



(43) International Publication Date
18 June 2015 (18.06.2015)

(10) International Publication Number
WO 2015/087314 A1

(51) International Patent Classification:
A61K 8/22 (2006.01)

(21) International Application Number:
PCT/IL2014/000028

(22) International Filing Date:
27 May 2014 (27.05.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/914,051 10 December 2013 (10.12.2013) US

(71) Applicant: **ILUMINAGE LTD.** [IL/IL]; Cochav Building, Industrial Area, P. O. Box 14, 2069201 Yokneam Illit (IL).

(72) Inventors: **KHAWALED, Kamal**; 260 Street, 20200 Shefaram (IL). **MUSHYAKOV, Tanya**; 16/3 Hagiborim, 20692 Yokneam Illit (IL).

(74) Agent: **BRONSTEIN, Rafi**; Daltan Consulting Ltd., P. O. Box 1146, 4411002 Kefar Sava (IL).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: BLEACHING GEL

(57) Abstract: Disclosed is a dental bleaching gel composition with high electric conductivity. It was the object of the present invention to provide a bleaching gel composition that is less initiating than prior art gels, and is highly efficient such that it can bleach within shorter time. The composition includes a peroxide, or a peroxide releasing compound such as carbamide peroxide, sodium perborate, or sodium percarbonate as a bleaching agent, a cross-linked polyacrylate polymer as a thickening component, and electrical conductivity enhancing ingredients such as electrolytes.



WO 2015/087314 A1

BLEACHING GEL

TECHNOLOGY FIELD

The present gel relates to the field of dental bleaching compositions and in particular to electrically conductive dental bleaching compositions.

BACKGROUND

Stained or discolored teeth are considered as a cosmetic impairment. Teeth's whitening is a cosmetic treatment done to improve the appearance of teeth. Teeth are whitened to remove the effects of coffee, cigarettes, and other substances that permanently stain or discolor teeth. Different techniques of teeth whitening or bleaching are known and relatively simple procedures improving the stained teeth appearance exist. The procedures can be conducted in a dental Clinique, office or in a residential environment.

A variety of dental bleaching compositions and dental bleaching devices or trays exist on the market. Such dental bleaching compositions are typically applied to a person's teeth using a dental tray configured so as to retain the dental composition against the person's teeth. The treatment continues for about 10 minutes to few hours and although conducted in residential environment it is somehow reducing the freedom of speech, movement and operation of the treated person. In addition, it is not comfortable for the treated person to hold the dental tray in the mouth over relatively long periods of time.

Treated person comfort during the teeth bleaching treatment may be improved by shortening the time of bleaching. Most common bleaching agents are peroxides, including but not limited to hydrogen peroxide, carbamide peroxide, sodium perborate, and sodium percarbonate. The simplest way to shorten the treatment time is to increase the concentration of the peroxide. This can however, result in irritation and even some damage of gums or lips or other soft tissue.

Another way to bleach teeth more quickly is to speed up the chemical reaction related to the bleaching process by heat or light. Both heat and light alone or in combination are known to accelerate chemical reactions. Different bleaching

compositions having increased bleaching activity have been developed for use in cooperation with heat or light.

SUMMARY

It was the object of the present invention to provide a bleaching gel composition that is less irritating than prior art gels, is highly efficient, can bleach within shorter time and results in whitened teeth when applied.

Presented is a dental bleaching gel composition characterized by high electric conductivity. The composition includes a peroxide, or a peroxide releasing compound such as carbamide peroxide, sodium perborate, or sodium percarbonate] as a bleaching agent, a cross-linked polyacrylate polymer as a thickening component, and electrical conductivity enhancing ingredients such as electrolytes. Alkali nitrates and/or alkali hydroxides are examples of such electrolytes. Each of them could be included alone in the composition or a mix of both of them could be used to enhance conductivity of the dental bleaching gel composition.

An aqueous solution comprising at least one alcohol, such as glycerin or propylene glycol is used as vehicle and solvent in which other ingredients or components are mixed to prepare the dental bleaching gel composition.

Other ingredients that are commonly used in bleaching gels, can be used in the composition of the present invention as well, in the amounts that are normally used, as long as such an ingredient is dentally acceptable. Examples are agents affecting antimicrobial and oxidizing properties of the gel, binding agents, mouth refreshing and flavouring components and components improving bleaching gel viscosity and wetting properties which are added as required to the composition.

DESCRIPTION

The present invention provides a bleaching gel composition that is less irritating than prior art gels, is highly efficient, can bleach within short time and results in whitened teeth when applied only few times for some minutes, such as twice a week for only some minutes. The gel has a composition allowing it to penetrate deep within the enamel to erase most of embedded stains without sensitivity or irritation.

The favourable effect is achieved by using the components as defined in the claims. The gel of the present invention when activated by a micro-current is highly efficient.

Definitions

In the context of the present disclosure the terms "dental bleaching" and "dental whitening" have the same meaning.

A peroxide can be any known peroxide that is compatible with the human skin and mucous. Hydrogen peroxide is one example.

A "peroxide releasing compound" comprises compounds that when activated by a micro-current release peroxide. Examples are carbamide peroxide, sodium perborate, or sodium percarbonate.

The term "micro-current" when used in this application refers to current of 25 milli-Ampere or less.

Electric current is known to accelerate the bleaching reaction. The electric current is activating the bleaching agent and accelerating the bleaching reaction. The current activates certain ingredients of a specially formulated whitening gel, allowing it to penetrate deep within the enamel to erase most of embedded stains without sensitivity or irritation. Use of electrical current and specially formulated gel has proved to deliver whitening results much better than light or heat activated teeth whitening treatments.

The present invention allows to use micro-current for activating the bleaching agent. The term "micro-current" when used in this application has its common meaning and particularly refers to a current of 25 milli-Ampere or less, in particular 15 milli-Ampere or less, preferably 1 to 10 milli-Ampere. Application of electric current to the bleaching gel composition is less expensive than application of light generated by an assembly of LEDs and or heat. Electric current is also simpler and easier to control and regulate. The dental bleaching composition of the present invention with certain level of electric conductivity allows the use of electric current to activate the bleaching agent and accelerate the bleaching reaction.

It has been found that when using a composition having a certain degree of electric conductivity as outlined below, activation can occur using micro-current.

Although bleaching gels are known that comprise ionic compounds, their electric conductivity is not sufficient to produce an electric current supporting activation of the bleaching agent and acceleration of the bleaching reaction. Currently available on the market dental bleaching compositions are either electrically non-conductive or have very low conductivity typically below 200 microsiemens/cm.

A bleaching gel as described herein having an electric conductivity of at least 250 milliSiemens/cm can be activated by a low current, in particular by a micro-current to become efficient enough to allow teeth whitening even with application for a short time.

A dental bleaching gel composition of the present invention having a significantly higher electric conductivity can support faster development and commercialization of dental bleaching devices using electric current to accelerate the bleaching reaction. Such dental bleaching gels and devices or trays can reduce the cost of dental bleaching and are more effective in whitening or bleaching teeth than existing products currently available on the market.

The dental bleaching gel of the present invention at least comprises a bleaching agent, a thickening agent, a vehicle and an electric conductivity increasing agent. The combination of ingredients provides for a stable gel that allows flow of micro-current. When micro-current is applied to the gel this will create peroxide radicals that are then available for the bleaching reaction.

The dental bleaching gel compositions can further include a number of ingredients that are typically present in this type of compositions and in particular, apart from a bleaching agent, a thickening agent, and a vehicle can include a liquid component, a basic component, a flavoring component, and some other components as it could be desired to achieve a particular dental bleaching gel composition properties. For example, the composition could further include light sensitive or heat sensitive ingredients that upon action of light or heat will accelerate the teeth bleaching process.

The dental bleaching gel ingredients listed in different examples follow the International Nomenclature of Cosmetic Ingredients, abbreviated (INCI).

Whenever amounts of ingredients are mentioned in percent, these refer to % w/w, i.e. weight of the ingredient per weight of the final composition.

An essential ingredient of the present bleaching gel is a peroxide or a peroxide releasing agent as bleaching agent; examples are hydrogen peroxide, or a carbamide peroxide, sodium perborate, or sodium percarbonate. The bleaching agent is used in an amount that provides at least some whitening of teeth but less than an amount that irritates or hurts the tissue or mucous membrane. The amount of bleaching agent can be in a range of 1 to 35 % w/w, in particular 3 to 10 % w/w or 6 to 9 % w/w peroxide, based on the weight of the final bleaching gel composition.

Another essential ingredient is a thickening agent. Thickening agents for preparing bleaching gels are known and can be used for the present composition. The thickening agent is used to adapt the rheology/viscosity of the gel such that it can be applied easily and does not flow away when applied. An example for a thickening agent is a cross-linked polyacrylate. The thickening agent is used in an amount that provides for the desired viscosity of the gel, the skilled artisan can find a suitable amount in known manner. A useful amount is in the range of 1 to 5 % w/w.

Thickening agent gel component is a rheology modifier that increases the viscosity of the dental bleaching composition to prevent runoff of the dental bleaching gel composition out of the dental tray. Increased viscosity of the dental bleach composition is also useful in reducing contact with soft tissues such as gums, lips and some internal surface of the mouth tissue. In one example, a cross-linked polyacrylate polymer commercially available from the Lubrizol Corporation Wickliffe, Ohio 44092 USA under trade name Carbopol 940 or 980 in concentration of 1% to 5% w/w is used as a thickening agent.

Furthermore, the bleaching gel comprises an aqueous vehicle that preferably includes at least one alcohol, such as glycerol, a glycol, or a mixture thereof. Examples for a vehicle are a mixture of water and glycerol and/or a glycol. The glycol can be propylene glycol. In one embodiment the vehicle is a mixture of water and glycerol, glycerol improves wetting of the tooth surface and, thus, facilitates application of the bleaching gel.

The aqueous vehicle is preferably present in amount of 45 to 85 % w/w, where 20 to 35 % w/w can be an alcoholic component, such as glycerol or glycol.

Another essential ingredient is an electrical conductivity enhancing compound or electrolyte, such as a salt or a base. Examples for electrical conductivity enhancing compounds are an alkali hydroxide, such as potassium hydroxide, or an alkali nitrate, such as potassium nitrate, or a mixture thereof. A combination of potassium hydroxide and potassium nitrate has been found particularly valuable. As the bleaching gel is applied to mucous, the amount of alkali hydroxide should not be too high to not irritate the mucous. An amount that results in a pH in the range of 5 to 7 has been found useful. Other ingredients could be added to adapt the pH if necessary.

The electrical conductivity enhancing compound is used in an amount such that the conductivity of the final bleaching gel is higher than 250 microsiemens/cm. The amount of the above mentioned electrolytes can be in the range of 1 to 10 % w/w, for example 1 to 5 % w/w alkali hydroxide and 1 to 5 % w/w alkali nitrate.

In one example, the bleaching gel could include an electrical conductivity enhancing ingredient or a number of ingredients. The electrical conductivity enhancing ingredient could be electrolytes, such as for example, potassium nitrate or potassium hydroxide in different amounts or percentage. A mix of both of them could also be used to enhance conductivity of the dental bleaching gel composition. Potassium nitrate could also be used to lower the tooth sensitivity and the potassium hydroxide could be used to adjust the bleaching gel pH. Electric current could be used to accelerate destabilization of the peroxides and facilitate release of oxygen ions and oxygen radical's derivative participating among others in the process of the dental bleaching. Potassium hydroxide concentration in the dental bleach composition could be 1% to 5% by weight. And the Potassium nitrate concentration in the dental bleach composition could be 1% to 5% by weight.

In one embodiment of the bleaching gel a bleaching agent comprising hydrogen peroxide (H_2O_2) is used in combination with potassium hydroxide (KOH). The concentration of hydrogen peroxide could be 1% to 35% by weight, based on the weight of the final bleaching gel, and the concentration of potassium hydroxide used as a 50% solution in D.I water could be 1% to 5% by weight. Hydrogen peroxide is

commercially available from a number of suppliers, for example, from Sigma-Aldrich Co. LLC, Missouri 63031 USA.

According to some examples, glycerin and water are used as liquid components in the present dental bleaching gel composition. Glycerin is also used as a humectant facilitating better wetting of teeth surface by the dental bleaching gel composition. In some examples, glycerin is included in a concentration of 20% to 35% w/w and water is included in a concentration of 25% to 50% w/w.

For stabilization the bleaching gel can include further ingredients. Binding agents like polyvinyl pyrrolidone have been found useful, they can be used in an amount of 0.5 to 2 % w/w. Moreover, complexing agents such as disodium ethylene diamine tetraacetic salt can be used to improve stability of the gel. An amount of 0.1 to 1 % w/w has been found suitable.

To improve the taste of the dental bleaching gel composition a flavoring agent or a sweetener could be added to the composition. Examples of such sweeteners could include saccharin sodium salt hydrate in concentration of 0.1% to 0.3%. Flavorings could include mint and peppermint oil in concentration of 0.1% to 0.3% and the like. Both flavorings are commercially available, for example from Sigma-Aldrich Co. LLC, Missouri 63031 USA.

The gel can additionally include heat or light sensitizers to further increase the activity.

The bleaching gel is used for bleaching teeth by application of a micro-current. Another aspect of this application is thus a method for bleaching teeth comprising:
applying to the teeth to be bleached a layer of gel with electrical conductivity higher than 250 microsiemens/cm;
applying to the teeth covered by a layer of gel with electrical conductivity higher than 250 microsiemens/cm electric current of at least 1 milliampere; and
bleaching the teeth.

It has been found that by using the bleaching gel of the present invention and a low current of about 1 to 10 milliampere teeth can be bleached within minutes, for example within 5 to 10 minutes. The gel is not irritating and the low current is not harmful or unpleasant for the user.

Dental bleaching gel application and testing procedure

The dental bleaching gel as described above is used for bleaching teeth in combination with a micro-current device that provides current for the activation of peroxide. A useful micro-current device that can be used with the gel of the present application is Pearl™ dental bleaching tray, commercially available from Syneron Beauty Ltd., Yoqneam 2069202 Israel. This bleaching tray was used for testing the bleaching gel:

- a. The Pearl™ dental bleaching tray commercially available from Syneron Beauty Ltd., Yoqneam 2069202 Israel was filled in with the present gel in an amount sufficient to form layer of gel on at least the surface of the teeth to be bleached.
- b. The tray with the gel was placed in the mouth and electric current supply was activated for 5 minutes.
- c. At the end of the treatment, the remaining gel was removed by washing the teeth.

Further embodiments are outlined in the following examples.

EXAMPLE 1 DENTAL BLEACHING GEL

A gel comprising 6 % hydrogen peroxide was prepared using the following ingredients:

Ingredient	Concentration (%) w/w
Glycerin	25-30
Carbopol 940/Carbopol 980	1-5
Hydrogen Peroxide 30%	20-25
Deionized Water	40-50
Potassium Nitrate	2-3
Potassium Hydroxide (50% in water)	2-3
PVP(Polyvinylpyrrolidone)	0.5-2
EDTA (Disodium Ethylenediaminetetraacetic salt)	0.1-1
Saccharin sodium salt hydrate	0.2
Peppermint oil	0.2

120 gram of the 6% HP dental gel bleaching composition were prepared by combining the following ingredients according to the following procedure:

3.6g of potassium nitrate were mixed with 0.24g of saccharine, 0.6g EDTA and dissolved at room temperature in 40 ml of water. Two to three drops of KOH were added to the mixture.

A mixer was used to stir the mixture for about 5-10 (five-ten) minutes. At the beginning of the stirring 3 grams of Carbopol® (cross-linked polyacrylate polymer) was added to the mixture. The mixture was stirred at a low speed of 200 – 250 RPM.

After about 5-10 minutes of stirring the mixture, 40 ml (32g) of glycerol were added to the mixture and the stirring continued for another 5-10 minutes at a speed of 500-700 RPM.

Following this 24 ml of hydrogen peroxide (30%W/W solution) were added to the mixture and the mixture was stirred for another 5-10 minutes at a speed of 500-700 RPM.

Three (3) milliliter of potassium hydroxide 50%W/W solution were added to the mixture and the mixture stirring continued for another five (5-10) minutes at a speed of 750- 1000 RPM.

Peppermint oil in amount of 0.2% w/w was added to the mixture and stirred for about a minute at a speed of 1000 RPM.

PVP (Polyvinylpyrrolidone) in an amount of 0.6g was added to the almost ready composition and stirred for another 10 minutes at a speed of 1000 RPM.

The process produced about 120 g of ready to use gel composition. The produced dental bleaching gel composition was stable and was able to adhere and retain in a dental tray in place against a person's teeth. The dental bleaching composition had a conductivity of 500 - 700 microsiemens/cm.

Pearl™ dental tray was used to test the bleaching properties of the bleaching gel composition of Example 1. Application of electric current of about 6 milliampere for 5 minutes bleached or whitened the teeth. The result was compared visually to teeth

bleaching procedure using the Pearl™ teeth whitening system and commercially available teeth bleaching gels with electrical conductivity below 200 microsiemens/cm. The current teeth bleaching gel was found to result in two or three additional whitening shades as compared to the teeth bleaching performed by the Pearl™ system for 5 minutes using commercially available teeth bleaching gel.

Gel composition conductivity was measured by Digital Conductivity Meter model Traceable 4063, manufactured by Control Company, Friendswood, TX 77546, USA, (www.control3.com). The measurement was performed by a probe that contained platinum electrodes and a thermistor.

EXAMPLE 2 DENTAL BLEACHING GEL

Ingredient	Concentration w/w (%)
Glycerin/propylene glycol	25-30
Carbopol	1-5
Hydrogen Peroxide 30% w/w	25-35
Deionized Water	30-40
Potassium Nitrate	2-3
Potassium Hydroxide (50% in water)	2-3
PVP(Polyvinylpyrrolidone)	0.5-2
EDTA (Disodium Ethylenediaminetetraacetic salt)	0.1-1
Saccharin sodium salt hydrate	0.2
Peppermint oil	0.2

In Example 2, 9% HP w/w gel dental bleaching composition was prepared using the following ingredients and according to the following procedure:

3.6g of potassium nitrate were mixed with 0.24g saccharine, 0.6g EDTA and dissolved at room temperature in 42 ml of water. Two or three drops of KOH were added to the mixture.

A mixer was used to stir the mixture for about 5-10 minutes. At the beginning of the stirring 3 grams of Carbopol® were added to the mixture. The mixture was stirred at a low speed of 200 – 250 RPM.

After about 5-10 minutes of stirring the mixture, 40 ml (32g) of glycerol were added to the mixture and the stirring continued for another 5-10 minutes at a speed of 500 - 700 RPM.

Following this 36 ml of hydrogen peroxide (30% solution) were added to the mixture and the mixture was stirred for another 5-10 minutes at a speed of 500 – 700 RPM.

Three (3) milliliter of potassium hydroxide 50% w/w solution where added to the mixture and the mixture stirring continued for another five (5 - 10) minutes at a speed of 750 - 1000 RPM.

Peppermint oil in amount of 0.2% w/w was added to the mixture and stirred for about a minute at a speed of 1000 RPM.

PVP (Polyvinylpyrrolidone) in an amount of 0.6g was added to the almost ready composition and stirred for another 10 minutes at a speed of 1000 RPM.

The process produced about 120 g of ready to use gel composition. The produced dental bleaching gel composition was stable and was able to adhere and retain in a dental tray in place against a person's teeth. The dental bleaching composition had a conductivity of 250 - 500 microsiemens/cm. Syneron Medical Ltd., Pearl™ dental tray was used to test the bleaching properties of the bleaching gel composition of Example 2. Application of electric current of about 10 milliampere for 5 minutes bleached or whitened the teeth. The result was compared visually to teeth bleaching procedure using the Pearl™ teeth whitening system and the current gel and commercially available teeth bleaching gels with electrical conductivity below 200 microsiemens/cm. The current gel was found to be superior to the commercially available teeth bleaching gels and resulted in 3 to 4 additional white shades as compared to teeth bleaching performed by using the Pearl™ tray with commercially available teeth bleaching gel for 5 minutes.

Gel composition conductivity was measured by Digital Conductivity Meter model Traceable 4063, manufactured by Control Company, Friendswood, TX 77546, USA, (www.control3.com). The measurement was performed by a probe that contained platinum electrodes and a thermistor.

EXAMPLE 3 DENTAL BLEACHING GEL

Ingredient	Concentration (%) w/w
Glycerin /propylene glycol	20 - 30
Carbopol 940/ Carbopol 980	1 – 5
Hydrogen Peroxide 30%	25 – 35
Deionized Water	30 – 40
Potassium Nitrate	2 – 3
Sodium fluoride	0.1 – 1.0
Potassium hydroxide 30%w/w	2 – 3
PVP (Polyvinylpyrrolidone)	0.5 – 2.0
EDTA (Disodium Ethylenediaminetetraacetic salt)	0.1 – 1
Saccharin sodium salt hydrate	0.2
Peppermint oil	0.2

A dental bleaching composition was prepared by combining the ingredients (in weight percent) as shown in the above table.

The procedure produced about 120 g of ready to use gel composition. The produced dental bleaching composition was stable and was able to adhere and retain a dental tray in place against a person's teeth. The dental bleaching composition had a conductivity of 800 - 1000 microsiemens/cm. Pearl™ dental tray was used to test the bleaching properties of the bleaching gel composition of Example 3. Application of electric current of about 10 milliamperes for 5 minutes bleached or whitened the teeth. The result was compared visually to teeth bleaching procedure using the Pearl™ tray with commercially available teeth bleaching gels with electrical conductivity below 200 microsiemens/cm. The results of the teeth bleaching using the present gel were found to be superior to teeth bleaching performed by the Pearl™ system for 5 minutes using the commercially available teeth bleaching gels with low electric conductivity.

Gel composition conductivity was measured by Digital Conductivity Meter model Traceable 4063, manufactured by Control Company, Friendswood, TX 77546, USA, (www.control3.com). The measurement was performed by a probe that contained platinum electrodes and a thermistor.

EXAMPLE 4 Comparative Teeth Whitening Test Results

In order to compare electric current assisted teeth whitening method efficacy with the non-current assisted teeth whitening methods a test procedure was set. The experimental set-up included a mock-up of twenty teeth stained to different levels of shades. The mock-up teeth were cut perpendicular to their long axis and divided into a total of forty mock-up teeth. Then the prepared specimens were divided into two groups; Group A and Group B with each group including twenty teeth with shades identical to the shades of the second group.

Twenty teeth of Group A were treated using the present electrically conductive whitening gel. A total of ten teeth whitening treatments was conducted. Duration of each treatment was 5 minutes. Applied electrical current was about 10 milliampere.

Twenty teeth of Group B were treated using commercially available teeth whitening gels without application of electrical current. A total of ten teeth whitening treatments was conducted. The duration of each treatment was 5 minutes.

Whitening of the teeth with an electrically conductive gel assisted by electric current resulted in 35% better average teeth whitening than using commercially available gels without electric current application. Teeth shades were measured by SpectroShade spectrometer commercially available from MHT Optic Research AG, CH-8155 Niederhasli Switzerland. Tooth color shade was evaluated using an established and standardized scale of 16 shades, VITA Classical shade guide (Vident™, Brea, California USA). Teeth shades were measured immediately following completion of each teeth whitening treatment.

Use of electrically conductive gel with application of electric current of about 3-15 milliampere whitened a larger amount of teeth to the whitest A1 color. Electric current assisted tooth whitening treatment was almost 100% more effective than treatment with commercially available gels and without electric current.

Use of electrically conductive gel with application of electric current bleached 90% of the teeth to the whitest A1 shade as compared to only 45% of the teeth treated by commercially available teeth whitening gels and without application of electric current.

100% of the Group A teeth with baseline shade of A3 after treatment with electrically conductive whitening gel and application of electric current have become teeth with A1 shade as compared with 64% of the teeth treated by commercially available dental whitening gel and without application of electric current.

100% of the Group A teeth after treatment with electrically conductive whitening gel and application of electric current have shown whitening of seven shades, as compared with 50% of the teeth treated by commercially available dental whitening gel and without application of electric current.

25% of the Group A teeth treated with electrically conductive whitening gel and application of electric current have shown whitening of ten shades, as compared with 5% of the teeth treated by commercially available dental whitening gel and without application of electric current.

Improvement in whitening of Group B teeth (without application of electric current) has stopped after about 40min of accumulated treatment time, whereas improvement in teeth whitening results of Group A teeth (with application of electric current) continued even after 50min of accumulated treatment time.

EXAMPLE 5 DENTAL BLEACHING GEL

Further formulations were prepared and tested, wherein the bleaching agent was carbamide peroxide. Furthermore, no binding agent is present.

Ingredient	Concentration w/w (%)
Glycerin/propylene glycol	25-30
Carbopol	1-5
Carbamide peroxide	25-35
Deionized Water	30-40
Potassium Nitrate	2-3
Potassium Hydroxide (50% in water)	2-3
EDTA (Disodium Ethylenediaminetetraacetic salt)	0.1-1
Saccharin sodium salt hydrate	0.2
Peppermint oil	0.2

The formulation was tested as above in example 4. The results are shown in the following table. The formulation using carbamide peroxide was also active when applied and activated with micro-current. This formulation was also stable although it did not comprise a binding agent showing that the essential ingredients as defined in claim 1 are sufficient to prepare a stable and active bleaching gel.

Tooth bleaching results using the current gel and electric current of 3-15milliampere

Tooth No.	Baseline Shade	Tooth shade change
T2	A3	7
T4	A3	7
T6	A3.5	10
T8	A3	7
T10	A3	7
T12	A3	7
T14	C4	7
T16	D3	8
T18	A3	7
T20	A3.5	10
T22	A3	7
T24	C4	11
T26	A3	7
T28	A3.5	10
T30	A3	7
T32	A3	7
T34	A3.5	10
T36	A3	7
T38	A3	7
T40	A3	7
Average		7.85

Tooth bleaching results using a commercially available gel without electric current application

Tooth No.	Baseline Shade	Tooth shade change
T1	A3	7
T3	A3	7
T5	A3.5	4
T7	A3	7
T9	A3	4
T11	A3	7
T13	D3	5
T15	D3	5
T17	A3	4
T19	A3	7
T21	A3	4
T23	A4	5
T25	A3.5	10
T27	A3	4
T29	A3.5	3
T31	A3	7
T33	A3.5	5
T35	A3	7
T37	A3	7
T39	A3	7
Average		5.8

Claims

1. A dental bleaching gel composition comprising:
a peroxide or peroxide releasing compound,
a cross-linked polyacrylate polymer, an aqueous vehicle; and
at least one electrical conductivity enhancing ingredient;
wherein the electrical conductivity of the gel is at least 250 microsiemens/cm.
2. The dental bleaching gel composition according to claim 1 wherein the electrical conductivity enhancing ingredient is at least one of a group consisting of alkali nitrate in an amount of 1 to 5% w/w and alkali hydroxide in amount of 1 to 5% w/w.
3. The dental bleaching gel composition according to claim 1 or 2 wherein the amount of alkali hydroxide is such that the gel pH is adjusted to 5-7.
4. The dental bleaching gel composition according to one of the preceding claims wherein the aqueous vehicle comprises at least one alcohol, in particular one of glycerin, propylene glycol, or a mixture of them.
5. The dental bleaching gel composition according to one of the preceding claims wherein the alkali hydroxide is potassium hydroxide and/or wherein the alkali nitrate is potassium nitrate.
6. The dental bleaching gel composition according to one of the preceding claims wherein the amount of glycerin is 20 to 30% w/w; and/or wherein the amount of water is 25 to 50% w/w.
7. The dental bleaching gel according to one of the preceding claims wherein the amount of peroxide is 3 to 35% w/w.

8. The dental bleaching gel composition according to one of the preceding claims wherein the amount of a cross-linked polyacrylate polymer is 1 to 5% w/w.
9. The dental bleaching gel composition according to one of the preceding claims wherein the dental bleaching gel additionally includes a fluoride in amount of 0.1 to 1.0% w/w.
10. The dental bleaching gel composition according to one of the preceding claims wherein the dental bleaching gel additionally includes at least one alkali hydroxide w/w in amount of 0.5 to 3.0% w/w.
11. The dental bleaching gel composition according to one of the preceding claims wherein the dental bleach gel additionally includes a polymeric binder, preferably polyvinylpyrrolidone in an amount of 0.5 to 2.0% w/w.
12. The dental bleaching gel composition according to one of the preceding claims wherein the dental bleaching gel additionally includes a complexing agent, preferably disodium ethylenediamine tetraacetic salt (EDTA) in an amount of 0.1 to 2.0% w/w.
13. The dental bleaching gel composition according to one of the preceding claims wherein the dental bleaching gel additionally includes flavoring ingredients in an amount of 0.1 to 0.5% w/w.
14. The dental bleaching gel composition according to one of the preceding claims wherein the flavoring ingredients are at least one of a group consisting of saccharin sodium salt hydrate and peppermint oil and a mix of both of them.
15. A teeth bleaching method comprising:
 - applying to the teeth to be bleached a layer of gel with electrical conductivity higher than 250 microsiemens/cm;
 - applying to the teeth covered by a layer of gel with electrical conductivity higher than 250 microsimens/cm electric current of at least 1 milliampere; and
 - bleaching the teeth.

16. Use of a dental bleaching gel as defined in one of claims 1 to 14 for bleaching teeth by applying the gel to the teeth and applying a micro-current of at least 1 milliampere.

INTERNATIONAL SEARCH REPORT

14/000028 19-09-2014

International application No.

PCT/IL2014/000028

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 8/22 (2014.01)

CPC - A61C 19/066 (2014.09)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61C 19/6; A61K 8/19, 8/22 (2014.01)

CPC - A61C 19/063, 19/066; A61K 8/19, 8/22 (2014.09)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 433/25, 32, 215

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Orbit, Google Patents, Google Scholar, Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/0065376 A1 (HODOSH) 22 March 2007 (22.03.2007) entire document	1-3
Y	US 2010/0135921 A1 (HUGHES et al) 03 June 2010 (03.06.2010) entire document	1-3, 15
Y	US 2008/0003540 A1 (KHAWALED et al) 03 January 2008 (03.01.2008) entire document	15
A	US 2002/0187108 A1 (RAJIAH et al) 12 December 2002 (12.12.2002) entire document	1-3, 15
A	US 2005/0175965 A1 (CRAIG et al) 11 August 2005 (11.08.2005) entire document	1-3, 15

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

28 August 2014

Date of mailing of the international search report

19 SEP 2014

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 4-14, 16
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.