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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES
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REF.: Expediente No. 07 007.211 - Solicitud de Patente FASE NACIONAL Corresp. a la Solicitud Internacional PCT/US2005/025866.

S a nombre de: COLGATE-PALMOLIVE COMPANY

Titulada: COMPOSICIONES PARA EL CUIDADO ORAL CON POLIMEROS FORMADORES DE PELICULA.

JUAN PABLO CADENA SARMIENTO, vecino de Bogota, portador de la tarjeta profesional No. 57492 del Consejo Superior de la Judicatura, obrando como apoderado de la Sociedad COLGATE-PALMOLIVE COMPANY, segün lo acredita el documento de poder presentado en esa DivisiOn, de acuerdo con el ArtIculo 44 de la DecisiOn 486 de la Comisión de la Comunidad Andina, me permito solicitar que se examine si la invenciOn contenida en la solicitud en referenda es patentable.

De acuerdo con lo anterior, me permito anexar el recibo oficial de caja No. 08-44,633 por valor de $420,000.

De la SeæoraJefe atentamente,

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JUAN PABLO CADENA SARMIENTO
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Bogota, 10 dejulio de 2008
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DIVISION DE NUEVAS CREACIONES

RADICACION EXPEDIENTE No. 07-07211

EL EXTRACTO DE LA PRESENTE SOLICITUED DE PATENTE DE INVENCION

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No 587 DE

FECHA 18 DE ENERO DE 2008 ELTERMINO HABIL SEIcIALADO POR LA LEY

EXPIRA EL 16 DE ABRIL DE 2008

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicaciOn
en la gaceta de Propiedad Industrial, deberÆ solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, do acuerdo con lo establecido en el ArtIculo 44 de la Decision 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

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(54) HYDROGEL COMPOSITIONS FOR TOOTH
WHITENING

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Related U.S. Application Data

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(60) Provisional application No. 60/288,008, filed on May 1, 2001.

Publication Classification

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(52) U.S. Cl..424/53; 424/62

(57) ABSTRACT

A composition is provided, wherein the composition com-prises a water-swellable, water-insoluble polymer, a blend of a hydrophilic polymer and a complementary oligomer capable of hydrogen bonding to the hydrophilic polymer, and a whitening agent, preferably a peroxide. The compo-sition finds utility as a tooth whitening composition and is applied to the teeth in need of whitening, and then removed when the degree of whitening has been achieved. In certain embodiments, the composition is translucent. Methods for preparing and using the compositions are also disclosed.

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HYDROGEL COMPOSITIONS FOR TOOTH WHITENING

CROSS-REFERENCE TO RELATED
APPLICATIONS

[0001] This application is a continuation in part of U.S
patent application Set. No. 10/137,664, filed May 1, 2002, which claims priority under 35 U.S.C. § 119(e)(1) to pro-visional U.S. Patent Application Serial No. 60/288.008, filed May 1, 2001.

TECHNICAL FIELD

[0002] This invention relates generally to hydrogel coin-
positions for dental care, and more particularly relates to novel hydrogel compositions useful in the whitening of an individu at’s teeth.

BACKGROUND

[0003] Discoloration of the teeth occurs widely in society,
and is estimated to occur in two out of three adults. Dental discoloration is considered an aesthetic Raw or defect, and can have negative consequences in an affected person’s life by causing self-consciousness, and even inhibiting smiling. ’tooth discoloration can be particularly distressing or troublesome in situations and professions where showing clean and white teeth is essential.

[0004] A tooth is comprised of an inner dentin layer and an
outer hard enamel layer that is slightly porous. The outer layer is the protective layer of the tooth. ’The natural color of the tooth is opaque to translucent white or slightly off-white. Staining of teeth arises as a result of exposure of compounds such as tannins and other polyphenolic compounds to the teeth. These compounds become trapped or bound to the proteiriaceous layer on the surface of teeth, and can penetrate the enamel and even the dentin. On occasion, staining can arise from sources within the tooth, such as tetracycline, which may become deposited in the teeth if administered to an individual when young,

[0005] Surface staining can usually be removed by
mechanical tooth cleaning. However, discolored enamel or dentin is not amenable to mechanical methods of tooth cleaning, and chemical methods, which can penetrate into the tooth structure, are required to remove the stains. The most effective treatments for dental discoloration are coin-positions containing an oxidizing agent, such as hydrogen peroxide, that is capable of reacting with the chromogen molecules responsible for the discoloration, and rendering them either colorless or water-soluble, or both.

[0006] Consequently, tooth whitening compositions gen-
erally fall into two categories: (1) gels, pastes, or liquids, including toothpastes that are mechanically agitated at the stained tooth -surface in order to affect tooth stain removal through abrasive erosion of surface stains; and (2) gels, pastes, or liquids that accomplish a tooth-bleaching effect by a chemical process while in contact with the stained tooth surface for a specified period, after which the formulation is removed. In some cases, an auxiliary chemical process, which may be oxidative or enzymatic, supplements the mechanical process.

[0007] Some dental compositions such as dentrifices,
toothpastes, gels, and powders contain active oxygen or

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hydrogen peroxide liberating bleaching agents. Such bleach-ing agents include peroxides, percarbonates and perborates of the alkali and alkaline earth metals or complex com-pounds containing hydrogen peroxide. Also, peroxide salts of the alkali or alkaline earth metals are known to be useful in whitening teeth.

[0008] Of the many peroxides available to the formulator
of tooth whitening compositions, hydrogen peroxide (and its adducts or association complexes, such as earhamide per-oxide and sodium percarhonate) has been used almost exclusively. The chemistry of hydrogen peroxide is well known, although the specific nature of its interactions with tooth chromogens is poorly understood. It is believed that hydrogen peroxide destroys tooth chromogens by oxidizing unsaturated carbon-carbon, carbon-oxygen, and carbon-ni-trogen bonds found in the stain molecules, thus rendering them colorless or soluble.

[0009] A related class of compound, the peroxyacids, has
been used in laundry detergents to effectively whiten clothes, due primarily to their stability in solution and their specific binding abilities to certain types of stain molecules. A number of stable, solid peroxyacids have been used, including diperoxydodecanoic acid and the magnesium salt of monoperoxyphthalic acid. Other peroxyacids, such as peroxyacetic acid, are available as solutions containing an equilibrium distribution of acetic acid, hydrogen peroxide, peroxyacetic acid and water, Alternatively, a peroxide donor such as sodium perhorate or sodium percarbonate is formu-lated together with a peroxyacid precursor. Upon contact with water, the peroxide donor releases hydrogen peroxide which then reacts with the peroxyacid precursor to form the actual peroxyacid. Examples of peroxyacids created in situ include peroxyacetic acid (from hydrogen peroxide and tetra aceiylethylenediamine) and peroxynonanoic acid (from hydrogen peroxide and noriarioyloxyhenzenc solfon ate).

[0010] Pcroxyacids have also been used in oral care com-
positions to whiten stained teeth. U.S. Pat. No. 5,279,816 describes a method of whitening teeth comprising the appli-cation of a peroxyacetic acid-containing composition having an acid pH. EP 545,594 Al describes the use of peroxyacetic acid in preparing a composition for whitening teeth. The peroxyacetic acid may be present in the composition, or alternatively, may be generated in situ by combining a peroxide source with a peroxyacetic acid precursor during use, For example, U.S. Pat. No. 5,302,375 describes a composition that generates peroxyaeetic acid within a vehicle in situ by combining water, acetylsalicylic acid and a water-soluble alkali metal perearbonate.

[0011.] The most commonly used dental whitening agent is
carbamido peroxide (CONH2)l-I2O), also called urea hydrogen peroxide, hydrogen peroxide carharnide, and per-hydrol-urea. Carhamide peroxide had been used by dental clinicians for several decades as an oral antiseptic, and tooth bleaching was an observed side effect of extended contact time. Over-the-counter compositions of 1017r) carbamide peroxide are available as GLY-OXIDE by Marion Labo-ratories and PROXIGELfi by Reed and Carnniclç which are low-viscosity compositions that must be held in a tray or similar container in order to provide contact with the teeth. A bleaching gel which is able to bold a comfortable-.fitting dental tray in position for an extended time period is available under the trademark OPALESCENCEfi from Ultradetit Products, Inc. in South Jordan, Utah.

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[00:12] In order for such compositions to stay in place, the
compositions must he a viscous liquid or a gel. The use of dental trays also requires that the tray be adapted for comfort and fit so that the tray will not exert pressure or cause irritation to the person’s teeth or gums. Such whitening compositions necessarily should be formulated so as to be sufficiently sticky and viscous to resist dilution by saliva.

[0013] In one method of whitening an individual’s teeth,
a dental professional will construct a custom made dental bleaching tray for the patient from an impression made of the patient’s dentition and prescribe the use of an oxidizing gel to he dispensed into the bleaching tray and worn inter-mittently for a period of from about 2 weeks to about 6 months, depending upon the severity of tooth staining. These oxidizing compositions, usually packaged in small plastic syringes or tubes, are dispensed directly by the patient into the custom-made tooth-bleaching tray, held in place in the mouth for contact times of greater than about 60 minutes, and sometimes as long as S to 12 hours. The slow rate of bleaching is in large part the consequence of the very nature of formulations that are developed to maintain sta-bility of the oxidizing composition.

[0014] For example, U.S. Pat. No. 6,368,576 to Jensen
describes tooth whitening compositions that are preferably used with a tray so that the composition is held in position adjacent to the person’s tooth surfaces to be treated. These compositions are described as a sticky matrix material formed by combining a sufficient quantity of a tackifying agent, such as earhoxypolytnethylene, with a solvent, such as glycerin, polyethylene glycol, or water

[00J5] in another example, U.S. Pat. No. 5,718,886 to
Pellico describes a tooth whitening composition in the form of a gel composition containing carbamide peroxide dis-persed in an anhydrous gelatinous carrier, which includes a polyol, a thickener, and xanthan gum.

[0016] Yet another example is described in U.S. Pat, No.
6,419,905 to Hernandez, which describes the use of com-positions containing carbamide peroxide (0.3-60%), xylitoi (05-50%), a potassium salt (0.001-105c) and a fluorine salt (0.15-3%), formulated into a gel that contains between 0.5 and 6% by weight of an appropriate gelling agent,

[0017] A tooth whitening composition that adheres to the
teeth is described in U.S. Pat. Nos. 5,989,569 and 6,045,811 to Dirksing. According to these patents, the gel contains 30-85% glycerin or polyethylene glycol,.10-221X-) urea;1-ty-drogen peroxide complex, 0-12% carboxypolymethylene, 04% sodium hydroxide, 0-100% triethanulamine (TEA), 0-40% water, 0-1% tlavor, 0-15% sodium citrate, and 0-5% ethylcnediaminetetraacetic acid. The preferred gel according to Dirkaing has a viscosity between 200 and 1,000,000 cps at low shear rates (less than one 1/seconds), and is suffi-ciently adhesive so as to obviate the need for a tray.

[0018] Currently available tooth-bleaching compositions
have a significant disadvantage in that they cause tooth sensitization in over 50% of patients. Tooth sensitivity may result from the movement of fluid through the dentinal tubules, which is sensed by nerve endings in the tooth, due to the presence of glycerin, propylene glycol and polyeth-ylene glycol in these compositions. This can result in varying amounts of tooth sensitivity following exposure of the teeth to heat, cold, overly sweet substances, and other causative agents.

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[0019] Prolonged exposure of teeth to bleaching compo-
sitions, as practiced at present, has a number of adverse effects in addition to that of tooth sensitivity. These adverse effects include leaching of calcium from the enamel layer at a pH less than 5.5; penetration of the intact enamel and dentin by the bleaching agents and risking damage to pulpal tissue; and dilution of the bleaching compositions with saliva resulting in leaching from the dental tray and subse-quent ingestion by the user.

[0020] Some oxidizing compositions (generally having
relatively high concentrations of oxidizers) are applied directly to the tooth surface of a patient in a dental office setting under the supervision of a dentist or dental hygienist. Theoretically, such tooth whitening strategies yield faster results and better overall patient satisfaction. However, clue to the high concentration of oxidizing agents contained in these SC) called "in-office" compositions, they can be haz-ardous to the patient and practitioner alike if not handled with care, The patient’s soft tissues (the gingiva, lips, and other mucosal surfaces) must first he isolated from potential exposure to the active oxidizing agent by the use of a perforated rubber sheet (known as a rubber dam), so that only the teeth protrude. Alternatively, the soft tissue may he isolated from the oxidizers to he used the whitening process by covering the soft tissue with a polymerizable composition that is shaped to conform to the gingival contours and subsequently cured by exposure to a high intensity light source. Once the soft tissue has been isolated and protected, the practitioner may apply the oxidizing agent directly onto the stained tooth surfaces for a specified period of time or until a sufficient change in tooth color has occurred. Typical results obtained through the use of an in-office tooth whitener, range from about 2 to 3 shades (as measured with the VITA Shade Guide, VITA Zahnfarbik.

[0021] The range of tooth shades in the Vl’fA Shade Guide
varies from very light (Bi) to very dark (C4). A total of 16 tooth shades constitute the entire range of colors between these two entipoiots on a scale of brightness. Patient satis-faction with a tooth whitening procedure increases with the number of tooth shade changes achieved, with a generally accepted minimum change desirable of about. 4 to 5 VITA shades,

[0022] It is desirable, with respect to dental care products
for tooth whitening, to provide dental care products utilizing an adhesive hydrogel that includes a whitening agent for removing stains from an individual’s teeth. Compositions are desired that do not require the use of dental trays to provide contact between the bleaching agent and the teeth. Such products ideally would cause minimal or no tooth sensitivity, would minimize or eliminate leakage of the whitening agent resulting in ingestion by the user or result-ing in damage or irritation to the gams or mucous mem-branes of the mouth, would provide for longer wear dura-tion, sustained dissolution of the tooth whitening agent, improved efficacy, and be well tolerated by patients. It would also he desirable to provide a tooth whitening dental care product that is a solid composition and self-adhesive but which does not stick to the fingers of the user, or that is a non-solid (e.g., liquid or gel) and winch forms a film when dry. The instant invention addresses these needs. SUMMARY OF ThE INVENTION

[0023] One aspect of the invention relates to a composi-
tion comprising a water-swellable, water-insoluble polymer,

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a blend of a hydrophilic polymer and a complementary oligomer capable of hydrogen bonding or electrostatic bond-ing to the hydrophilic polymer, and a whitening agent.

[0024] In a preferred embodiment, the water-swellable,
water-insoluble polymer is a cellulose ester, or an acrylate-based polymer or copolymer; the hydrophilic polymer is an poly(N-vinyl lactam), poty(N-vinyl amide), poly(Nalky-lacrylamide), or copolymer and blend thereof; the comple-mentary oligomer capable of hydrogen bonding to the hydrophilic polymer is a polyallcylenc glycol or a carboxyl-terminated polyalkylene glycol; and the whitening agent is a peroxide

[0025] The composition optionally comprises a low molecular weight plasticizer, and may also comprise at least one additive selected from the group consisting of fillers, preservatives, pH regulators, softeners, thickeners, colora.nt.s (e.g., pigments, dyes, refractive particles, etc.), flavorants (e.g., sweeteners, flavors), stabilizers, toughening agents and detackifiers.

[0026] Ina preferred method of using the composition, the
composition is a tooth whitening composition and is applied to the teeth in need of whitening, and then removed when the degree of whitening has been achieved. In certain embodi-ments, the tooth whitening composition is translucent, and the composition is removed when the user is satisfied with the degree of whitening achieved.

[0027] Yet another aspect of the invention pertains to a
composition comprising a water-swellable, waler-insoluble polymer, a blend of a hydrophilic polymer and a coniple-roentary oligomer capable of hydrogen bonding to the hydrophilic polymer, and an agent selected from the group consisting of peroxides, metal chlorites, perborates, percar-honates, peroxyacids, and combinations thereof.

[0028] Another aspect of the invention relates to a method
for preparing a hydrogel film suitable fdr incorporation into a tooth whitening composition is provided. This method comprises preparing a solution or a gel of a water-swellahie, water-insoluble polymer, a hydrophilic polymer, and a complementary oligonier capable of hydrogen bonding or electrostatic bonding to the hydrophilic polymer, in a sol-vent; depositing a layer of the solution on a substrate to provide a coating thereon; and heating the coaled substrate to a temperature in the range of about 800 C. to about 100° C. for a linac period in the range of about.1 to about 4 hours, thereby providing a hydrogel film on the substrate.

[0029] In another method of forming a tooth whitening
composition, the method comprises melt processing through an extruder a mixture of a water-swellablc, water-insoluble polymer, a hydrophilic polymer, and a complementary oli-gomer capable of hydrogen bonding or electrostatic bonding to the hydrophilic polymer, to form an extruded composi. lion; wherein the composition is extruded as a film of desired thickness onto a suitable substrate.

[0030] The method further comprises loading the hydrogel
film with the whitening agent, thereby providing the tooth whitening composition.

[0031] The adhesive tooth whitening compositions of the
invention provide a number of significant advantages rela-tive to the prior art. In particular, the present compositions:

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[0032] (1) provide ease of handling;

[0033] (2) are readily modified during manufacture
so that properties such as adhesion, absorption, trans-hicence, and swelling can be controlled and opti-mized;

[0034] (3) can be formulated so that tack increases or
decreases in the presence of moisture so that the composition is not sticky until moistened;

[0035] (4) minimize leakage of the whitening agent
from the composition into the user’s mouth;

[0036] (5) can he fabricated in translucent from,
enabling the user to view the extent of whitening without removing the hydrogel composition from the teeth;

[0037] (6) minimize damage to gums or rmlcous
membranes in the mouth;

[0038] (7) can be worn comfortably and unobtru-
sively;

[0039] (8) are easily removed from the teeth, and
leave no residue;

[0040] (9) are amenable to extended duration of wear
or action; and

[0041] (10) sustained and controlled release of the
whitening agent.

DETAILED DESCRIPTION OF THE
INVENTION

I. Definitions and Nomenclature

[0042] Before describing the present invention in detail, it
is to he understood that unless otherwise indicated this invention is not limited to specific hydrogel materials or manufacturing processes, as such may vary. It is also to he understood that the terminology used herein is for the Purpose of describing particular embodiments only, and is not intended to he limiting. It most be noted that, as used in this specification and the appended claims, the singular forms "a,"an." and "the" include plural referents unless the context clearly dictates otherwise. ’[bus, for example, ref-erence to "a hydrophilic polymer" includes not only a single hydrophilic polymer but also a combination or mixture of two or more different hydrophilic polymers, reference to "a plasticizer" includes a combination or mixture of two or more different plasticizers as well as a single plasticizer, and the like.

0043] In describing and claiming the present invention,
the following terminology will be used in accordance with the definitions set out below.

[0044] The definitions of "hydrophobic" and "hydro-
philic" polymers are based on the amount of water vapor absorbed by polymers at 100% relative humidity. According to this classification, hydrophobic polymers absorb only up to 1 wt % water at 100% relative humidity ("rh"), white moderately hydrophilic polymers absorb 1-10% WI % water, hydrophilic polymers are capable of absorbing inure than 10 wt % of water, and hygroscopic polymers absorb more than 20 wt % of water. A "water-swellable" polymer is one that absorbs an amount of water greater than at least 25 wt % of its own weight, and preferably at least 50 wt % of its own weight, upon immersion in an aqueous medium.

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the blend. The water-swellable, water-insoluble polymer is selected so as to provide the desired adhesion profile with respect to hydration. That is, when the water-swell able., water-insoluble polymer is a cellulose ester, the composition is generally tacky prior to contact with water (e.g., with a moist surface) but gradually loses tack as the composition absorbs moisture. When the wa ter-swellable, water-in-soluble polymer is an acrylate polymer or copolymer, a composition is provided that is generally substantially non-tacky prior to contact with water, but becomes tacky upon contact with a moist surface,

[0059) The water-swellable, water-insoluble polymer is capable of at least some degree of swelling when immersed in an aqueous liquid but is insoluble in water. The polymer may be comprised of a cellulose ester, for example, cellulose acetate, cellulose acetate propionate (CAP), cellulose acetate butyfate (CAB), cellulose propionate (CP), cellulose hutvrale (CB), cellulose propionate butyrate (CPB), ceihi - lose diacetate (CDA), cellulose triacetate (CTA), or the like. These cellulose esters are described in U.S. Pat, Nos, 1,698,049, 1,683,347, 1,880,808, 1,880,560, 1,984,147, 2,129,052, and 3,617,201, and may be prepared using tech-niques known in the art or obtained commercially. Com-mercially available cellulose esters suitable herein include CA320, CA 398, GAB 381, CA13 551, CAB 553, CAP 482, CAP 504, all available from Eastman Chemical Company, Kingsport, Tenn, Such cellulose esters typically have a number average molecular weight of between about 10,000 and about 75,0(1),

[0060] Generally, the cellulose ester comprises a mixture of cellulose and cellulose ester monomer units; for example, commercially available cellulose acetate butyrate contains cellulose acetate mon.nner units as well as cellulose hutyrate monomer units and uncsterificd cellulose nionomer units, while cellulose acetate proprionale contains monomer units such as cellulose proprionate. Preferred cellulose esters herein are cellulose acetate propionate compositions and cellulose acetate butyrate compositions having the hutyryl, propionyl, acetyl, and unesterifled (014) cellulose content as indicated below

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propionate tends to improve cohesive strength to a greater degree than cellulose acetate butyrate).

[0062] Other preferred water-swellahic polymers are acry-late polymers, generally formed from acrylic acid, meth-acrylic acid, methyl acrylate, ethyl acrylate, methyl meth-acrylate, ethyl methacrylate, and/or other vinyl monomers. Suitable acrylate polymers are those copolymers available under the tradename ’1irtth’agit" from Rohm Pharma (Ger-many). The Eudragit series E, L, S. RL, RS and NE copolymers are available solubilized in organic solvent, in an aqueous dispersion, or as a dry powder. Preferred acrylate polymers are copolymers of methacrylic acid and methyl methacrylate, such as the Pudragit I. and Eudragit S series polymers. Particularly preferred such copolymers are Eudragit L-300-55 and Eudragit L-100-55 (the latter copolymer is a spray-dried form of Eudragit 1--30D-55 that can he reconstituted with water). The molecular weight of the Eudragit L-30D-55 and Euciragir L-100-55 copolyrncr is approximately 135,000 Da, with a ratio of free carboxyl groups to ester groups of approximately 1 1. The copolymer is generally insoluble in aqueous fluids having a pH below 5.5. Another particularly suitable rnethacrylic acid-methyl methaerylate copolymer is hudragit 8-100, which differs from Eudragit L-300-55 in that the ratio of free carboxyl groups to ester groups is approximately 1:2. Eudragit S-lOft is insoluble at pH below 5.5, but unlike Eudragit 1.-30D-55, is poorly soluble in aqueous fluids having a pH in the range of 5.5 to 7.0. This copolymer is soluble at pH 7.0 and above. Eudragit L-100 may also be used, which has a p11-dependent solubility profile between that of Eudragit L-30]3-55 and Fudragit S-100, insofar as it is insoluble at a pH below 6.0. It will he appreciated by those skilled in the art that Eudragit L-30D-55, L-100-55, L-100, and S-100 can he replaced with other acceptable polymers having similar pH-dependent solubility characteristics. Other suitable aerdate polymers are those methacrvlic acid/ethyl acrylate copolymers avail-able under the tradename "Koilicoat" from BASE AG (Ger-many). For example, Kollicoat MAE has the same molecular structure as Eudragit L-100-55.

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[0061] The preferred molecular weight, glass transition temperature (T5) and melting temperature (T01) are also indicated. Also, suitable cellulosic polymers typically have
an inherent viscosity (IV.) of about 0,2 to about 3,0 deci-liters/gram, preferably about.1 to about 1.6 deciliters/gram,

as measured at a temperature of 25e C. for a 0.5 gram sample in 100 ml of a 60/40 by weight solution of phenol/tetrachln-roetharie. When prepared using a solvent casting technique, the watcr-swellahle, water-insoluble polymer should be selected to provide greater cohesive strength and thus facili-tate film forming (generally, for example, cellulose acetate

[0063] When the water-sweilable polymer is an acrylic acid or acrylate polymer, a hydrogel is provided that can be reversibly dried, i.e., after removal of water and any other solvents, the dried hydrogcl may he reconstituted to its original state by addition of water. In addition, hydrophulie hydrogels prepared with an acrylic acid/acrylate water-swellable polymer are generally substantially nontacky prior to contact with water, but become tacky upon Contact with a moist surface, such as is found in the interior Of the mouth, such as on the surface of the teeth. ’This property of being nontacky prior to contact with water enables positioning or repositioning on a chosen surface before, or as the hydrogel

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becomes tacky. Once hydrated, the hydrogel becomes tacky and adheres to the surface of the teeth.

[0064] In addition, acrylate-containing compositions can
generally provide swelling in the range of about 400% to 1500% upon immersion of the hydrogel composition in water or other aqueous liquid, at a p1-I of less than 5.5, although the ratio of the acrylate polymer to the hydrophilic polymer/complementary oligomer blend can he selected such that the rate and extent of swelling in an aqueous environment has a predetermined pH-dependence. This fea-ture also provides for retroactive incorporation of whitening agents or other agents, such as loading the composition with peroxide, peroxy acids, chlorites, stabilizers, flavoring agents, etc.

[0065] By contrast, incorporating a cellulose ester as the
water-swellable polymer renders the hydrogel tacky prior to application to a moist surface, but nontacky upon absorption of water, it will he appreciated that such a composition may he desirable when a decrease in tack is desired for ultimate removal of the product from the teeth.

[0066] The second component of the hydrogel composi-
tion is a blend of a hydrophilic polymer and a complemen-tary oligomer capable of hydrogen bonding to the hydro-philic polymer, and optionally capable of iuuically or covalently bonding to the hydrophilic polymer as well. Suitable hydrophilic polymers include repeating units derived from an N.vinyl lactam monomer, a carboxy vinyl monomer, a vinyl ester monomer, an ester of a carboxy vinyl monomer a vinyl amide monomer, and/or a hydroxy vinyl monomer. Such polymers include, by way of example, poly(N-vinyl lactams), poly(N-vinyl acrylamides), poly(N-alkylacrylamides), substituted and unsubstituted acrylic and mcthacrylic acid polymers (e.g., polyacrylic acids and poly-methacrylic acids), polyvinyl alcohol (PVA), polyviny-lamine, copolymers thereof and copolymers with other types of hydrophilic monomers (e.g. vinyl acetate).

[0067] PoIy(N-vinyl lactams) useful herein are preferably
noncrusslinked homopolymers or copolymers of N-vinyl lactam monomer units, with N-vinyl lactam monomer units representing the majority of the total monor.neric units of a poly(N-vinyl lactams) copolymer. Preferred poly(N-vinyl lactams) for use in conjunction with the invention are prepared by polymerization of one or more of the following N-vinyl lactam monomers: N-vinyl-2-pyrrolidonc; N-vinyl-2-valcrolact am; and N-yin yl-2-caprolactam. Nonlimiting examples of non -N -vinyl lactam comonomers useful with N -vinyl lactam monomeric unils include N,N-dimethylacry-lamide, acrylic acid, methacrylic acid, hydroxyethyl-tncthacrylate, acrylamide, 2-acrylarrrido-2-methyl-i -pro-pane sulfonic acid or its salt, and vinyl acetate.

[0068] Poly (N-alkylacrylamides) include, by way of
example, puly(mcthacrylamide) and poiy(N-isopropyl acry-lam idc)(PNIPAM).

[0069] Polymers of carboxy vinyl monomers arc typically
formed from acrylic acid, rnethacrylic acid, crotonic acid, isoerotonic acid, itaconic acid and anhydride, a 1,2-dicar-hoxylic acid such as malcic acid or fumaric acid, maleic anhydride, or mixtures thereof, with preferred hydrophilic polymers within this class including polyacrylic acid and polymethacrylic acid, with polyacrylic acid most preferred.

[0070] Preferred hydrophilic polymers herein are the fol-
lowing: poly(N-vinyl lactams), particularly polyvinyl pyr-

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rolidone (PVP) and polyvinyl caprdlactam (PVCap); poly(N-vinyl acetamides), particularly polyacetamide per se; polymers of carboxy vinyl monomers particularly poly-acrylic acid and polyrneihacrylic acid; and copolymers and blends thereof. PVP and PVCap are particularly preferred.

[0071] The molecular weight of the hydrophilic polymer is
not critical; however, the number average molecular weight of the hydrophilic polymer is generally in the range of approximately 100,000 to 2,000,000, more typically in the range of approximately 500,000 to 1,500,000. The oligomer is ’cornplenientary" to the hydrophilic polymers in that it is capable of hydrogen bonding thereto. Preferably, the complementary oligomer is terminated with hydroxyl groups, amino or carboxyl groups. The oligomer typically has a glass transition temperature 1’ in the range of about 100° C. to about 30° C. and a melting temperature T,,, lower than about 20° C. The oligomer may be also amor-phous. The difference between the T values of the hydro-philic polymer and the oligomer is preferably greater than about 50° C., more preferably greater than about 1.00° C,, and most preferably in the range of about 150° C. to about 300° C. The hydrophilic polymer and complementary oh-gomner should be compatible, i.e. capable of forming a homogeneous blend that exhibits a single T, intermediate between those of the unhlended components.

[0072] Generally, the complementary oligomer will have a
molecular weight in the range from about 45 to about 800, preferably in the range of about 45 to about 600. The complementary oligomer is preferably a low molecular weight po1yallylene glycol (molecular weight 30(1-600) such as polyethylene glycol 400, which can also serve as a low molecular weight plasticizer. Alternatively, a different compound can be incorporated as an additional low molecu-lar weight plasticizer, in which case any of the low triolecu-lan weight plasticizers described below can be used. In one embodiment of the invention, the complementary oligonien is a complementary low molecular weight or oligonienic plasticizer that contains at least two functional groups per molecule that are capable of hydrogen bonding to the hydrophilic polymer.

[0073] Examples of suitable complementary oligonaers
include, but are not limited to, low molecular weight poly-alcohols (e.g. glycerol), monomeric and oligoalkylene gly-cols such as ethylene glycol and propylene glycol, ether alcohols (e.g., glycol ethcrs), carbonic diacids, alkane diols from butane diol to octane diol, including carboxyl-tetmi-nated and amino -terminated derivatives of polvaLkylene glycols. Polyalkylene glycols, optionally carboxyl-termi-nated, are preferred herein, and polyethylene glycol having a molecular weight in the range of about 300 to 600 Is an optimal complementary oligomer.

[0074] It will he appreciated from the foregoing that a
single compound, e.g., a low molecular weightolyailtylcne glycol such as polyethylene glycol having a molecular weight in the range of about 300 to 600, can serve as both the complementary oligomer and the low molecular weight plasticizer.

[0075] As discussed in U.S. Patent Publication No, 2002/
0037977 for ’Preparation of Hydrophilic Pressure Sensitive Adhesives Having Optimized Adhesive Properties," the ratio of the hydrophilic polymer to the complementary oligorncr in the aforementioned blend affects both adhesive

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V. Methods of Use

[0.128] In practice, the compositions can be used simply by
removing the product from its package, removing a release liner (when included) and applying the adhesive layer to the teeth that it is desired to whiten (or to any body surface it another utility of the whitening agent is to he used). The tooth whitening systems described herein can be provided in a variety of sizes, so that the composition can be applied to the entirety or any portion of a tooth, and to any number of teeth at one time. The substrate, when occlusive, reduces or prevents leakage of the whitening agent, from the compo-sition, while the user wears the composition for the desired amount of time. The composition can he maintained in the desired location for as little time as a few minutes, several hours, all day or overnight, and then removed when the desired degree of whitening has been achieved. If desired, a translucent composition can he provided, and is worn with-out being obtrusive or noticeable to others.

[0129] The composition can he worn for an extended
period of time, but will typically be worn for a predeter-mined period of time of from about 10 minutes to about 24 hours. For tooth whitening application, a preferred time period is from about 10 minutes to about S hours (e.g., overnight), with 30 minutes to about 1 hour also being a preferred embodiment.

[0130] A user can form the composition around the upper
or lower teeth by applying normal manual pressure to the substrate with the tips of the fingers and thumbs, optionally by moistening the composition prior to application. Assum-ing the surface area of the average adult finger or thumb tip is approximately one square centimeter, the normal pressure generated by the finger and thumb tips is about 100,000 to about 150,000 Pascals (i.e., about 3 lbs. or 1.36 kg) per square centimeter. The pressure is typically applied to the composition by each finger and thumb tip for about one or two seconds. Once the pressure applied to the substrate by the tips of the fingers and thumbs is removed, the compo-sition remains in the shape of, and adherent to, the surface of the teeth and adjoining soft tissue onto which it was formed.

[0131] When the user is ready to remove the composition,
the composition can be removed simply by peeling it away from the surface of the teeth or other body surface. If desired, the composition can he re -adhered for additional whitening time. Any residue left behind is minimal, and can he removed using conventional tooth cleansing methods.

[0132] In one embodiment of the Invention, the composi-
tion is a solid and is a pressure sensitive adhesive and absorbs water.

[0133] The composition can also he applied as a non-solid
composition, for example applied as a liquid or gel. For example, the user can extrude the composition from a tube onto a finger for application to the teeth, extrude the coot-- position from a tube directly onto the teeth, apply the composition by means of a brush or other applicator, and so forth. After the evaporation of solvent, the liquid or gel composition dries to form a matrix-type polymer film or gel on the surface of the teeth. In one embodiment of this liquid or gel film-former composition, the hydrogel contains suf-ficient water or other solvent to provide flowable property. In another embodiment of this composition, the polymer

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components of the liquid or gel composition are soluble in
a water-ethanol mixture both at ambient temperature and at refrigeration temperatures of about 40 C., and are miscible upon solvent evaporation. In yet another embodiment of this liquid or gel film-former composition, the polymeric com-position has a Lower Critical Solution Temperature of about 360 C. in an ethanol-water mixture. The resulting film (after solvent evaporation) is preferably insoluble or slowly soluble in saliva at body temperature so as to provide long lasting contact between the hydrogen peroxide and the dental enamel. Finally, the hydrogen peroxide should be stable both in the liquid or gel composition, as well as-within polymer film upon drying.

[0134] The practice of the present invention will employ,
unless otherwise indicated, conventional techniques of poly-mer chemistry, adhesive manufacture, and hydrogel prepa-ration, which are within the skill of the art. Such techniques are fully explained in the literature.

[0135] It is to be understood that while the invention has
been described in conjunction with the preferred specific embodiments thereof, the foregoing description, as well as the examples that follow, are intended to illustrate and not limit the scope of the invention. Other aspects, advantages and modifications will be apparent to those skilled in the art to which the invention pertains. All patents, patent applica-tions, journal articles and other references cited herein are incorporated by reference in their entireties.

[0136] The following examples are put forth so as to
provide those of ordinary skill in the art with a complete disclosure and description of how to make and use the compounds of the invention, and are not intended to limit the scope of what the inventors regard as their invention. Efforts have been made to ensure accuracy with respect to numbers (e.g., amounts, temperatures, etc.) but some errors and deviations should be accounted for. Unless indicated other-wise, parts are parts by weight, temperature is in degrees Celsius (° C), and pressure is at or near atmospheric.

[0137] The following abbreviations and tradenamcs are
used in the examples:

Eudragit 1,100-55 mrthacrvlir acid copolymer, (Robin America Inc,) MG polyethylene glycol 400
PVP t’i.oiiidort (5 pu[yvhiyipyrrolidonn (BASt)

EXAMPLES

Example 1

[0138] Preparation of Solid Composition

[01.39] Ono embodiment of a composition for tooth whit-
ening WSS prepared from the following ingredients using a melt extrusion process:

Eudragli 1,100-55 9 W
PVt’ 44 w
P150 23 wt 52

Hydrogen peroxide S wt 92
Wrter, stabilii.cra, p1-i modulators 19 Wt IN,

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[0:140] The ingredients were melt processed in a Bra-
bender single screw extruder as follows: The Eudragit 1.100-55 was added to the extruder first, followed by PVP and PEG, at a temperature of 100 to 150" C. The cotupo-sition was extruded to a thickness of 0.35 mm between two polyethylene terephthalatc release liners. Hydrogen perox-ide solution was added to the extruded film.

Example 2

[0141] In Vitro Release of Hydrogen Peroxide from a
Solid Composition

[0142] The release of hydrogen peroxide from the tooth
whitening compositions of the invention in vitro, in pH 7,0 buffer, was investigated and compared with the peroxide released from a commercial product, Crest WhitestripsT" (a product of the Proctor & Gamble Co., Cincinnati, Ohio and referred to as the "Crest product"), The Crest product contains 5.3176 hydrogen peroxide in a Carbopol 956 gel on a thin polyethylene film.

[0143] The in vitro release of hydrogen peroxide from the
compositions containing 3%, 6% or 9% peroxide (formu-lated as set forth in Example 1) was compared with the release of hydrogen peroxide from the Crest product, i’he test composition or the Crest product was allowed to release peroxide into solution through filter paper, and the peroxide was measured using standard analytical techniques. For the Crest product, the peroxide levels observed decreased to baseline within about 30 minutes. This data is similar to published data (Pagel, P. A., et al. (2000) Vital Tooth Whitening with a Novel Hydrogen Peroxide Strip System: Design, Kinetics, and Clinical Response. Compendium, Suppi. 29, Vol. 21: SlO-S15).

[0144] The tooth whitening compositions of the invention
released peroxide at a rate proportional to the starting concentration. The compositions of the invention were also found to release peroxide at a higher rate than the Crest product at all times the peroxide content was tested: 5, 30 and 60 minutes. The peroxide release for the composition containing 6% peroxide, which is close to the Crest product, was approximately 7.5, 24 and 10 times greater as the release rate for the Crest product at each time point, respec-tively. The peroxide release for the composition containing 3% peroxide, was approximately 3, 7 and 5 times greater as the release rate for the Crest product at each time point, respectively.

Example 3

[0145] Efficacy of a Solid Composition

[0146] The efficacy of the tooth whitening compositions
was tested using the following procedure. A subject tested the efficacy of the tooth whitening composition prepared according to the procedure described in Example 1 by applying the composition to the lower set of teeth once a day for 1 hour, for 6 consecutive days. The shade of the subject’s teeth was measured using the Professional Tooth Shade Guide before and after treatment of the teeth with the tooth whitening composition. On day 1, the subject’s teeth were graded shade 12, and after one hour of treatment with the tooth whitening composition, the teeth were graded shade :10. After one hour of treatment with the tooth whitening composition on clay 2, the subject’s teeth were graded shade

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8. After one hour of treatment on day 3, the subject’s teeth were graded shade 5. Similarly, after one hour of treatment on day 4, the subject’s teeth were graded shade 4/5. On day 5, after one boar of treatment, the subject’s teeth were graded shade 2/3. The lightest shade was achieved after a further one half hour of treatment on day 6, reaching a shade of 2. Thus, the efficacy of the tooth whitening composition was apparent, with measurable results within one hour of
treatment.

Example 4

[01473 Preparation of a Non -Solid Composition

[0148] A composition for tooth whitening was prepared
from the following ingredients (Formula A):

nciunucd waur 25.0 wt ’a
uthanot 35.0 wt
Fochagit L 100-55 4.00 wt
PEO 1.00 wt%
PVP 7,00 wt
Caibairicle pcioxidc 18.0 wt 0
rjtralc 0.13 wt

[0149] The composition was mixed in a Cole-Parmer
high-torque low-speed lab mixer supplied with Totlon coated impeller (2 inches in diameter) as follows. Deionized water was mixed with ethanol, followed by the addition of PEG. Sodium citrate was then added under vigorous stirring conditions. Euclragit L 100-55 powder was added slowly within 2-5 ruin) under vigorous stirring (500-600 rpm). After about 5-10 ruin (it is not necessary to wait until all Eudragit is dissolved), PVP powder was slowly added (within 5 ruin). The high stirring rate was maintained over 5-10 ruin. Carhamide peroxide powder was added (within 1-2 ruin) and the mixture stirred to obtain i homogeneous solution (approximately 30 minutes at 800i900 rpm). The solution was then stored over a period of 2-5 hours to let the air bubbles dissipate.

Example 5

[0150] Preparation of a Non -Solid Composition

[0151] A composition for tooth whitening was prepared
from the following ingredients (Formula B):

Deioi.iizecl water 35.0 wt.
Ethanol 35.0 wt
Eudrait 1, 100-55 2.50 WI
PEG 1.92 WI
I’VP 6.00 Wi
Carbarnido peroxide 18.0 Wi
Sodium citrate 0.04 Wi
Maitiocnl A4C 1.50 Wt

[0152] The composition was mixed in a Cole-Parmer
high-torque low-speed lab mixer supplied with Teflon coated impeller (2 inches in diameter). Deionized water was mixed with ethanol, followed by the addition of PEG. Sodium citrate was then added under vigorous stirring conditions. Euclragit L 100-55 powder was added slowly (within 5 ruin) under vigorous stirring (500600 rpm), fin-

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US 20030235549A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2003/0235549 Al Singh et al. (43) Pub. Date: Dec. 25, 2003

(54) HYDROGEL COMPOSITIONS
DEMONSTRATING PHASE SEPARATION ON
CONTACT WITH AQUEOUS MEDIA

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(22) Filed: May 19 2003

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/359,548, flied on Feb. 5, 2003, which is a continuation-in-part
of application No. 10/137,664, filed on May 1, 2002.

(60) Provisional application No, 60/288,008, filed on May 1, 2001.

Publication Classification

(51) Int. Cl.’............................... A6IK 7/06; A6IK 7/1.1
(52) U.S. Cl......................................424/70.13; 424/70,16

(57) ABSTRACT

A composition is provided, wherein the composition com-prises a water-swcllahle, water-insoluble polymer, a blend of a hydrophilic polymer and a complementary oligorner capable of hydrogen bonding to the hydfophilic polymer. The composition also includes a second water-swell able, water-insoluble polymer that provides for a phase separating film forming composition. Active ingredients, such as a whitening agent, may he included. The cumposition finds utility as an oral dressing, for example, a tooth whitening composition that is applied to the teeth in need of whitening, and removed when the degree of whitening has been achieved. In certain embodiments, the composition is trans-lucent. Methods for preparing and using the compositions are also disclosed.

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SUPERINTENDENCIA DE INDUSTRIA V COMERCIO DIRECCION DE NUEVAS CREACIONES

2020
Bogota, D.C.,

Abogado: Juan Pablo Cadena Sarmiento

ASUNTO: Radicación No, 07-007211
TrÆmite 002
Evento 001
Actuación 430
Oficia
Folios

Como resultado del Examen de Fondo, realizado con fundamento en el artIcul’o 45 de la Decision 486 de la Comisión de la Comunidad Andina, Se comunica:

Documentos estudiados:

DescripciOn: Folios 70 a 122 como se radicó inicialmente.
Reivindicaciones: Folios 123 a 128 como se radicó inicialmente.
Prioridad: US 200410902720 (2004-07-29)

Objeto de la Invención

Titulo de la invención: Composiciones para el cuidado oral con poilmeros formadores de pelicula.

Problema TØcnico Planteado: necesidad de obtener una formulación de cuidado oral que permita el blariqueamiento de una superficie dental a la cual es aplicado.

Solución: formulación para el cuidado oral que contienen un agente blanqueador y un pollmero formador de peilcula que maritenga el efecto blanqueador.

PC: A61 K8/02C; A61 K8122; A61 K8/81 K4; A61 K8/81 R2

AnÆlisisde la Solicitud de Patente

Reivindicaciones (Art 30 D 486, Art 22 PCT)

Claridad y ConcisiOn:

Las reivindicaciones I y 18 haceri referenda a dos composiciones diferentes, es
decir a dos objetos de reivindicaciOn difererites. Es as que la reivindicaciOn 18, reivindica un material activo, un polimero de Æcido acrIlico y un alcohol inferior de carÆcter muy general en comparaciOn a la reivindicaciOn I que reivindica un agente blanqueador (como
material activo) y un polimero acrilico. Se sugiere al solicitante limite el objeto de
invención a un solo tipo de composición, ya que para el experto en la materia no es claro cual de los dos objetos se quiere proteger.

La reivindicación 26 reivindica un mØtodo para entregar un material activo para el cuidado oral, que comprende aplicar a dicha superficie una cantidad segura y efectiva de un material activo y un polimero de acido acrilico, teniendo en cuenta Ia anterior, el mØtodo esta definido por la composición del polimero mÆs no par la forma como se aplicara el producto por tal razOn carece de claridad esta reivindicación y sus reivindicaciones dependientes

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Determinación del Estado de la TØcnica

El Estado de la TØcnica se determinó con base an la fecha de solicitud prioritaria 2004-07-29 y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

Item Documento TItulo Fecha de

Publicacion

D1 US 2003152528 Hydrog composiUon for tooth whitening 2003-08-14

02 US 2003235549 Hydrogel compositions demonstrating phase 2003-12-25 separation on contact with aqueous media
D3 W02004035683 Acrylic film and laminates the same 2004-04-29

D4 US09112542 Oral compositions exhibiting enhanced ant/plaque 1998-0709 efficacy

AnÆlisisde Patentabilidad (Art 14 D486)

Novedad (Art 16 D486)

Respecto a la solicitud an estudio:

La reivindicaciÆn 1 dice: "Una composiciOn para el cuidado oral, que comprende:
a) un agente blanqueador; y
b) Un polimero acrilico formador de pelicula."

Respecto at estado de la TØcnica, Dl describe composiciones tipo hidrogel para el cuidado oral, especialmente para blanquear los dientes, que comprenden un agente que se hincha con el agua, un pollmero insoluble an agua, un polimero hidrofIlico y un agente blanqueador, esta composición se caracteriza por tener un efecto blanqueador y de cuidado de los dientes porque genera una pelicula an la superficie de estos cuando se
seca.

Las caracterIsticas esenciales de Ia composiciôn de la reivindicación 1 habian sido divulgadas an Dl as decir: Un agente que se hincha con el agua (polimero insoluble en agua), un polimero hidrofulico y un agente blanqueador, (Pagina 2 -3 pÆrrafo 0023),asi mismo esta composición se caracteriza por generar una pelicula an la superficie de la zoria de apiicaciOn. (PÆgina 5 pàrrafo 0063, pagina 12 pârrafo 0133). Por 10 cual la reivindicación no as nueva.

La reivindicación 18 dice: "Una composición para et cuidado oral, que comprende:
a) un material activo; y
b) Un polimero de 6cido acrilico...; y
c) un alcohol inferior

Respecto at estado de la TØcrilca, Dl describe composiciones tipo hidrogel para el cuidado oral, un polimero insoluble an agua, un polimero hidrofIlico, un agente blanqueador (principio activo) y un alcohol de bajo peso molecular.

Las caracterIsticas esenciales de la composiciôn de la reivindicación 18 habian sido divulgadas an Dl, as decir: un polimero insoluble an agua (polilimero de acido acrilico, metacrilico, etc)(PÆgina 5 pÆrrafo 0058 y 0062), un principio activo seleccionado entre perOxidos, perboratos, percarbonatos, etc (PØgina 3 pÆrrafo 0027)y un alcohol inferior o de bajo peso molecular (PÆgina 6 pârrafo 0073, ejemplos 4 y 5). Por lo cual la reivindicaciOn no as nueva.

De igual manera Dl describe las caracterIsticas de las reivindicaciones dependientes 2 a 25 an cuanto a que:
a) La composición del polimero formador de peIcuIa (polimero insoluble y agente que se hincha) consiste an polimero tipo acrilato 0 un copolimero formado por âcido acrilico, àcido metacrilico, acrilato de metilo, acrilato de etilo o monOmeros de

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vinilo, acrilamidas, entre otros (Pagina 5- pÆrrafos 0062-0063; PÆgina 6- pÆrrafos 0066-0067)
b) Coma polImeros hidrofilicos a agentes de adición, son recomendados polivinilpirrolidona (PVP) (PÆgina6 prrafo 0070)
C) El agente blanqueador es preferiblemente perOxido de hidrógeno. (Pâgina 1-pªrrafos 0008-0011; PÆgina 3 pÆrrafo0027)
d) Contiene un alcohol inferior tipo etanol (Pagina 13 - Ejemplos 4 y 5)

De acuerdo a Ia descrito en la anterioridad Dl se observa que todas las caracterIsticas tØcnicas de una composicion para el cuidado oral que contiene un agente blanqueador y un polimero acrIlico formador de peilcula, ya eran conocidas en el estado de la tØcnica. Par lo tanto la reivindicación 1 y sus dependientes no son nuevas.

Conclusion

Los requisitos de Patentabilidad de la presente Solicitud se encuentran afectados asi:

No Documento Reivindicaciones afectadas Requisito que afecta

Dl US 2003152528 1-25 Novedad

En cumplimiento del articulo 45 de la Decision 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del tØrmino de 60 dias contados a partir de (a fecha de notificación de (a presente comunicación. En caso de no dar respuesta al presente requerimiento, 0 SI a pesar de la respuesta subsistieran los impedimentos pars la concesiOn, se denegarÆla patente.

NotifIquese el presente oficio conforme a lo dispuesto en el numeral 52, literal e), del capitulo quinto deltItulç prime_d (a Circular Unica No 10 de 2001.

ALIX CARMENZA’CESPEDES DE VERGEL
Jefe de DivisiOn,de Nuevas Creaciones

.... El interior requerimiento fue notificado por fijacion en lista, de fecha

CONCEPTO TECNICO EXAMINADOR TECN(CO
NUMERO: 2190 _j202093

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