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Señora

**JEFE DE DIVISIÓN DE NUEVAS CREA
SUPERINTENDENCIA DE INDUSTRIA**

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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REF: Expediente No. 06 117 705 – solicitud de patente de invención a favor
de COLGATE PALMOLIVE COMPANY

Respuesta al oficio No. 2236 del 19 de febrero de 2010

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, según lo acredita el documento de poder presentado ante esa División me permito dar respuesta a las observaciones de carácter técnico y jurídico, relacionadas con la patentabilidad, para la concesión de la patente de acuerdo con la Decisión 486 según el concepto técnico No. 258 notificado por fijación en lista de fecha 19 de febrero de 2010 y cuyo término fue prorrogado el 19 de mayo de 2010

En primer lugar, adjuntamos un nuevo capítulo reivindicatorio de 1-9 reivindicaciones que subsana las objeciones realizadas por el Señor Examinador, el cual no amplía la materia divulgada inicialmente y se encuentra debidamente sustentado en la descripción. Para diseñar este capítulo, hemos seguido atentamente las sugerencias realizadas por el Señor Examinador, por lo que consideramos que el mismo guarda total claridad y concisión.

Ahora en cuanto a las objeciones a la novedad, en vista del documento D1 (US2004/0062724) es preciso indicar que, dadas las modificaciones realizadas a las reivindicaciones, el documento D1 no divulga todos y cada uno de los elementos reclamados en la presente invención. Por esta razón, la

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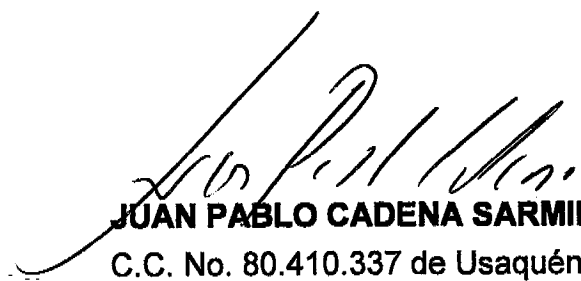
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composición específica reclamada constituye un diseño diferencial sobre todo lo establecido en el arte previo, por lo que se cumple entonces con el requisito de novedad.

Adicionalmente, no existe alguna motivación o sugerencia en el estado de la técnica que permita a un técnico entrenado en la materia llegar de manera obvia a la materia reivindicada, lo cual resulta en el cumplimiento adecuado de los requisitos de patentabilidad.

En vista de lo anteriormente expuesto, respetuosamente solicitamos el retiro de las objeciones a la presente solicitud y la concesión del privilegio solicitado, ya que en opinión del solicitante cumple con todos los requisitos establecidos en la decisión 486.

De la señora Jefe,


JUAN PABLO CADENA SARMIENTO

C.C. No. 80.410.337 de Usaquén

T.P. No. 57492 del C.S.J.

Calle 70A No. 4-41

Bogotá, 18 de junio de 2010

MXB/NFA

Anexo

REIVINDICACIONES

1. Una película de blanqueamiento dental recubierta que contiene:

- un polímero hidratable formador de película; y
- un agente blanqueador;

dicha película caracterizada porque:

- el polímero comprende un polímero poli (etilen-óxido);
- tiene un recubrimiento hidrofóbico sobre una superficie;
- tiene un recubrimiento adherente a los dientes sobre la superficie opuesta;

X al menos uno de la película o el recubrimiento hidrofóbico contiene un agente saborizante que comprende un extracto o aldehído, cetona, ester o alcohol saborizantes, que imparten sabor seleccionado del grupo que consiste de menta verde, menta, gaulteria, sasafrás, clavo, salvia, eucalipto, mejorana, canela, limón, lima, uva, naranja, manzana, pera, durazno, fresa, cereza, melocotón, sandía, banano, café, cocoa, mentol, carvona, anetol y combinaciones de los mismos.

2. La película de acuerdo a la reivindicación 1, caracterizada porque dicho polímero hidratable formador de película comprende un polímero poli (etilen-óxido) con un peso molecular promedio en número, rango de viscosidad, promedio en peso o promedio Z entre 10.000 y 10.000.000.

3. La película de acuerdo a la reivindicación 1, caracterizada porque el agente blanqueador se selecciona del grupo que consiste de peróxidos, cloritos de metal, complejo de PVP-peróxido de hidrógeno, perboratos, percarbonatos, persulfatos, perfosfatos, persilicatos, peroxiácidos, y/o sus sales y combinaciones de los mismos.

4. La película de acuerdo a la reivindicación 1, caracterizada porque el recubrimiento hidrofóbico comprende un polímero seleccionado del grupo que consiste de una etil celulosa, una propil celulosa, una isopropil celulosa, una butil celulosa, una t-butil celulosa, un acetato de celulosa,

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un acetato de polivinilo, una laca, un copolímero de acrilato y combinaciones de los mismos.

5. La película de acuerdo a la reivindicación 1, caracterizada porque el recubrimiento adherente a los dientes comprende un polímero seleccionado del grupo que consiste de pirrolidonas de polivinilo, alcoholes de polivinilo, fosfonatos de polivinilo, fosfonatos de polietileno, ácidos poliacrílicos, sales de poliacrilato, ácido polimetacrílico, sal de polimetacrilato, polimetil metacrilatos, fosfonatos de polibuteno, polimaleatos, polímeros de vinilcaprolactam/acrilato de sodio, poliestirenos, polímeros de fosfonato estireno, terpolímeros de monómeros de ácido sulfónico de acrilometil propil/metacrilato/estireno, ácido poliaspártico, poli(2-acrilamido-2metilpropano sulfonato), copolímeros de monómeros de acetato de vinilo y ácido crotónico, polímeros de silicona, poliacrilamida, polisiloxanos, polímeros de alquil celulosa, polímeros de hidroxialquil celulosa, polímeros de carboximetil celulosa, alginatos de sodio, ácidos algínicos, copolímeros de polimetil vinil éter/anhídrido maléico, ácidos poliacrílicos con enlaces cruzados, sales de poliacrilato con enlaces cruzados, y combinaciones de los mismos.

6. Una película de blanqueamiento dental recubierta que contiene:

- un polímero hidratable formador de película; y
- un agente blanqueador;

dicha película caracterizada porque:

- tiene, en al menos una superficie, un recubrimiento hidrofóbico que contiene un agente saborizante; y
- dicho agente saborizante comprende un extracto o aldehído, cetona, ester o alcohol saborizantes, que imparten sabor seleccionado del grupo que consiste de menta verde, menta, gaulteria, sasafrás, clavo, salvia, eucalipto, mejorana, canela, limón, lima, uva, naranja, manzana, pera, durazno, fresa, cereza, melocotón, sandía, banano, café, cocoa, mentol, carvona, anetol y combinaciones de los mismos.

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7. La película de acuerdo a la reivindicación 6, caracterizada porque dicho polímero hidratable comprende un polímero poli (etilen-óxido) con un peso molecular promedio en número, rango de viscosidad, promedio en peso o promedio Z entre 10.000 y 10.000.000.
8. La película de acuerdo a la reivindicación 6, caracterizada porque el agente blanqueador se selecciona del grupo que consiste de peróxidos, cloritos de metal, complejo de PVP-peróxido de hidrógeno, perboratos, percarbonatos, persulfatos, perfosfatos, persilicatos, peroxiácidos, y/o sus sales y combinaciones de los mismos.
9. La película de acuerdo a la reivindicación 6, caracterizada porque comprende un polímero seleccionado del grupo que consiste de una etil celulosa, una propil celulosa, una isopropil celulosa, una butil celulosa, una t-butil celulosa, un acetato de celulosa, un acetato de polivinilo, una laca, un copolímero de acrilato y combinaciones de los mismos.



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D2 #5
15(19) **United States**(12) **Patent Application Publication**
Chang et al.(10) **Pub. No.: US 2003/0194382 A1**(43) **Pub. Date: Oct. 16, 2003**(54) **MULTI-LAYER PATCHES FOR TEETH
WHITENING**(76) **Inventors: Sug-Youn Chang, Daejeon (KR);
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LAWRENCEVILLE, NJ 08648 (US)**(21) **Appl. No.: 10/177,689**(22) **Filed: Jun. 20, 2002****Related U.S. Application Data**(60) **Provisional application No. 60/324,555, filed on Sep.
25, 2001.**(30) **Foreign Application Priority Data**Jun. 23, 2001 (KR)..... 01-0036024
Jul. 4, 2001 (KR)..... 01-0039847**Publication Classification**(51) **Int. Cl.⁷ A61K 7/20**
(52) **U.S. Cl. 424/53**(57) **ABSTRACT**

The present invention relates to a dry type teeth whitening patch with a multi-layer structure of three or more layers. More particularly, in the dry type patch, a contact adhesive layer substantially free of peroxide comprises a hydrophilic glass polymer as a base polymer so that it provides substantial adhesive strength when hydrated by water, an active material reservoir layer comprises peroxide as a teeth whitening agent, and a backing layer which is impermeable to water. The dry type patch of the present invention has superior teeth whitening effect and excellent peroxide stability at a high temperature since the peroxide-containing layer is covered and protected by other layers.

MULTI-LAYER PATCHES FOR TEETH WHITENING

[0001] This application claims the benefit under 35 U.S.C. §119 of U.S. provisional patent application number 60/324,555 filed Sep. 25, 2001 which is hereby incorporated by reference in its entirety for all purposes.

TECHNICAL FIELD

[0002] The present invention relates to a dry type patch that removes stains from teeth and whitens teeth only through attachment to the teeth. More particularly, it relates to a dry type patch comprising a peroxide, known as an excellent teeth whitening agent, which is capable of remaining in the attached site for a desired period of time, thereby achieving a teeth whitening effect in a short period of time. In particular, the dry type patch of the present invention consists of a multi-layer structure having three or more layers, which has excellent adhesive strength and peel-off property, and is thereby convenient to use. Further, it has good stability at high temperatures and good ability to maintain shape during storage, which makes it comfortable to carry. In addition, due to the dry nature of the patch, the peroxide-containing layer does not stick to the user's hands or face during the process of its attachment to the teeth. Further, since the patch comprises three or more layers, the peroxide-containing layer is covered with and protected by other layers, which improves its safety to human tissue.

BACKGROUND OF THE INVENTION

[0003] As people's interest in whitening their teeth increases, a number of toothpastes having teeth whitening effect have become commercially available. However, even though the toothpaste contains a teeth whitening agent having good performance, it is hard to achieve significant whitening effect in a short period of time by brushing teeth with only 1 to 3 minutes of contact time between teeth and toothpaste.

[0004] Recently, in order to solve the above problems, a number of patent applications related thereto have been filed and teeth whitening products of various formulations have appeared on the market.

[0005] For example, in the case of professional whitening gel, a dentist manufactures an individualized mouth tray, which precisely fits the teeth of the patient. The patient applies the whitening gel in a prescribed amount to inner walls and trough of the tray following instructions at home. Therefore, this whitening method has disadvantages in terms of convenience and cost. Furthermore, this method may present problems with safety and comfort, since the surplus peroxide gel and the mouth tray itself may cause irritation or damage to the gums or oral cavity.

[0006] In order to solve these problems, Japanese Patent No. 10,017,448, assigned to Lion Corp., discloses a sheet-shaped oral plaster, which comprises a teeth adhesive layer and supporting layer. A whitening agent used in the plaster includes kojic acid and derivatives thereof, ascorbic acid and derivatives thereof, carbamide peroxide and the like, among which kojic acid and various salts thereof are described as being effective. However, the above-mentioned whitening agents have a strong acidity, which may cause irritation to oral cavity. Further, since these agents effect whitening at a

high acidity, it is difficult to produce good whitening without irritation. When this two-layer patch structure contains a high reactivity material such as a whitening agent, its stability degrades at high temperatures even though being stored with a release liner attached.

[0007] U.S. Pat. Nos. 5,879,691, 5,891,453 and 5,989,569, and WO 98/55044, assigned to Procter & Gamble, disclose a delivery system for a teeth whitener, comprising a thin, transparent and flexible polyethylene strip having a professional whitening gel thereon, wherein the professional whitening gel is pre-coated during the manufacturing process or applied to the strip or teeth directly before the attachment to the teeth. Since it does not use a mouth tray, the usage is facilitated and improved. Further, because the strip is thin and transparent, its use does not present an obstacle to the daily life. However, the delivery system disclosed therein is a wet type whitening layer constructed by using a teeth whitening substance along with a gelling agent, preferably carboxypolymethylene, obtained from B.F. Goodrich Company under the trade name of Carbopol, water, pH adjusting agent and additive carrier materials and applying the resultant highly viscous gel onto a strip of flexible polyethylene strip. When attaching and wearing the system onto teeth, the teeth whitening gel containing high concentration peroxide may adhere to and remain on hands, tongue, gums and the like. That is, such wet type gel systems have room for improvement in terms of handling. Further, in the two-layer embodiment consisting of a teeth whitening substance and strip, the peroxide stability is not sufficiently assured and the whitening effect may be diminished when stored at a high temperature or for a long period of time.

[0008] U.S. Pat. Nos. 5,310,563 and 5,639,445, assigned to Colgate-Palmolive Company, disclose a dental formulation comprising an active component dispersed in a polysiloxane polymer composition, available under the trade name of Dow Corning 3179 Dilatant Compound by Dow Corning Corporation, which is attached to the teeth by pressing it against the teeth and gum, and is easily removed from the teeth. The two-layer embodiment has the active whitening component encapsulated in the polymer. Therefore, the stability of the active peroxide component can be improved to some degree. However, this product has a disadvantage in that the active ingredient cannot be easily released from the Dilatant Compound in a short period of time, and consequently, an extended contact time is required to obtain the desired teeth whitening effect.

[0009] Therefore, there is a need for a dry type teeth whitening patch, which has improved peroxide stability at high temperature and safety to the human tissue during its attachment to the teeth.

SUMMARY OF THE INVENTION

[0010] The present invention relates to a dry type teeth whitening patch with a multi-layer structure of three or more layers. More particularly, in the dry type patch, a contact adhesive layer substantially free of peroxide comprises a hydrophilic glass polymer as a base polymer so that it provides substantial adhesive strength when hydrated by water, an active material reservoir layer comprises peroxide as a teeth whitening agent, and a backing layer which is impermeable to water. The dry type patch of the present invention has superior teeth whitening effect and excellent

ture transpired from the skin, whereby its permeability to drug is increased. In this case, a hydrophilic glass polymer is used as the barrier material.

[0034] The present inventors used a hydrophilic glass polymer in a contact adhesive layer of a matrix type patch so that the adhesive layer acquires adhesiveness or strengthens its adhesiveness when hydrated by moisture on the teeth while having little or no adhesive strength when stored or handled with hands to be attached to the teeth. Most of such glass polymers, when hydrated, provide sufficient adhesive strength to enable the patch to be fixed at the contact site of the teeth surface. Thus, according to the present invention, no additional means for fixing the patch to the teeth is required to attain sufficient contact time between the whitening agent and teeth, such as a marginal adhesive strip to be folded onto the back side of teeth. Once the contact adhesive layer is hydrated to have adhesive strength, the active material reservoir layer is subsequently hydrated and begins to release a teeth whitening agent.

[0035] The patch of the present invention does not generate significant irritation of gums or skin in the oral cavity even though it directly contacts with them since it contains a small amount of whitening agent. In addition, the patch of the present invention is attachable to teeth only, so that whitening agent is not released onto gums.

[0036] Thus, the dry type patch according to the present invention provides the above features by comprising multi-layer structure of three or more layers, wherein the contact adhesive layer contains a hydrophilic glass polymer, the active material reservoir layer contains peroxide and the backing layer is impermeable to water.

[0037] For these purposes, the polymers which can be used in the contact adhesive layer of the patch according to the present invention include polyalkylvinyl ether-maleic acid copolymer (PVM/MA copolymer) such as Gantrez AN 119, AN 139 and S-97, polyvinyl alcohol, polyacrylic acid, Poloxamer 407 (Pluronic), polyvinyl pyrrolidone-vinyl acetate copolymer (PVP/VA copolymer) such as Luviskol VA and Plasdone S PVP/VA, polyethylene oxide (Polyox), polyvinyl pyrrolidone (PVP, K-15~K-120), Polyquaternium-11 (Gafquat 755N), Polyquaternium-39 (Merquat plus 3330), carboxypolymethylene (Carbopol), hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, gelatin and alginate salt such as sodium alginate. The above-described polymers can be used alone or in mixtures thereof. Solvents for these polymers includes water, ethanol or mixtures thereof. Further, other organic solvents such as ethyl acetate, methylene chloride, isopropyl alcohol, acetonitrile or mixtures thereof with varied ratios may be also used as a solvent.

[0038] The patch to be attached onto teeth should be flexible enough to be deformable so that it conforms to contours of teeth. Since some polymers have a poor flexibility, suitable plasticizers may be added. Polypropylene glycol, glycerin, polyethylene glycol are generally used as the plasticizers.

[0039] For the active material reservoir layer containing peroxide, all the hydrophilic polymers which may be used in the contact adhesive layer are preferably used. In addition, shellac, a polymer used as enteric coating material, which is soluble in water at pH 6 or higher and is compatible with peroxide, can be used in the active material reservoir layer.

[0040] The above-described hydrophilic polymers may be used in the contact adhesive layer or other layers which contain no peroxide, without affecting the stability of peroxide. Considering the peroxide stability at a high temperature in the patch formulation, however, a hydrophilic glass polymer which is compatible with peroxide is preferably used in the active material reservoir layer containing peroxide.

[0041] Hydrophilic glass polymers such as polyvinyl pyrrolidone (PVP, K-15~K-120), polyquaternium-11, polyquaternium-39, polyvinyl pyrrolidone-vinyl acetate copolymer (PVP/VA copolymer) have good compatibility with peroxide and are easily soluble in water, ethanol or mixtures thereof. They also have good solubility in organic solvents. Accordingly, peroxide in the patch can be stabilized by using organic solvents alone or mixed with water, for example, by using the mixture of water and ethanol in the ratio of 9:1 to 0:10, without using a stabilizer therefor. Polyethylene oxide, which is not soluble in ethanol but easily soluble in water or other organic solvents, has good compatibility with peroxide.

[0042] Polyvinyl pyrrolidone (PVP) is the most preferred hydrophilic glass polymer to be used in the active material reservoir layer containing peroxide. It is believed that the good compatibility of polyvinyl pyrrolidone with peroxide results from the stabilization of peroxide by formation of complexes with polyvinyl pyrrolidone via hydrogen bonding. Among the available PVP, K-15~K-120 are used, and K-90 (PVP) is preferably used in the patch of the present invention. K-30 (PVP) is more preferable since higher gel content is desired in the efficiency upon producing by casting method. Preferably, the PVP has a relatively high molecular weight, preferably greater than about 500,000, more preferably greater than about 1,000,000. In a preferred embodiment, PVP having a molecular weight of 1,270,000 is used. Further, peroxides are found to be compatible with polymers having quaternary ammonium structure, such as polyquaternium.

[0043] According to the present invention, an organic solvent or mixtures of water and ethanol are used as solvent for adhesive materials. Glass polymers which are highly compatible with peroxide are typically so hydrophilic that they cannot be uniformly coated on the surface of release liner or other sheet. An organic solvent or mixtures of water and ethanol can solve such problem so as to form a uniform sheet layer. When the above-mentioned polymers which are highly compatible with peroxide are used, sufficient peroxide stability is obtained without using a stabilizer in the active material reservoir layer.

[0044] The active material reservoir layer also has plasticizer for the same reason as in the contact adhesive layer. Although a suitable plasticizer may vary according to the polymer used, polypropylene glycol, glycerin, polyethylene glycol are generally used.

[0045] When a polymer of low compatibility with peroxide is used in the active material reservoir layer, a stabilizer is preferably added to overcome the expected problems. A peroxide stabilizer in the formulation is one or more selected from the group consisting of alkylaryl sulphonates, alkyl sulphonates, alkyl carboxylates, alkyldiphenyloxide disulphonates, a series of Span such as Span 20 (sorbitan monolaurate), Span 40 (sorbitan monopalmitate), Span 60 (sor-

bitan monostearate), Span 80 (sorbitan monooleate) and Span 85 (sorbitan trioleate), POE sorbitan fatty acid esters (TWEEN), glycerin fatty acid esters, esters, organic acid monoglycerides, sodium stearyl lactates and polysorbates.

[0046] The teeth whitening agent contained in the active material reservoir layer may be selected from a group consisting of hydrogen peroxide, carbamide peroxide, calcium peroxide, sodium percarbonate, sodium perborate, tetrasodium pyrophosphate peroxidate and mixtures thereof.

[0047] Generally, in the two-layer patch having an adhesive layer containing peroxide as a whitening agent and a backing layer, the peroxide content decreases as time passes when the patch is stored at a temperature of 40° C. Accordingly, the whitening effect of the patch in vitro is also observed to be lower, compared to a new patch. For a gel type formulation, loss of peroxide over time is small even when excessive polymer is used as a film-forming agent and a peroxide stabilizer is not added. Even when the formulation has low peroxide stability, the desired effect can be obtained by using a small amount of chelating agent, such as EDTA or sodium citrate, known as a common peroxide stabilizer.

[0048] In a teeth whitening patch wherein the solvent of the gel layer is evaporated to form a sheet-shaped patch, when a stabilizer is not used in the composition, the peroxide stability is diminished, compared to the gel type formulation. It is also observed that the addition of a chelating agent results in a decrease in the peroxide stability of the patch, compared to a patch without a chelating agent. Furthermore, even when using Dequest phosphonates, which are known for their superior peroxide stabilizing effect, suitable peroxide stabilization cannot be obtained.

[0049] As described above, the reason why the peroxide stability in the patch differs in accordance with formulation type such as gel, liquid or sheet may be explained in a variety of ways. According to U.S. Pat. No. 4,320,102, peroxide is described as being readily decomposed through a reaction catalyzed by a minimal amount of metal contained in the composition. There have been reported data showing that the presence of 0.1 mg of iron, 0.2 mg of copper, 0.1 mg of magnesium or 0.02 mg of chromium per 1 l of peroxide will lead to decomposition of peroxide. A sheet-type patch formed by evaporation of the solvent in a solution-type or gel-type patch would include a high content of metal on the thin sheet of patch. Further, a sheet-type patch has a large surface area, which allows a high rate of reaction on the surface, and also lowers the stability of the peroxide.

[0050] The stabilizer used in the patch according to the present invention is mostly surfactant or emulsifier, which is believed to form micelles and produce a preferred effect on the peroxide stabilization of the product. In practice, it was found that when gel is applied thinly over a large surface area, the residual amount of peroxide decreases over time, while a gel of the same composition, contained in a container, is stable at a relatively high temperature.

[0051] However, according to the present invention, it is possible to solve the problem associated with peroxide stability in the patch at a high temperature, by using a dry type patch having multi-layer structure of three or more layers in which the layer containing peroxide is protected by the other layers. In a dry type patch having a two-layer

structure, the peroxide stability at a high temperature may be improved by using a glass polymer having good compatibility with peroxide in the adhesive layer and by using a peroxide stabilizer, when compared to the wet type patch. However, the dry type patch having multi-layer structure of three or more layers according to the present invention can achieve even better peroxide stability.

[0052] Further, the dry type patch according to the present invention may include a polyphosphate as an additional whitening agent along with peroxide in order to enhance the whitening effect.

[0053] Polyphosphates which can be used in the present invention include one or more selected from a group consisting of tetrasodium pyrophosphate (TSPP), sodium acid pyrophosphate (SAPP), sodium hexametaphosphate (SHMP), sodium tripolyphosphate (STP), sodium potassium tripolyphosphate (SKTP), tetrapotassium pyrophosphate (TKPP), acidic sodium metapolyphosphate and acidic sodium polyphosphate. In general, it is known that polyphosphate may be used effectively as a tartar controller in toothpaste to inhibit the formation of tartar or to remove tartar. Polyphosphate is also known as a good chelating agent to enhance the teeth whitening effect to some extent since it can effectively remove stains formed on the surface of the teeth, especially those formed of metal such as iron, calcium, magnesium, etc. derived from foods or working circumstances. It has been found that polyphosphate used along with peroxide in the patch according to the present invention may inhibit tartar formation and remove tartar by lengthening the contact time between teeth and polyphosphate. In practice, it is observed that when attaching the patch of the present invention to teeth, surface of teeth and gaps between teeth get cleaned.

[0054] Polymers which can be used in the backing layer of the patch according to the present invention include cellulose acetate phthalate, polyvinyl acetate, ethyl cellulose, polymethyl methacrylate, methacryloyl ethyl betain/methacrylate copolymer, commercially available under the trade name of Yukaformer manufactured by Mitsubishi, methacrylic acid copolymers such as Eudragit L 100, Eudragit L 125, Eudragit L 100-55, Eudragit L 30D-55, aminoalkyl-methacrylate copolymers such as Eudragit E 100, Eudragit E 125, Eudragit RL 100, Eudragit RL 30D), or mixtures thereof. In addition, a polymer used as enteric coating material, which is not dissolved at pH 6 to 8 in oral cavity may be used.

[0055] In addition to the casting process using solvents, sheets of the patch may be manufactured by an extrusion process using thermoplastic polymers. Considering the efficiency of manufacturing process, a thin and flexible sheet, which is insoluble in water and impermeable to water, made of polyethylene (PE), ethylvinyl acetate (EVA), ethylvinyl alcohol, polyester or polyurethane is preferably used as the backing layer, since it is possible to omit the manufacturing process of the backing layer.

[0056] The backing layer may contain any plasticizer for the same reason in the contact adhesive layer and the active material reservoir layer. In this case, including the plasticizers described above, such as propylene glycol, glycerin, polyethylene glycol. Many kinds of plasticizer can be used depending on the solvent used. For example, castor oil or hydrogenated castor oil may also be used.

[0069]

Solution for preparing backing layer	
Polyvinyl acetate	5%
Glycerin	5%
Ethanol	to 100%

Example 2

[0070]

Solution for preparing contact adhesive layer	
Polyvinyl pyrrolidone	5%
Hydroxypropylmethyl cellulose	5%
Propylene glycol	5%
l-menthol (flavor)	1%
Ethanol	to 100%

[0071]

Solution for preparing active material reservoir layer containing peroxide	
Polyethylene oxide	6%
Polyvinyl pyrrolidone	20%
Sodium percarbonate	15%
Propylene glycol	3%
Ethanol	to 100%

[0072]

Solution for preparing backing layer	
Ethyl cellulose	16%
Castor oil	8%
Ethanol	to 100%

Example 3

[0073]

Solution for preparing contact adhesive layer	
Polyquaternium-39	10%
Water	to 100%

[0074]

Solution for preparing active material reservoir layer containing peroxide	
Polyethylene oxide	15%
Carbamide peroxide	10%
Methyl Salicylate (flavor)	0.4%

-continued

Ethanol	50%
Water	to 100%
Backing layer	
Polyethylene	

Example 4

[0075]

Solution for preparing contact adhesive layer	
Hydroxypropyl cellulose	10%
Ethanol	to 100%

[0076]

Solution for preparing active material reservoir layer containing peroxide	
PVP/VA copolymer	20%
Hydroxyethyl cellulose	20%
Hydrogen peroxide	3%
SAPP	3%
Alkyldiphenyloxide disulphonate	1%
Glycerin	5%
Water	to 100%

[0077]

Solution for preparing backing layer	
Budragit	15%
Propylene glycol	5%
Ethanol	to 100%

Example 5

[0078]

Solution for preparing contact adhesive layer	
Hydroxypropyl cellulose	10%
Polyvinyl pyrrolidone	5%
Ethanol	to 100%

[0079]

Solution for preparing active material reservoir layer containing peroxide	
Polyalkylvinyl ether-maleic acid copolymer	12%
Polyvinyl alcohol	5%
Tetrasodium pyrophosphate peroxidate	6%

Example 9

[0089]

Solution for preparing contact adhesive layer	
Carboxypolymethylene	2%
Fe	0.1%
Water	to 100%

[0090]

Solution for preparing barrier layer	
Hydroxypropyl methyl cellulose	5%
Hydroxypropyl methyl cellulose	0.3%
Ethanol	to 100%

[0091]

Solution for preparing active material reservoir layer containing peroxide	
Polyethylene oxide	10%
Polyquaternium	10%
Hydrogen peroxide	5%
Propylene glycol	7%
Ethanol	to 100%

[0092]

Solution for preparing backing layer	
Cellulose acetate phthalate	30%
Castor oil	6%
Mixture of acetone and ethanol (acetone: ethanol = 4:1)	to 100%

Example 10

[0093]

Solution for preparing contact adhesive layer	
Hydroxyethyl cellulose	20%
Polyalkyvinyl ether-maleic acid copolymer	5%
NaOH	appropriate (pH up to 8)
Water	to 100%

[0094]

Solution for preparing active material reservoir layer containing peroxide	
Polyquaternium	10%
Polyvinyl pyrrolidone-vinyl acetate copolymer	5%
Sodium percarbonate	20%
Glycerin	5%
Ethanol	to 100%

[0095]

Solution for preparing active material reservoir layer	
Polyvinyl alcohol	15%
Dextranase	0.1%
Glucose oxidase	0.1%
Water	to 100%

[0096]

Solution for preparing backing layer	
Ethyl cellulose	12%
Titanium dioxide	2%
Vulcanizer	1%
Ethanol	to 100%

Comparative Example 1

[0097]

Solution for preparing adhesive layer containing active material	
Polyvinyl alcohol	10%
PEG-ascorbic acid	6%
Propylene glycol	3.1%
Water	to 100

[0098]

Solution for preparing backing layer	
Ethyl cellulose	10%
Castor oil	4%
Ethanol	to 100

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCION DE NUEVAS CREACIONES**

2020
Bogotá, D.C.

Abogado
JUAN PABLO CADENA SARMIENTO

ASUNTO	Radicación	2006-117705
	Trámite	011
	Evento	376
	Actuación	519
	Oficio	16443
	Folios	012

Patente de Invención	☒	Patente de Modelo de Utilidad	☐
Vía Nacional	☐		
Vía PCT (fase nacional)	☒	Cap. I	☐
		Cap. II	☒
No. Sol. Internacional		PCT/US2005/016165	

Fecha de Presentación Internal.

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados

- | | | | |
|------|--------------------------|-----------------|-----------------------------|
| 1.1. | <u>Descripción:</u> | Folios: 35 a 57 | como se radicó inicialmente |
| 1.2. | <u>Reivindicaciones:</u> | Folios: 58 a 62 | como se radicó inicialmente |

Folios: 112-114

modificado, 2010/06/18.

1.3. Prioridad: 10/05/2004, US, 10/842,152

1.4 Respuesta del solicitante Folios: 110 a 114.

Título de la invención: BANDAS MULTIPLACAS BLANQUEADORAS DE DIENTES.

Problema Técnico Planteado: Necesidad de nuevos sistemas para aplicar a los dientes productos blanqueadores basados en peróxidos (folio 35, pg1)

Solución: una película blanqueadora para recubrir dientes, caracterizada porque comprende: polímero formador de película, agente blanqueador, cubierta hidrofóbica, cubierta adherente (reiv 1, folio 58, pg 24).

IPC: A61K7/16.

2. De la solicitud de Patente

2.1. Reivindicaciones (artículo 30 D 486)

La materia de las reivindicaciones 6 a 9, ya esta comprendida en el grupo de reivindicaciones de la 1 a la 5, por lo tanto no es claro para que repetir. Como se trata de la misma materia, se tomará en cuenta, este último grupo.

3. Determinación del Estado de la Técnica

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

Fecha de presentación de la solicitud prioritaria: 10/05/2004.

Teniendo en cuenta la fecha indicada se realizó la búsqueda en el estado de la técnica de documentos relacionados con la solicitud encontrándose los siguientes documentos más relevantes:

Nº	Documento	Título	Fecha de publicación*
D1	US2004/0062724	Erodible film for treating the surfaces of teeth	Abril 1 de 2004
D2	US2003/0194382	Multi-layer patches for teeth whitening	Octubre 16 de 2003

D1 (folios: 101-104), se trata de un dispositivo en capas que se adhiere a las superficies húmedas de los dientes y libera un agente blanqueador sobre dicha superficie manchada, en un período de tiempo.

D2 (folios: 115-120), divulga un parche blanqueador de dientes, con una estructura multicapas, que contiene saborizantes.

4. Análisis de patentabilidad (artículo 14 D486)

4.1 Nivel inventivo (artículo 18 D486)

La reivindicación 1, consiste en:

Una película de blanqueamiento dental recubierta que contiene:

- Un polímero hidratable formador de película; y
- Un agente blanqueador;

Dicha película caracterizada porque:

- el polímero comprende un polímero poli (etilen-óxido);
- tiene un recubrimiento hidrofóbico sobre una superficie;
- tiene un recubrimiento adherente a los dientes sobre la superficie opuesta;

- al menos uno de la película o el recubrimiento hidrofóbico contiene un agente saborizante que comprende un extracto o aldehído, cetona, éster o alcohol saborizantes, que imparten sabor seleccionado del grupo que consiste de menta verde, menta, gaulteria, sasafrás, clavo, salvia, eucalipto, mejorana, canela, limón, lima, uva, naranja, manzana, pera, durazno, fresa, cereza, melocotón, sandía, banano, café, cocoa, mentol, carvona, anetol, y combinaciones de los mismos.

El Estado de la Técnica más cercano es D1, porque divulga una película multicapas que se adhiere a la superficie de los dientes (abstract, folio 101 y folio

102, párrafos 5 y 6), que comprende:

un polímero formador de película (folio 103, pg 2, párrafos 14-15),

un agente blanqueador (folio 103, pg 2, párrafo 16),

una cubierta hidrofóbica (folio 104, pg 3, párrafo 22),

una cubierta adherente (folio 104, pg 3, párrafo 26) y;

otros ingredientes en menor cantidad, tales como saborizantes (folio 103, pg2, párrafo 21).

La película de blanqueamiento dental, objeto de esta solicitud se diferencia de las de D1, en que menciona saborizantes seleccionados del grupo que consiste de: menta verde, menta, gaulteria, sasafrás, clavo, salvia, eucalipto, mejorana, canela, limón, lima, uva, naranja, manzana, pera, durazno, fresa, cereza, melocotón, sandía, banano, café, cocoa, mentol, carvona, anetol, y combinaciones de los mismos.

El efecto logrado por esta diferencia, es una película para blanqueamiento con sabor.

El Problema Técnico Objetivo era "cómo modificar las composiciones de D1 para lograr una película para blanqueamiento con sabor".

Además, D2 describe una manera de solucionar el problema técnico, mediante parches de múltiples capas para blanquear los dientes, que comprende un polímero y un agente blanqueador de dientes (folio 115, abstract, folio 116, párrafo 10, folio 117, párrafo 41, folio 118, párrafos 46, 54) y que contiene saborizantes tales como: mentol y menta limón (folio 119, ejemplo 2, folio 120, ej 9).

Por tanto, el Experto en la Materia enfrentado al problema de "cómo modificar las composiciones de D1 para lograr una película para blanqueamiento con sabor", tomaría en cuenta las enseñanzas de D2, en cuanto a los saborizantes utilizados, para incluirlos en la película multicapa, divulgada en D1, obteniéndose de esta forma la película objeto de esta solicitud; lo cual permite concluir que la película reivindicada, no tiene nivel inventivo, así como tampoco sus dependientes 2-5.

5. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

N°	Documento N°	Reivindicaciones afectadas	Requisito que afecta
D1	US2004/0062724	1-5	Nivel inventivo
D2	US2003/0194382	1-5	Nivel inventivo

6. Respuesta a los argumentos del solicitante:

El solicitante en su respuesta presenta un nuevo capítulo reivindicatorio de 1-9 reivindicaciones, donde afirma que subsana las objeciones realizadas por el señor examinador, el cual no amplía la materia divulgada inicialmente y se encuentra debidamente sustentado en la descripción.

Se aclara que, no obstante el nuevo capítulo reivindicatorio presentado no amplía la materia divulgada inicialmente, este presenta falta de claridad, lo cual fue requerido en el numeral 2.1.

Argumenta el solicitante, en cuanto a las objeciones a la novedad, "en vista del documento D1(US2004/0062724) es preciso indicar que, dadas las modificaciones realizadas, el documento D1 no divulga todos y cada uno de los elementos reclamados en la presente invención. Por esta razón, la composición específica reclamada constituye un diseño diferencial sobre todo lo establecido en el arte previo, por lo que se cumple entonces con el requisito de novedad.

Se aclara que, tal como se presenta el nuevo capítulo reivindicatorio, la composición es nueva.

En cuanto al nivel inventivo, el solicitante argumenta que: "Adicionalmente, no existe motivación ó sugerencia en el estado de la técnica que permita a un técnico entrenado en la materia llegar de manera obvia a la materia reivindicada, lo cual resulta en el cumplimiento adecuado de los requisitos de patentabilidad".

Se aclara que D1, se tomó como documento más cercano porque contiene la mayor parte de las características esenciales de la película reivindicada, así

mismo D2 divulga algunos saborizantes que contiene la película reclamada, lo que demuestra que sí existe motivación ó sugerencia en el estado de la técnica que permita a un técnico entrenado en la materia llegar de manera obvia a la materia reivindicada; por lo tanto no se cumple con todos los requisitos de patentabilidad.

Adicionalmente, el ejemplo 3 (folio 55), que ilustra la preparación de la película reivindicada, se comparó con una película B (US 5894017 de Abril 13 de 1999), que no es la más cercana a la película reclamada; por lo tanto no se puede reconocer altura inventiva, en la solicitud.

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

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única N° 10 de 2001.


JOSE LUIS SALAZAR LÓPEZ
Director de Nuevas Creaciones (E)

El anterior requerimiento fue notificado por fijación en lista, de fecha
123 DIC. 2010

CONCEPTO TÉCNICO No.3633	EXAMINADOR TÉCNICO Código No.202078
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