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(54) Title: PHARMACEUTICAL COMPOSITION COMPRISING OLEIC ACID, PALMITIC ACID, LINOLEIC ACID AND LINOLENIC ACID

(57) Abstract: "Pharmaceutical composition". In a first aspect, the present invention relates to a topical cosmetic, dermatological or pharmaceutical composition comprising a mixture of acids consisting of 85-97% by weight of oleic acid, 1.5-6% by weight of palmitic acid, 1.5-6% by weight of linoleic acid, and 0.2-6% by weight of linolenic acid, with respect to the total weight of the acid mixture. In a preferred aspect, the composition of the present invention further comprises hydrogen peroxide. In a second aspect, the present invention relates to a method for preparing such cosmetic composition by mixing such acid mixture with hydrogen peroxide.

PHARMACEUTICAL COMPOSITION COMPRISING OLEIC ACID, PALMITIC ACID, LINOLEIC ACID AND LINOLENIC ACID

DESCRIPTION

Field of the invention

The present invention relates to a cosmetic, dermatological and/or pharmaceutical composition. In particular, the present invention relates to a pharmaceutical composition useful as cell stimulant and/or as healer.

State of the art

Pharmaceutical compositions comprising lipid based mixtures are known in the art. For example, European patent application EP 0 527 101-A1 discloses a pharmaceutical composition comprising a mixture comprising 38-43% by weight of oleic acid, 11-12% by weight of myristic acid, 10-11% by weight of palmitic acid, 21-25% lauric acid and smaller percentages by weight of palmitoleic acid, linoleic acid and linolenic acid with respect to the composition total weight; such a pharmaceutical composition is useful for the treatment of prostate.

International application WO 87-03490 discloses a pharmaceutical preparation based on 1-40% by weight of oleic acid and 50-100% by weight of 2-ethyl-1,3-hexanedyol for the transdermal administration of a drug to a patient improving the percutaneous penetration.

International application WO 00-27372 discloses a pharmaceutical preparation comprising non-steroidal anti-inflammatory drugs and oleic acid as percutaneous absorption promoter combined with a specific aqueous alcohol solvent, the amount of oleic acid being at most 15% by weight of the total composition.

Russian application RU 2141845 discloses a pharmaceutical composition of an analgesic agent comprising a carrier comprising 30-65% by weight of oleic acid ethyl ester to improve the parenteral absorption.

The Korean application published as KR 100732727 discloses a pharmaceutical composition for the treatment of hypercholesterolemia

comprising a mixture of lipids with 35-45% by weight of oleic acid, 25-35% of linolenic acid, 20-30% of stearic acid and other acids in smaller amounts.

Cardoso CRB et al., in "Influence of topical administration of N-3 and N-6 nonessential fatty acids on the healing of cutaneous wounds", Wound Repair and Regeneration, Mosby-Year Book, St. Louis, MO, US, Vol. 12. no. 2, 01.01.2004, pages 235-243, describes some compositions comprising linolenic acid, linoleic acid or oleic acid, taken individually and not in combination with one another, useful for accelerating the healing of wounds.

Likewise, Leonardo M. Pereira et al., in "Effect of oleic and linoleic acids on the inflammatory phase on wound healing in rats", Cell biochemistry and function, Vol. 26, no. 2, 01.03.2008, pages 197-204, describes the use of oleic acid or linoleic acid separately, thus not in combination, for healing wounds.

The Applicant has also noted that the above pharmaceutical compositions are not suitable as regenerating substances of the cells present in the human and animal body. Indeed, the molecules of such compositions are very complex, branched chains; accordingly, such molecules of lipid mixtures are hardly crushable and thus not capable of quickly releasing the regenerating substances carried by the same. Moreover, a much extended chain product is hardly degradable by the organism, with the risk of creating deposits within the same cells, thereby increasing the energy consumption of the cells to clear the substance.

The Applicant has further noted that pharmaceutical compositions with such percentages by weight of oleic acid are not suitable to be used as efficient wound healers; in fact, using such pharmaceutical compositions, the healing times are too low. Moreover, it has also been noted that even other pharmaceutical compositions, based for example on hyaluronic acid and reported as effective for generating the new skin tissue where a wound has occurred, actually have especially long healing times.

Summary of the invention

The Applicant has therefore noted the need to provide oxygen-rich pharmaceutical compositions capable of quickly healing wounds and/or regenerating the cells of the human and animal body.

Therefore, in a first aspect, the present invention relates to a composition according to claim 1.

In fact, the Applicant of the present application has surprisingly found that a topical cosmetic, dermatological and/or pharmaceutical composition comprising a mixture of acids consisting of 85-97% by weight of oleic acid, 1.5-6% by weight of palmitic acid, 1.5-6% by weight of linoleic acid, and 0.2-6% by weight of linolenic acid, with respect to the acid mixture total weight, is a rich composition adapted to absorb gaseous substances and to efficiency carry them into the human and animal body, so as to heal wounds very quickly and effectively regenerate and reactivate the biological processes of cells having any position in the human and/or animal body, while not having any contraindications from the toxicology and allergy point of view.

In this way, since the composition mainly consists of oleic acid and smaller percentages by weight of other lipid acids, on one hand it has the advantage of having a still simple molecular structure, like that entirely consisting of oleic acid, capable of absorbing and carrying gaseous substances, such as for example oxygen, and of being easily broken upon the contact with the cells of the human or animal body to be regenerated, and thus release the regenerating gaseous substances contained in said composition or absorbed and carried by the same in short times. Moreover, on the other hand, the presence in smaller but still significant (at least 3% with respect to the weight of the acid mixture) percentages, leads to the presence of a certain number of unstable bonds that make the composition of the present invention more easily catalyzed by many substances, thereby increasing the possibility of absorbing oxygen or other gaseous substances. However, the percentages of said other lipid acids should not be greater than

15% of the total weight of the composition of the present invention for not reducing the cutaneous penetration of the same composition; in fact, percentages greater than 15% do not allow the penetration into the deeper skin layers, stopping almost at the surface and thereby slowing down the absorption by the organism.

The composition of the present invention, wherein the above acids are provided in combination, has some advantages compared to compositions known in the art which only included such acids taken individually, such as for example better cutaneous penetration and better healing.

Preferably, the acid mixture of the composition of the present invention further comprises 0.2-2% by weight of at least one acid selected from the group consisting of palmitoleic acid, myristic acid, stearic acid, nervonic acid and/or margaric acid, with respect to the total weight of the acid mixture.

Preferably, the acid mixture of the composition of the present invention comprises 86-94% by weight of oleic acid, 2.5-5% by weight of palmitic acid, 2.5-5% by weight of linoleic acid, 0.2-2% by weight of linolenic acid and 0.2-2% by weight of at least one acid selected from the group consisting of palmitoleic acid, myristic acid, stearic acid, nervonic acid and/or margaric acid, with respect to the total weight of the acid mixture.

Preferably, the cosmetic, dermatological and/or pharmaceutical composition of the present invention further comprises hydrogen peroxide; more preferably, said acid mixture and said hydrogen peroxide are in a ratio of parts by weight in the range between 1.5:1 and 2.5:1.

In this way, the composition of the present invention showed further advantages given by the presence of hydrogen peroxide which contributed to providing a synergic strengthening of all the features of the single fatty acids of said acid mixture.

Preferably, the composition of the present invention has such

molecular structure to not be salified; in this way it is capable of keeping its own pharmacological properties even upon the contact with other chemical substances, or after a long storage (for example, more than 1 year) at room temperature or yet after storage for short periods at such temperatures to freeze the composition (for example, between 0 °C and -10 °C).

On the contrary, if salified, the composition of the present invention would decrease its feature of absorbing and carrying gaseous substances.

Preferably, the composition of the present invention is free from any diluents; in this way, the lipid mixture that forms the composition of the present invention may be used as such with the further advantage of not undergoing bacterial contaminations since it has antibacterial properties itself.

Preferably, the composition of the present invention has a pH in the range between 2.5 and 4.0, more preferably between 2.8 and 3.8. In this way, a good cutaneous penetration is obtained without sensitizing and/or irritating the skin at the same time.

Preferably, the oleic acid provided in the composition of the present invention has a purity greater than 80%, more preferably greater than 90%.

In this way, since the purity of the oleic acid is very high, the presence of other lipid acids provided in smaller percentages in the composition of the present invention also determines moderate changes in the molecular structure of the same oleic acid.

Preferably, the composition of the present invention further comprises phosphoric acid; more preferably, the composition of the present invention further comprises phosphoric acid from 0.001 % to 2% by weight of the total weight of the acid mixture.

This increases the feature of the composition of the present invention of promoting the nourishment, with regenerating substances, of the human and/or animal cells that use the material provided for their self-rebuilding, thereby accelerating the cell reactivation.

Moreover, the presence of phosphoric acid in the composition of the present invention allows the dissolution of lipid masses present in the human and/or animal organism to be promoted, thereby promoting the dissolution of blood clots, such as even deep venous or aortic thrombi, since thrombi also consist of a lipid part.

Preferably, the composition of the present invention further comprises magnesium hydrogen carbonate, tin phosphate, copper phosphate and/or colloidal silver.

In this way, the presence of a metal compound allows the composition of the present invention to be further enriched with certain chemical-physical and healing properties to transfer to the cells.

Preferably, the composition of the present invention further comprises magnesium hydrogen carbonate, tin phosphate, copper phosphate and/or colloidal silver in an amount between 0.00001% and 0.0005% by weight of the total weight of the acid mixture.

In this way, said metal compounds in minimum percentages reduce the possibility of intoxication and allow a cutaneous penetration of the same composition in still acceptable terms. Higher percentage by weight values may be counter-productive from both the intoxication and the cutaneous penetration point of view.

In a second aspect, the present invention relates to a method for preparing a composition described above as defined in claim 9.

The Applicant of the present application, in fact, has surprisingly found that a method for preparing a topical cosmetic, dermatological and/or pharmaceutical composition which comprises an acid mixture consisting of 85-97% by weight of oleic acid, 1.5-6% by weight of palmitic acid, 1.5-6% by weight of linoleic acid, and 0.2-3% by weight of linolenic acid, with respect to the total weight of the acid mixture, and 0.2-2% by weight of at least one acid selected from the group consisting of palmitoleic acid, myristic acid, stearic acid, nervonic acid and/or margaric acid, with respect

to the total weight of acid mixture, said method comprising the steps of:

a) centrifuging said acid mixture and hydrogen peroxide;

b) stirring the resulting mixture with a stirrer set at a temperature in the range between 100 and 400 °C for a period in the range between 10 and 80 minutes;

c) letting the end product reach a temperature in the range between 90 and 125 °C;

d) letting the hydrogen peroxide residue separate from the rest of the mixture and draw such residue away;

e) stabilizing the resulting product to a temperature in the range between 15 and 40 °C,

is capable of obtaining a product capable of absorbing and carrying gaseous substances, such as oxygen, and transferring it to the cells to regenerate.

Such method of the present invention for preparing such cosmetic, dermatological and/or pharmaceutical composition does not need the presence of any catalyst, nor any type of solvent for obtaining the end product.

Preferably, said acid mixture and said hydrogen peroxide are in a ratio of parts by weight in the range between 1.5:1 and 2.5:1.

Preferably, in said step a), the centrifugation initially takes place at a temperature in the range between about 15 °C and 25 °C and then at a temperature in the range between about 20 °C and 30 °C.

In this way, the increase in temperature causes an initial process of breakage of the weaker bonds present in said composition.

Preferably, in said step b), the stirrer is set at a temperature in the range between 150 and 350 °C for a period in the range between 15 and 70 minutes.

In fact, if times outside such preferred range are used, the resulting product would be too reactive and the acidic pH would be too high for the intended objects.

Preferably, in said step e) the product is stabilized to a temperature in the range between 20 and 30 °C.

A clear, substantially odorless and colorless product is thus obtained, with a density around 0.90.

Preferably, during step c), the resulting mixture is subjected to magnetic stirring; preferably, said magnetic stirring lasts for a period from 20 to 50 minutes. Preferably, said magnetic stirring is obtained by activating, for example, a magnetic plate.

In a third aspect, the present invention relates to the use of the above-described composition in various aspects of the medical treatment of diseases.

For example, the above composition may be used for carrying gaseous substances in the organism of a human and/or animal body, and therefore for regenerating the cells contained therein.

Preferably, said composition may be used for regenerating the stem cells of a human or animal organism.

The composition of the present invention is particularly used through the blood cycle, through which it travels inside the human or animal organism, thus contacting various sites of the organism. In this way, the composition of the present invention is capable of facilitating the electron exchange with the cells of the human or animal organism in need, actually considerably strengthening the cell breathing (a mechanism through which in the presence of oxygen, cells are capable of obtaining energy usable in vital processes) and accelerating the activation of many biological processes, preferably those in stem cells for regenerating cells poor in oxygen. Stem cells are at the basis of structural regenerative processes and as per recent studies in the medical field, it has been found that stem cells are capable of carrying out a plurality of actions in both the human and animal organisms.

Therefore, the composition of the present invention may be used in any organ where stem cells can be activated and regenerated, accelerating

the cell regenerative process and determining a fast rebuilding and normalizing action of all body tissues. In fact, the cell regeneration is a process where the stem cells of blood, skin and various organs activate and act in promoting the production of a new skin, muscular, venous, nervous, bony tissue upon a damage due for example to muscle strains, bone fractures or lesions of other type.

In another aspect of the present invention, the above-described composition of the present invention may be used for quickly healing wounds. In fact, it has been noted that in healing processes, both of the skin and of internal organs, the above-described composition is capable of stimulating these particular cells to produce and activate the healing mechanisms of the new tissue in much faster times than the known techniques.

In further aspects of the present invention, the above-described composition of the present invention may be used in various other fields of medicine and cosmetics where the capability of said composition of carrying and transferring regenerating gaseous substances to the cells of the human or animal body can be used.

For example, the composition may also be used as anti-inflammatory agent; in fact, it is capable of promoting a quick expectoration of the lungs at systemic level, directly acting on the secretory glands and easily freeing the respiratory passages from obstructions of thick and compact mucus, without causing any damage to the tissues but rather promoting the normalization of inflamed tissues.

Moreover, the composition of the present invention may also be used as anti-thrombosis agent; in fact, it is capable of constantly dissolving thrombi of both a coagulative and lipid nature with no side effects.

Moreover, the composition of the present invention may also be used as hemostatic agent; in fact, the composition of the present invention is capable of quickly blocking the bleeding by mixing with blood and creating

a film thereon in few seconds, prevents the forming of hematomas and accelerates the absorption thereof, if present. It prevents blood extravasations and is easily carried by the blood flow in any district, including the brain.

Furthermore, the composition of the present invention may also be used as antibacterial agent. In fact, it is a strong contact bacteriostatic agent, is effective in effectively fighting bacterial infections and destroys mycosis, dermatitis, psoriasis, etc.

By virtue of its easiness in regenerating cells, the composition of the present invention may also be used in various further fields of medicine and cosmetics, such as for example against herpes simplex, as topical antifungal agent, as painkiller, as anti-burn agent, anti-ulcer agent, for gout and arthritic problems, for sunburns or thermal burns from salty water, cardiac lesions, necrosis, as anti-wrinkle, and others.

Further features and advantages of the present invention will appear more clearly from the review of the following detailed description of a preferred but non-exclusive embodiment, shown by way of a non-limiting example.

Detailed description

The following detailed description relates to a particular embodiment of a composition according to the present invention.

Example 1 (invention).

1 part by weight of hydrogen peroxide was placed in a Pyrex glass beaker with 2 parts by weight of a mixture of lipid acids comprising 88% of oleic acid, 4% of palmitic acid, 1.1% of palmitoleic acid, 0.5% of myristic acid, 0.5% of stearic acid, 5% of linoleic acid, 0.5% of linolenic acid and 0.2% of margaric acid and 0.2% of nervonic acid, all the percentages being expressed by weight with respect to the total weight of the acid mixture. The parts were initially centrifuged at a temperature of about 15 °C at a rotation speed of 1200 revolutions/minute, for 30 minutes. The temperature was then

increased by about 8 °C due to the fast centrifugation and consequent molecular friction that caused an initial process of breaking the weaker bonds of the mixture molecule.

A magnetic stirrer plate was then activated and the beaker was placed thereon, at the temperature of about 250 °C, decreasing the rotation speed to 720 revolutions/minute. After about 10 minutes since the activation of the plate, the mixture reached the temperature of about 70 °C, and a slight evaporation begun. The magnetic stirring continued for about 40 minutes more up to reaching a temperature of about 115 °C. At that point, the stirring was interrupted thus preventing the hydrogen peroxide to fully react; the residual hydrogen peroxide left to deposit on the beaker bottom was about half the amount of hydrogen peroxide initially used. The lipid acid mixture was totally clear, transparent, colorless or at most with some very clear straw-yellow reflection. The hydrogen peroxide thus naturally separated from the lipid acid mixture was drawn away. After such drawing, a gaseous oxygen cloud formed inside the container and remained trapped therein, thus opacifying the lipid acid mixture.

The product was then placed in a hermetically sealed vessel and left to stabilize at room temperature in the dark for about ten days.

At the end of this stabilization step, the product reabsorbed all the gaseous cloud and the air present therein, thus becoming transparent again.

A sample 1 was thus obtained comprising a lipid acid mixture rich in oxygen, capable of catalyzing and carrying said oxygen into the human or animal organism.

Example 2 (invention).

Likewise, a sample 2 of the invention was prepared, using a mixture of lipid acids comprising 88% of oleic acid, 3.5% of palmitic acid, 1.2% of palmitoleic acid, 0.5% of myristic acid, 0.5% of stearic acid, 4.5% of linoleic acid, 0.5% of linolenic acid and 0.3% of margaric acid, and 1% of phosphoric acid, all the percentages being expressed by weight with respect

to the total weight of the acid mixture.

Example 3 (comparison).

Likewise, a comparison sample 3 was prepared, using a mixture of lipid acids comprising 60% of oleic acid, 18% of palmitic acid, 17% of lauric acid, 3% of myristic acid and 2% of stearic acid, all the percentages being expressed by weight with respect to the total weight of the acid mixture.

Example 4 (comparison).

Likewise, a comparison sample 4 of a standard lard composition was prepared, comprising an acid mixture consisting of 39% of oleic acid, 24% of palmitic acid, 17% of stearic acid, 9% of linolenic acid, 3% of palmitoleic acid and smaller percentages of other lipid acids, all the percentages being expressed by weight with respect to total weight of the acid mixture.

Example 5 (comparison).

Likewise, a comparison sample 5 of a standard lard composition was prepared, comprising 100% of oleic acid.

The comparison samples 3 and 4, where the percentage by weight of oleic acid with respect to the total weight of the sample was 60% and 39% respectively, therefore less than the minimum required of 82% of the present invention, proved to have a very high density and a highly viscous composition, with the presence of highly complex, branched polymeric and molecular chains such as to not allow a quick, efficient cutaneous penetration.

On the contrary, samples 1 and 2 of the present invention, having a very high percentage by weight of oleic acid (87-88% with respect to the total weight of the sample) proved to have a good cutaneous penetration. In such samples 1 and 2 of the invention, the presence of other lipid acids in smaller percentages (less than 15% by weight with respect to the total weight of the composition) promoted the reaction with hydrogen peroxide by acting as catalysts, thus increasing the possibility of absorbing hydrogen

or other gaseous substances, compared to the comparison sample 5 which only contained oleic acid.

Experimentation on patients. Samples 1 and 2 of the invention thus prepared were tested on a large number of patients in order to assess its use for various purposes.

Healing effect. Samples 1-5 were used for checking the healing times on wounds of the same type on a same patient, repeating the experiment on about a hundred different patients.

Sample 1 (and separately samples 2-5 in similar tests) was applied onto the wound by mixing with blood and creating a film in few seconds, allowing an even layer with a plastic appearance to be formed. The plastic film was left in contact with the air, without placing any bandages, patches or other similar protections, so as to allow the samples of the invention to absorb oxygen from the air and transfer it into the cells in the wound to be healed. The samples of the present invention acted both on the surface and at a deeper level, quickly crossing the surface layers of the cells, to be absorbed by the blood flow both on the surface and in depth. At the end of the healing process, the wound disappeared, thus leaving the skin perfectly healthy and without scars.

The healing times using samples 1 and 2 of the present invention were about 5-6 days with a reduction of over 60% in the time needed by the organism for healing the wound using the comparison samples 3-5, for which the healing time was about 15 days. This is explained by the fact that samples 1 and 2 of the present invention were capable of carrying oxygen as regenerating substance in the human organism and of quickly stimulating and positively activating the healing mechanisms of stem cells, which produced a new skin tissue.

No toxic effect nor allergy was noted in the patients subjected to such treatment, even in pregnant women.

Samples 1 and 2 of the present invention also showed a reduction in

the healing time by about one third compared to compositions based on hyaluronic acid, known in the art as effective healing substances.

Moreover, sample 2 of the present invention, where also phosphoric acid was provided, showed a better enrichment of certain chemical-physical and healing properties to be transferred to the cells.

On the contrary, the use of oleic acid only (comparison sample 5) or the use of acid mixtures containing a reduced percentage of oleic acid (comparison samples 3 and 4) were not able to produce such effects; in fact, slow skin healing times were obtained, producing a modest healing effect on the wounds.

Sun, thermal and radiation burns.

Samples 1 and 2 were used on a series of patients suffering from burns, extended to the face and to the head, from radiations due to radiotherapy. After just 5 days since the application, the total remission of burns was noted.

Samples 1 and 2 were also used by applying them on patients suffering from sunburns or hot water scalds; acting very quickly, before a surface layer of dead skin is formed, blisters with serum was prevented from forming, thus making the burn regress in few hours.

On the contrary, in the case of scalds, the comparison sample 5 (comprising oleic acid only) placed on the skin just burnt produced an immediate warmth feel and considerable irritation, and serum blisters formed after some minutes, thus preventing the healing of the lesion.

Antithrombotic effect.

Samples 1 and 2 also showed beneficial effects on venous and arterial thrombosis. In fact, as the samples were easily carried by the blood flow in any district, including the brain, they were capable of dissolving the clots in few days, without fluidizing the blood, normalizing the blood vessel lumen, eliminating plaques and any obstructions, restoring the elasticity and tone of the structures.

On the contrary, the use of oleic acid only (comparison sample 5) did not show a good capability of penetrating into the deep derma tissues, as it did not even reach the lumen of the first vessels. Therefore, the comparison sample 5 did not carry out any systemic action from the skin point of view.

Anti-inflammatory and painkiller effect.

In case of the presence of pain, after the application of samples 1 and 2 of the present invention, the pain quickly decreased and the inflammation decreased as the cell regeneration progressed. Unlike painkillers known in the art, by the application of samples 1 and 2 of the present invention, pain was not hidden but effectively healed by the cell regenerative process, directly removing the inflammation of the lesion and blocking the painful feel in few hours.

Even in the case of bone pains, such pains begun to alleviate after few hours since the topical application of samples 1 and 2 of the invention.

Any modifications and variants of the preferred embodiments described will obviously be apparent to those skilled in the art, without departing from the scope of the invention. Therefore, the invention is not limited to the preferred embodiments described, shown by way of illustration and not of limitation, but it is limited by the claims that follow.

For example, the composition of the present invention may be used in any human and/or animal organ where stem cells can be activated and regenerated, even for purposes other than those exemplified above, accelerating the cell regenerative process and determining a fast rebuilding and normalizing action of all body tissues.

Moreover, the composition of the present invention may be used as antibiotic, since it is effective in quickly fighting both gram negative and gram positive bacterial infections, reducing the reaction time by few minutes to some hours in the cases of more extended and deeper infections, with no side effect. Since the composition of the present invention is capable of easily crossing the brain membrane, it carries out its antibiotic functions also

within the brain, with the same action speed that it has in the organism, without producing waste and toxins.

Moreover, the composition of the present invention may be used in rebuilding nails suffering from fungi, eliminating the problem in shorter times compared to topical antifungal agents known in the art, with no toxic side effect, like in those cases related to arthritic problems or gout, where the painful states and inflammations are significantly reduced quickly.

Moreover, the composition may be used as expectorant of the lungs at systemic level, directly acting on the secretory glands and by stimulation of the vagus nerve, easily freeing the respiratory passages from obstructions of thick and compact mucus, without causing any damages to the tissues but rather promoting the normalization of inflamed tissues. It is capable of positively solving bronchitis, pneumonia and pleurisy with few applications.

The composition of the present invention may also be used in cardiac muscle lesions as it is capable of easily penetrating into the blood flow, especially if it is applied onto the neck or in situ where the skin has a smaller thickness and where large vessels are very superficial. The application 3 times a day for 10 days promotes the healing of the cardiac muscle lesions, normalizing the heartbeat.

The composition of the present invention is also capable of blocking bone degenerative processes, effectively treats arthrosis, arthritis, various bone degenerations, aids the bone consolidation from osteoporosis, making the bone pain quickly disappear, and it is capable of treating gangrene and all necrotizing processes, promoting the tissue oxygenation and the consequent recovery of the normal biological activity. It is also suitable for chilblains, frostbites and various circulatory problems.

Moreover, the composition of the present invention may also be used for treating patients suffering from diabetes. In fact, a test run on 30 diabetic patients showed that after said patients had eaten food that considerably increased their glycemic levels, applying the composition of the present

invention in the neck zone where it is immediately put in circulation by means of large vessels, a decrease of glycemic levels was noted in just one application from about 300 to less than 70 in all the tested patients. With an extended application treatment of the composition of the present invention, a significant reduction of the insulin amount that the patients have to take was further observed, without negative side effects.

Moreover, by a finger oximeter it has been observed that upon the application of a dose of the composition of the present invention onto the neck, just 5 minutes after such application the oxygen levels in blood drastically increased, remaining stable for several hours.

CLAIMS

1. A topical cosmetic, dermatological or pharmaceutical composition comprising a mixture of acids consisting of 85-97% by weight of oleic acid, 1.5-6% by weight of palmitic acid, 1.5-6% by weight of linoleic acid, and 0.2-6% by weight of linolenic acid, with respect to the total weight of the acid mixture.

2. A composition according to claim 1, wherein said acid mixture further comprises 0.2-2% by weight of at least one acid selected from the group consisting of palmitoleic acid, myristic acid, stearic acid, nervonic acid and/or margaric acid, with respect to the total weight of the acid mixture.

3. A composition according to claim 1 or 2, wherein said acid mixture comprises 86-94% by weight of oleic acid, 2.5-5% by weight of palmitic acid, 2.5-5% by weight of linoleic acid, 0.2-2% by weight of linolenic acid and 0.2-2% by weight of at least one acid selected from the group consisting of palmitoleic acid, myristic acid, stearic acid, nervonic acid and/or margaric acid, with respect to the acid mixture total weight.

4. A composition according to any one of claims 1-3, wherein said composition further comprises hydrogen peroxide.

5. A composition according to claim 4, wherein said acid mixture and said hydrogen peroxide are in a ratio of parts by weight in the range between 1.5:1 and 2.5:1.

6. A composition according to any one of claims 1-5, wherein said composition is free from any diluents.

7. A composition according to any one of claims 1-6, wherein said oleic acid has a purity higher than 80%.

8. A composition according to any one of claims 1-7, wherein said composition has a pH in the range between 2.5 and 4.0.

9. A method for preparing a topical cosmetic, dermatological and/or pharmaceutical composition comprising an acid mixture consisting of 85-

97% by weight of oleic acid, 1.5-6% by weight of palmitic acid, 1.5-6% by weight of linoleic acid, 0.2-6% by weight of linolenic acid and 0.2-2% by weight of at least one acid selected from the group consisting of palmitoleic acid, myristic acid, stearic acid, nervonic acid and/or margaric acid, with respect to the total weight of the acid mixture, wherein said method comprises the steps of:

a) centrifuging said acid mixture and hydrogen peroxide;

b) stirring the resulting mixture with a stirrer set at a temperature in the range between 100 and 400 °C for a period in the time range between 10 and 80 minutes;

c) letting the end product reach a temperature in the range between 90 and 125 °C;

d) letting the hydrogen peroxide residue separate from the rest of the mixture and draw such residue away;

e) stabilizing the resulting product at a temperature in the range between 15 and 40 °C.

10. A method according to claim 9, wherein said acid mixture and said hydrogen peroxide are in a ratio of parts by weight in the range between 1.5:1 and 2.5:1.

11. A method according to claim 9 or 10, wherein in said step a) the centrifugation initially takes place at a temperature in the range between about 15 °C and 25 °C and then at a temperature in the range between about 20 °C and 30 °C.

12. A method according to any claim from 9 to 11, wherein in said step b) the stirrer is set at a temperature in the range between 150 and 350 °C for a period in the time range between 15 and 70 minutes, and wherein in said step e) the product is stabilized at a temperature in the range between 20 and 30 °C.

13. Use of a composition according to any one of claims 1-8 for medical treatment in the healing of wounds.

14. Use of a composition according to any one of claims 1-8 for medical treatment in regenerating the cells of a human and/or animal body.

15. Use of a composition according to any one of claims 1-8 for medical treatment of diabetes.

5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/063421

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K31/20 A61K31/201 A61K31/202 A61P17/00 A61P43/00
ADD.

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)
A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, BIOSIS, CHEM ABS Data, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CARDOSO C R B ET AL: "INFLUENCE OF TOPICAL ADMINISTRATION OF N-3 AND N-6 ESSENTIAL AND N-9 NONESSENTIAL FATTY ACIDS ON THE HEALING OF CUTANEOUS WOUNDS", WOUND REPAIR AND REGENERATION, MOSBY-YEAR BOOK, ST. LOUIS, MO, US, vol. 12, no. 2, 1 January 2004 (2004-01-01), pages 235-243, XP003014130, ISSN: 1067-1927, DOI: 10.1111/J.1067-1927.2004.012216.X abstract page 242, column 1, paragraph 4 ----- -/--	1-8,13, 14

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"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

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"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	Date of mailing of the international search report
17 September 2012	27/09/2012

Name and mailing address of the ISA/	Authorized officer
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1

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	MITTAL ASHU ET AL: "Status of Fatty Acids as Skin Penetration Enhancers-A Review", CURRENT DRUG DELIVERY, BENTHAM SCIENCE PUBLISHERS, HILVERSUM, NL, vol. 6, no. 3, 1 July 2009 (2009-07-01), pages 274-279, XP008144430, ISSN: 1567-2018, DOI: 10.2174/156720109788680877 page 275, column 1, paragraph 4 - page 278, column 1	1-15
Y	US 4 701 471 A (LOUCKS SR JOSEPH [US] ET AL) 20 October 1987 (1987-10-20) page 1, column 1, paragraph 1; claims; example 1	1-15
Y	DE 20 2008 007621 U1 (ZIMMER BRUNO [DE]) 6 November 2008 (2008-11-06) claim 1	1-15
Y	WO 97/17953 A1 (ARCTURUS PHARM CORP [US]; CHEN WEN G [US]; CIFUENTES MARIA [US]; GALLI) 22 May 1997 (1997-05-22) page 14, lines 31-34 page 1, paragraph 1	1-15
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International application No
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