100

Drigard & Castro
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AS: 88.956

Señores
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES
E. S. D.

REF.: Expediente No. 02 079.084 solicitud de Patente FASE NACIONAL
Corresp. a la Solicitud Internacional PCT/US01/06899
a nombre de **COLGATE – PALMOLIVE COMPANY**
Titulada: COMPOSICIÓN DENTÍFRICA DE COMPONENTE DUAL PARA FLÚORIZAR LOS DIENTES

JUAN PABLO CADENA SARMIENTO, vecino de Bogotá, portador de la tarjeta profesional No. 57492 del Consejo Superior de la Judicatura, obrando como apoderado sustituto de la Sociedad **COLGATE – PALMOLIVE COMPANY**, según lo acredita el documento de poder anexo al presente escrito, de acuerdo con el Artículo 44 de la Decisión 486 de la Comisión de la Comunidad Andina, me permito solicitar que se examine si la invención contenida en la solicitud en referencia es patentable.

De acuerdo con lo anterior, me permito anexar los recibos oficiales de caja Nos. 04-77,678 y 78,949 por valor de $177.000.

Señor Superintendente,

JUAN PABLO CADENA SARMIENTO
C.C. No. 80.410.337 de Usaquén
T.P. No.57492 del C.S.J.
Cra. 7 No. 16-56 Piso 9

Noviembre 23, 2004
CHP/MEV/hsr.

001

SUPERINDUSTRIA Y COMERCIO
Radicacion : 00079884 00000004
Fecha (AMD): 2004-11-24 08:53:03 Folios:
Tramite : 011 PCT-PATENT 379 FASE NACI 538 PETICI
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 04 - 77,679
FECHA : OCTUBRE 1 DE 2004

C O N S I G N A C I O N

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
BRIGARD & CASTRO LTDA	CONSIGNACION	BANCO POPULAR	050-00110-6	21591332	01/10/2004	26,757,000.00

C O N C E P T O

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	02 INVOCACION DE UNA PRIORIDAD EN NU	118,000.00
		TOTAL : $	118,000.00

SON: CIENTO DIEZ Y OCHO MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

102

NIT : 900176089-2

SUPERINDUSTRIA Y COMERCIO
Radicacion : 04079884 00000004 Folios: 8
Fecha (AMD): 2004-11-24 08:55:03
Tramite : 011 PCT-PATENT 379 FASE NACI 536 PETICION
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

RECIBO OFICIAL DE CAJA : 04 - 78,949
FECHA : OCTUBRE 7 DE 2004

C O N S I G N A C I O N

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
BRIGARD & CASTRO LTDA	CONSIGNACION	BANCO POPULAR	050-00110-6	21591354	07/10/2004	19,333,000.00

C O N C E P T O

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	90005-01-01 SOLICITUDES	83 INVOCACION DE UNA PRIORIDAD EN SI	59,000.00
		TOTAL : $	59,000.00

SON: CINCUENTA Y NUEVE MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

88453
X
103

Apostille

(Convention de La Haye du 5 Octobre 1961)

1. Country: **United States of America**

   This public document

2. has been signed by **Norman Goodman**
3. acting in the capacity of **County Clerk**
4. bears the seal/stamp of the county of **New York**

Certified

5. At New York, New York 6. the 30th day of October 2001
7. by Special Deputy Secretary of State, State of New York
8. No. NYC-9786540B
9. Seal/Stamp 10. Signature

23 NOV 2004
OSCAR ALARCON NUÑEZ
NOTARIO CUARENTA Y SEIS

Aqil M. Qureshi
Special Deputy Secretary of State

05 DIC 2003
OSCAR ALARCON NUÑEZ
NOTARIO CUARENTA Y SEIS

04135565.RSL (REV 2/8/98)

104

Brigard & Castro

SANTA FE DE BOGOTA - COLOMBIA

PODER

Yo (nosotros)

domiciliado(s) en

Nombro(amos) a: RAMIRO CASTRO DUQUE y/o JUAN PABLO CADENA SARMIENTO y/o BEATRIZ JARAMILLO S.
de Santafé de Bogotá, Colombia, apoderados verdaderos y legales con poder especial, amplio y suficiente, para recabar de las oficinas y autoridades colombianas administrativas, judiciales y de policía, en cualquier instancia o recurso, la obtención de patentes de invención, registros de marcas, diseños industriales, modelos de utilidad, depósitos de nombres comerciales y enseñas, registros de derechos de autor y contratos sobre los mismos, obtención de certificados de obtentor de variedades vegetales, así como sus prórrogas, renovaciones, anotaciones de traspaso, cambios de nombre y/o domicilio; elaborar, tramitar y registrar contratos de licencia y licencias de cualesquiera clases; intervenir como demandante o como demandado en cualquier instancia y recurso ante cualquier juez, corporación, funcionario público o autoridad en acciones judiciales, administrativas y de policía tales como: oposiciones al registro de marcas; acciones de caducidad, cancelación y nulidad; acciones reivindicatorias, acciones derivadas de la obtención o explotación de licencias; acciones de competencia desleal; demandas penales; acciones de indemnización de perjuicios, reclamos y observaciones a solicitudes de patentes, diseños industriales, modelos de utilidad, en el ejercicio de medidas cautelares y en otras acciones o medidas similares.

A este efecto, lo(s) faculto(amos) para elevar solicitudes, formular descripciones, enmiendas, protestas, declaraciones, oposiciones, cancelaciones, nulidades, apelaciones y reclamos; pagar impuestos, cuotas y gravámenes prescritos por la ley; renunciar o desistir a derechos concedidos o en curso de concesión; recibir toda clase de documentos y valores, dando el descargo respectivo, y, en general, para dar ante dichas autoridades todos los pasos necesarios al efecto indicado y tomar todas las medidas que creyeren conducentes al resguardo de mis (nuestros) intereses), con todas las demás facultades legales necesarias.

Este poder comprende la facultad de ratificar o confirmar en mi (nuestro) nombre, lo actuado así como la facultad de desistir, transigir, comprometer, y la de sustituirlo en todo o en parte y revocar sustituciones. Asimismo nombro(amos) a: RAMIRO CASTRO DUQUE y/o JUAN PABLO CADENA SARMIENTO y/o BEATRIZ JARAMILLO S.
domiciliado(s) en la Carrera 7 No. 16-56 Piso 9, mis (nuestros) apoderados en Colombia, con facultades para recibir notificaciones y designar apoderados judiciales o extrajudiciales.

Otorgado y firmado en

hoy de de 200

Firma

Nombre

POWER OF ATTORNEY

I (We) COLGATE-PALMOLIVE COMPANY, a Delaware

domiciled corporation, of 300 Park Avenue, New York, New York 10022, U. S. A.

Hereby appoint RAMIRO CASTRO DUQUE and/or JUAN PABLO CADENA SARMIENTO and/or BEATRIZ JARAMILLO S.
of Santafé de Bogotá, Colombia, my (our) true and lawful attorneys with special, ample and sufficient power to obtain from the Colombian administrative, judicial and police offices and authorities, in any instance, privileges of patents of invention, registration of trademarks, industrial designs and utility models; registration of commercial names and emblems, registration of copyright and contracts related thereto, certificates of obtainers of vegetables varieties, as well as extensions, renewals and recordal of assignments and changes of name and domicile related to the above; to prepare, prosecute and register licenses of any kind; to act as plaintiff or defendant in any instance or recourse, and before any judge, corporation, public official or authority in judicial, administrative and police actions, such as: oppositions to the registration of trademarks; caducity, cancellation and nullity actions; claim actions derived from the obtaining or explotation of licenses, action of unfair competition; penal demands, actions of indemnities for damages: claims or observations on patent applications, models, industrial designs and utility models; in the exercise of preventive measures; and in other actions or similar proceedings.

To that effect they are hereby empowered to file applications, formulate descriptions, amendments, protests, declarations, oppositions, cancellations, nullities, appeals and claims; to pay taxes, quotas and assessments prescribed by law, renounce or waive the rights granted or in the process of granting; to receive all kind of documents and valuables, ... the respective release of receipts ... before said auth... such effect, and any ... pertinent to the safeguard of my (our) interests, with all the other necessary legal powers.

This power includes the faculty to ... confirm desist, settle and compromise on my (our) behalf and to substitute this power in whole or in part and to revoke substitutions. ... hereby appoint RAMIRO CASTRO DUQUE and/or JUAN PABLO CADENA SARMIENTO and/or BEATRIZ JARAMILLO S. domiciled in Carrera 7 No. 16-56 Piso 9, my (our) attorneys in fact, with powers to receive notifications and to designate judicial and extrajudicial attorneys.

23 NOV 2004

OSCAR ALARCON NUÑEZ

05 DIC 2003

OSCAR ALARCON NUÑEZ
NOTARIO ...

Granted and signed in

VICE PRESIDENT &
ASSOCIATE GENERAL COUNSEL
TRADEMARK

this OCT 29 2001 day of 200_

Signature [signature]

Name

105
X0

CLERK
NEW YORK
COUNTY

Form 1

State of New York
County of New York, ss.:

I, NORMAN GOODMAN, County Clerk and Clerk of the Supreme Court of the State of New York, in and for the County of New York, a Court of Record, having by law a seal,

DO HEREBY CERTIFY pursuant to the Executive Law of the State of New York, that

Rosie S. Dizon

whose name is subscribed to the annexed affidavit, deposition, certificate of acknowledgment or proof, was at the time of taking the same a NOTARY PUBLIC in and for the State of New York duly commissioned, sworn and qualified to act as such; that pursuant to law, a commission or a certificate of his official character, with his autograph signature has been filed in my office; that at the time of taking such proof, acknowledgment or oath, he was duly authorized to take the same; that I am well acquainted with the handwriting of such NOTARY PUBLIC or have compared the signature on the annexed instrument with his autograph signature deposited in my office, and I believe that such signature is genuine.

IN WITNESS WHEREOF, I have hereunto set my hand affixed my official seal this

OCT 30 2001

FEE PAID $3.00

County Clerk and Clerk of the Supreme Court, New York County

COMO NOTARIO CUARENTA Y SEIS DEL CIRCULO DE SANTAFE DE BOGOTA, HAGO CONSTAR QUE ESTA COPIA FOTOSTATICA CONCIDE CON FOTOCOPIA AUTENTICADA QUE HE TENIDO A LA VISTA.
SANTAFE DE BOGOTA D.C. REPUBLICA DE COLOMBIA
23 NOV 2004
OSCAR ALARCON NUÑEZ
NOTARIO CUARENTA Y SEIS

COMO NOTARIO CUARENTA Y SEIS DEL CIRCULO DE SANTAFE DE BOGOTA, HAGO CONSTAR QUE ESTA COPIA FOTOSTATICA CONCIDE CON EL ORIGINAL QUE HE TENIDO A LA VISTA.
SANTAFE DE BOGOTA D.C. REPUBLICA DE COLOMBIA
05 DIC 2003
OSCAR ALARCON NUÑEZ
NOTARIO CUARENTA Y SEIS

X106

CERTIFICADO NOTARIAL (SOCIEDAD)

Hoy de de personalmente compareció ante mí

a quien conozco; y de quien me consta que firmó el anterior documento, debidamente juramentado declaró y dijo que él es

de

Sociedad legalmente constituida para un periodo de duración que aún no ha terminado; que el declarante está autorizado por dicha compañía para conferir este poder; que el sello estampado por él al pie de tal poder, en nombre y representación de la expresada compañía, es el sello oficial de ella; y que el objeto para el cual se confiere este instrumento está comprendido dentro del de la sociedad.

El suscrito Notario hace constar que tuvo a la vista las pruebas de la existencia de la sociedad.

Estado de
con fecha

y que quien confiere el presente poder es su representante.

Notario Público (sello)

NOTARIAL CERTIFICATE (CORPORATION)

On this [illegible] day of [illegible] personally appeared before me

SCOTT E THOMPSON

to me known, and known to me to be the person who signed the foregoing instrument who being by me duly sworn did depose and say that he (she) is the

VICE PRESIDENT & ASSOCIATE GENERAL COUNSEL TRADEMARK

of

COLGATE-PALMOLIVE COMPANY

Which is legally constituted for a term not yet expired, that deponent is authorized by said Company to confer this Power of Attorney; that the seal affixed hereunto by the deponent in the name and on behalf of said Corporation is the corporate seal thereof; and that the purpose for which this instrument is granted is included within the corporate purpose of company.

The undersigned Notary Public attests that he has seen the documents that prove the existence of the company.

State of Delaware
under date of May 13, 1997

and that he (she) who grants the present power of attorney is its Representative.

Notary Public (Seal)

ROSIE S. DIZON
Notary Public, State of New York
No. 31-4941117
Qualified in New York County
Commission Expires Aug. 15, 2002

CERTIFICADO NOTARIAL PERSONA NATURAL

Hoy de de , comparecié(eron) ante mí

a quien (es) conozco y me consta que es(son) la(s) persona(s) firmante(s) del documento que precede y quien(es) declara(n) que otorgan el mismo para los fines y propósitos que en él se expresan.

Notario Público (sello)

LEGALIZACION POR APOSTILLA ES REQUERIDA.

NOTARIAL CERTIFICATE

On this OCT 29 2001 day of personally appeared before me

SCOTT E THOMPSON

who is(are) known to me and who I attest executed the foregoing document and he (they) declare he (they) grant(s) the document for the uses and purposes therein expressed.

Notary Public (Seal)

ROSIE S. DIZON
Notary Public, State of New York
No. 31-4941117
Qualified in New York County
Commission Expires Aug. 15, 2002

LEGALIZATION BY APOSTILLE IS REQUIRED.

COUNTY

[illegible] NOTARIO CUARENTA Y SEIS DEL CIRCULO DE SANTAFE DE BOGOTA D.C. HAGO CONSTAR QUE ESTA FOTOCOPIA COINCIDE CON FOTOCOPIA AUTENTICADA QUE HE TENIDO A LA VISTA. SANTAFE DE BOGOTA D.C. REPUBLICA DE COLOMBIA

23 NOV 2004

OSCAR ALARCON NUÑEZ
NOTARIO CUARENTA Y SEIS

[illegible] SANTAFE DE BOGOTA D.C. REPUBLICA DE COLOMBIA

05 DIC 2005

OSCAR ALARCON NUÑEZ
NOTARIO CUARENTA Y SEIS

107

REPÚBLICA DE COLOMBIA

GAVIRI A

ORGANIZACION ELECTORAL
REGISTRADURÍA NACIONAL DEL ESTADO CIVIL

REGISTR CIVIL DE DEFUNCIÓN

Indicativo Serial 5562241

Datos de la oficina de registro

Clase de oficina: Registraduría [ ] Notaría [X] Consulado [ ] Corregimiento [ ] Insp. de Policía [ ] Código 9795

País - Departamento - Municipio - Corregimiento e/o Inspección de Policía

COLOMBIA CUNDINAMARCA BOGOTA D..C NOTARIA 32.

Datos del inscrito

Apellidos y nombres completos

CASTRO DUQUE RAMIRO

Documento de identificación (Clase y número)	Sexo (en Letras)
C.C.No. 170322 DE BOGOTA ------------	MASCULINO

Datos de la defunción

Lugar de la Defunción: País - Departamento - Municipio - Corregimiento e/o Inspección de Policía

COLOMBIA CUNDINAMARCA BOGOTA D.C.

Fecha de la defunción	Hora	Número de certificado de defunción
Año 2004 Mes 10 Día 30	04:10 PM	A- 2094375.

Presunción de muerte

Juzgado que profiere la sentencia	Fecha de la sentencia
------------------	Año Mes Día

Documento presentado	Nombre y cargo del funcionario
Autorización judicial [ ] Certificado Médico [X]	ANDRES- DIAZ CAMPOS.- R.M. No. 79982662

Datos del denunciante

Apellidos y nombres completos

EDGAR DAVID REGINO H.

Documentos de identificación (Clase y número)	Firma
C.C.No. 15.030.154 DE LORICA/ CORDOBA	[firma]

Primer testigo

Apellidos y nombres completos

Documentos de identificación (Clase y número)	Firma
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Segundo testigo

Apellidos y nombres completos

Documentos de identificación (Clase y número)	Firma
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Fecha de inscripción	Nombre y firma del funcionario que autoriza
Año 2004 Mes 11 Día 02	BLANCA CECILIA NOLECO RESTREPO NOTARIA

ESPACIO PARA NOTAS

PADRES: ALFON SO CASTRO
MERCEDES- DUQUE.

ORIGINAL PARA LA OFICINA DE REGISTRO

D1

108

US005855871A

United States Patent [19]

Masters et al.

[11] **Patent Number: 5,855,871**

[45] **Date of Patent: Jan. 5, 1999**

[54] **EFFERVESCENT TWO COMPONENT BICARBONATE AND ACID CONTAINING DENTIFRICE**

[75] Inventors: **James Masters**, Flemington; **Kim Carvino**, Somerset; **David Viscio**, Monmouth Junction; **James Kemp**, Somerset; **Salim Nathoo**, Piscataway, all of N.J.

[73] Assignee: **Colgate-Palmolive Company**, New York, N.Y.

[21] Appl. No.: **909,582**

[22] Filed: **Aug. 12, 1997**

[51] Int. Cl.[6] **A61K 7/16**; A61K 7/20; A61K 33/10

[52] U.S. Cl. **424/49**; 424/44; 424/53; 424/57

[58] Field of Search 424/49–58

[56] **References Cited**

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4,487,757	12/1984	Kinzpeopiou	424/49
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WO/PCT95/02392	1/1995	WIPO .
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Rustogi et al, The Journal of Clinical Dentistry, vol. III, Supplement C, pp. C9–C12 entitled "Refinement of the Modified Navy Plaque Index to Increase Plaque Scoring Efficiency in Gumline and Interproximal Tooth Areas".

Primary Examiner—Shep K. Rose
Attorney, Agent, or Firm—Henry S. Goldfine

[57] **ABSTRACT**

A two component efficacious dentifrice composition, having a first alkali metal bicarbonate containing dentifrice component and a second acid-containing dentifrice component; the first and second components being separated prior to use; wherein, the pH of the two components when combined upon application to the teeth is between about 6.0 and about 7.1; whereby, the dentifrice provides enhanced removal of plaque growth and a tingly mouth feel.

12 Claims, No Drawings

EFFERVESCENT TWO COMPONENT BICARBONATE AND ACID CONTAINING DENTIFRICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a two component dentifrice composition, having a first component containing an alkali metal bicarbonate salt and a second component containing an acid and more particularly to such a composition which exhibits a novel tingling mouth effect and enhanced removal of plaque growth.

2. The Prior Art

The addition of alkali metal bicarbonates to toothpaste for medicinal, general cleansing, or aesthetic purposes is known in the art. These bicarbonates are used as abrasives or polishing agents in dentifrice compositions providing moderate abrasion to remove debris and stained pellicle from tooth surfaces which are accessible to the toothbrush bristles. Further, it is known that bicarbonate-acid mixtures in toothpaste formulations will create an effervescent effect and that that effervescent effect can provide certain mouth feel and moderate cleaning benefits.

British Patent 1 209 319 discloses a bicarbonate containing foaming toothpaste, based on a single composition of an alcohol-containing gel, thickened to a paste with colloidal silica and an acid salt to initiate an acid reaction. The CO_2 released from the acid reaction enhances the cosmetically desirable froth formation of the active detergent conventionally present in toothpaste. However, the disclosed formulation is primarily non-aqueous, having a water content of not more than 10% by weight. For such a non-aqueous dentifrice to generate any appreciable effervescence, the stabilized ingredients will have to go into solution, a relatively slow process when the neat toothpaste is first applied to the teeth. Further, the non-aqueous formulation is composed of from 20 to 50% by weight of ethanol and/or propanol, having significant taste, mouth feel and potential irritation negatives.

U.S. Pat. No. 4,487,757 discloses a dual component alkali metal bicarbonate and acid containing toothpaste, wherein the bicarbonate containing component is isolated from the acid containing component in separate sections of a multi-section storage dispenser, to avoid any chemical reaction between the bicarbonate and acid during storage. Upon dispensing the two components first contact each other and are further brought into intimate contact upon use, fostering the acid-base reaction between the bicarbonate and the acid. U.S. Pat. No. 4,487,757 discloses an effervescence which helps clean the teeth; a clean mouth or a clean "mouth feel effect"; and an initial taste which may be somewhat acidic and also salty and becomes subsequently sweeter when the acid is combined with the bicarbonate containing component, in use, in the mouth.

U.S. Pat. No. 5,474,761 discloses oral compositions effective against plaque and gingivitis, containing a nonionic water insoluble antibacterial agent, in which an essential component is bicarbonate salt. The bicarbonate is usually used at a level of from 1 to about 50 percent. Further, the pH of the disclosed oral compositions and/or the pH of such compositions in the mouth is disclosed as being safe for the mouth's hard and soft tissues, from about 8.5 to about 9.5. As will hereinafter be shown, such high pH, bicarbonate containing dentifrices will not yield any appreciable acid-base reaction and hence, will not yield any appreciable effervescence nor the desired associated attributes therewith.

U.S. Pat. No. 5,215,740 discloses a one component dentifrice composition comprising sodium bicarbonate, one or more alkali metal pyrophosphate salts, a soluble fluoride ion source and other adjuvants, in admixture with a buffering agent. The buffering agent is incorporated in the dentifrice sufficient to buffer the pH to about 8.2 to 8.9, so as to decrease the risk of irritation of the oral mucosa or desquamation, as compared with dentifrices excluding such a buffering agent. However as will hereinafter be shown, such an alkaline pH, will inhibit any significant base/acid reaction with the bicarbonate and minimize any effervescence and associated product attributes.

There is an ongoing need for new and novel mouth feel benefits to promote the use of toothpaste, especially by children, as well as, for enhanced cleaning of the oral surfaces to better remove plaque growth and hence, reduce the oral decay and disease associated with plaque.

SUMMARY OF THE INVENTION

The present invention encompasses a two component dentifrice composition, having a first alkali metal bicarbonate containing dentifrice component and a second acid-containing dentifrice component; the first and second components being separated prior to use, wherein, the pH of the two components when combined upon application to the teeth is between about 6.0 and about 7.1; whereby unexpectedly, the dentifrice provides enhanced removal of plaque growth and the user experiences a desirable tingly mouth feel.

As will hereinafter be demonstrated, at higher pH ranges, e.g. such as described in U.S. Pat. No. 5,474,761 and U.S. Pat. No. 5,215,740, bicarbonate and acid containing dentifrices do not yield any appreciable effervescence, nor any of the other attributes associated therewith.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In use, the components of the two component dentifrice of the present invention, the first containing an alkali metal bicarbonate and the second containing an acid are combined in approximately equal weight proportions, so that only about one-half of the concentration of any particular ingredient within either component will be present when the components are combined and applied to the teeth, as by brushing. Both components are formulated similarly, with the significant exception being the presence of the bicarbonate in the first component and the acid in the second component. This similarity of ingredients is to provide similar apparent physical characteristics to promote similar rheology so that the two components are delivered in the desired equal measure by extrusion from a dual compartment tube or pump device.

Dentifrice Vehicle Common to Both Components

In the preparation of the both components of the present invention, the respective acid or bicarbonate is incorporated within a pharmaceutically-acceptable dentifrice vehicle suitable for use in the oral cavity, which contains water, humectant, surfactant and a polishing agent or abrasive. The humectant is generally a mixture of humectants, such as glycerol, sorbitol and polyethylene glycol of a molecular weight in the range of 200–1000, but other mixtures of humectants and single humectants may also be employed. The humectant content within each of the two components is in the range about of 10% to about 30% by weight and preferably about 10 to about 20% by weight. The water

content which is from about 30% to about 60%, and preferably from about 40 to 55% by weight.

First Component

The first toothpaste component, containing the alkali metal bicarbonate salt, is stable and non-effervescent and contains from about 5 up to, but less than, 15 percent by weight of bicarbonate. It is essential in the practice of the present invention that the pH of the toothpaste when the components are mixed in the mouth as by brushing be from about 6.0 to about 7.1. To obtain this pH in the combined toothpaste, the quantity of bicarbonate in the first component is preferably from about 8 to about 12 percent, and most preferably about 10 percent by weight whereby a pH within the first component is from about 7.5 to 9.5 and preferably from about 8.5 to 9.0. This quantity of bicarbonate salt will, in the combined toothpaste provide the desired pH and resulting effervescence, with the added benefit that the salty taste associated with bicarbonate salts is minimized.

Alkali metal bicarbonate present in the first component of the dentifrice of the present invention, includes potassium bicarbonate or sodium bicarbonate; however, sodium bicarbonate is preferred. Sodium bicarbonate is a powder composed of relatively soft particles compared to most conventional abrasive particles used in toothpastes. The size of the sodium bicarbonate particles may vary from course to fine; it is preferred that they be largely below about 0.4 mm in diameter, with a major proportion by weight being below about 0.01 mm. in diameter. Although, the vehicle in which the sodium bicarbonate particles are dispersed is an aqueous vehicle; a significant amount of the sodium bicarbonate will remain undissolved in the vehicle. However, it should be understood, that when the teeth are brushed with the combined two dentifrice components, the remaining undissolved sodium bicarbonate particles will tend to dissolve in the saliva. Such dissolving is helped by the presence of water in the toothpaste and upon such dissolution the effervescence development is speeded, and the tingly and other taste characteristics associated with the effervescence and the sodium bicarbonate are released.

Certain common toothpaste ingredients, which are basic in nature and hence not compatible with the acidic second component must, if present, be formulated in this first component of the toothpaste of the present invention. Examples of such common toothpaste ingredients include anti-tartar ingredients, such as sodium tripolyphosphate and tetrasodium pyrophosphate, and polishing agents, such as calcium carbonate and hydrated alumina.

Second Component

The second component of the toothpaste in the present invention, which is maintained physically separate from the first component prior to extrusion form the two component toothpaste tube or pump, includes within the above described pharmaceutically-acceptable dentifrice vehicle an acidic compound. Acidic compounds which can be present in the second component are malic acid, alginic acid, citric acid, succinic acid, lactic acid, tartaric acid, potassium bitartrate, acid sodium citrate, phosphoric acid, and acid phosphate and pyrophosphate salts, such as monosodium phosphate and disodium pyrophosphate. It is preferred that sodium dihydrogen phosphate, o-phosphoric acid, or sodium acid pyrophosphate be used individually or in combination. The quantity of acid compound will be from about 5 to about 15% by weight of the second component and preferably from about 8 to about 12% by weight of the second component; such that the pH of the second component is from about 1.5 to about 4.5, and preferably from about 2.5 to about 3.5; so that the pH of the combined dentifrice components upon application to the teeth is from about 6.0 to about 7.1.

Common Ingredients Within Both Components

Supplemental polishing agents or abrasives to the bicarbonate may be present in both components of the dentifrice and include sodium metaphosphate, potassium metaphosphate, tricalcium phosphate, dihydrated dicalcium phosphate, aluminum silicate, calcined alumina, or siliceous materials or combinations thereof. Preferred polishing agents include dicalcium phosphate and siliceous materials, such as silica and more preferably a precipitated amorphous hydrated silica, such as Zeodent 115, marketed by J. M. Huber Chemicals Division, Havre de Grace, Md. 21078, or Sylodent 783 marketed by Grace Davidson, Baltimore, Md. 21203.

Inorganic or organic thickeners (i.e. polymeric binders) may be included in the dentifrice of the present invention. Organic thickeners such as natural and synthetic gums and colloids may also be incorporated in the present invention. Examples of such organic thickeners include carrageenan (Irish moss), xanthan gum and sodium carboxymethyl cellulose, starch, polyvinylpyrrolidone, hydroxyethylpropyl cellulose, hydroxybutyl methyl cellulose, hydroxypropylmethyl cellulose, and hydroxyethyl cellulose. Inorganic thickeners are preferred, include amorphous silica compounds which function as thickening agents include, colloidal silicas compounds available under tradenames such as Cab-o-sil fumed silica manufactured by Cabot Corporation and distributed by Lenape Chemical, Bound Brook, N.J., Zeodent 165 from J. M. Huber Chemicals Division, Havre de Grace, Md. 21078, and Sylox 15 from Grace Davidson, Baltimore, Md. 21203. Either inorganic or organic thickening agents, or combinations thereof, may be present in both components of the instant dentifrice in proportions of about 0.1 to about 10% by weight, preferably about 5 to about 8% in each of the two components of the instant dentifrice.

Surface active agents may be incorporated in both components of the instant invention as an ingredient to aid in the thorough dispersion of the dentifrice throughout the oral cavity when applied thereto, as well as, to improve cosmetic acceptability and the foaming properties. The surface active agents which can be included within the vehicle of both components of the instant invention include anionic, nonionic or ampholytic compounds, anionic compounds being preferred. Examples of suitable surfactants include salts of the higher alkyl sulfates, such as sodium lauryl sulfate or other suitable alkyl sulfates having 8 to 18 carbon atoms in the alkyl group; sodium lauryl sulfoacetate, salts of sulfonated monoglycerides of higher fatty acids, such as sodium coconut monoglyceride sulfonate or other suitable sulfonated monoglycerides of fatty acids of 10 to 18 carbon atoms; salts of amides of higher fatty acid, e.g., 12 to 16 carbon atom acids, with lower aliphatic amino acids, such as sodium-N-methyl-N-palmitoyl tauride, sodium N-lauroyl-, N-myristoyl- and N-palmitoyl sarcosinates; salts of the esters of such fatty acids with isotonic acid or with glycerol monosulfate, such as the sodium salt of monosulfated monoglyceride of hydrogenated coconut oil fatty acids; salts of olefin sulfonates, e.g. alkene sulfonates or alkene sulfonates or mixtures thereof having 12 to 16 carbon atoms in the carbon chain of the molecule; and soaps of higher fatty acids, such as those of 12 to 18 carbon atoms, e.g., coconut fatty acids. The cation of the salt may be sodium, potassium or mono-, di or triethanol amine.

The surface active agent can be present in one or both components of the instant inventive compositions of the present invention at a concentration of about 0.5 to about 5.0% by weight, preferably about 1 to about 2% by weight of the particular component.

A striped dentifrice product may be obtained using the multicomponent dentifrice of the present invention, wherein colorants of contrasting colors are incorporated in each of the dentifrice components to be dispensed; the colorants being pharmacologically and physiologically non-toxic when used in the suggested amounts. Colorants used in the practice of the present invention include both pigments and dyes.

Pigments used in the practice of the present invention include non-toxic, water insoluble inorganic pigments such as titanium dioxide and chromium oxide greens, ultramarine blues and pinks and ferric oxides as well as water insoluble dye lakes prepared by extending calcium or aluminum salts of FD&C dyes on alumina such as FD&C Green #1 lake, FD&C Blue #2 lake, FD&C R&D #30 lake and FD&C # Yellow 15 lake. The concentration of the dye in the dentifrice composition in an amount from about 0.0005 percent to about 2 percent by weight of the respective component.

Other ingredients which may be incorporated in one or both components of the present invention, include sweetener, flavor and preservative. The sweetener content will normally be that of an artificial or synthetic sweetener and the normal proportion thereof present will be in the range of 0.1 to 1% by weight of the respective component, preferably 0.2 to 0.5% by weight the respective component. The flavor content, which is preferably of a mixed peppermint/menthol flavor, will usually be in the range of 0.5 to 2% by weight of the respective component, preferably 0.5 to 1.0% by weight of the respective component. The contents of other components or adjuvants of the potassium salt containing dentifrice component will normally not exceed 10% by weight, often will be less than 5% by weight, and can be as low as 0%.

To prepare each of the individual dentifrice components, generally the humectants e.g. glycerin, polyethylene glycol ingredients, are mixed with any organic thickener, polymeric binder, to form a first mix. A second mix of fluoride, sweetener and water (in the case of the bicarbonate first dentifrice component, only one-half of the formulation water is added at this point) is simultaneously prepared. For the acidic second component, the acid is added into this second mix. The first and second mixes are dispensed together in a conventional mixer until the mixture therein becomes a homogeneous gel phase. Into the gel phase are added any inorganic abrasive/polishing agent or thickener, including into the first component the sodium bicarbonate which is predissolved, as much as possible, in the balance of the first component water. These ingredients are mixed until a homogeneous phase is obtained. Thereafter the flavor and surfactant ingredients are added and the ingredients mixed at high speed under vacuum of about 20–100 mm Hg. The resultant product is in each case a homogeneous, semi-solid, extrudable paste product.

The two component dentifrice composition of the present invention is packaged in a suitable dispensing container in which the components are maintained physically separated and from which the separated components may be dispensed synchronously as a ribbon for application to a toothbrush. Such containers are known in the art. An example of such a container is a two compartment dispensing container having collapsible sidewalls, as disclosed in U.S. Pat. No. 4,487,757 and U.S. Pat. No. 4,687,663 wherein the container body is formed from a collapsible plastic web and is provided with a partition within the container body defining separate compartments in which the physically separated components are stored and from which they are dispensed through a suitable dispensing outlet.

The following examples are further illustrative of the present invention, but it are understood that the invention is not limited thereto. All amounts and proportions referred to herein and the appended claims are by weight.

EXAMPLE 1

The tooth cleaning and plaque removal efficacy of the multicomponent toothpaste of the present invention was assessed using a modified protocol based on the Rustogi Modification of the Navy Plaque index method (hereinafter Rustogi method), see Rustogi et al., *The Journal of Clinical Dentistry*, Vol. III, Supplement C, pages C9–C12 (1992). This index measures plaque removal efficacy by assessing the presence of plaque over the surface of any given tooth, both lingual and buccal, or 9 total subdivisions per side or 18 subdivisions per whole tooth, by identifing any plaque growth on the 18 subdivisions using a red plaque disclosing solution, such as D&C Red #28, marketed as Sultan Disclosing Solution Concentrate, Sultan Chemists, Inc., Englewood, N.J. 07631.

The total score for each tooth is the sum total of all sites of stained plaque on the tooth, each site either exhibiting a stain (counted as 1) or showing no stain (counted as 0). Accordingly, each tooth has a potential score of 18, if all sites show stain, indicating plaque accumulation. There is a direct correlation between the number of sites not having plaque growth and the tooth cleaning, plaque removal, efficacy of the dentifrice being tested. The lower the number having plaque or the lesser percentage of sites indicating plaque accumulation, the more effective is the antiplaque efficacy of the toothpaste.

After a week of usage, the Rustogi method was used to assess the cleaning efficacy of a two component dentifrice composition of the present invention by a panel of 5 human subjects, screened for good health and the absence of oral disease, in a cross-over, double blind (i.e. panelists and examiners are both unaware of the product being tested) panel test. The first component of the assessed dentifrice composition was an alkali metal bicarbonate containing component of the present invention, the formulation of which is presented in Table I, below. The second component of the assessed dentifrice composition was an acid containing or acidic component of the present invention, its formulation is presented in Table II, below. The combined components were designated as "Composition A."

After six days of brushing at least twice daily with Composition A, each panelist abstained from oral hygiene for a 24 hour period. After this abstention period, each of the panelists had their base-line plaque buildup assessed and scored using the Rustogi method, as discussed above. Each panelists then brushed his or her teeth using Composition A for a period of one minute and was reassessed, the plaque buildup rescored, and the reduction in sites determined to establish plaque removal efficacy. This reduction, after the one minute brushing with Composition A is recorded in Table V for each panelist.

TABLE I

Formulation Bicarbonate Component*

Ingredients	% by Weight
Glycerins - USP	18.31
Polyethylene Glycol 600	1.00
Deionized Water - Irradiated	49.83
Sodium Lauryl Sulfate	1.50
Xanthan Gum	1.25
Flavor	0.90
Sodium Fluoride	0.49
Titanium Dioxide	0.30
Tetrasodium Pyrophosphate	0.50
Sodium Saccharin	0.30
Sodium Bicarbonate	10.00
Zeodent 165	5.62
Syloblanc 783	10.00
Total	100.00

*Note: The level of each ingredient in the combination of the two component dentifrice is equal to approximately 50% of that shown within this one component.

The first bicarbonate containing component whose formulation is presented in Table I, was prepared by dispersing the formula quantities of xanthan gum and tetrasodium pyrophosphate in the glycerine and polyethylene glycol 600, using a high speed bench top mixer until a homogenous first pre-mix formed; one-half of the formula quantity of water was then used to dissolve the formula quantities of the sodium fluoride and the sodium saccharin using the high speed bench mixer to form a homogenous second premix; the balance of the water was then used to dissolve as much as possible of the sodium bicarbonate to form a third pre-mix; the first two pre-mixes were then mixed together using the high speed mixer to form a homogenous mixture and the third pre-mix was then added thereto and the mixing continued for about 15 minutes until a homogenous gel phase formed. This homogenous gel phase was transferred to a Ross type vacuum mixer and the formula quantities of the Zeodent 165 thickener and Zeodent 783 abrasive were added thereto and the mixing continued under 30 mm of Hg vacuum for 15 minutes. The formula quantities of the remaining ingredients, the sodium lauryl sulfate and flavor were then added to the Ross type vacuum mixer and this complete mixture was mixed under 30 mm of Hg vacuum for 10 minutes.

TABLE II

Formulation of Acidic Component*

Ingredients	% by Weight
Glycerine - USP	14.60
Polyethylene Glycol 600	1.00
Deionized Water - Irradiated	50.00
Sodium Lauryl Sulfate	1.50
Xanthan Gum	1.75
Flavor	0.90
Titanium Dioxide	0.30
Sodium Saccharin	0.30
Zeodent 165	7.65
Syloblanc 783	11.50
Sodium Dihydrogen Phosphate	5.50
o-Phosphoric Acid	3.00
Sodium Acid Pyrophosphate	2.00
Total	100.00

*Note: The level of each ingredient in the combination of the two component dentifrice is equal to approximately 50% of that shown within this one component.

The second acid containing or acidic component whose formulation is presented in Table II, was prepared by dispersing the formula quantities of xanthan gum in the glycerins and polyethylene glycol 600, using a high speed bench top mixer until a homogenous first pre-mix formed; one-half of the formula quantity of water was then used to dissolve the formula quantity of the titanium dioxide and the sodium saccharin using the high speed bench mixer to form a homogenous second pre-mix; the balance of the water was then used to dilute the formula quantity of o-phosphoric acid, sodium dihydrogen phosphate and sodium acid pyrophosphate to form a third pre-mix; the three pre-mixes were then mixed together using the high speed mixer to form a homogenous gel phase which was transferred to a Ross type vacuum mixer. Into this gel phase within the Ross type vacuum mixer was added the Zeodent 165 thickener and Zeodent 783 abrasive and this resulting product was mixed for 15 minutes under 30 mm of Hg vacuum. The formula quantities of the remaining ingredients, the sodium lauryl sulfate and flavor were then added to the Ross type vacuum mixer and this complete mixture was mixed under 30 mm of Hg vacuum for 20 minutes.

For purposes of comparison, the procedure of the Example I was repeated with two conventional one component dentifrice formulations, designated Control B and Control C, with the results recorded with those of Composition A in Table V. The formulations of comparative Control B and comparative Control C are shown below in Tables III and IV, respectively.

TABLE III

Comparative Control B Formulation

Ingredients	% by Weight
Deionized Water-Irradiated	7.04
Polyethylene Glycol 600	3.00
Sorbitol - 70% sol'n	60.737
Sodium Lauryl Sulfate	1.20
Sodium CMC	0.60
Flavor	0.72
Sodium Fluoride	0.243
Tetrasodium pyrophosphate	0.50
Sodium saccharin	0.30
Zeodent 115	25.5
Blue Toothpaste Color Sol'n	0.16
Total	100.00

TABLE IV

Comparative Control C Formulation

Ingredients	% by Weight
Deionized Water-Irradiated	24.94
Dicalcium Phosphate Dihydrate	48.76
Glycerine-USP	22.00
Sodium Lauryl Sulfate	1.20
Sodium CMC	1.00
Flavor	0.89
Sodium Monofluorophosphate	0.76
Tetrasodium Pyrophosphate	0.25
Sodium Saccharin	0.20
Total	100.00

TABLE V

Plaque Removing

Panelist Number	Dentifrice	Scoring Sites Tooth surfaces examined, at 18 sites per tooth	% of Sites with Plaque After 24 Hours
1	Composition A	504 (28 teeth)	44%
1	Control B	504	58%
1	Control C	504	60%
2	Composition A	468 (26 teeth)	54%
2	Control B	468	74%
2	Control C	468	85%
3	Composition A	486 (27 teeth)	49%
3	Control B	486	59%
3	Control C	486	65%
4	Composition A	486 (27 teeth)	63%
4	Control B	486	70%
4	Control C	486	88%
5	Composition A	432 (24 teeth)	49%
5	Control B	432	68%
5	Control C	432	50%

The pH of Composition A, a dentifrice of the present invention, was approximated at brushing conditions in the mouth by diluting 1 part Composition A with 3 parts water to be 6.86. The pH of comparative dentrifrices Control B and Control C, were likewise ascertained at a 1:3 dilution to be 7.7 and 7.2, respectively. Referring to Table V, the plaque removal or cleaning by the two component combination of Composition A, of the present invention, was statistically different and more effective for removing plaque growth than the standard, comparative Control B (wherein p=0.02 comparing Composition A to Control B) and Control C dentifrices (wherein p<0.01 comparing Composition A to Control C).

EXAMPLE 2

The taste and mouth feel of the two component dentifrice of the present invention, Composition A, was assessed by a panel of 79 panelists using a randomized sequential monadic design test. Each panelist was given a sample of the two component dentifrice of the present invention of the formula as presented in Example I and after using it three times over the course of a day, was asked to rate the intensity level of the samples taste and sensory attributes, such as cooling, grittiness, foam, moistness, dryness, coating, tingle, salty, bitter, etc. The intensity levels were rated on a 10 level scale, from the attribute not being present at 0, to very strongly present at 10.

For purposes of comparison, the procedure of the Example 2 was repeated with a standard dentifrice of the formula of Control C, as detailed above, and with a one component, sodium bicarbonate/calcium peroxide dentifrice, Control D (having a pH of 8.65 at a 1:3 dentifrice to water dilution). The formulations of comparative Control D is presented in Table VI, below.

An analysis of the results showed that Composition A, the two component effervescent dentifrice of the present invention with a dilute "in the mouth" pH of 6.86 gave a significant tingling mouth feel. The one component, standard dentifrice of formula Control C, having a pH of 7.21, was found to give only a nominal tingling mouth feel, statistically different than the significant mouth feel provided by Composition A (within a statistically significant p=0.10). Further, the bicarbonate/peroxide dentifrice of formula Control D, with a pH of 8.65 and nominal effervescence, provided only a nominal tingling mouth feel, statistically to a significance of p=0.10, the same as the standard dentifrice of Control C and less than that of Composition A.

TABLE VI

Comparative Control D Dentifrice

Ingredient	Weight Percent
Glycerine	26.00
Carrageenan	0.20
Sodium CMC	0.20
Polyethylene Glycol	15.89
Sodium Saccharin	0.20
Sodium monofluorophosphate	0.76
Tetrasodium pyrophosphate	2.00
Sodium Tripolyphosphate	3.00
Deionized Water	10.00
Titanium Dioxide	0.30
Zeodent 115	20.00
Zeodent 165	1.50
Sodium Bicarbonate	16.00
Sodium Hydroxide - 50% Solution	1.50
Calcium Peroxide	0.50
Flavor	0.75
Sodium Lauryl Sulfate	1.20
Total	100.00

EXAMPLE 3

To better understand the relationship between pH and the effervescence in acid-base dentifrices, a dentifrice of the present invention was prepared using the formula of Composition A.

In a constant temperature bath, at 37° C., 10.0 grams of the bicarbonate component of Composition A (per Table I) was mixed with 10.0 grams of the acidic component of Composition A (per Table II) and 1 part of this mixture was then diluted with 3 parts water to form a slurry. The pH of this slurry was adjusted by adding 1molar HCl or 1 molar NaOH, as required, and the CO_2 produced was accumulated and measured. The pH was adjusted over a range of from 5.6 to 8.8 and the quantity of CO_2 produced from each individual slurry was measured, the results are shown in Table VII, below.

TABLE VII

Effervescence Produced at Varying pH

pH of Dilute Dentifrice	CO_2 Generated (in ml)
5.6	36
6.2	37
6.8	35
7.1	33
7.6	17
8.2	6
8.8	5

The results recorded in Table VII indicate that a pH of 7.1 or less is necessary to generate the significant CO_2 necessary to provide the enhanced plaque growth removal/cleaning and novel tingly mouth feel properties disclosed by the present invention. However, while pH levels less than 6.0 do generate significant CO_2 in dentifrices of the present invention, such lower pH imparts a negative acid taste to the dentifrice which is generally unacceptable to consumers.

What is claimed is:

1. A two component dentifrice composition comprising a first dentifrice component containing alkali metal bicarbon-

ate in a vehicle with a humectant content of from about 10 to about 30% and a water content of about 40 to about 55% and a second dentifrice component containing acid in a vehicle with a humectant content of from about 10 to about 30% and a water content of about 40 to about 55%; the first and second dentifrice components being separated in separate compartments of a two component dentifrice dispensing means prior to use; wherein, the pH of the two dentifrice components when combined upon dispensing and application to the teeth is between about 6.0 and about 7.1; whereby, the dentifrice provides enhanced removal of plaque growth and a tingly mouth feel.

2. The composition of claim 1, wherein the alkali metal bicarbonate is sodium bicarbonate.

3. The composition of claim 1, wherein the second acid-containing dentifrice component contains either malic acid, alginic acid, citric acid, succinic acid, lactic acid, tartaric acid, potassium bitartrate, acid sodium citrate, phosphoric acid, acid phosphate or disodium pyrophosphate or combinations thereof.

4. The composition of claim 1, wherein the first alkali metal bicarbonate dentifrice component contains either sodium metaphosphate, potassium metaphosphate, tricalcium phosphate, dihydrated dicalcium phosphate, calcium carbonate, aluminum silicate, hydrated alumina, calcined alumina, or siliceous materials or combinations thereof.

5. The composition of claim 4, wherein the siliceous material is amorphous hydrated silica.

6. The composition of claim 1, wherein the first alkali metal bicarbonate component contains sodium tripolyphosphate or tetrasodium pyrophosphate or a combination thereof.

7. A method for enhancing the removal of plaque growth and providing a novel tingling mouth feel which comprises preparing a two component dentifrice; the first dentifrice component containing an alkali metal bicarbonate in a vehicle with a humectant content of from about 10 to about 30% and a water content of about 40 to about 55%, the second dentifrice component containing an acid in a vehicle with a humectant content of from about 10 to about 30° and a water content of about 40 about 55% maintaining the first and second dentifrice components separate from each other in respective compartments of a two component dentifrice dispensing means until dispensed for application to teeth; whereupon the pH of the two dentifrice components when combined to form the dentifrice composition and applied to the teeth will be between about 6.0 and 7.1.

8. The method of use of claim 7, wherein the alkali metal bicarbonate is sodium bicarbonate.

9. The method of use of claim 7, wherein the second acid-containing dentifrice component contains either malic acid, alginic acid, citric acid, succinic acid, lactic acid, tartaric acid, potassium bitartrate, acid sodium citrate, phosphoric acid, acid phosphate or disodium pyrophosphate or combinations thereof.

10. The method of use of claim 7, wherein the first alkali metal bicarbonate dentifrice component contains either sodium metaphosphate, potassium metaphosphate, tricalcium phosphate, dihydrated dicalcium phosphate, calcium carbonate, aluminum silicate, hydrated alumina, calcined alumina, or siliceous materials or combinations thereof.

11. The method of use of claim 7, wherein the siliceous material is amorphous hydrated silica.

12. The method of use of claim 7, wherein the first alkali metal bicarbonate component contains sodium tripolyphosphate or tetrasodium pyrophosphate or a combination thereof.

* * * * *

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(54) Title: DUAL COMPONENT DENTIFRICE COMPOSITION FOR DENTAL FLUORIDATION

(57) Abstract

A dual component dentifrice composition in which the first component is a stable, semi-solid, extrudable dentifrice composition containing a fluoride ion releasable compound in which calcium ion is absent and the second component is a semi-solid, extrudable dentifrice composition containing a dicalcium phosphate abrasive having a magnesium ion content less than about 0.5 % by weight wherein increased fluoride uptake is achieved when the components are mixed upon application to dental tissue.

Example I

A combined dentifrice composition of the present invention, designated "Composition X", composed of a Component (A) and a Component (B) was prepared wherein the individual components contained the ingredients as set forth in the Table below.

Ingredients	Dentifrice X (Wt.%)	
	Component A	Component B
Deionized water	3.000	24.940
Glycerin (99.3%)	25.000	22.000
Sorbitol (70%)	41.676	--
Sodium lauryl sulfate	1.200	1.200
Dicalcium phosphate dihydrate (DCPD)	--	49.520
Titanium oxide	0.500	--
Saccharin	0.200	0.200
Sodium fluoride	0.484*	--
Flavor	0.890	0.890
Polyethylene glycol 600	3.000	--
Sodium carboxymethyl cellulose	0.350	1.000
Food Color FDC Blue #1 (1%)	0.200	--
Silicon Dioxide	18.000	--
Amorphous Silica	5.500	--
Tetrasodium pyrophosphate	--	0.250
Total	100.000	100.000

*1100 ppm releasable F^- in combined components.

The DCPD abrasive used in the preparation of Component A had a magnesium content of zero and a pyrophosphate content in the range of 0.1 - 0.4% by weight of the abrasive.

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CLAIMS

What is claimed is:

1. A dual component dentifrice composition for the fluoridation of tooth structures in which a first component is a stable, semi-solid, extrudable dentifrice composition which is free of calcium ion and contains a fluoride releasable salt and the second component is a semi-solid, extrudable dentifrice composition containing a dicalcium phosphate abrasive having a magnesium ion content less than about 0.5% by weight based on the weight of the abrasive, the first and second dentifrice components having substantially equivalent viscosities to obtain synchronous extrusion of the components when dispensed for application to the teeth, the components when mixed upon application to teeth providing increased deposition of fluoride thereon.

2. The composition of claim 1 wherein the dicalcium phosphate abrasive is dicalcium phosphate dihydrate.

3. The composition of claim 1 wherein the fluoride releasable salt is NaF.

4. The composition of claim 1 wherein the magnesium ion concentration of the dicalcium phosphate abrasive is from 0 to 0.3% by weight.

5. The composition of claim 1 wherein the first and second components are physically segregated prior to extrusion.

6. The composition of claim 1 wherein the components are extrudable at a volume ratio of 0.9:1 to 1:0.9.

7. The composition of claim 1 wherein the components are extrudable at a volume ratio of 1:1.

8. A method for fluoridation of teeth which comprises preparing a dual component dentifrice composition in which a first component is a stable, semi-solid, extrudable dentifrice composition which is free of calcium ion and contains a fluoride releasable salt and the second component is a semi-solid, extrudable dentifrice composition containing a dicalcium phosphate abrasive having a magnesium ion content less than about 0.5% by weight based on the weight of the abrasive, the first and second

dentifrice components having substantially equivalent viscosities, synchronously extruding the components for application to the teeth and then mixing the components upon application to the teeth whereby enhanced deposition of fluoride on the teeth is obtained.

9. The method of claim 8 wherein the dicalcium phosphate abrasive is dicalcium phosphate dihydrate.

10. The method of claim 8 wherein the fluoride releasable salt is NaF.

11. The method of claim 8 wherein the magnesium ion concentration of the dicalcium phosphate abrasive is from 0 to 0.3% by weight.

12. The method of claim 8 wherein the first and second components are physically segregated prior to being dispensed.

13. the method of claim 8 wherein the components are extrudable at a volume ratio of 0.9:1 to 1:0.9.

14. The method of claim 8 wherein the components are extrudable at a volume ratio of 1:1.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

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Título de la solicitud: "COMPOSICIÓN DENTÍFRICA DE COMPONENTE DUAL PARA FLÚORIZAR LOS DIENTES"

Como resultado del examen de patentabilidad de la solicitud de patente de invención, realizado según lo establece el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se notifica el siguiente concepto técnico:

Documentos estudiados

Para el presente estudio se tuvieron en cuenta el capítulo descriptivo comprendido en los folios 5 - 21 y el capítulo reivindicatorio de los folios 22 – 23 de la solicitud.

Objeto de la Invención

El objeto de la presente solicitud de patente de invención consiste en:

Un método para la fluorización de dientes que utiliza un dentífrico de dos componentes, libre de calcio soluble en agua, comprende los pasos de (1) preparar un componente de fluoruro de sodio y pH 7,5, y otro componente de iones fosfato y un ácido para mantener el pH en 2,5 - 5,0; ambos componentes de dentífrico contienen un abrasivo de sílice; (2) mantener los primer y segundo componentes de dentífrico separados el uno del otro hasta la aplicación a los dientes que requieren de fluorización; (3) mezclar los primer y segundo componentes y (4) aplicar la mezcla a los dientes.

El problema planteado en esta solicitud es la necesidad de un método para la fluorización de dientes.

Para resolver este problema técnico la solicitud en estudio proporciona un método que comprende los pasos de (1) preparar dos componentes de dentífrico; (2) mantenerlos separados; (3) mezclarlos y (4) aplicar la mezcla a los dientes.

El objeto de la invención definido anteriormente se clasificó de acuerdo con la IPC: A 61 K 7/16, A 61 K 7/18.

También se reivindica prioridad de la Solicitud de Patente de los Estados Unidos US 09 067 819 de abril 28 de 1998, con respecto a la cual la fecha de presentación de la actual solicitud cumple el plazo máximo permitido.

Unidad de Invención

El artículo 25 de la Decisión 486 establece: *"La solicitud de patente sólo podrá comprender una invención o un grupo de invenciones relacionadas entre sí, de manera que conformen un único concepto inventivo".*

En una solicitud de patente se puede reivindicar:
a) una sola invención; o
b) un grupo de invenciones relacionadas entre sí por un único concepto inventivo.
Cuando se trate del caso b), se debe considerar que el concepto inventivo único que relaciona las invenciones debe ser técnico, cumplir por sí mismo con los requisitos de novedad y nivel inventivo, y ser común a todas las reivindicaciones.

Las reivindicaciones no mencionan en forma clara y ordenada su objeto. Contienen elementos tan diferentes como:
- Un método para la fluorización de dientes
- Una composición dentífrica
- Y su uso, que consiste en aplicarla a los dientes,

No mantienen el principio de la unidad de invención porque no pertenecen al mismo campo técnico.

Debe hacerse la corrección respectiva.

Usos

El artículo 21 de la Decisión 486 de la Comisión de la Comunidad Andina establece que: *"Los productos o procedimientos ya patentados, comprendidos en el estado de la técnica, de conformidad con el artículo 16 de la presente Decisión, no serán objeto de nueva patente, por el simple hecho de atribuirse un uso distinto al originalmente comprendido por la patente inicial".*

El artículo 14 de la Decisión 486 de la Comisión de la Comunidad Andina establece que *"Los Países Miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial".*

El Artículo 19 de la Decisión 486 de la Comisión de la Comunidad Andina establece que *"Se considerará que una invención es susceptible de aplicación industrial, cuando su objeto pueda ser producido o utilizado en cualquier tipo de industria, entendiéndose por industria la referida a cualquier actividad productiva, incluidos los servicios."*

Las reivindicaciones se refieren al uso de un dentífrico de dos componentes, uno contiene fluoruro de sodio y pH 7,5, y otro iones fosfato y un ácido para mantener el pH en 2,5 - 5,0; ambos componentes de dentífrico contienen un abrasivo de sílice y se mantienen separados hasta la aplicación a los dientes.

Se aclara que, de acuerdo con el Art 14, no se puede otorgar patente a usos porque estos no son un producto ni un procedimiento tecnológico.

De otro lado, de acuerdo con el Art 19, se considera que los usos no tienen aplicación industrial porque no se refiere a un tipo de producción ó utilización en ningún tipo de industria.

Además el uso reivindicado no puede ser objeto de nueva patente, aunque el

solicitante lo considere distinto al originalmente comprendido por la patente US 5855 871 que enseña el uso de uso del dentífrico de dos componentes (ver columnas 11 y 12).

Determinación del Estado de la Técnica

El artículo 16 de la decisión 486 de la comisión de la Comunidad Andina que establece que "*El estado de la técnica comprenderá todo lo que haya sido accesible al publico por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida.*

Solo para el efecto de la determinación de la novedad, también se considerará dentro del estado de la técnica, el contenido de una solicitud de patente en trámite ante la oficina nacional competente, cuya fecha de presentación o de prioridad fuese anterior a la fecha de presentación o de prioridad de la solicitud de patente que se estuviese examinando, siempre que dicho contenido esté incluido en la solicitud de fecha anterior cuando ella se publique o hubiese transcurrido el plazo previsto en el articulo 40".

Considerando que la fecha de presentación de la primera solicitud de patente de la cual se reivindica prioridad es Marzo 6 de 2000, se consultaron las bases de datos y los archivos con que cuenta la entidad con fecha de publicación anterior y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

No.	Documento	Título	Fecha de Publicación
D1	US 5 855 871	Effervescent two component bicarbonate and acid containing dentifrice	Ene 5, 1999
D2	WO 97 46216	Dual component dentifrice composition for dental fluoridation	Dic 11, 1997

Evaluación de los requisitos de Patentabilidad

El artículo 14 de la Decisión 486 de la Comisión de la Comunidad Andina establece que "*Los Países Miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial*".

En cumplimiento del artículo 14 de la Decisión 486, se procedió a evaluar el cumplimiento de los requisitos de novedad, nivel inventivo y aplicación industrial, con el fin de establecer la patentabilidad de la invención reivindicada en la solicitud en estudio.

Evaluación de la Novedad

El Art. 16 de la Decisión 486 de la Comisión de la Comunidad Andina establece: "*Una invención se considerará nueva cuando no está comprendida en el estado de la técnica. El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente, o, en su caso, de la prioridad reconocida.*

Solo para el efecto de la determinación de la novedad, también se considerará dentro del estado de la técnica, el contenido de una solicitud de patente en trámite ante la oficina nacional competente, cuya fecha de presentación o de prioridad fuese anterior a la fecha de presentación o de prioridad de la solicitud de patente que se estuviese examinando, siempre que dicho contenido esté incluido en la solicitud de fecha anterior cuando ella se publique o hubiese transcurrido el plazo previsto en el Art 40".

Se observa que los elementos característicos del dentífrico reivindicado, es decir **dos componentes**, uno contiene **fluoruro de sodi y pH 7,5**, y otro iones

fosfato y un **ácido** para mantener el **pH en 2,5 - 5,0**; donde ambos componentes contienen un **abrasivo de sílice** y se mantienen **separados** hasta la aplicación a los dientes eran conocidos en D1 (ver columna 7), por lo cual no puede considerarse nuevo.

Evaluación del Nivel Inventivo

El artículo 18 de la Decisión 486 de la Comisión de la Comunidad Andina establece que *Se considerará que una invención tiene nivel inventivo, si para una persona del oficio normalmente versada en la materia técnica correspondiente, esa invención no hubiese resultado obvia ni se hubiese derivado de manera evidente del estado de la técnica.*

D1 enseña los elementos mencionados en las reivindicaciones: **dentífrico de dos componentes**, uno contiene **fluoruro de sodio** y **pH 7,5**, y otro iones **fosfato** y un ácido para mantener el **pH en 2,5 - 5,0**; ambos componentes de dentífrico contienen un abrasivo de **sílice** y se mantienen **separados** hasta la aplicación a los dientes.
Debido a que D2 también sugiere **el dentífrico**, una persona conocedora del arte tomaría en consideración tales enseñanzas y llegaría al reivindicado en esta solicitud. No se observa un efecto inesperado en el dentífrico reivindicado, por lo cual es obvio y no tiene nivel inventivo.

Lo reivindicado tendría nivel inventivo si presentara propiedades sorprendentes en comparación con el estado del arte y resolviera un problema que no se hubiese resuelto en la técnica.

Conclusión

En conclusión, los requisitos de patentabilidad de la presente solicitud están afectados así:

Item	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	US 5 855 871	1 – 12	Novedad y Nivel inventivo
D2	WO 97 46216	1 – 12	Novedad y Nivel inventivo

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de la notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Unica No. 10 de 2001.

ALIX CARMENZA CESPEDES DE VERGEL
Jefe de la División de Nuevas Creaciones.

El anterior requerimiento fue notificado por fijación en lista, de fecha 19 ENE. 2007

CONCEPTO TÉCNICO No. 35	EXAMINADOR TÉCNICO Código 202007