)

(74) Representative: **Jenkins, Peter David et al**
Page White & Farrer
Bedford House
John Street
London WC1N 2BF (GB)

(56) References cited:
WO-A-2004/071323 **WO-A-2004/103328**
US-A- 4 032 627 **US-A1- 2003 152 528**
US-A1- 2003 235 549

Printed by Jouve, 75001 PARIS (FR)

EP 1 771 227 B1

Description

INTRODUCTION

[0001] The present invention relates to oral care compositions comprising certain polymers. Embodiments of the present invention include compositions comprising film forming polymers, and methods for whitening teeth using such compositions.

[0002] 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.

[0003] A tooth is comprised of an inner dentin layer and an outer hard enamel layer that is the protective layer of the tooth. The enamel layer of a tooth is naturally opaque, and white or a slightly off-white color. The enamel layer is composed of hydroxyapatite mineral crystals that create a somewhat porous surface. These hydroxyapatite crystals form microscopic hexagonal rods or prisms that make up the enamel surface. As a result, the surface of the enamel presents microscopic spaces or pores between the prisms. Without limiting the composition, mechanism, or utility of present invention, it is believed that this porous nature of the enamel is where discoloring substances permeate the enamel and discolor the teeth.

[0004] 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 most commonly accepted chemicals used in teeth whitening today are peroxides. Peroxides are generally deemed safe from a physiological standpoint, and can be effective to whiten teeth. Such peroxides include hydrogen peroxide, carbamide peroxide, sodium perborate, and sodium percarbonate. When these peroxides are in appropriate contact with teeth they will usually oxidize stains, rendering the teeth whiter.

[0005] Many professional dental treatments include a tooth surface preparation step, 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. (See, e.g., U.S. Patents 5,425,953 and 5,766,574.) These procedures provide rapid results, but are expensive and often require several trips to the dentist. In many treatments, the patient's lips are uncomfortably retracted and the patient is confined to sitting in the dental chair.

[0006] 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 used while performing other personal tasks or errands, relaxing or sleeping

[0007] Current home treatment methods include abrasive toothpastes, toothpastes that produce oxides, whitening gels for use with a dental tray and whitening strips. The effectiveness of such techniques depends on a variety of factors including the type and intensity of the stain, bleaching agent contact time on the teeth, the amount of available bleaching active in the composition, and consumer compliance. Effectiveness is also dependant on the amount of bleaching active in the composition, the ability of the active to be released during use, and the stability of the active in the product. However, the effectiveness of many of these treatments is adversely affected because of deficiencies in one or more factors relating to the composition and consumer compliance.

[0008] US-A-2003/0152528 discloses hydrogel compositions for tooth whitening which contain polymers.
US-A-2003-0235549 discloses hydrogel compositions demonstrating phase separation on contact with saliva which contain polymers.
US-A-4032627 discloses tooth whitening cosmetic compositions.

SUMMARY

[0009] The present invention provides an oral care composition according to claim 1.
The present invention further provides a non-therapeutic method of delivering an oral care active according to claim 12.

[0010] It has been discovered that compositions and methods of this invention afford advantages over oral care compositions among those known in the art. Such compositions comprising a whitening active may exhibit one or more of such benefits, including enhanced whitening efficacy, providing a higher available concentration of bleaching agent, tooth adherence in the presence of saliva without the use of a dental tray and release of the bleaching agent over a

period of time. Further uses, benefits and embodiments of the present invention are apparent from the description set forth herein.

DESCRIPTION

[0011] The following definitions and non-limiting guidelines must be considered in reviewing the description of this invention set forth herein. The headings (such as "Introduction" and "Summary,") and sub-headings (such as "Compositions" and "Methods") used herein are intended only for general organization of topics within the disclosure of the invention, and are not intended to limit the disclosure of the invention or any aspect thereof. In particular, subject matter disclosed in the "Introduction" may include aspects of technology within the scope of the invention, and may not constitute a recitation of prior art. Subject matter disclosed in the "Summary" is not an exhaustive or complete disclosure of the entire scope of the invention or any embodiments thereof. Classification or discussion of a material within a section of this specification as having a particular utility (e.g., as being an "active" or a "carrier" ingredient) is made for convenience, and no inference should be drawn that the material must necessarily or solely function in accordance with its classification herein when it is used in any given composition.

[0012] The citation of references herein does not constitute an admission that those references are prior art or have any relevance to the patentability of the invention disclosed herein. Any discussion of the content of references cited in the Introduction is intended merely to provide a general summary of assertions made by the authors of the references, and does not constitute an admission as to the accuracy of the content of such references.

[0013] The description and specific examples, while indicating embodiments of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention. Moreover, recitation of multiple embodiments having stated features is not intended to exclude other embodiments having additional features, or other embodiments incorporating different combinations the stated of features. Specific Examples are provided for illustrative purposes of how to make and use the compositions and methods of this invention and, unless explicitly stated otherwise, are not intended to be a representation that given embodiments of this invention have, or have not, been made or tested.

[0014] As used herein, the words "preferred" and "preferably" refer to embodiments of the invention that afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the invention.

[0015] As used herein, the word 'include," and its variants, is intended to be non-limiting, such that recitation of items in a list is not to the exclusion of other like items that may also be useful in the materials, compositions, devices, and methods of this invention.

[0016] As referred to herein, all compositional percentages are by weight of the total composition, unless otherwise specified.

Compositions

[0017] The present invention provides oral care compositions and methods for administration or application to, or use with, a human or other animal subject. As referred to herein, an "oral care composition" is any composition that is suitable for administration or application to the oral cavity a human or animal subject for enhancing the health, hygiene or appearance of the subject, preferably providing such benefits as the prevention or treatment of a condition or disorder of the teeth, gums, mucosa or other hard or soft tissue of the oral cavity; the prevention or treatment of a systemic condition or disorder; the provision of sensory, decorative or cosmetic benefits; and combinations thereof. In various preferred embodiments, an oral care composition is not intentionally swallowed, but is rather retained in the oral cavity for a time sufficient to effect the intended utility. Preferably, specific materials and compositions to be used in this invention are pharmaceutically- or cosmetically-acceptable. As used herein, such a "pharmaceutically acceptable" or "cosmetically acceptable" component is one that is suitable for use with humans and/or animals to provide the desired therapeutic, prophylactic, sensory, decorative, or cosmetic benefit without undue adverse side effects (such as toxicity, irritation, or allergic response) commensurate with a reasonable benefit/risk ratio.

[0018] The present invention provides oral care compositions comprising:

a) an oral care active; and
b) an acrylic film forming polymer.

Acrylic Polymer:

[0019] The compositions of the resent invention comprise an acrylic film forming polymer. Such polymers are terpolymers which comprise monomeric units selected from the group consisting of acrylic acid, methacrylic acid, acrylates,

and combinations thereof, and are operable to form a film, preferably when cast on a substrate from a solution. The compositions of the present invention comprise an acrylic copolymer of a first monomeric unit selected from the group consisting of acrylic acid and methacrylic acid a second monomeric unit selected from the group consisting of acrylates, acrylamides and vinyl acetates, wherein the polymer is a terpolymer comprising a combination of said second monomeric units.

[0020] Second monomeric units include acrylates, acrylamides and vinyl acetates. Acrylates include isobutyl acrylate, tert-butyl acrylate, 2-ethylhexyl acrylate, lauryl acrylate, lauryl/tridecyl acrylate, cetyl acrylate, stearyl acrylate, cyclohexyl acrylate, benzyl acrylate, isobornyl acrylate, 2- methoxyethyl acrylate, 2-ethoxyethyl acrylate, 2-ethoxyethoxyethyl acrylate, 2- phenoxyethyl acrylate, tetrahydrofurfuryl acrylate, 2-hydroxyethyl acrylate, 2-hydroxypropyl acrylate, 4-hydroxybutyl acrylate, dimethylaminoethyl acrylate, and 1,4-butanediol acrylate. Diacrylates include the diacrylates of: 1,4-butanediol, 1,6-hexanediol, tetraethylene glycol, tripropylene glycol, and ethoxylated bisphenol-A. Triacrylate monomers include those of: trimethylol propane, ethoxylated, glyceryl propoxy, and pentaerythritol.

[0021] Acrylates further include methacrylates such as methyl methacrylate, ethyl methacrylate, n-butyl methacrylate, isobutyl methacrylate, tert-butyl methacrylate, 2-ethylhexyl methacrylate, lauryl methacrylate, alkyl methacrylate, tridecyl methacrylate, stearyl methacrylate, cyclohexyl methacrylate, benzyl methacrylate, isobornyl methacrylate. 2-hydroxyethyl methacrylate, 2-hydroxypropyl methacrylate, dimethylaminoethyl methacrylate, diethylaminoethyl methacrylate, glycidyl methacrylate, tetrahydrofurfuryl methacrylate, allyl methacrylate, ethylene glycol methacrylate, triethylene glycol methacrylate, tetraethylene glycol methacrylate, 1,3-butyleneglycol methacrylate, 1,6-hexanediol methacrylate, trimethylopropane methacrylate, ethoxyethyl methacrylate and trifluoroethyl methacrylate. Additional preferred second monomeric units include ethyl acrylate, butyl acrylate, N-tertbutyl acrylamide, hydroxyethyl methacrylate, and combinations thereof.

[0022] Acrylamides includes, but are not limited to, acrylamide, methacrylamide and di(C_1 - C_{30}) alkyl -acrylamides and -methacrylamides such as those of methyl, ethyl, propyl, butyl, pentyl, and hexyl. N-substituted acrylamides that are also suitable include N-ethylacrylamide, N-tert-butylacrylamide, N-tert-octylacrylamide, N-octylacrylamide, N-decylacrylamide, N-dodecylacrylamide and the corresponding N-substituted methacrylamides. Other N-substituted acrylamides include N-hydroxymethyl acrylamide, N-isopropylacrylamide, N- methylacrylamide, N,N'-methylenebisacrylamide, N-isobutoxymethylacrylamide, N,N-dimethylacrylamide and 2-acrylamido-2-methylpropanesulfonic acid.

[0023] Acetates include vinyl acetate.

[0024] In the oral care composition, the polymer is a terpolymer. The terpolymer first comprises a monomeric unit, two different second monomeric units. A preferred terpolymer is the terpolymer of N-tert-butyl acrylamide, ethyl acrylate and acrylic acid (Ultrahold Strong®, marketed by BASF, Mount Olive, New Jersey, USA).

[0025] One embodiment comprises ethyl acrylate, t-butyl acrylate and methacrylic acid. Such a polymer is commercially available as Luvimer®, marketed by BASF, Mount Olive, New Jersey, USA.

[0026] Preferably, the polymer carrier is alcohol soluble, substantially water insoluble, substantive to the teeth or other surfaces of the oral cavity, and stable to the active material (e.g., peroxide). Preferably such compositions do not exhibit adverse aesthetic effects, such as with respect to taste and mouthfeel (e.g., do not exhibit stickiness to surfaces other than those to which they are applied, or unpleasant texture). Without limiting the composition, method or utility of the present invention, it is believed in various embodiments the polymer have the characteristics of providing a film that is secured against the dental surface. Such embodiments comprise:

a) an active material; and
b) a polymer comprising a hydrophobic moiety and a calcium complexation moiety.

[0027] Preferably, the calcium complexation moiety comprises a monomeric unit selected from the group consisting of acrylic acid and methacrylic acid, including first monomeric units as discussed above. Preferably, the hydrophobic moiety comprises a monomeric unit selected from the group consisting of acrylates, acrylamides and vinyl acetates, including second monomeric units as discussed above. In such an embodiment, the polymer induces additional interaction with the teeth enamel by complexation with Ca^{2+} components of teeth, such as hydroxyapatite. The complexing provides increased adhesion of the polymer with the teeth and this adhesion affords controlled release of peroxide compound from the composition. The hydrophobic moiety induces resistance of the polymer to removal from the teeth by saliva.

[0028] Oral care compositions of this invention comprise from 0.2% to 60% of the polymer. In a most preferred embodiment, the polymer comprises from 10% to 30% of the oral care composition.

Active Materials:

[0029] The compositions of the present invention comprise a whitening agent and optionally an active material, 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. In various embodiments, the active

is a "systemic active" which is operable to treat or prevent a disorder which, in whole or in part, is not a disorder of the oral cavity. In various embodiments, the active is an "oral care active" operable to treat or prevent a disorder or provide a cosmetic benefit within the oral cavity (e.g., to the teeth, gingival or other hard or soft tissue of the oral cavity). Oral care actives among those useful herein include anticaries agents, tartar control agents, antiplaque agents, periodontal actives, abrasives, breath freshening agents, malodor control agents, tooth desensitizers, salivary stimulants, and combinations thereof. It is understood that while general attributes of each of the above categories of actives may differ, there may some common attributes and any given material may serve multiple purposes within two or more of such categories of actives. Preferably, such actives are selected for compatibility with the peroxide complex, peroxide compound, and with other ingredients of the composition. Actives among those useful herein are disclosed in U.S. Patent Publication 2003/0206874, Doyle et al., published November 6, 2003; U.S. Patent 6,290, 933, Durga et al., issued September 18, 2001; and U.S. Patent 6,685,921, Lawlor, issued February 3, 2004.

[0030] Actives useful herein are optionally present in the compositions of the present invention in safe and effective amounts. A "safe and effective" amount of an active is an amount that is sufficient to have the desired therapeutic or prophylactic effect in the human or lower animal subject to whom the active is administered, without undue adverse side effects (such as toxicity, irritation, or allergic response), commensurate with a reasonable benefit/risk ratio when used in the manner of this invention. The specific safe and effective amount of the active will vary with such factors as the particular condition being treated, the physical condition of the subject, the nature of concurrent therapy (if any), the specific active used, the specific dosage form, the carrier employed, and the desired dosage regimen.

[0031] The compositions of the present invention comprise a whitening agent. As further discussed below, a "whitening agent" is a material which is effective to effect whitening of a tooth surface to which it is applied. In various embodiments, the compositions of this invention comprise a peroxide whitening agent, comprising a peroxide compound. As referred to herein, a "peroxide compound" is an oxidizing compound comprising a bivalent oxygen-oxygen group. Peroxide compounds include peroxides and hydroperoxides, such as 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 carbamide peroxide (also known as urea hydrogen 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 persulfate, dipersulfate, percarbonate, perphosphate, perborate and persilicate salts of alkali and alkaline earth metals such as lithium, potassium, sodium, magnesium, calcium and barium, and mixtures thereof. In various embodiments, the peroxide compound comprises hydrogen peroxide, urea peroxide, sodium percarbonate and mixtures thereof. In one embodiment, the peroxide compound comprises hydrogen peroxide. In one embodiment, the peroxide compound consists essentially of hydrogen peroxide. The peroxide compound comprises from 0.1% to 50%, optionally from 1% to 40%, optionally from 10% to 30% of the oral care composition.

[0032] In one embodiment, the peroxide compound is part of a peroxide composite. In one embodiment, the composite comprises an N-vinyl heterocyclic polymer. Such embodiments of this invention comprise:

a) a peroxide composite comprising hydrogen peroxide and an N-vinyl heterocyclic polymer;
b) an acrylic polymer as defined in claim 1 ; and
c) an orally acceptable non-aqueous carrier.

[0033] In one embodiment, the particulates comprise an N-vinyl heterocyclic polymer which is derived from a N-vinyl heterocyclic vinyl monomer, preferably comprising, N-vinyl heterocyclic monomer having from 3 to 7 atoms in a heterocyclic ring, including a carbonyl carbon atom and a nitrogen heteroatom containing a vinyl group. Preferably the ring contains 5 or 6 atoms, comprises heteroatoms such as sulfur or oxygen, and may be substituted or unsubstituted.

[0034] Certain embodiments of such polymers are the polymers of specific N-vinyl heterocyclic monomers such as N-vinyl imides to form poly-N-vinyl polyimides, and N-vinyl lactams to form poly-N-vinyl polylactams, and mixtures thereof. Suitable N-vinyl imides include: N-vinyl malonimide; N-vinyl succinimide; N-vinyl glutarimide; N-vinyl naphthalimide; N-vinyl β-methylglutarimide; N-vinyl α amylsuccinimide; and N-vinyl adipimide.

[0035] Suitable N-vinyl lactams include: N-vinyl piperidone; N-vinyl caprolactam; N-vinyl-3-methyl pyrrolidinone, piperidone, or caprolactam; N-vinyl-4-methyl pyrrolidinone, or piperidone or caprolactam; N-vinyl-5-methyl pyrrolidinone or piperidone; N-vinyl-3-ethyl pyrrolidinone; N-vinyl-4,5-dimethyl pyrrolidinone; N-vinyl-5,5-dimethyl pyrrolidinone; N-vinyl-3,3,5-trimethyl pyrrolidinone; N-vinyl-5-methyl-5-ethyl pyrrolidinone; N-vinyl-3,4,5-trimethyl-3-ethyl pyrrolidinone; N-vinyl-6-methyl-2-piperidone; N-vinyl-6-ethyl-2-piperidone; N-vinyl-3,5-dimethyl-2-piperidone; N-vinyl-4,4-dimethyl-2-piperidone; N-vinyl-7-methyl caprolactam; N-vinyl-7-ethyl caprolactam; N-vinyl-3,5-dimethyl caprolactam; N-vinyl-4,6-dimethyl caprolactam; N-vinyl-3,5,7-trimethyl caprolactam.

[0036] Embodiments containing poly-N-vinyl polylactams, include but are not limited to poly-N-vinyl pyrrolidone, poly-

N-vinyl-2-piperidone, poly-N-vinyl-2-caprolactam, poly-N-vinyl-3-methyl-2-caprolacam, poly-N-vinyl-3-methyl-2-piperidone, poly-N-vinyl-4-methyl-2-piperidone, poly-N-vinyl-4-methyl-2-caprolactam, poly-N-vinyl-3-ethyl-2-pyrrolidone, poly-N-vinyl-4,5-dimethyl-2-pyrrolidone and mixtures thereof. Preferably, the polymer is selected from the group consisting of poly-N-vinyl poly-2-pyrrolidone, poly-N-vinyl-poly-2-piperidone, poly-N-vinyl-poly-2-caprolactam and mixtures thereof.

[0037] In a preferred embodiment, the polymer is poly-N-vinyl-poly-2-pyrrolidone. The poly-N-vinyl-poly-2-pyrrolidone is also commonly known as polyvinylpyrrolidone or "PVP". PVP refers to a polymer containing vinylpyrrolidone (also referred to as N-vinylpyrrolidone, N-vinyl-2-pyrrolidione and N-vinyl-2-pyrrolidinone) as a monomeric unit. The monomeric unit consists of a polar imide group, four non-polar methylene groups and a non-polar methane group. The polymers include soluble and insoluble homopolymeric PVPs. Copolymers containing PVP include vinylpyrrolidone/vinyl acetate (also known as Copolyvidone, Copolyvidonum or VP-VAc) and vinylpyrrolidone/dimethylamino-ethylmethacrylate.

[0038] Soluble PVP polymers among those useful herein are known in the art, including Povidone, Polyvidone, Polyvidonum, poly (N-vinyl-2-pyrrolidinone), poly (N-vinylbutyrolactam), poly(1-vinyl-2-pyrrolidone) and poly [1-(2-oxo-lpyrrolidinyl)ethylene]. These PVP polymers are not substantially cross-linked.

[0039] In various embodiments of this invention, an insoluble cross-linked homopolymer is preferred. Such polymers include those common referred to in the art as polyvinylpolypyrrolidone, cross-povidone, PVP and cPVP, and are referred to herein as "cPVP". The homopolymer is prepared by free radical polymerization of the monomer vinylpyrrolidone.

[0040] In one embodiment, the poly-N-vinyl-poly-2-pyrrolidone has a lactam of the pyrrolidone ring that provides the hydrophilic characteristics. Without limiting the composition, mechanism or utility of the invention, it is believed that such groups allow the peroxide compound to bind to the cPVP. The hydrophobic characteristics attributed to the methylene groups in the ring and the linear aliphatic backbone prevent the peroxide complex from reacting with saliva while still maintaining the peroxide available to whiten the teeth. The surface characteristics of the cPVP serve as a barrier to the passage of the peroxide component and prevents the premature distribution of the peroxide component upon application of the oral care composition in the oral cavity. The cPVP linked peroxide is released over a period of time through diffusion, temperature variance, moisture levels and other factors.

[0041] The cPVP is a white or slightly yellow hygroscopic powder. As used herein, "hygroscopic" refers to the property of readily absorbing moisture. In various embodiments, the polymer has a moisture absorption of from about 10% to about 40% by weight of the peroxide compound.

[0042] cPVP is particularly suitable for trapping a peroxide to form a peroxide polymer composite. Without limiting the composition, mechanism or utility of the present invention, it is believed in various embodiments that the surface characteristics of the cross-linked polymer serves as a barrier to the passage of the peroxide and prevents the premature distribution of the peroxide upon application of the oral care composition to the oral cavity, while maintaining the peroxide available to whiten the teeth.. The cPVP linked peroxide is released over a period of time through diffusion, temperature variance, moisture levels and other factors. This provides a significant advantage over other oral whitening compositions.

[0043] The polymer particulates useful herein are made by well established processes. The poly-N-vinyl polylactams are produced by polymerizing a vinyl lactam in the presence of an alkaline catalyst. *(See* U.S. Patents 2,938,017, Grosser, et al, issued May 24, 1960; 3,277,066, Grosser, et al, issued October 4, 1966 and 3,306,886, Grosser, et al, issued February 28, 1967). Embodiments containing poly-N-vinyl polyimides are produced by heating an N-vinyl imide in the presence of a catalyst. *(See* U.S. Patent No. 3,306,881, Grosser, et al, issued February 28, 1967). In alternative embodiments comprising a co-polymer of the N-vinyl heterocyclic compound is produced by polymerizing N-vinyl heterocyclic and dissimilar vinyl monomers. *(See* U.S. Patent Nos. 2,667,473, Momer, et al, issued January 26, 1954; and 2,947,633, Perry et al, issued August 2, 1960).

[0044] Porous cross-linked polymers among those useful herein include those commercially available as: Luvicross®, Kollidon® CL, Divergan® F, Divergan HM and Divergan RS, marketed by BASF, Mount Olive, New Jersey, USA; and PolyPlasdone®, marketed by ISP, Wayne, New Jersey, USA. It is understood that embodiments of the invention are not limited to a PVP of a specific molecular weight and that any equivalent PVP of acceptable purity, preferably pharmaceutical grade, is within the scope of embodiments of this invention.

[0045] In various embodiments, the peroxide polymer particulates are made by suspending the polymer (preferably cPVP) in a suitable anhydrous organic solvent. An anhydrous solution of the peroxide component is made, preferably utilizing the same organic solvent as the PVP suspension. The peroxide solution is combined with the PVP suspension in an amount corresponding to the desired molar ration of polymer peroxide of the peroxide complex. See U.S. Patents 5,108,742, Merianos, issued April 28, 1992; and 4,564,514, Druaz, et al, issued January 14, 1986. In one embodiment, the peroxide complex has an equal (1:1) molar ratio of hydrogen peroxide to the polymer.

[0046] In one embodiment, the concentration of the peroxide complex is limited so that the hydrogen component is no more than 6%, so as to maintain a preferred viscosity. In such an embodiment, the combination of the peroxide complex and peroxide compound comprise a total peroxide concentration of greater than 6%, operable to provide more effective bleaching. Furthermore, in alternative embodiments where a peroxy acid serves as the peroxide component, the oxidizing strength of the oral care composition is increased due to the leaving qualities of the RCO_2-component of the peroxy acid.

[0047] The peroxide compound comprises from 0.1% to 50% of the oral care composition. In a preferred embodiment, the peroxide comprises from 2% to 15% of the oral care composition.

[0048] The compositions of the present invention optionally comprise a non-peroxide whitening agent. Whitening agents among those useful herein include non-peroxy compounds, such as chlorine dioxide, chlorites and hypochlorites. Chlorites and hypochlorites include those of alkali and alkaline earth metals such as lithium, potassium, sodium, magnesium, calcium and barium. Non-peroxide whitening agents also include colorants, such as titanium dioxide and hydroxyapatite. One or more whitening agents are optionally present in a tooth-whitening effective total amount, typically 0.1% to 90%, for example 0.5% to 50% or 1% to 20% by weight of the composition.

[0049] The compositions of the present invention optionally comprise an abrasive. In various embodiments, an abrasive is useful for example as a polishing agent. Any orally acceptable abrasive can be used, but 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 silica, for example in the form of silica gel, hydrated silica or precipitated silica, alumina, insoluble phosphates, calcium carbonate, resinous abrasives such as ureaformaldehyde condensation products and mixtures thereof. 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. One or more abrasives are optionally present in an abrasive effective total amount, typically 5% to 70%, for example 10% to 50% or 15% to 30% by weight of the composition. Average particle size of an abrasive, if present, is generally 0.1 to 30 μm, for example 1 to 20 μm or 5 to 15 μm.

[0050] The compositions of the present invention optionally comprise a tartar control (anticalculus) agent. Tartar control agents among those useful herein include phosphates and polyphosphates (for example pyrophosphates), polyaminopropanesulfonic acid (AMPS), polyolefin sulfonates, polyolefin phosphates, diphosphonates such as azacycloalkane-2,2-diphosphonates (e.g., azacycloheptane-2,2-diphosphonic acid), N-methyl azacyclopentane-2,3-diphosphonic acid, ethane-1-hydroxy-1,1-diphosphonic acid (EHDP) and ethane-1-amino-1,1-diphosphonate, phosphonoalkane carboxylic acids and salts of any of these agents, for example their alkali metal and ammonium salts. Useful inorganic phosphate and polyphosphate salts include monobasic, dibasic and tribasic sodium phosphates, sodium tripolyphosphate, tetrapolyphosphate, mono-, di-, tri- and tetrasodium pyrophosphates, sodium trimetaphosphate, sodium hexametaphosphate and mixtures thereof, wherein sodium can optionally be replaced by potassium or ammonium. Other useful anticalculus agents include polycarboxylate polymers and polyvinyl methyl ether/maleic anhydride (PVME/MA) copolymers, such as those available under the Gantrez™ brand from ISP, Wayne, New Jersey. One or more anticalculus agents are optionally present in an anticalculus effective total amount, typically 0.01% to 50%, for example 0.05% to 25% or 0.1% to 15%.

[0051] The compositions of the present invention optionally comprise a fluoride ion source useful, for example, as an anti-caries agent. Any orally acceptable fluoride ion source can be used, including potassium, sodium and ammonium fluorides and monofluorophosphates, stannous fluoride, indium fluoride and mixtures thereof. In various embodiments, water-soluble fluoride ion sources are used. One or more fluoride ion sources are optionally present in an amount providing a total of 0.0025% to 2%, for example 0.005% to 1% or 0.01% to 0.3%, of fluoride ions.

[0052] The compositions of the present invention optionally comprise a stannous ion source useful, for example, as a periodontal active, tartar control agent, anticaries agent or tooth desensitizer. Any orally acceptable stannous ion source can be used, including stannous fluoride, other stannous halides such as stannous chloride dihydrate, organic stannous carboxylate salts such as stannous formate, acetate, gluconate, lactate, tartrate, oxalate, malonate and citrate, stannous ethylene glyoxide. One or more stannous ion sources are optionally present in a total amount of from 0.01% to 10%, optionally from 0.1% to 7% or from 1% to 5%.

[0053] The compositions of the present invention optionally comprise an antimicrobial (e.g., antibacterial) agent. Any orally acceptable antimicrobial agent can be used, including Triclosan (5-chloro-2-(2,4-dichlorophenoxy)phenol); 8-hydroxyquinoline and salts thereof; zinc and stannous ion sources such as zinc citrate, zinc sulphate, zinc glycinate, sodium zinc citrate and stannous pyrophosphate; copper (II) compounds such as copper (II) chloride, fluoride, sulfate and hydroxide; phthalic acid and salts thereof such as magnesium monopotassium phthalate; sanguinarine; quaternary ammonium compounds, such as alkylpyridinium chlorides (e.g., cetylpyridinium chloride (CPC), combinations of CPC with zinc and/or enzymes, tetradecylpyridinium chloride, and N-tetradecyl-4-ethylpyridinium chloride,); bisguanides, such as chlorhexidine digluconate, hexetidine, octenidine, alexidine; halogenated bisphenolic compounds, such as 2,2'-methylenebis-(4-chloro-6-bromophenol); benzalkonium chloride; salicylanilide, domiphen bromide; iodine; sulfonamides; bisbiguanides; phenolics; piperidino derivatives such as delmopinol and octapinol; magnolia extract; grapeseed extract; thymol; eugenol; menthol; geraniol; carvacrol; citral; eucalyptol; catechol; 4-allylcatechol; hexyl resorcinol; methyl salicylate; antibiotics such as augmentin, amoxicillin, tetracycline, doxycycline, minocycline, metronidazole, neomycin, kanamycin and clindamycin; and mixtures thereof. A further illustrative list of useful antibacterial agents is provided in U.S. Patent 5,776,435, Gaffar, et al., issued July, 7, 1998.

[0054] 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.

[0055] The compositions of the present invention optionally comprise a saliva stimulating agent, useful for example in amelioration of dry mouth. Any orally acceptable saliva stimulating agent can be used, including without limitation food acids such as citric, lactic, malic, succinic, ascorbic, adipic, fumaric, and tartaric acids, and mixtures thereof. One or more saliva stimulating agents are optionally present in a saliva stimulating effective total amount.

[0056] The compositions of the present invention optionally comprise a breath freshening agent. Any orally acceptable breath freshening agent can be used, including without limitation zinc salts such as zinc gluconate, zinc citrate and zinc chlorite, α-ionone and mixtures thereof. One or more breath freshening agents are optionally present in a breath freshening effective total amount.

[0057] The compositions of the present invention optionally comprise an antiplaque (e.g., plaque disrupting) agent. Any orally acceptable antiplaque agent can be used, including without limitation stannous, copper, magnesium and strontium salts, dimethicone copolyols such as cetyl dimethicone copolyol, papain, glucoamylase, glucose oxidase, urea, calcium lactate, calcium glycerophosphate, strontium polyacrylates and mixtures thereof.

[0058] The compositions of the present invention optionally comprise an anti-inflammatory agent. Any orally acceptable anti-inflammatory agent can be used, including steroidal agents such as flucinolone and hydrocortisone, and nonsteroidal agents (NSAIDs) such as ketorolac, flurbiprofen, ibuprofen, naproxen, indomethacin, diclofenac, etodolac, indomethacin, sulindac, tolmetin, ketoprofen, fenoprofen, piroxicam, nabumetone, aspirin, diflunisal, meclofenamate, mefenamic acid, oxyphenbutazone, phenylbutazone, and mixtures thereof.

[0059] The compositions of the present invention optionally comprise an H_2 antagonist. H_2 antagonists useful herein include cimetidine, etintidine, ranitidine, ICIA-5165, tiotidine, ORF-17578, lupititidine, donetidine, famotidine, roxatidine, pifatidine, lamtidine, BL-6548, BMY-25271, zaltidine, nizatidine, mifentidine, BMY-52368, SKF-94482, BL-6341A, ICI-162846, ramixotidine, Wy-45727, SR-58042, BMY-25405, loxtidine, DA-4634, bisfentidine, sufotidine, ebrotidine, HE-30-256, D-16637, FRG-8813, FRG-8701, impromidine, L-643728, HB-408.4, and mixtures thereof.

[0060] The compositions of the present invention optionally comprise a desensitizing agent. Desensitizing agents useful herein include potassium citrate, potassium chloride, potassium tartrate, potassium bicarbonate, potassium oxalate, potassium nitrate, strontium salts, and mixtures thereof. Alternatively or in addition a local or systemic analgesic such as aspirin, codeine, acetaminophen, sodium salicylate or triethanolamine salicylate can be used.

[0061] The compositions of the present invention optionally comprise a nutrient. Suitable nutrients include vitamins, minerals, amino acids, and mixtures thereof. Vitamins include Vitamins C and D, thiamine, riboflavin, calcium pantothenate, niacin, folic acid, nicotinamide, pyridoxine, cyanocobalamin, paraaminobenzoic acid, bioflavonoids, and mixtures thereof. Nutritional supplements include amino acids (such as L-tryptophane, L-lysine, methionine, threonine, levocarnitine and L-carnitine), lipotropics (such as choline, inositol, betaine, and linoleic acid), fish oil (including components thereof such as omega-3 (N-3) polyunsaturated fatty acids, eicosapentaenoic acid and docosahexaenoic acid), coenzyme Q 10, and mixtures thereof.

[0062] The compositions of the present invention optionally comprise proteins. Suitable proteins include milk proteins and enzymes such as peroxide-producing enzymes, amylase, plaque-disrupting agents such as papain, glucoamylase, glucose oxidase, and "next generation" enzymes."

Orally Acceptable Carrier.

[0063] The present invention provides compositions comprising an orally acceptable carrier. As used herein, an "orally acceptable carrier" refers to a material or combination of materials that are safe for use in the compositions of the present invention, commensurate with a reasonable benefit/risk ratio, with which the peroxide complex may be associated while retaining significant efficacy. Preferably, the carrier does not substantially reduce the efficacy of the active material. Selection of specific carrier components is dependant on the desired product form, including dentifrices, rinses, gels, and paints. In various embodiments, the carrier is operable to sufficiently adhere the active material against surfaces within the oral cavity to which the composition is administered, without concomitant use of a dental tray, mouthpiece, tape, or similar appliance. In various embodiments, the carrier is operable for use with a tape, tray, mouthpiece or similar appliance.

[0064] In various embodiments, the compositions of the present invention comprise no carrier materials. (It is understood, without limiting the composition, function or utility of the present invention that the acrylic acid polymer may function as a carrier in various embodiments.) In other embodiments, the compositions additionally comprise one or more carrier materials. Such carrier materials among those useful herein include adhesion agents, viscosity modifiers, diluents, surfactants, foam modulators, peroxide activators, peroxide stability agents, abrasives, pH modifying agents, humectants, mouth feel agents, sweeteners, flavorants, colorants, 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, such carrier materials are selected for compatibility with the peroxide complex and with other ingredients of the composition.

20

[0065] Preferably, the composition comprises a lower (i.e., C_2 - C_5) alcohol, preferably in which the acrylic acid polymer is dissolved. A preferred lower alcohol is ethanol. In one embodiment, the composition comprises an alcohol solution of the acrylic acid polymer, comprising from 50% to 60% alcohol, by volume. As discussed above, preferably the acrylic acid polymer is substantive to, and forms a film on, teeth. In one embodiment, such adherence is increased using rheology modifiers that control and maintain the viscosity of the composition at around 10,000 to about 700,000 cps, preferably below about 400,000 cps, and most preferably around 200,000 cps. Suitable rheology modifiers include cPVP, petrolatum, and silicone.

[0066] In various embodiments, the carrier comprises an adhesion agent. As referred to herein, an adhesion agent is a material or combination of materials that enhance the retention of the peroxide complex on the oral cavity surface onto which the composition is applied. Such adhesion agents include adhesives, film forming materials, viscosity enhancers and combinations thereof. Such materials include hydrophilic organic polymers, hydrophobic organic polymers, silicone gums, silicas, and combinations thereof. Adhesion agents are preferably present at a level of from 0.01% to 75%, optionally from 1% to 40%.

[0067] Hydrophilic organic polymers useful herein include polyethylene glycols, nonionic polymers of ethylene oxide, block copolymers of ethylene oxide and propylene oxide, carboxymethylene polymers, polyvinyl pyrrolidone (PVP) and mixtures thereof. Nonaqueous hydrophilic polymers useful in the practice of the present invention preferably provide a viscosity for the composition in the range between about 10,000 cps to 600,000 cps.

[0068] Hydrophilic polymers also include polymers of polyethylene glycols and ethylene oxide having the general formula:

$$HOCH_2(CH_2OCH_2)_nOH$$

wherein n represents the average number of oxyethylene groups. Polyethylene glycols available from Dow Chemical (Midland, Michigan, U.S.A.) are designated by number such as 200, 300, 400, 600, 2000 which represents the approximate average molecular weight of the polymer. Polyethylene glycols 200, 300, 400 and 600 are clear viscous liquids at room temperature, and are preferred for use in the practice of the present invention.

[0069] Another hydrophilic polymer useful herein is comprised of a water soluble, nonionic block copolymer of ethylene oxide and propylene oxide of the formula: $HO(C_2H_4O)_a(C_3H_6O)_b(C_2H_4O)_cH$. The block copolymer is preferably chosen (with respect to a, b and c) such that the ethylene oxide constituent comprises from about 65 to about 75% by weight, of said copolymer molecule and the copolymer has an average molecular weight of from about 2,000 to about 15,000, with the copolymer being present in oral care composition.

[0070] A block copolymer useful herein is Pluraflo® L1220, marketed by BASF, Mount Olive, New Jersey, U.S.A., which has an average molecular weight of about 9,800. The hydrophilic poly(ethylene oxide) block averages about 65% by weight of the polymer.

[0071] Organic polymers useful as adhesion enhancing agents include hydrophilic polymers such as carbomers such as carboxymethylene polymers such as acrylic acid polymers, and acrylic acid copolymers. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups. A carboxypolymethylene is Carbopol® 974 marketed by Noveon, Inc., Cleveland, Ohio, U.S.A..

[0072] Hydrophobic organic materials useful as adhesion enhancing agents in the practice of the present invention include hydrophobic materials such as waxes such as bees wax, mineral oil, mineral oil and polyethylene blends (e.g., Plastigel®, marketed by Lyne Laboratories, Brockton, Massachusetts, USA.) petrolatum, white petrolatum, liquid paraffin, butane/ethylene/styrene hydrogenated copolymer) blends (e.g., Versagel®, marketed by Penreco, Houston, Texas, U.S.A.), acrylate and vinyl acetate polymers and copolymers, polyethylene waxes, silicone polymers as discussed further herein and polyvinyl pyrrolidone/vinyl acetate copolymers. In embodiments of the present invention containing a hydrophobic polymer, present in ratios of about 1 to about 85% weight of the composition.

[0073] Silicone polymers useful herein include, but are not limited to, silicone adhesives, silicone elastomers, silicone fluids, silicone resins, silicone gums and mixtures thereof. In one embodiment, the carrier comprises a pressure sensitive adhesive (PSA) composition, including those that are well known in the art. Generally, silicone based PSA's are produced by condensing a silicone resin and an organosiloxane such as a polydiorganosiloxane. Suitable silicone polymers include the copolymer product of mixing a silanol terminated polydiorganosiloxane such as polydimethyl siloxane with a silanol-containing silicone resin whereby the silanol groups of the polydiorganosiloxane undergo a condensation reaction with the silanol groups of the silicone resin so that the polydiorganosiloxane is lightly cross-linked by the silicone resin (that is, the polydiorganosiloxane chains are bonded together through the resin molecules to give chain branching and entanglement and/or a small amount of network character) to form the silicone pressure sensitive adhesive. A catalyst, for example an alkaline material such as ammonia, ammonium hydroxide or ammonium carbonate can be mixed with the silanol-terminated polydiorganosiloxane and the silicone resin to promote this cross-linking reaction. Copolymerizing the silicone resin with the silanol terminated polydiorganosiloxane affords a self adhering property and cohesive soft elastomer matrix. Modifying the silicone resin to polydiorganosiloxane ratio of the pressure sensitive adhesive will modify

the tackiness of the oral care composition. For example PSAs are available from the Dow-Corning Corporation, Midland, Michigan, U.S.A., under the brand name BIO-PSA. A preferred adhesion agent is Dow Corning Silicone Adhesive 8-7016 marketed by Dow-Corning Corporation. The silicone based pressure sensitive adhesive is present in the liquid whitening compositions of the present invention at a concentration of 0.5% to 99%, optionally from 5% to 60%, optionally from 10% to 40%.

[0074] Silicone gums useful herein include high molecular weight polydiorganosiloxanes having a viscosity at 25°C. of from about 500,000 cS up to about 50,000,000 cS. Such silicone gums include those polydiorganosiloxanes with an average molecular weight of greater than 500,000. The polysiloxane gums for use herein can be linear or cyclic, and branched or unbranched. Substituents may have any structure as long as the resulting polysiloxanes are hydrophobic, are not irritating, toxic or otherwise harmful when applied to the oral cavity, and are compatible with the other components of the composition. Specific examples of siloxane gums include polydimethylsiloxane, methylvinylsiloxane, copolymer, poly(dimethylsiloxane, diphenyl, methyvinylsiloxane) copolymer and mixtures thereof. Silicone gums include those commercially available, such as SE30, marketed by General Electric.

[0075] Polysiloxane fluids useful herein include those with a viscosity, at 25° C., of from 1 cStk to 1000 cS, preferably from 2 cS to 500 cS, and optionally from 5 cS to 400 cS. Polysiloxane fluids for use herein can be linear or cyclic, and can be substituted with a wide variety of substituents (including as described above). Preferred substituents include methyl, ehtyl and phenyl substituents. Suitable polysiloxane fluids include linear polysiloxane polymers such as dimethicone and other low viscosity analogues of the polysiloxane materials, preferably having a viscosity at 25°C of 200 cS or less and cyclomethicone, and other cyclic siloxanes having for example a viscosity at 25°C of 200 cS or less. Commercial examples of materials that are suitable for use herein include DC200 series fluids marketed by Dow-Corning Corporation and the AK Fluid series marketed by Wacker-Chemie GmbH, München, Germany.

[0076] Adhesion agents also include inorganic materials. Such inorganic materials include silicon polymers such as amorphous silica compounds which function as thickening agents (e.g., Cab-o-sil® fumed silica manufactured by Cabot Corporation, Boston, Massachusetts, U.S.A.; and Sylox 15 also known as Sylodent 15, marketed by Davison Chemical Division of W.R. Grace & Co., Columbia, Maryland, U.S.A.).

[0077] Thickening agents among those useful herein include carboxyvinyl polymers, carrageenans (also known as Irish moss and more particularly iota-carrageenan), cellulosic polymers such as hydroxyethylcellulose, carboxymethylcellulose (carmellose) and salts thereof (e.g., carmellose sodium), natural gums such as karaya, xanthan, gum arabic and tragacanth, colloidal magnesium aluminum silicate, colloidal silica and mixtures thereof. One or more thickening agents are optionally present in a total amount of 0.01 % to 15%, for example 0.1% to 10% or 0.2% to 5% by weight of the composition.

[0078] Viscosity modifiers among those useful herein include mineral oil, petrolatum, clays and organomodified clays, silica and mixtures thereof. In various embodiments, such viscosity modifiers are operable to inhibit settling or separation of ingredients or to promote redispersibility upon agitation of a liquid composition. One or more viscosity modifiers are optionally present in a total amount of 0.01% to 10%, for example 0.1% to 5% by weight of the composition.

[0079] Diluents among those useful herein include materials or combinations of materials that are operable to solubilize and/or suspend other components of the composition. In various embodiments, diluents are operable to adjust the viscosity of the composition, optionally in conjunction with viscosity modifiers (as discussed herein) and other components of the composition. The composition is preferably non-aqueous, i.e., does not contain appreciable amounts of chemically-unbound water. In one embodiment, the composition comprises less than about 5% water. Diluents include glycerin and lower alcohols, e.g., ethanol. Diluents are optionally present in the nonaqueous liquid whitening compositions of the present invention in amounts of 0.1% to 98%, optionally in various embodiments from 0.5% to 70%, from 0.5% to 50%, from 0.5% to 35%.

[0080] Surfactants among those useful herein include anionic, nonionic, and amphoteric surfactants. Surfactants may be used, for example, to provide enhanced stability of the formulation, to help in cleaning the oral cavity surfaces through detergency, and to provide foam upon agitation, e.g., during brushing with a dentifrice composition of the invention. Suitable anionic surfactants include water-soluble salts of C_{8-20} alkyl sulfates, sulfonated monoglycerides of C_{8-20} fatty acids, sarcosinates, taurates and mixtures thereof. Illustrative examples of these and other surfactants are sodium lauryl sulfate, sodium coconut monoglyceride sulfonate, sodium lauryl sarcosinate, sodium lauryl isoethionate, sodium laureth carboxylate, sodium dodecyl benzenesulfonate, and mixtures thereof. Suitable nonionic surfactants include poloxamers, polyoxyethylene sorbitan esters, fatty alcohol ethoxylates, alkylphenol ethoxylates, tertiary amine oxides, tertiary phosphine oxides, dialkyl sulfoxides and mixtures thereof. Suitable amphoteric surfactants include derivatives of C_{8-20} aliphatic secondary and tertiary amines having an anionic group such as carboxylate, sulfate, sulfonate, phosphate or phosphonate. A suitable example is cocoamidopropyl betaine. One or more surfactants are optionally present in total amounts of 0.01% to 10%, for example 0.05% to 5% or 0.1% to 2%. Preferably, the surfactant is nonionic and compatible with peroxide compounds such as polyethylene oxide. Nonionic surfactants are present in embodiments of the invention at levels of from 0.01% to 1%.

[0081] Foam modulators useful herein include materials operable to increase amount, thickness, stability of foam

generated by the composition (e.g., dentifrice compositions) upon agitation. Any orally acceptable foam modulator can be used, including polyethylene glycols (PEGs), also known as polyoxyethylenes. High molecular weight PEGs are suitable, including those having an average molecular weight of 200,000 to 7,000,000, for example 500,000 to 5,000,000 or 1,000,000 to 2,500,000. One or more PEGs are optionally present in a total amount of 0.1% to 10%, for example 0.2% to 5% or 0.25% to 2%.

[0082] Humectants useful herein include polyhydric alcohols such as glycerin, sorbitol, xylitol or low molecular weight PEGs. In various embodiments, humectants are operable to prevent hardening of paste or gel compositions upon exposure to air. In various embodiments humectants also function as sweeteners. One or more humectants are optionally present in a total amount of 1% to 50%, for example 2% to 25% or 5% to 15%.

[0083] Peroxide activators such as sodium bicarbonate, sodium carbonate, manganese gluconate are optionally incorporated in the compositions of the present invention that comprise a peroxide. The activator is relatively nonactive with the peroxide whitening agent in the nonaqueous liquid compositions. In various embodiments, the activator is operable to react with the peroxide to release oxygen when the liquid whitening composition applied to the teeth is contacted with saliva in the oral cavity. The peroxide activator is optionally present in embodiments of this invention at a concentration of 0.1% to 50%.

[0084] pH modifying agents among those useful herein include acidifying agents to lower pH, basifying agents to raise pH, and buffering agents to control pH within a desired range. For example, one or more compounds selected from acidifying, basifying and buffering agents can be included to provide a pH of 2 to 10, or in various embodiments from 2 to 8, from 3 to 9, from 4 to 8, from 5 to 7, from 6 to 10, and from 7 to 9. Any orally acceptable pH modifying agent can be used, including without limitation carboxylic, phosphoric and sulfonic acids, acid salts (e.g., monosodium citrate, disodium citrate, monosodium malate), alkali metal hydroxides such as sodium hydroxide, carbonates such as sodium carbonate, bicarbonates, sesquicarbonates, borates, silicates, phosphates (e.g., monosodium phosphate, trisodium phosphate, pyrophosphate salts), imidazole and mixtures thereof. One or more pH modifying agents are optionally present in a total amount effective to maintain the composition in an orally acceptable pH range.

[0085] Mouth-feel agents include materials which impart a desirable texture or other feeling during use of the composition. Such agents include bicarbonate salts, which in various embodiments impart a "clean feel" to teeth and gums due to effervescence and release of carbon dioxide. Any orally acceptable bicarbonate can be used, including without limitation alkali metal bicarbonates such as sodium and potassium bicarbonates, ammonium bicarbonate, and mixtures thereof. One or more bicarbonate salts are optionally present in a total amount of 0.1% to 50%, for example 1% to 20%.

[0086] Flavorants among those useful herein include any material or mixture of materials operable to enhance the taste of the composition. Any orally acceptable natural or synthetic flavorant can be used, such as flavoring oils, flavoring aldehydes, esters, alcohols, similar materials, and combinations thereof. Flavorants include vanillin, sage, marjoram, parsley oil, spearmint oil, cinnamon oil, oil of wintergreen (methylsalicylate), peppermint oil, clove oil, bay oil, anise oil, eucalyptus oil, citrus oils, fruit oils and essences including those derived from lemon, orange, lime, grapefruit, apricot, banana, grape, apple, strawberry, cherry, pineapple, bean- and nut-derived flavors such as coffee, cocoa, cola, peanut, almond, adsorbed and encapsulated flavorants, and mixtures thereof. Also encompassed within flavorants herein are ingredients that provide fragrance and/or other sensory effect in the mouth, including cooling or warming effects. Such ingredients include methol, menthyl acetate, menthyl lactate, camphor, eucalyptus oil, eucalyptol, anethole, eugenol, cassia, oxanone, α-irisone, propenyl guaiethol, thymol, linalool, benzaldehyde, cinnamaldehyde, N-ethyl-p-menthan-3-carboxamine, N,2,3-trimethyl-2-isopropylbutanamide, 3-1-menthoxypropane-1,2-diol, cinnamaldehyde glycerol acetal (CGA), methone glycerol acetal (MGA) and mixtures thereof. One or more flavorants are optionally present in a total amount of 0.01% to 5%, optionally in various embodiments from 0.05 to 2%, from 0.1% to 2.5%, and from 0.1 to 0.5%.

[0087] Sweeteners among those useful herein include orally acceptable natural or artificial, nutritive or non-nutritive sweeteners. Such sweeteners include dextrose, polydextrose, sucrose, maltose, dextrin, dried invert sugar, mannose, xylose, ribose, fructose, levulose, galactose, corn syrup (including high fructose corn syrup and corn syrup solids), partially hydrolyzed starch, hydrogenated starch hydrolysate, sorbitol, mannitol, xylitol, maltitol, isomalt, aspartame, neotame, saccharin and salts thereof, sucralose, dipeptide-based intense sweeteners, cyclamates, dihydrochalcones and mixtures thereof. One or more sweeteners are optionally present in a total amount depending strongly on the particular sweetener(s) selected, but typically at levels of from 0.005% to 5%, optionally from 0.01% to 1%.

[0088] Colorants among those useful herein include pigments, dyes, lakes and agents imparting a particular luster or reflectivity such as pearling agents. In various embodiments, colorants are operable to provide a white or light-colored coating on a dental surface, to act as an indicator of locations on a dental surface that have been effectively contacted by the composition, and/or to modify appearance, in particular color and/or opacity, of the composition to enhance attractiveness to the consumer. Any orally acceptable colorant can be used, including talc, mica, magnesium carbonate, calcium carbonate, magnesium silicate, magnesium aluminum silicate, silica, titanium dioxide, zinc oxide, red, yellow, brown and black iron oxides, ferric ammonium ferrocyanide, manganese violet, ultramarine, titaniated mica, bismuth oxychloride, FD&C dyes, and mixtures thereof. One or more colorants are optionally present in a total amount of 0.001% to 20%, for example 0.01% to 10% or 0.1% to 5%.

[0089] In one embodiment, the present invention provides compositions comprising:

a) from 0.5% to 60% of an active, preferably a peroxide composite comprising hydrogen peroxide and an N-vinyl heterocyclic polymer;
b) from 0.2% to 60% of an acrylic polymer as defined in claim 1 and
(c) from 0.5% to 99.5% of ethyl alcohol.

Optionally, the composition additionally comprises one or more components including from 1 to 50 of % of a block copolymer of ethylene oxide and propylene oxide, from 1% to 30% of a petrolatum, from 1% to 40% of polyvinylpyrrolidone, and from 1% to 40% of hydrogen peroxide.

Methods of Manufacture

[0090] The compositions of the present invention are made by any variety of methods, including adding and mixing the ingredients of the composition in a suitable vessel such as a stainless steel tank provided with a mixer. In one embodiment, the composition components are added to the mixing vessel in the following order: adhesive polymer, diluent, thickener ingredients, peroxide composite (or other active) and any flavoring, colorant or sweetener. In one embodiment, the adhesive polymer is dissolved in ethyl alcohol at room temperature. Pluraflo IA370 and petrolatum are then added and the solution is mixed for five minutes. The peroxide or other active is added and the solution is mixed for 20 minutes until the mixture is homogenous. Additional ingredients such as flavorant, coloring or sweeteners are added at any point during the mixing process but in various embodiments, such ingredients are preferably added last or close to last.

Methods

[0091] The present invention provides non-therapeutic methods for whitening a tooth surface using compositions according to the present invention. As referred to herein, "tooth" or "teeth" refers to natural teeth, dentures, dental plates, fillings, caps, crowns, bridges, dental implants, and any other hard surfaced dental prosthesis either permanently or temporarily fixed within the oral cavity. As used herein, "whitening" refers to a change in visual appearance of a tooth, preferably such that such that the tooth has a brighter shade. Increase in whiteness of a dental surface can be observed visually, for example with the aid of color comparison charts or gauges, or measured by colorimetry, using any suitable instrument such as a Minolta Chromameter, e.g., model CR-400 (Minolta Corp., Ramsey, NJ). The instrument can be programmed, for example, to measure Hunter Lab values or L*a*b* values according to the standard established by the International Committee of Illumination (CIE). The L*a*b* system provides a numerical representation of three-dimensional color space where L* represents a lightness axis, a* represents a red-green axis and b* represents a yellow-blue axis. The L* and b* axes are typically of greatest applicability to measurement of tooth whiteness. Increase in whiteness can be computed from differences in L*, a* and b* values before and after treatment, or between untreated and treated surfaces. A useful parameter is ΔE*, calculated as the square root of the sum of the squares of differences in L*, a* and b* values, using the formula:

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

A higher value of ΔE* indicates greater increase in whiteness. In various embodiments, the method of the present invention can effect a ΔE* of at least about 1, or at least about 3, or at least about 4, or at least about 5.

[0092] Accordingly, the present invention provides methods for whitening a tooth surface, comprising applying to the surface a safe and effective amount of a peroxide compound or peroxide complex and an acrylic polymer as defined in claim 1. As referred to herein, "applying" refers to any method by which the peroxide complex is placed in contact with the tooth surface. Such methods, in various embodiments, comprise direct application of a composition by such methods as rinsing, painting, and brushing. In various embodiments, application of the composition comprises the use of an application device which aids in maintaining contact of the complex to the tooth surface for sufficient time so as to allow whitening.

[0093] Suitable application devices include dental trays, mouthpieces, floss, fibers, chips, strips and tapes. Strips among those useful herein comprise polymers, natural and synthetic woven materials, non-woven material, foil, paper, rubber and combinations thereof. Preferably the strip of material is substantially water insoluble. Suitable polymers include polyethylene, ethylvinylacetate, polyesters, ethylvinyl alcohol, fluoroplastics, and combinations thereof. In various embodiments, the strip of material is generally less than about 1 mm (millimeter) thick, optionally less than about 0.05

mm thick, optionally about 0.001 to about 0.03 mm thick. The shape of the strip is any shape and size that covers the desired oral surface. In one embodiment, the length of the strip material is from about 2 cm (centimeter) to about 12 cm, in another embodiment from about 4 cm to about 9 cm. The width of the strip material will also depend on the oral surface area to be covered. The width of the strip is generally from about 0.5 cm to about 4 cm, in one embodiment from about 1 cm to about 2 cm. The strip material may comprise shallow pockets, optionally filled by a composition of this invention so as to provide reservoirs of peroxide complex. Strips among those useful herein are disclosed in U.S. Patent 6,514,484, Rajaiah et al. issued February 4, 2003.

[0094] In one preferred embodiment, the whitening composition is applied using a "paint on" technique. A small application device, such as a brush or spatula is coated with a composition of this invention and the composition is then placed on a tooth surface. Preferably, the composition be spread evenly on such surfaces, in sufficient quantity to deliver a whitening amount of the peroxide complex.

[0095] The present invention also provides methods for effecting the controlled release of an oxidizing peroxide species onto a tooth surface, comprising contacting the surface with a peroxide composite of the present invention. As referred to herein, such controlled release in various embodiments comprises sustained release of the peroxide complex. Without limiting the mechanism, function or utility of present invention, in some embodiments contact with saliva causes the release of an effective amount of peroxide active from the cross-linked polymer matrix to the applied tooth site over a period of time.. Preferably, the composition is contacted with the tooth surface for at least about 30 seconds, optionally at least about 1 minute.

[0096] In various embodiments, it is preferred that the subject does not eat or drink while the composition is in contact with the dental surface. The whitening composition can be removed as and when required, at will, by an employment of standard oral hygiene procedures such as brushing or by rinsing, e.g., with a mouthwash. The process can be repeated several times until the desired whitening results are achieved.

[0097] The present invention is further illustrated through the following non-limiting examples.

Example 1

[0098] A composition (not in accordance with the present invention is made, as follows:

Ingredients	Weight %
3M Silicone "Plus" Polymer VS 80	20
ethyl alcohol	35
cPVP-H_2O_2 powder	20
Pluraflo L4370	10
snow white petrolatum	15
Total (%)	100

[0099] The VS-80 adhesive polymer is dissolved in the ethyl alcohol. The Pluraflo and petrolatum are then added and the solution is mixed for five minutes. The peroxide is added and the solution is mixed for 20 minutes until the mixture is homogenous.

Example 2

[0100] A composition of the present invention is made, as follows:

Ingredients	Weight %
Luvimer 100P	18
ethyl Alcohol	35
cPVP-H_2O_2 powder	27
Pluraflo L4370	10
snow white petrolatum	10
Total (%)	100

[0101] The composition is made by a process generally as described above in Example 1.

Example 3

[0102] A composition of the present invention is made, as follows:

Ingredients	Weight %
Luvimer 100P	20
ethyl alcohol	35
cPVP-H_2O_2 powder	25
Pluraflo L4370	10
snow white petrolatum	10
Total (%)	100

[0103] The composition is made by a process generally as described above in Example 1.

Claims

1. An oral care composition, comprising:

   (a) a whitening agent; and
   (b) an acrylic film forming polymer, wherein the acrylic film forming polymer comprises a copolymer of a first monomeric unit selected from the group consisting of acrylic acid and methacrylic acid, with a second monomeric unit selected from the group consisting of acrylates, acrylamides and vinyl acetates, wherein the polymer is a terpolymer comprising a combination of said second monomeric units.

2. An oral care composition according to Claim 1, wherein said polymer is a terpolymer of t-butyl acrylate, ethyl acrylate, and methacrylic acid.

3. An oral care composition according to Claim 1, comprising from 0.2% to 60% of said polymer.

4. An oral care composition according to Claim 3, comprising from 10% to 30% of said polymer.

5. An oral care composition according to Claim 1, wherein said whitening agent comprises a peroxide compound selected from the group consisting of hydrogen peroxide, organic peroxy compounds, peroxy acids, and mixtures thereof.

6. An oral care composition according to Claim 5, wherein said peroxide compound comprises hydrogen peroxide.

7. An oral care composition according to Claim 6, wherein said peroxide compound comprises a complex of hydrogen peroxide and an N-vinyl heterocyclic polymer.

8. An oral care composition according to Claim 1, wherein said composition is substantially non-aqueous, and additionally comprises a lower alcohol.

9. An oral care composition according to Claim 8, additionally comprising an adhesion agent selected from the group consisting of silicone polymers, waxes, mineral oil, petrolatum, hydrophilic polymers, silicas, and mixtures thereof.

10. An oral care composition according to Claim 8, additionally comprising a hydrophilic polymer selected from the group consisting of polyethylene glycols, nonionic polymers of ethylene oxide, block copolymers of ethylene oxide and propylene oxide, carboxymethylene polymers, polyvinyl pyrrolidone, and mixtures thereof.

11. An oral care composition according to Claim 8, additionally comprising a silicone polymer selected from the group

consisting of silicone adhesives, silicone elastomers, silicone fluids, silicone resins, silicone gums and mixtures thereof.

12. A non-therapeutic method of delivering an oral care active, comprising applying to a dental surface a safe and effective amount of an oral care active and an acrylic acid polymer which is a terpolymer of t-butyl acrylate, ethyl acrylate, and methacrylic acid.

13. A method according to Claim 12, wherein said oral care active is a whitening agent.

14. A method according to Claim 13, wherein said whitening agent comprises a peroxide compound.

15. A method according to Claim 14, wherein said peroxide compound comprises hydrogen peroxide.

16. A method according to Claim 15, wherein said peroxide compound comprises a composite of hydrogen peroxide and an N- vinyl heterocyclic polymer.

Patentansprüche

1. Mundpflegezusammensetzung, umfassend:

(a) ein Aufhellungsmittel; und
(b) ein filmbildendes Acrylpolymer, wobei das filmbildende Acrylpolymer ein Copolymer einer ersten Monomereinheit, ausgewählt aus der Gruppe bestehend aus Acrylsäure und Methacrylsäure, mit einer zweiten Monomereinheit ist, die aus der Gruppe bestehend aus Acrylaten, Acrylamiden und Vinylacetaten ausgewählt ist, wobei das Polymer ein Terpolymer ist, das eine Kombination der zweiten Monomereinheiten umfasst.

2. Mundpflegezusammensetzung nach Anspruch 1, wobei das Polymer ein Terpolymer von t-butylacrylat, Ethylacrylat, und Methacrylsäure ist.

3. Mundpflegezusammensetzung nach Anspruch 1, die 0,2% bis 60% des Polymers umfasst.

4. Mundpflegezusammensetzung nach Anspruch 3, die 10% bis 30% des Polymers umfasst.

5. Mundpflegezusammensetzung nach Anspruch 1, wobei das Aufhellungsmittel eine Peroxidverbindung umfasst, die aus der Gruppe bestehend aus Wasserstoffperoxid, organischen Peroxidverbindungen, Peroxidsäuren und Mischungen davon ausgewählt ist.

6. Mundpflegezusammensetzung nach Anspruch 5, wobei die Peroxidzusammensetzung Wasserstoffperoxid umfasst.

7. Mundpflegezusammensetzung nach Anspruch 6, wobei die Peroxidzusammensetzung einen Komplex von Wasserstoffperoxid und einem N-vinyl-heterocyclischen Polymer umfasst.

8. Mundpflegezusammensetzung nach Anspruch 1, wobei die Zusammensetzung im Wesentlichen nicht wässrig ist und zusätzlich einen niederen Alkohol umfasst.

9. Mundpflegezusammensetzung nach 8, die zusätzlich ein Adhäsionsmittel umfasst, das aus der Gruppe bestehend aus Silikonpolymeren, Wachsen, Mineralöl, Petrolaten, hydrophilen Polymeren, Kieselgelen und Mischungen davon ausgewählt ist.

10. Mundpflegezusammensetzung nach Anspruch 8, die zusätzlich ein hydrophilies Polymer umfasst, das aus der Gruppe bestehend aus Polyethylenglykolen, nichtionischen Polymeren von Ethylenoxid, Block-Copolymeren von Ethylenoxid und Propylenoxid, Carboxymethylenpolymeren, Polyvinylpyrrolidon und Mischungen davon ausgewählt ist.

11. Mundpflegezusammensetzung nach Anspruch 8, das zusätzlich ein Silikonpolymer umfasst, das aus der Gruppe bestehend aus Silikonadhäsiven, Silikonelastomeren, Silikonflüssigkeiten, Silikonharzen, Silikongummis und Mischungen davon ausgewählt ist.

12. Nicht therapeutisches Verfahren zur Verabreichung eines zur Mundpflege aktiven Mittels, bei dem einer Zahnoberfläche eine sichere und effektive Menge eines zur Mundpflege aktiven Mittels und ein Acrylsäurepolymer verabreicht wird, das ein Terpolymer von t-butylacrylat, Ethylacrylat und Methacrylsäure ist.

13. Verfahren nach Anspruch 12, wobei das zur Mundpflege aktive Mittel ein Aufhellungsmittel ist.

14. Verfahren nach Anspruch 13, wobei das Aufhellungsmittel eine Peroxidverbindung umfasst.

15. Verfahren nach Anspruch 14, wobei die Peroxidverbindung Wasserstoffperoxid umfasst.

16. Verfahren nach Anspruch 15, wobei die Peroxidverbindung eine Zusammensetzung von Wasserstoffperoxid und einem N-vinyl-heterocyclischen Polymer umfasst.

Revendications

1. Composition de soin buccal, comprenant :

   (a) un agent blanchissant ; et
   (b) un polymère filmogène acrylique, où le polymère filmogène acrylique comprend un copolymère d'un premier motif monomère choisi dans le groupe constitué de l'acide acrylique et l'acide méthacrylique avec un deuxième motif monomère choisi dans le groupe constitué d'acrylates, acrylamides et acétates de vinyle, où le polymère est un terpolymère comprenant une combinaison desdits deuxièmes motifs monomères.

2. Composition de soin buccal selon la revendication 1, où ledit polymère est un terpolymère d'acrylate de t-butyle, d'acrylate d'éthyle, et d'acide méthacrylique.

3. Composition de soin buccal selon la revendication 1, comprenant de 0,2 % à 60 % dudit polymère.

4. Composition de soin buccal selon la revendication 3, comprenant de 10 % à 30 % dudit polymère.

5. Composition de soin buccal selon la revendication 1, où ledit agent blanchissant comprend un composé de peroxyde choisi dans le groupe constitué du peroxyde d'hydrogène, de composés peroxy organiques, de peroxyacides, et de mélanges de ceux-ci.

6. Composition de soin buccal selon la revendication 5, dans laquelle ledit composé peroxyde comprend du peroxyde d'hydrogène.

7. Composition de soin buccal selon la revendication 6, dans laquelle ledit composé peroxyde comprend un complexe de peroxyde d'hydrogène et un polymère hétérocyclique de N-vinyle.

8. Composition de soin buccal selon la revendication 1, où ladite composition est sensiblement non aqueuse, et comprend en outre un alcool inférieur.

9. Composition de soin buccal selon la revendication 8, comprenant en outre un agent d'adhésion choisi dans le groupe constitué de polymères de silicone, de cires, d'huile minérale, de pétrolatum, de polymères hydrophiles, de silices, et de mélanges de ceux-ci.

10. Composition de soin buccal selon la revendication 8, comprenant en outre un polymère hydrophile choisi dans le groupe constitué de polyéthylèneglycols, de polymères non ioniques d'oxyde d'éthylène, de copolymères séquencés d'oxyde d'éthylène et d'oxyde de propylène, de polymères de carboxyméthylcellulose, de polyvinylpyrrolidone, et de mélanges de ceux-ci.

11. Composition de soin buccal selon la revendication 8, comprenant en outre un polymère de silicone choisi dans le groupe constitué d'adhésifs de silicone, d'élastomères de silicone, de fluides de silicone, de résines de silicone, de gommes de silicone et de mélanges de ceux-ci.

12. Procédé non thérapeutique d'administration d'un composé actif de soin buccal, comprenant l'application sur une

surface dentaire d'une quantité sûre et efficace d'un soin buccal actif et d'un polymère d'acide acrylique qui est un terpolymère d'acrylate de t-butyle, d'acrylate d'éthyle, et d'acide méthacrylique.

13. Procédé selon la revendication 12, dans lequel ledit agent actif buccal est un agent blanchissant.

14. Procédé selon la revendication 13, dans lequel ledit agent blanchissant comprend un composé peroxyde.

15. Procédé selon la revendication 14, dans lequel ledit composé peroxyde comprend du peroxyde d'hydrogène.

16. Procédé selon la revendication 15, dans lequel ledit composé peroxyde comprend un composite de peroxyde d'hydrogène et un polymère hétérocyclique de N-vinyle.

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 5425953 A **[0005]**
- US 5766574 A **[0005]**
- US 20030152528 A **[0008]**
- US 20030235549 A **[0008]**
- US 4032627 A **[0008]**
- US 20030206874 A, Doyle **[0029]**
- US 6290933 A, Durga **[0029]**
- US 6685921 B, Lawlor **[0029]**
- US 2938017 A, Grosser **[0043]**
- US 3277066 A, Grosser **[0043]**
- US 3306886 A, Grosser **[0043]**
- US 3306881 A, Grosser **[0043]**
- US 2667473 A, Momer **[0043]**
- US 2947633 A, Perry **[0043]**
- US 5108742 A, Merianos **[0045]**
- US 4564514 A, Druaz **[0045]**
- US 5776435 A, Gaffar **[0053]**
- US 6514484 B, Rajaiah **[0093]**