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

REF: Expediente No. 04 122180 - solicitud de patente de invenciOn a favor de COLGATE PALMOLIVE COMPANY.

Respuesta a oficio No. 09880 del 01 de agosto de 2008

JUAN PABLO CADENA SARMIENTO, portador de la tarjeta profesional No. 57.492 del C.S.J., obrando como apoderado de la sociedad COLGATE PALMOLIVE COMPANY, segün 10 acredita el documento de poder presentado ante esa DivisiOn, me permito dar respuesta a las observaciones de carÆcter tØcnico y juridico, relacionadas con la patentabilidad, para la concesiOn de la patente de acuerdo con la DecisiOn 486 segUn el concepto tØcnico No. 1683 notificado por fijaciOn en lista de fecha 01 de agosto de 2008.

En primer lugar se adjunta un nuevo capitulo reivindicatorio de 1-8 reivindicaciones que atiende todos los requerimientos de patentabilidad realizados por el Seæor Examinador y elimina las reivindicaciones relativas a mØtodo de tratamiento; asimismo este nuevo capitulo reivindicatorio no amplia la materia inicialmente divulgada, y encuentra entero sustento en la descripciOn.

La nueva reivindicaciOn I incorpora elementos aUn mÆs definitorios de la composiciOn; dichos elementos cuentan con todo el soporte descriptivo y en ese sentido se solicita respetuosamente at Seæor Examinadordirigirse a las pÆginas 5-9, 22 y al Ejemplo 1; este ültimo que especIficamente evidencia composiciones como las que se reclaman en la nueva reivindicaciOn 1.

BRIGARD & CASTRO ABOGADOS S.A. - NIT. 860.047.372-8

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Sobre la observaciOn del SeæorExaminador sobre la falta de correlaciOn entre el
efecto demostrado y la segregaciOn que se presenta en el producto es deseo del solcitante aclarar enfÆticamente que la superioridad evidencada no se debe ü nicamente a la segregacion de los componentes, por el contrario esta superioridad se basa en la formulaciOn y el diseæo completos dela composiciôn oral reclamada, teniendo en cuenta su naturaleza fisica y sus elementos constitutivos como un todo.
Ahora bien, la comparaciOn realizada permite precisamente observar el efecto de la composición como un todo y en este sentido su superioridad queda manifiesta, sin existir entonces razón justificada para no atribuir el efecto evidenciado a la composición reclamada.

Por otro lado, en referenda a la objeciôn de nivel inventivo realizada por el Seæor Examinador a la luz del documento Dl es preciso seæalar que el documento Dl divulga composiciones duales en las que la enzima se encuentra en la fase grasa, en completa contraposición a la presente solicitud en donde se requiere que la enzima se encuentre en una fase acuosa junto con le humectante. AUn mÆs, las fases grasa y acuosa del Ejemplo I de Dl no se encuentran fIsicamente segregadas antes de su uso, como se requiere tambiØn en la presente invención y adicionalmente Dl carece de ensenanza o siquiera sugerencia alguna sobre el uso de un humectante y un abrasivo en cada uno de los componentes, ni brinda una motivaciOn particular para separar cada uno de los componentes, toda vez que la actividad de la enzima no se enseæa a ser destruida por el contacto.

AdemÆs de lo anterior, Dl indica expresamente en su pagina 3 que la variabilidad de las proporciones relativas de la pasta enzimÆticay no enzimÆtica es "de especial interØs" y de esta manera se requiere de diferentes proporciones relativas obtenibles del tubo dependiendo de la hora del dia (en la maæana despuØs del desayuno o en la noche luego de la cenao antes de dormir). Asi, las divulgaciones de Dl requieren de proporciones variables de dos pastas constitutivas. De ahI, que el problema tØcnico a resolverse en Dl sea Ia necesidad de una pasta con cantidades relativas y composiciones diferentes de las dos fases grasa y acuosa de manera que no entran en contacto dentro del

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BRIGi\RDS CARRERA7 #71 21 TORRE B - PISO 4

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tubo antes de su uso, siendo extruible a partir del tubo para ser utilizada en cantidades variables dependiendo del momento en que se use en el dIa.
En contraste el problema tØcnico enfrentado en la presente solicitud se refiere a proveer un primer y un segundo componente dentIfrico que comprendan una fase acuosa con humectante y que se encuentren segregados fisicamente previo a su uso, de to que ademÆsno existe sugerencia en DI.

En consecuencia, la invenciOn en su nuevo formato de reclamaciOn es inventiva en relaciOn con Dl.

En vista de lo anterior, respetuosamente olicitamos el retiro de las objeciones a la presente solicitud, sobre la base de los a.gumentos presentados y el nuevo capItulo reivindicatorio que, en opiniOn del sol&citante, cumple con todos los requisitos establecidos en la DecisiOn 486.

De la SeæoraJefe,

Atentamente,

ZPAB11CADENASARMIENTO
T.P. No. 57.492 del C.SJ.
C.C. 80.410.337 de Usaquen
Carrerä 7 No. 71-21, Torre B, Of. 402

Bogota, 24 de octubre de 2008

Anexos

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REIVINDICACIONES -

1. Una composición oral antiplaca de componente dual efectiva para reducir la placa y el mal olor que comprende un primer componente que contiene un humectante, un abrasivo y un agente antibacterial no iônico y el segundo componente que tiene un humectante, un abrasivo y una enzima proteolitica; los componentes primero y segundo estando combinados simultÆneamente para la aplicación a los dientes; los componentes primero y segundo estando segregados fisicamente antes del uso; los componentes cuando se mezclan con la aplicaciôn a los dientes proporcionan un efecto antiplaca con un beneficio superior en contra del mal olor.

2. La composición tal y como se reivindica en la reivindicaciôn 1,
caracterizada porque el dentifrico contiene un abrasivo de silice que tiene un valor de absorciOn de aceite de menos de 100cc/1Og de silice.

3. La composiciôn tal y como se reivindica en la reivindicaciôn 1,
caracterizada porque el abrasivo de silice de absorciOn de aceite baja estÆpresente en la composiciôn a una concentraciOn de airededor de 5 a airededor de 40% por peso de la composiciôn.

4. La composición tal y como se reivindica en la reivindicaciôn 1;
caracterizada porque la enzima proteolitica es papalna.

5. La composición tal y como se reivindica en la reivindicaciOn 1, caracterizada porgue la enzima proteolitica estÆpresente en el dentifrico en una combinación con una lipasa.

6. La composición tal y coma se reivindica en la reivindicaciOn 1, caracterizada porque la enzima proteolitica estÆ presente en la composiciOn dentifrica en combinaciOn con una lipasa y glicoamilasa.

7. La composición tal y coma se reivindica en la reivindicaciôn 1,
caracterizada porque cada enzima de la reivindicaciôn 6 estÆpresente en la composición a una concentraciOn de alrededor de 0,02 a airededor de 5,0% por peso de la composición.

8. La camposición tal y coma se reivindica en la reivindicaciôri 1,
caracterizada porque el agente antibacterial no iónico es Triclosan.

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(12) United States Patent (10) Patent No.: US 69379,654 Bi
Gebreselassie et al. (45) Date of Patent: Apr. 30, 2002

(54) ORAL COMPOSITION PROVIDING
ENHANCED TOOTH STAIN REMOVAL

(75) Inventors: Petros Gebreselassle, Piscataway;
Diego Hole, Highland Park, James G.
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West Windsor, all of NJ (US)

(73) Assignee: Colgate Palmolive Company, New York, NY (US)

() Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35
U.S.C. 154(b) by 43 days.

(21) AppI. No.: 09/698,453

(22) Filed: Oct. 27, 2000

(51) mt. C1,7............................A61K 7/28; A61K 7/16; A61K 7/18; A61K 38/43
(52) U.S. Cl.............................. 424/50; 424/49; 424/52; 424/94.1; 424/94.6; 424/94.63
(58) Field of Search.....................424/50, 52; 106/492;
514/23

(56) References Cited

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* cited by examiner

Primary ExaminerChristopher R. Tate
Assistant ExaminerRandall Winston

(74) Attorney, Agent, or FinnPaul Shapiro

(57) ABSTRACT

An abrasive dentifrice composition which effects enhanced tooth and stain removal which comprises an orally accept-able vehicle containing a combination of a low oil absorp-tion silica abrasive having an oil absorption value of less than 100 cc/100 g silica and an proteolytic enzyme.

14 Claims, No Drawings

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ORAL COMPOSITION PROVIDING
ENHANCED TOOTH STAIN REMOVAL

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to oral compositions for removing tooth stains, and more particularly, to enzyme enhanced silica abrasive containing dental compositions effecting stain removal from teeth.
1 The Prior Art

Many substances that a person confronts or comes in contact with on a daily basis can "stain" one’s teeth. In particular, foods, and fluids such as tea and coffee that one

consumes tend to stain one’s teeth. These products or substances tend to accumulate on the enamel layer of the
tooth and form a pellicle film over the teeth. These staining and discoloring substances can then permeate the enamel layer. This problem occurs gradually over many years, but imparts a noticeable discoloration of the enamel of one’s teeth.

Synthetically produced silicas incorporated in dentifrice compositions act as an abrasive to debride and physically

scrub the external surface of the teeth. This scrubbing action removes the organic film (i.e. the pellicle), formed of
salivary proteins which covers the teeth and which become stained and discolored. Such physical removal ofthe stained pellicle is a simple and effective means of removing the

undesirable surface staining and discoloration which occurs daily.
Synthetic silicas useful as dentifrice abrasives include both silica gels and precipitated silicas which are prepared

by the neutralization of aqueous silicate solutions with a strong mineral acid. In the preparation of silica gel, a silica
hydrogel is formed which is then typically washed to a low salt content. The washed hydrogel may be milled to the desired size, or otherwise dried, ultimately to the point where its structure no longer changes as a result of shrink-age. When preparing such synthetic silicas, the objective is to obtain abrasives which provide maximal cleaning (i.e. removal of stained pellicle) with minimal damage to the tooth enamel and other oral tissue.

U.S. Pat. No. 4,153,680 and GB PatentApplication 2,038,

303A both disclose the general use of silica hydrogels or hydrated silica gels as dental abrasives,
U.S. Pat. No. 5,939,051 discloses dentifrice compositions prepared with silica gels having low abrasion and high cleaning properties.
U.S. Pat. Nos. 5,658,553 and 5,651,958 disclose denti-frice compositions containing a combination of precipitated

silica and siliŁa gels having high cleaning and low abrasion as indicated by their low radioactive dentin abrasion (RDA)

values.

Copending patent application U.S. Ser. No. 09/567,402 filed May 9, 2000 discloses a silica hydrogel containing about 10 to about 35% by weight water, whereby the

dentifrice composition has an RDA of from 110 to 200, and a PCR of from about 150 to about 300. In spite of the extensive prior art relating to silica hydro- gels and other abrasive compounds used to prepare denti-
frice compositions for oral cleaning and stain removal, there is still a need for additional compositions providing improved pellicle cleaning and stain removal. SUMMARY OF THE ENVENTION

In accordance with the present invention there is provided a silica abrasive dentifrice composition which exhibits

heightened tooth stain removal which composition com- prises an orally acceptable vehicle containing a combination
of a low oil absorption silica abrasive having an oil absorp-tion value of less than 100 cubic centimeters (cc)/100 grams (g) silica and a proteolytic enzyme.
DETAILED DESCRIPTION OF THE
INVENTION

Low Oil Absorption Silica Abrasives
Silica abrasives useful in the practice of the present
10 invention include silica gels and precipitated amorphous silica having an oil absorption value of less than 100 cc/100 g silica and preferably in the range of from about 45 cc/100

g to less than about 70 cc/100 g silica. These silicas are colloidal particles having an average particle size ranging
15 from about 3 microns to about 12 microns, and more preferably between about 5 to about 10 microns and a pH

range from 4 to 10 preferably 6 to 9 when measured as a 5% by weight slurry.
Oil absorption values are measured using the ASTM
20 Rub-Out Method D281, The low oil absorption silica abra-sive is present in the oral are compositions of the present

invention at a concentration of about 5 to about 40% by weight and preferably about 10 to about 30% by weight.
Low oil absorption silica abrasives particularly useful in s the practice of the present invention are marketed under the
trade designation Sylodent XWA by Davison Chemical Division of W. R. Grace & Co., Baltimore, Md. 21203. Sylodent 650 XWA, a silica hydrogel composed of particles of colloidal silica having a water content of 29% by weight

30 averaging from about 7 to about 10 microns in diameter, and an oil absorption of less than 70 cc/100 g of silica is a preferred example of a low oil absorption silica abrasive

useful in the practice of the present invention.
Another low oil absorption silica abrasive particularly
35 useful in the practice of the present invention is marketed under the trade designation DP-105 by J. M. Huber Chemi-cals Division, Havre de Grace, Md. 21078 is a precipitated amorphous silica having an average particle size distribution from 5 to 12 microns and an oil absorption in the range of 40 50 to 70 cc/100 g.
The low oil absorption silica abrasive can be used as the sole abrasive in preparing the dentifrice composition of the present invention or in combination with other known dentifrice abrasives or polishing agents.
45 Commercially available abrasives which may be used in combination with the low oil absorption silica abrasive include precipitated silicas having a mean particle size of up to about 20 microns, such as Zeodent 115, marketed by J. M.

Huber Chemicals Division, Havre de Grace, Md. 21078, or 50 Sylodent 783 marketed by Davison Chemical Division ofW.

R. Grace & Company. Other useful dentifrice abrasives include sodium metaphosphate, potassium metaphosphate, tricalcium phosphate, dihydrated dicalcium phosphate, alu-minum silicate, calcined alumina, bentonite or other sili-
55 ceous materials, or combinations thereof.
The total quantity of abrasive present in the dentifrice compositions of the present invention is at a level of from about 5% to about 40% by weight, preferably from about 5% to about 30% by weight when the dentifrice composition is
60 a toothpaste.
Enzymes
The proteolytic enzymes useful in the practice of the present invention are those well known protein substances within the class of proteases, which breakdown or hydrolyze 65 proteins (proteases). The proteolytic enzymes are obtained from natural sources or by the action of microorganisms having a nitrogen source and a carbon source. Examples of

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proteolylic enzymes useful in the practice of the present invention include papain, bromelain, chymotrypsin, ficin and alcalase.
Papain obtained from the milky latex of the Papaya tree is the proteolytic enzyme preferred for use in the practice of

the present invention and is incorporated in the oral care composition of the present invention in an amount of about
0.1 to about 10% by weight and preferably about 0.5 to about 5% by weight, such papain having an activity of 150 to 300 units per milligram as determined by the Milk Clot Assay Test of the Biddle Sawyer Group (see J. Biol. Chem., vol. 121, pages 737-745).
Enzymes which may beneficially be used in combination with the proteolytic enzymes include carbohydrases such as glucoamylase, alpha-amylase, beta-amylase, dextranase and mutanase and lipases such as plant lipase, gastric lipase and pancreatic lipase.
Glucoamylase is a saceharifying glucoamylase of Aspergillus niger origin. This enzyme can hydrolyze both the alpha-D-1,6 glucosidic branch points and the alpha-1,4 glucosidic bonds of glucosyl oligosaccharides. The product of this invention comprises about 0.001 to 10% of the carbohydrases. The lipase enzyme used in this invention is derived from a select strain ofAspergilus niger. The enzyme has maximum lipolytic activity at pH 5.0 to 7.0 when assayed with olive oil. The enzyme has 120,000 lipase units per gram.
The carbohydrases and lipases may be included in the dentifrice composition at a concentration of about 0.10 to about 5.0% by weight and preferably about 0.2 to about 2% by weight. Among the carbohydrases useful in accordance with this invention are glucoamylase, alpha and beta-amylase, dextranase and mutanase.
Dentifrice Vehicle
The orally-acceptable dentifrice vehicle used to prepare the dentifrice composition comprises a water-phase, con-mining a humectant therein. The humectant is preferably glycerin, sorbitol, xylitol, and/or propylene glycol of molecular weight in the range of 200 to 1,000; but, other humectants and mixtures thereof may also be employed. The humectant concentration typically totals about 5 to about 70% by weight of the oral composition.
Reference hereto to sorbitol refers to the material typi-cally commercially available as a 70% aqueous solution. Water is present typically in amount of at least about 10% by weight, and generally about 25 to 70% by weight of the oral composition. Water employed in the preparation of com-mercially suitable toothpastes should preferably be deion-ized and free of organic impurities. These amounts of water include the free water which is added plus that which is introduced with other materials such as with sorbitol.

The dentifrice compositions of the present invention can contain a variety of optional dentifrice ingredients. As described below, such optional ingredients can include, but are not limited to, thickening agents, surfactants, a source of
fluoride ions, a synthetic anionic polycarboxylate, a flavor-ing agent, antibacterial agents, antitartar and coloring agents.
Thickening Agents
Thickeners used in the compositions ofthe present inven-tion include natural and synthetic gums and colloids. Not all

naturally occurring polymer thickeners (such as cellulose or carrageenans) are compatible with dentifrice ingredients
(specifically enzymes) of dentifrice compositions when for-mulated in the presence of proteolytic enzymes. Thickeners compatible with proteolytic enzymes include xanthan gum, polyglycols of varying molecular weights sold under the

tradename Polyox, and polyvinylpyrrolidone. Compatible inorganic thickeners include amorphous silica compounds which function as thickening agents and include colloidal silicas compounds available under the trade designation Cab-c-sil manufactured by Cabot Corporation and distrib-uted by Lenape Chemical, Bound Brook, NJ.; Zeodent 165 from J. M. Hither Chemicals Division, Havre de Grace, Md. 21078; and Sylodent 15, available from Davison Chemical Division ofW. R. Grace Corporation, Baltimore, Md. 21203. 10 Other inorganic thickeners include natural and synthetic clays, lithium magnesium silicate (laponite) and magnesium aluminum silicate (Veegum).
The thickening agent is present in the dentifrice compo-sition in amounts of about 0.1 to about 10% by weight, is preferably about 0.5 to about 4.0% by weight. Surfactants

Surfactants are used in the compositions of the present

invention to achieve increased prophylactic action and ren- der the dentifrice compositions more cosmetically accept- 20 able. The surfactant is preferably a detersive material which

imparts to the composition detersive and foaming properties.

Anionic surfactants such as higher alkyl sulfates such as sodium lauryl sulfate are not compatible with enzymes.
Anionic surfactants facilitate denaturing of the enzyme and 25 loss in activity. As a result, it is important to the practice of the present invention to use a surfactant or combination of surfactants that are compatible with the enzymes present in the toothpaste formulation and provide the requisite foaming characteristics. Examples of enzyme compatible surfactants

30 include nonanionic polyoxyethylene surfactants such as Polyoxamer 407, Steareth 30, Polysorbate 20, and PEG-40
castor oil and amphoteric surfactants such as cocamidopro-pyl betaine and cocamidopropyl betaine lauryl glucoside. Preferred surfactants include a combination of Polyoxamer 35 4.07, polysorbate 20, PEG-40 castor oil and cocamidopropyl betaine at a total surfactant concentration in the dentifrice composition ofbetween about 2 to about 1011b by weight and preferably between about 3.5 to about 6.5% by weight at weight ratios of 2.5 Polyaxomer 407,2.5 PEG-40 castor oil, 40 3.3 Polysorbate-20 and 1.0 cocamidopropyl betaine. Fluoride and Other Active Agents
The dentifrice composition of the present invention may also contain a source of fluoride ions or fluorine-providing component, as anticaries agent in amount sufficient to supply 45 about 25 ppm to 5,000 ppm of fluoride ions and include inorganic fluoride salts, such as soluble alkali metal salts. For example, preferred fluoride sources which are compat-ible with enzymes present in the composition are sodium

fluoride, potassium fluoride, sodium fluorosilicate, ammo- nium fluorosilicate, as well as tin fluorides, such as stannous
fluoride and stannous chloride. Sodium fluoride is preferred. In addition to fluoride compounds, there may also be included antitartar agents such as pyrophosphate salts including dialkali or tetraalkali metal pyrophosphate salts

55 such as Na4P207, içP207, Na2K2P207, Na2H2P2O7 and K2H2P207 long chain polyphosphates such as sodium hex-

ametaphosphate and cyclic phosphates such as sodium tn-metaphosphate. These antitartar agents are included in the dentifrice composition at a concentration of about 1 to about 60 5% by weight.
Another active agent useful in dentifrice compositions of
the present invention are antibacterial agents, which can be from 0.2 to 1.0% by weight of the dentifrice composition.

Such useful antibacterial agents include non-cationic anti- 65 bacterial agents which are based on phenolic or bisphenolic compounds, such as halogenated diphenyl ethers such as Triclosan (2,4,4-tricbloro-2’-hydroxydiphenyl ether).

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Enzyme Stabilizing Agents
The dentifrice composition of the present invention may also contain ingredients which stabilize enzymes in a den-tifrice environment. These stabilizers protect the enzyme from inactivation by chelating metal impurities present in the dentifrice composition which have the propensity to denature the active site of the enzyme by protecting the enzyme from oxidation. Chelating agents include, ethylene diamine tetraacetic acid (EDTA) and sodium gluconate at concentrations between 0.01 and 1%, preferably between 0.1 and 0.5%. Agents stabilizing the enzyme against oxida-tion include sodium bisulfite, metal gallates, sodium stan-nate and ascorbic acid at concentrations between about 0.1 and about 13%, preferably between about 0.3 and about 0.75%.

Anionic Polycarboxylate
Synthetic anionic polycarboxylates may also be used in the dentifrice compositions of the present invention as an efficacy enhancing agent for any antibacterial, antitartar or other active agent within the dentifrice composition. Such anionic polycarboxylates are generally employed in the form of their free acids or preferably partially or more preferably fully neutralized water soluble alkali metal (e.g. potassium and preferably sodium) or ammonium salts. Preferred are 1:4 to 4:1 copolymers of maleic anhydride or acid with another polymerizable ethylenically unsaturated monomer, preferably methylvinylether/maleic anhydride having a molecular weight (M.W.) of about 30,000 to about 1,800, 000 most preferably about 30,000 to about 700,000. Examples of these copolymers are available from GAF Corporation under the tradename Gantrez, e.g. AN 139 (M.W. 500,000), AN 119 (MW. 250,000); S-97 Pharmaceu-tical Grade (M.W. 700,000), AN 169 (M.W. 1,200,0004, 800,000), and AN 179 (M.W. above 1,800,000); wherein the preferred copolymer is S-97 Pharmaceutical Grade (M.W. 700,000).
When present, the anionic polycarboxylates is employed in amounts effective to achieve the desired enhancement of

the efficacy of any antibacterial, antitartar or other active agent within the dentifrice composition. Generally, the anionic polycarboxylates is present within the dentifrice composition from about 0.05% to about 4% by weight, preferably from about 0.5% to about 2,5% by weight. Flavor

The dentifrice composition of the present invention may also contain a flavoring agent. Flavoring agents which are used in the practice of the present invention include essential oils as well as various flavoring aldehydes, esters, alcohols, and similar materials. Examples of the essential oils include oils ofspearmint, peppermint, wintergreen, sassafras, clove, sage, eucalyptus, marjoram, cinnamon, lemon, lime, grapefruit, and orange. Also useful are such chemicals as

menthol, carvone, and anethole. Of these, the most com- monly employed are the oils of peppermint and spearmint.
The flavoring agent is incorporated in the dentifrice composition at a concentration of about 0.1 to about 5% by weight and preferably about 0.5 to about 1.5% by weight. Other Ingredients
Various other materials may be incorporated in the den-tifrice compositions of this invention, including desensitizers, such as potassium nitrate; whitening agents,

such as hydrogen peroxide, calcium peroxide and urea peroxide; preservatives; silicones; and chlorophyll com-
pounds. These additives, when present, are incorporated in the dentifrice composition in amounts which do not sub-stantially adversely affect the properties and characteristics desired.

Preparation of the Dentifrice
The preparation of dentifrices is well known in the art by reference. More specifically, to prepare a dentifrice of the

present invention, generally the humectants e.g. glycerin, s sorbitol, propylene glycol, and polyethylene glycol, are
dispersed in the water in a conventional mixer under agita-tion. Into the dispersion are added the enzyme or enzymes organic thickeners, such as xanthan gum; any anionic poly-carboxylate; any salts, such as sodium fluoride anticaries 10 agents; tetrasodium pyrophosphate, sodium tripolyphas-phate anticalculus salts and any sweeteners; the resultant mixture is agitated until a homogeneous gel phase is formed. Into the gel phase are added a pigment such as TiO2, and any

acid or base required to adjust the pH. These ingredients are 15 mixed until a homogenous phase is obtained. The mixture is
then transferred to a high speed/vacuum mixer; wherein, the inorganic silica thickener, such as Zeodent 165; and surfac-tant ingredients are added to the mixture. The low oil absorption silica abrasive is added at this point, along with 20 other abrasives to be used in the composition. Any water insoluble antibacterial agent, such as Triclosan, is solubi-Used in the flavor oils to be included in the dentifrice and the solution is added along with the surfactants to the mixture, which is then mixed at high speed for from 5 to 30 minutes, 25 under vacuum of from about 20 to 50 mm of Hg, preferably about 30 mm Hg. The resultant product is in each case a homogeneous, semi-solid, extrudable paste or gel product. The following example further describes and demon-strates preferred embodiments within the scope of the 30 present invention. The example is given solely for illustration, and are not to be construed as limitation of this invention as many variations thereof are possible without departing from its spirit and scope.

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EXAMPLE 1

A series of liquid solutions were prepared using the ingredients listed in Table I below.

TABLE I
40

Composition No, 1

weight

2 3 4

Ingredients

45 water 77.89 QS OS OS
Trisodiuin phosphate 1.10 1.1 Li 2.1
Sodium bisulfits 0.49 0.5 0.5 0.5
Disodium hydrogen phosphate 0.29 0.29 0.29 0.29
Sodium acid pyrophosphate 0.20 0.2 0.2 0.2
Sodium dihydrogen phosphate 0.30 0.3 0.3 0.3
50 Zeodent 115 silica abrasive 20 10 10
Sylodent 65OXWA silica gel"-’ 20 10 10
Papain 0.50 0.5

’Zeodent 115 is a precipitated silica abrasive having an oil absorption
value of 105-110 cc/100silica55
..Sylodent 65OXWA Is a low oil absorption silica hydrogel having an oil absorption value of lens than 70 cc/100 g silica

Composition 1 was a placebo solution containing 20% of a Zeodent 115, a silica abrasive outside the scope of the

present invention buffered to maintain the pH ofthe solution so at pH 7, Composition 2 was a comparative solution con- taining the low oil absorption silica abrasive Sylodent

65OXWA. Composition 3 contained a mixture of Zeodent
115 silica abrasive and the low oil absorption silica abrasive
Sylodent 65OXWA but without the enzyme papain being
65 present. Composition 4 contained both the low oil absorp-
tion silica Sylodent XWA650 silica abrasive, the Zeodent
115 abrasive and the enzyme papain.

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SUPERINTENDENCIA DE INDUSTRIA V COMERCIO DMSION DE NUEVAS CREACIONES

2020

Bogota, D.C.,

Abogado
JUAN PABLO CADENA SARMIENTO
Apoderado

ASUNTO Radicaciôn 04122180
TrÆmite 011
Evento 379
Actuaciôn 430

Oficio 5678
Folios 121

Patente de lnvención []

Via Nacional El

Via PT fase nadonal) [I]
No. Sol. Intemacional
Fecha de Presentaciôn Internal

Patente de Modelo de Utilidad

Cap.l [] Cap. II

PCT/US03II 4485
08/05/2003

I.

Como resultado del examen de fondo, realizado con fundamento en el articulo 45 de la DecisiOn 486 de la ComisiOn de la Comunidad Andina, se le comunica:

1. Documentos estudiados

DescripciOn: Folios: 28 a 53

Reivindicaciones: Folios 54 a 57
Folio 112 modificadas como respuesta al primer examen de
fondo

Prioridad: Fecha: 10/05/2002, pals: US, nimero: 10/143,395

Respuesta del solicitante: Folios: 109 a 111

2. Objeto de la invención

Titulo de la solicitud: Dentifrico antibacterial que exhibe propiedades antiplaca y de refrescamiento del aliento. Nümero de folio: I

El problema planteado en esta solicitud es la necesidad de composiciones orales antiplaca con propiedades contra el mal olor.

-.1-W

Para solucionar este problema tØcnico la solicitud en estudio proporciona una composición oral antiplaca de componente dual que tiene propiedades en contra del mal olor en la cual un primer componente contiene un agente bacterial y el segundo componente contiene una enzima proteolitica que cuando se mezclan con la aplicaciOn a los dientes proporcionan un efecto antiplaca con propiedades superiores en contra del mal olor.

CJasificación Intemacional de Patentes (IPC.): A61 7/16, A61 31/02, A61 1/02

3. Determinaciôn del Estado de la TØcnica

La fecha que se ha tenido en cuenta para determinar el Estado de la TØcnica es:

Fecha de presentaciôn de la solicitud prioritaria 10/05/2002

Teniendo en cuenta la fecha indicada se real izô Ia büsqueda en el estado de la tØcnica de documentos relacionados con la solicitud encontrÆndose los siguientes documentos mÆs relevantes:

No Documento Titulo Fechade
publicaciôn*
PROCEDE ET DISPOSIT1F

D1 FRA 2051992 POUR L’OBTENTION DE
MÉLANGES EXTEMPORANES 9/04/1971
ET MÉLANGES AINSI OBTENUS
ORAL COMPOSITION
D2 US 6379654 PROVIDING ENHANCED 30/04/2002
TOOTH STAIN REMOVAL

4. AnÆlisisde patentabilidad (articulo 14 0486)

Nivel inventivo (artIculo 18 D486)

La presente Solicitud de Patente reivindica

Reivindicaciones I - 8: Una composiciôn oral antiplaca de componente dual segregada antes del uso, que comprende:
a) Humectante
b) un abrasivo de silice con un valor de absorción de aceite de menos de

100 cc/I 00 g de silice, presente en 5-40% por peso c) un agente antibacterial no iOnico: triclosÆn
a) Humectante
b) un abrasivo de sIlice con un valor de absorción de aceite de menos de
100 cc/I 00 g de slIlce, presente en 5-40% por peso

C) una enzima proteolItica: papamna en combinaciôn con una lipasa yb glicoamilasa c/u 0.02-5% par peso.
Dicha composiciOn se ye afectado por los siguientes documentos:

D1 que enseæa(folios 100-104) una crema dental con dos fases una de las cuales comprende una enzima y la otra hexaclorofeno conocido como 2:2’-metilefl"bis [3,4,6- trisclorofeno] el cual es aniOnico) agente antibacterial (ejemplo 1) con efecto refrescante del aliento(folio 102). Las fases tiene la posibilidad de estar separadas totalmente independientes o no (pagina I), por una membrana en un tubo con dos compartimentos. La membrana no estÆa lo largo de todo el tubo permitiendo de esta forma que las dos fases se toquen antes de que el producto sea usado.

132 enseæa(ver folios 94-99, descripciôn, ejemplos 1-3, reivindicaciones 1-14) una composiciOn dentIfrica abrasiva cuyos efectos mejoran las propiedades antiplaca y refrescantes del aliento que comprende un vehIculo oral, una combinaciôn de una silica abrasiva con valores de absorción de aceite de menos de 100cc/I 00 g y una enzima proteolitica.

CARACTERISTICAS REMNDICADAS D1 D2

composiciOn oral antiplaca SI Si

PÆgI CI I In 6-9,65-67

componente dual SI

1,4 NO

segregada antes del uso SIPÆg NO

Fase I
Humectante SI
un abrasivo de silice con un valor de
absorciôn de aceite de menos de SI
100 cc/I 00 g de sIlice, presente en Pig 2
5-40% por peso
agente antibacterial no iOnico: SI
triclosÆn P.19 2
Fase 2

Humectante NO

SI
CI 3 In 37 en
adelante

un abrasivo de sIlice con un valor de
absorciOn de aceite de menos de Si Si
100 cc/1 00 g de sIlice, presente en PÆg2 Cl 2 In 3-5, 20-24
5-40% por peso

enzima proteolItica: papaina en SI combinaciôn con una lipasa SI

Pa 1 2 3 Cl 2 In 3-5
glicoamilasa c/u 0.02-5% por peso CI 3 In 4-9,13-15
agente antibacterial no iónico: SI
triclosÆn CI 4 In 61-67

La ünica diferencia con D1 es que en esta solicitud solamente hay humectante en una de las fases y la enzima se encuentra en la fase acuosa y no en la fase grasa pero esto no parece conceder un efecto tØcnico inesperado debido a que en DI no se encuentra afectada en ningün aspecto la actividad de la enzima.

El efecto tØcnico que logra la diferencia es una composiciOn oral antiplaca de componente dual, con fases segregadas que comprenda una fase acuosa con

numectante.

Por 10 tanto el problema tØcnico objetivo de la invenciOn podria definirse en: "como lograr proveer una composiciOn oral antiplaca de componente dual segregado fIsicamente previo a su uso, que comprenda una fase acuosa con humectante" (ver folio 111 respuesta del solicitante)

Por 10 tanto dicha composición se considera tan solo una altemativa, sin algün salto tecnológico que lo haga superior a lo previamente conocido.

La solicitud se considerarÆobvia mediante los conocimientos ensefiados por D1 y D2 porque un experto en la matena que conozca el estado de la tØcnica harla una combinaciôn de Østos documentos que contienen las caracteristicas esenciales que aparentemente le otorgan superioridad a la composiciOn llegando de tal manera a la propuesta de la presente solicitud.

En conclusion la solicitud no tiene nivel inventivo.

5. ConclusiOn:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados as[:

N° Documento N° Reivindicaciones Requisito que afecta afectadas
D1 FR A 2051992 1-8 NIVEL INVENTIVO
D2 US 6379654 1-8 NIVEL INVENTIVO

6. Respuesta a los argumentos del solicitante:

Afirma el solicitante que las fases en Dl no se encuentran fisicamente segregadas antes de su uso como se requiere en la presente invenciôn.
Se aclara al solicitante que se encuentra en Dl que de manera semejante a la solicitud los ejemplos I y 2 tienen 2 fases una fase grasa y una acuosa, separadas por una membrana dentro del tubo que se unen previo al uso (ver
ü ltimo pÆrrafo pÆginaI DI).

Afirma el solicitante que Dl carece de enseæanzao sugerencia sabre el uso de un humectante en cada fase

Si bien Dl carece de enseæanza osugerencia sobre usar humectante en las dos fases, usando solamente agua en una de las fases en D2 Øste 51 se enseæay se muestran sus ventajas.

Afirma el solicitante que el problema tØcnico (folio Ill) enfrentado en la

presente solicitud se refiere a proveer un primer y un segundo componente dentIfrico que comprendan una fase acuosa con humectante y que se

encuentren segregados fIsicamente previo a su uso, lo cual no estÆ sugerido
en Dl.

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Se reitera al solicitante que este problema tØcnico ha sido resuelto realizando
una combinaciOæde Dl (dos componentes en fase dual, segregados previo al
que pueden estar de forma independiente) con D2 (fase acuosa con
humectante donde se enseæansus ventajas).

En cumplimiento del artIculo 45 de la Decision 486 de la ComisiOn de la Comunidad Andina, se le indica que debe dar respuesta dentro del tØrmino de 60 dIas contados a partir de Ia fetha de notificaciOn de la presente comunicaciOn. En caso de no dar respuesta al presente requerimiento, a si a pesar de la respuesta subsistieran los impedimentos para Pa concesión, se denegarÆla patente.

Notifiquese el presente oficio conf9rrne a lo dispuesto en el numeral 5.2, literal e), del capItulo quinto

deFevasCreaciones

o 1e la Circular (mica NO 10 de 2001.

AUX ARMENZA C VERGEL
Jefe de Division de N

El anterior requerimiento fue notificado par fijaciOn en lista, de fecha
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CONCEPTO TECN1CO EXAM1NADOR TECNICO
No. 331 COdigo No. 202087