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(54) Method of production of an ozonized oil-based vehicle

(57) The present invention refers to a method of production of a saturated and stable ozonized oil-based vehicle, which comprises:
providing a pre-established amount of a pre-established unsaturated oil-based vehicle inside a tank;
a first insufflation step wherein a continuous gaseous flow comprising oxygen, ozone and at least one noble or inert gas is insufflated into the oil-based vehicle, until the oil-based vehicle is saturated with ozone;
a second insufflation step wherein a continuous gaseous flow comprising oxygen, ozone and at least one noble or inert gas is insufflated into the oil-based vehicle saturated with ozone, until a constant ozone concentration value is obtained in the oil-based vehicle for at least a pre-established time interval or number of measurements, with the stabilization of the saturated oil-based vehicle.

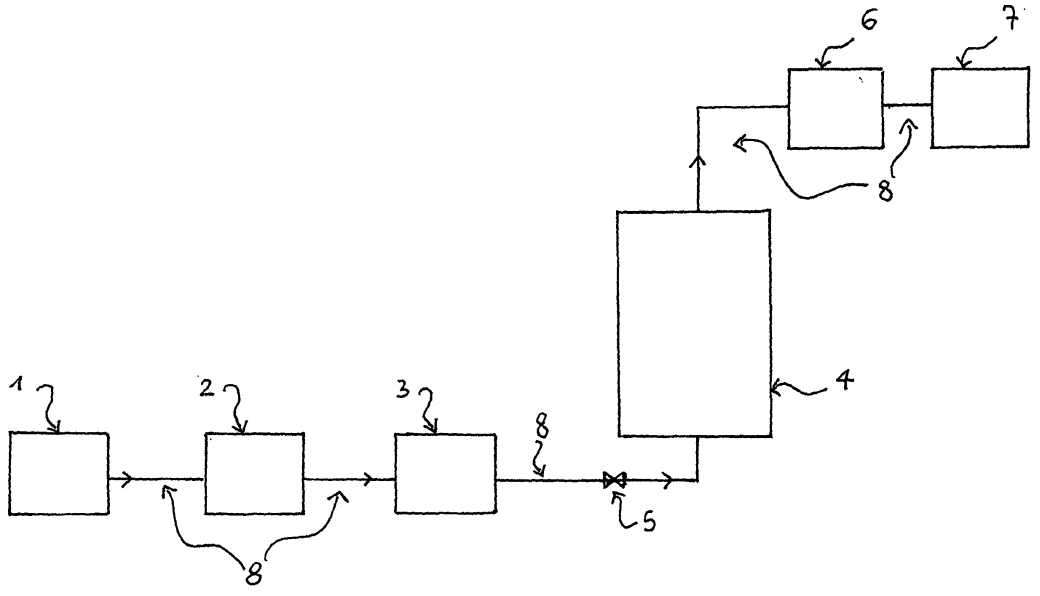

Fig. 1

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Description

Field of application

[0001] The present invention refers, in its most general aspect, to a method of production of an ozonized oil-based vehicle or substrate.

[0002] In particular, the invention refers to a method of the aforesaid type wherein such oil-based vehicle or substrate, for example an unsaturated vegetable oil such as virgin or extra-virgin olive oil, corn oil, sunflower oil, linseed oil, almond oil, walnut oil, poppy oil, sesame oil, soy oil, palm oil, peanut oil, jojoba oil and similar oils, is ozonized until saturation with ozone is obtained and stabilized in such a manner that such saturation is long-preserved, and in any case for a time useful for its use as saturated ozonized oil.

[0003] The present method provides an oil-based vehicle or substrate as considered above, i.e. ozonized, saturated and stable, particularly suitable for being used for cosmetic purposes and/or as medicament for the treatment of numerous pathologies and/or diseases, both pure and diluted with another oil that is not ozone-saturated, of same or different nature, and also in association with further substances for example in formulations, compositions, suspensions etc.

[0004] The invention also provides an apparatus for carrying out the aforesaid method.

Prior Art

[0005] The oxidizing properties of ozone are well-known: ozone has in fact long been used for its high bactericide and antiseptic capacity, both in gaseous flow and in other vehicles such as for example oil-based substrates.

[0006] Along with said properties, use of ozone must account for its high instability and for the fact that, in particular in the case of oil-based substrates comprising unsaturated fatty acids, its use determines the formation of undesired by-products, mainly aldehydes and ketones.

[0007] The prior art, therefore, provided a large number of methods of production of ozonized oil-based substrates that were particularly aimed at stabilizing the presence of the ozone in the oil-based vehicle and at minimizing the final content of undesired by-products.

[0008] The document US 5,183,911 describes, for example, a method for producing stable ozonized oil, starting from an unsaturated vegetable oil.

[0009] The method described in the aforesaid document comprises an ozone saturation step, conducted by means of bubbling a mixture of oxygen and ozone in the vegetable oil, and an extraction step of the by-products formed during such ozone-saturation step.

[0010] The by-products extraction step is preceded by an acidification step, by a dilution step with aqueous solution, and it is followed by a removing step of the aqueous phase.

[0011] The product obtained from such method is a stable ozonized oil comprising peroxides and essentially without aldehydes.

[0012] While advantageous, a method like that considered above is not without drawbacks, including a high number of process steps, which make the process quite difficult as well as expensive.

[0013] Moreover, even if such method allows the removal of the undesired by-products without causing a substantial decrease in the peroxide content, the final product obtained cannot be properly defined a saturated ozonized oil (and in fact it is not defined as such), since the by-products extraction method inevitably leads to a loss of ozone content, even if to a limited extent.

[0014] Therefore, it would be desirable to provide a method of production of an oil-based vehicle or substrate, here also simply identified as oil, which allows to make a complete saturation of such oil-based vehicle without forming undesired by-products, as well as a stabilization of the same, so as to provide an ozonized oil which preserves the saturation ozone content for a long period of time, in any case for a time interval useful for its use particularly in cosmetic treatments and/or as medicament for therapeutic treatments.

Summary of the invention

[0015] The present invention provides a method of production of an ozonized oil-based vehicle or substrate which overcomes the drawbacks mentioned with reference to the prior art, i.e. a method of production of a saturated and stable ozonized oil, lacking undesired substances, such as in particular aldehydes and ketones which are advantageously not formed during the method, but also lacking nitrogen oxides and compounds deriving from such oxides such as nitrates, micro-particulates and other substances generally comprised in the surronding air, wherein with the term saturated it is intended that the oil is saturated with ozone, and with the term stable it is intended that the ozone-saturation is preserved for a long time, and in any case preserved for a time interval useful for the use of such oil as an ozone-saturated product, also after a stocking and/or preservation period of the oil itself.

[0016] The process according to the invention comprises:

providing a pre-established amount of a pre-established unsaturated oil-based vehicle inside a container or tank;

a first insufflation step in which a continuous gaseous flow is insufflated in said oil-based vehicle, said flow comprising oxygen, ozone and at least one noble or inert gas, until said oil-based vehicle is saturated with ozone;

a second insufflation step in which, in said ozone-saturated oil-based vehicle, a continuous gaseous flow is insufflated comprising oxygen, ozone and at least one noble or inert gas, until a constant ozone concentration value is obtained in said oil-based vehicle for at least a predetermined time interval, with the stabilization of said saturated oil-based vehicle.

[0017] In accordance with the invention, it has been verified that the presence of at least one noble or inert gas in the gaseous flow insufflated in the oil-based vehicle prevents the formation of aldehydes from the respective fatty acids, which otherwise would occur due to the action of the ozone both during the first insufflation step, i.e. during the saturation step, and during the second insufflation step, i.e. during the stabilization step of the saturated oil-based vehicle.

[0018] Therefore, according to the invention, the aforesaid gaseous flow insufflated in the oil-based vehicle in the aforesaid first and second insufflation steps comprises at least one noble or insert gas in a quantity comprised between 4 and 8% by weight.

[0019] The at least one noble or inert gas is selected from the group comprising helium, neon, argon, krypton, xenon, radon, and similar inert gases or their mixtures, such that the total quantity is in the aforesaid range of 4-8% by weight.

[0020] In accordance with the invention, it has also been verified that the presence of inert or noble gases prevents the formation of aldehydes from the respective fatty acids, which would possibly occur if the gaseous flow insufflated into the oil-based vehicle accidentally comprised nitrogen, even traces thereof.

[0021] Therefore, preferably, the aforesaid gaseous flow comprising oxygen, ozone and noble gases is obtained via electrical discharge of a gaseous flow comprising ultrafiltrated oxygen in an amount at least equal to 92% by weight.

[0022] Preferably, the aforesaid first and second insufflation steps are consecutively carried out without interruption.

[0023] Preferably, the aforesaid first and second insufflation steps are carried out such that the respective gas flows bubble from the bottom towards the top in said tank.

[0024] Preferably, the aforesaid first and second insufflation steps are carried out at low pressure, preferably not greater than 185 KPa and at constant temperature, advantageously room temperature.

[0025] Preferably, the ozone concentration in said insufflated gaseous flow insufflated in said second insufflation step is greater than the ozone concentration in the gaseous flow insufflated in said first insufflation step.

[0026] Advantageously, the aforesaid ozone-saturation of the oil-based vehicle is indicated by an ozone concentration value measured in the aforesaid gaseous flow at an outlet point from said tank, that is, downstream thereof, equal to an ozone concentration value measured at an inlet point to said tank, that is, upstream thereof or in any case by equivalent concentration values measured before and after the transit through the oil-based liquid head, i.e. in the gaseous flow insufflated into the oil-based vehicle and in the residual gaseous flow.

[0027] Alternatively, the aforesaid ozone-saturation of the oil-based vehicle is indicated by a maximum value of the residence time (or a minimum value of the speed of transit) through the liquid head of the oil-based vehicle measured for the gaseous flow.

[0028] Advantageously, the aforesaid stabilization of the ozone content in the saturated oil-based vehicle is indicated by a constant value, measured for a predetermined time interval or number of measurements, of the differential percentage of the aforesaid ozone concentration in the gaseous flow upstream and downstream of said tank, or in any case determined by concentration values measured before and after the transit through the oil-based vehicle by the gaseous flow, i.e. in the gaseous flow insufflated into the oil-based vehicle and in the residual gaseous flow.

[0029] Alternatively, the aforesaid stabilization of the ozone content in the saturated oil-base vehicle is indicated by a constant value, measured for a predetermined time interval or number of measurements, of the aforesaid maximum value of the residence time (or minimum speed of transit) through the oil-based vehicle head measured for the aforesaid gaseous flow.

[0030] In accordance with the invention, the present method can be standardized, so that, for a given oil-based vehicle, the attainment time of said constant ozone concentration value is based on a predetermined quantity of ozone insufflated in said oil-based vehicle.

[0031] In practice, it has been shown that for fixed temperature and pressure values, a given oil-based vehicle which has been saturated with ozone and stabilized in accordance with the present method, comprises a specific (constant) concentration of ozone and derived compounds, concentration which, at the aforesaid temperature and pressure values, is reached upon the insufflation of a predetermined total amount of ozone insufflated into the oil-based vehicle, amount which is proportional to the quantity of, and specific for, the given oil-based vehicle.

[0032] Therefore, in accordance with the present invention, once the oil-based vehicle is determined, the aforesaid constant ozone concentration value in the oil-based vehicle is reached on the basis of a predetermined (pre-calculated) total amount of ozone insufflated in the oil-based vehicle in a predetermined time interval (also pre-calculated), advantageously reducing the number of the aforesaid measurements to one, i.e. one single control upon completion of the process, if not even zero controls, since the aforesaid process is standardized and thus tested for obtaining the saturation with ozone and the stabilization of a given quantity of a given oil.

[0033] Further characteristics and advantages of the present invention will result from the following description of several embodiments provided for illustrating and non-limiting purposes, with reference to the attached drawings.

Brief description of the drawings

[0034] In such drawings:

- Figure 1 schematically illustrates an apparatus for carrying out a method of production of an ozonized oil in accordance with a first embodiment of the invention;
- Figure 2 illustrates a further embodiment of the apparatus of figure 1;
- Figure 3 illustrates a further embodiment of the apparatus of figure 1;
- Figure 4 illustrates a detail of a further embodiment of the apparatus of figure 1;
- Figure 5 illustrates a detail of a further embodiment of the apparatus of figure 1;
- Figures 6-6a and 7 illustrate, in respective tables 1 and 2, characteristic parameters of an oil-based vehicle subjected to the present process and a related oil-based vehicle obtained therefrom in accordance with the invention.

Detailed description of the invention

[0035] A first aspect of the present invention is a method of production of an ozonized oil-based (oil) vehicle or substrate, with saturation and stability characteristics, which does not comprise undesired by-products, particularly indicated for being used in cosmetic treatments and also as medicament, for the topical treatment of numerous pathologies and diseases.

[0036] The present invention has shown that, in particular conditions, an unsaturated vegetable oil can be ozonized until complete ozone saturation is attained, without forming undesired by-products, and that such saturation can be preserved for an extended time interval, useful for using the oil as saturated ozone product, i.e. as a product whose effectiveness in cosmetic treatments or as medicament for topical use is considered maximum, due to the high content of ozone and peroxides.

[0037] In particular, a vegetable oil was obtained saturated with ozone, stable and lacking undesired by-products such as aldehydes and nitrogen oxides, through a process which comprises:

providing a pre-established amount of an unsaturated vegetable oil inside a container or tank;

a step of saturating or first insufflation step, wherein a continuous gaseous flow comprising oxygen, ozone and noble or inert gases is insufflated into the oil, until ozone saturation is obtained;

a step of stabilizing, or second insufflation step, wherein a continuous gaseous flow comprising oxygen, ozone and noble or inert gases is insufflated into the saturated oil, in particular until the ozone concentration in the oil remains constant for a pre-established time interval or for a predetermined number of measurements.

[0038] The present invention has shown that the presence of noble or insert gases in the gaseous flow insufflated into the oil prevents the formation of undesired by-products, mainly aldehydes, which would otherwise be obtained via reaction of the ozone with the unsaturated fatty acids present in the oil.

[0039] Moreover, the present invention has shown that the presence of noble or inert gases in the gaseous flow insufflated in the oil also prevents the formation of undesired by-products which would be obtained if the gaseous flow insufflated into the oil-based vehicle comprised nitrogen, which even if not provided in the flow supplied and insufflated into the oil, as will appear in the following description, can also by chance be present in traces.

[0040] Moreover, the present invention has shown that even if it is possible to rather easily obtain a saturation with

ozone of the oil, without a stabilization of the oil itself, i.e. of the ozone and the peroxides formed in the oil, the ozone content and the same peroxides will not remain at the saturation value for a prolonged time interval, useful for using the oil as saturated ozone product, but to the contrary almost instantaneously decreases, and in any case rather quickly due to the instability of the ozone itself and of the peroxides.

[0041] Therefore, according to the invention, the present method provides for ozonizing the oil up to saturation by means of a gaseous mixture comprising oxygen, ozone and noble or inert gases, the latter present in the gaseous flow insufflated into the oil in a quantity preferably comprised between 4 and 8% by weight.

[0042] Therefore, according to the invention, the aforesaid gaseous flow comprising oxygen, ozone and noble or insert gases is obtained by electrical discharge of a gaseous flow comprising ultrafiltrate oxygen in an amount at least equal to 92% by weight.

[0043] Advantageously, the gaseous flow insufflated into the oil can comprise any one of the following: helium, neon, argon, krypton, xenon, radon or also their mixtures, since it was verified, without wishing to be bound to any scientific theory, that their presence ensures a kind of "chemical mediation" which does not allow the formation of the aldehydes from the respective fatty acids due both to the action of the ozone and possibly to the presence of nitrogen, also in traces.

[0044] It is useful to indicate, in particular, that the effects due to the possible presence of nitrogen in the gaseous flow insufflated into the oil are actually cancelled by the presence of the aforesaid noble or inert gases, which advantageously "compete" with the nitrogen itself.

[0045] Therefore, it should be indicated that the use of a gaseous flow composed of a mixture of oxygen and ozone, which would derive from the electrical excitation of pure medical oxygen (99.9% oxygen), as in use in numerous methods of the prior art, would not benefit from a retardant and mediation action of the noble or inert gases as described above.

[0046] Also the use of a gaseous flow comprising ozone obtained via direct electrical excitation of ambient air would not have the same advantageous result as that obtained by the present invention, since the ambient air comprises numerous reactive compounds, several of which in considerably quantities including in particular nitrogen, which would largely cancel the effect of the aforesaid noble or inert gases.

[0047] That set forth above is of considerable importance in the context of the present invention, which is also directed to the use of the saturated and stable ozonized oil provided by the present method, in particular as product for cosmetic treatments or as medicament for topical use mainly directed to promote a vasal and tissue neoformation action in the treatment of numerous pathologies and diseases.

[0048] Preventing the formation of aldehydes in the present oil signifies preventing the astringent action that the aldehydes intrinsically possess, which could cancel or substantially reduce the effectiveness of the tissue or vasal neoformation or reparation mechanism which one wishes to obtain with the topical application on humans of the saturated and stable ozonized oil in accordance with the invention, as will be clearer from the following description.

[0049] The present method is preferably conducted at low pressure, advantageously not over 185 KPa and still more advantageously is conducted at room temperature, preferably at a temperature of 16-22°C, better yet 18-20°C.

[0050] Preferably, the aforesaid saturation and stabilization steps, i.e. the first and the second insufflation steps, are carried out consecutively without interruption.

[0051] Preferably, the ozone concentration in the gaseous flow insufflated in the second insufflation step is greater than the ozone concentration in the gaseous flow insufflated in the first insufflation step.

[0052] The increase of the ozone amount insufflated per cubic meter of gaseous flow or per time unit in the oil after its saturation is preferred, since it has been shown that the stabilization step is facilitated by a greater supply of ozone, an over-saturation equilibrium in such a manner being forced.

[0053] Preferably, the first and second insufflation steps are carried out such that the respective gaseous flows bubble from the bottom towards the top in the crossing of the oil, i.e. in the tank.

[0054] In accordance with the present method, the saturation with ozone of the oil is indicated through a measurement of the ozone concentration, and in particular in accordance with the invention by measuring the ozone concentration in the gaseous flow in a measurement point placed at the outlet of said tank (thus downstream of the oil or tank in a residual gaseous flow) and in a measurement point placed at the inlet of said tank (thus upstream of the oil or tank in an insufflated gaseous flow), or in any case before and after the passage of the gaseous flow in the oil.

[0055] A correspondence of the aforesaid measured ozone concentration values indicates that saturation has been reached.

[0056] In accordance with the invention, the saturation with ozone of the oil can also be detected by measuring the residence time that the insufflated gaseous flow takes for crossing the oil, i.e. the oil head inside said tank.

[0057] A maximum residence time value corresponds with a minimum speed of transit value through the oil by the gaseous flow.

[0058] In accordance with the invention, the stabilization of the ozone content in the saturated oil is indicated by a constant value, measured for a predetermined time interval or number of measurements, of the differential percentage of the aforesaid ozone concentration in the gaseous flow measured at a point upstream and downstream of said tank, or in any case determined by the gaseous flow insufflated in the oil head and in the residual gaseous flow.

[0059] In accordance with the invention, the stabilization of the ozone content in the saturated oil can also be indicated by a constant value, obtained for a predetermined time interval or number of measurements, of the aforesaid maximum value of the residence or travel time (or minimum speed of transit) through said head measured for the gaseous flow.

[0060] In practice, in accordance with the invention, the insufflation in the oil of the gaseous flow comprising oxygen, ozone and noble or inert gases, is continuous and extends for a time interval sufficient for oil saturation, and necessary for the stabilization of the saturated oil.

[0061] In detail, with the start of the first step of insufflating the gaseous flow comprising oxygen, ozone and noble gases into the oil, there begins the dissolution of the ozone in the oil and its combination with the unsaturated fatty acids contained in the oil itself.

[0062] The ozone (O_3), allotrope of oxygen (O_2), is composed of two stable oxygen atoms and a third unstable oxygen atom in so-called singlet configuration, characterized by a high tendency to accept electrons.

[0063] This tendency, which can be defined as "electron suction" capacity, is at the base of the ozone's oxidizing action.

[0064] During the continuous insufflation of the gaseous flow into the oil, and thus of ozone, this oxidizing capacity causes, over time, the saturation of the oil.

[0065] The ozone tends to occupy all of the sites provided with available electrons provided by the base components of the oil, oxidizing them, and moreover tends to dissolve itself in the oil-based vehicle.

[0066] The unsaturated fatty acids contained in the oil are then saturated.

[0067] In other words, the exposure of the oil to the gaseous flow comprising oxygen, ozone and noble or inert gases ensures that all the free electrons are "picked up or caught" (oxidation process) until the oil itself is saturated.

[0068] By maintaining the insufflation of the gaseous flow over time, i.e. after reaching saturation, a substantial equilibrium is reached so that, with certain conditions, the oil is stabilized.

[0069] In other words, during most of the first insufflation step of the gaseous flow, which corresponds to the saturation step, all of the insufflated ozone is retained by the oil, i.e. there is no ozone in the residual gaseous flow.

[0070] The difference of ozone concentration in the gaseous flow insufflated into the oil from the ozone concentration in the residual gaseous flow determines the concentration index of the ozone in the oil.

[0071] The more the oil is saturated, or better yet approaches saturation, the more the difference of ozone concentration between the gaseous flow put in the oil (insufflated gaseous flow) and the residual gaseous flow tends to decrease, tending towards zero.

[0072] That set forth above shows that the gaseous flow insufflated in the oil, during the passage in bubble form which crosses the oil, loses its ozone component, which is dissolved until the oil is saturated.

[0073] Therefore, the ozone concentration in the residual gaseous flow is about zero, until the saturation step has been completed which, therefore, in accordance with the present method, occurs from the bottom towards the top.

[0074] Continuing with the insufflation of the gaseous flow, one reaches an equilibrium situation between the afferent and efferent ozone concentration, i.e. substantial correspondence between the ozone concentrations measured in the gaseous flow insufflated in the oil and in the residual gaseous flow.

[0075] Once the saturation is completed, the aforesaid ozone concentration values are equivalent (equilibrium condition).

[0076] Continuing such correspondence over time, one then obtains the stabilization of the saturated oil.

[0077] In practice, a complete saturation is first attained, indicated by a zero difference between the concentration of ozone insufflated in the oil and the concentration of the residual ozone, while then the continuing repetition of the same differential percentage over time demonstrates the stabilization of the saturated oil, which changes state, passing from a sol to a gel.

[0078] The aforesaid stabilization is necessary so that the ozone saturated oil does not lose the saturation in a short time period, with consequent depletion of the high therapeutic capacities marking it, due to the dispersion of the ozone and alterations of the same oil due to the passing of time, and also to a possible unsuitable preservation of the oil as will be better illustrated below.

[0079] It should be observed that the ozone concentration in the gaseous flow insufflated into the oil is generally determined also by the quantity and type of oil to be saturated, but in any case always comprised in the medical ozone concentration range for human applications, i.e. between 10 and 80 g/m^3.

[0080] Lower concentrations did not prove to be very useful, while higher concentrations were dangerous and hard to manage.

[0081] That stated above is confirmed with the fact that the oxidation of the oil with ozone saturation leads to a thickening of the oil itself, which passes from the sol state to the gel state.

[0082] This is probably due to the fact that the transformation of the basal components of the oil and the saturation with ozone cause an increase of the molecular cohesion forces (surface tension).

[0083] In practice, with the present method, there will be a first fluidification of the oil, deriving from the molecular whirling motion due to the passage of ozone for insufflation of the gaseous flow, indicator of the capacity of the oil for combination reactions with the ozone, which can be indicated by a first decrease of the residence time value of the

gaseous flow in the oil, followed by a gelling (hardening) of the oil, by an increase of the surface tension forces of the same oil, with transformation of the polyunsaturated fats, which can be detected with the dilation of the residence time of the gaseous flow moving through the oil.

[0084] The measurement of the oil viscosity, in particular an increase of the viscosity following the insufflation of the gaseous flow, and thus a decrease of the gaseous flow speed of transit and hence an increase of the residence time, supports that stated above.

[0085] The surface tension forces increase the viscosity of the oil until a certain maximum level is reached, which can be inferred from the decrease of the gaseous flow residence or transit speed in the oil, which reaches a minimum value.

[0086] When the aforesaid maximum viscosity value, or minimum speed is reached, the oil saturation is obtained.

[0087] When the aforesaid minimum speed of transit value remains constant over time, i.e. constant for a predetermined time interval or measurement number, with a further continuous insufflation of the gaseous flow comprising oxygen, ozone and noble or inert gases, the stabilization has been obtained.

[0088] In substance, the denser the oil, the more the residence or transit speed decreases.

[0089] When the aforesaid speed of transit reaches a minimum value, which can be indicated chronometrically, for example, and the timing allows superimposing the data a number of times, the completion is obtained both of the saturation and stabilization.

[0090] It should be noted that the saturation and the stabilization (or their respective parameters) cannot be superimposed, if not after a certain over-insufflation period, probably since the saturation with a highly unstable gas like ozone allows the free electrons to occupy all the available sites, but with a bond that at first is extremely weak.

[0091] The over-saturation with ozone instead allows the stabilization of the oil, allowing the strengthening of all the bonds.

[0092] In this manner, the saturated and stabilized oil can transfer ozone and peroxides in particular thermal and pressure conditions, as will be clearer below.

[0093] A second aspect of the present invention is an apparatus for actuating the method described above, which essentially comprises, as illustrated in figure 1:

at least one oxygen generator-synthesizer 1;

at least one ozone generator 2 arranged downstream of the aforesaid oxygen generator-synthesizer 1 and in fluid communication therewith;

a first detection unit 3 for measuring an ozone concentration value in an insufflation gaseous flow coming from said ozone generator (afferent flow), arranged downstream of the aforesaid ozone generator 2;

a containment tank 4 of a pre-established oil-based (oil) vehicle arranged downstream of the aforesaid first detection unit 3, provided with inlet and outlet openings, in unidirectional fluid communication with said ozone generator;

an antireflux valve 5 arranged between the first detection unit 3 and the tank 4 for the aforesaid unidirectional fluid communication from the aforesaid ozone generator 2 to the aforesaid tank 4;

a second detection unit 6 for measuring an ozone concentration value in a residual gaseous flow (efferent flow), arranged downstream of the aforesaid tank 4 and in fluid communication therewith;

an ozone removal unit 7 arranged downstream of the aforesaid second detection unit 6 and in fluid communication therewith;

a transport duct 8 of a gaseous flow which achieves the aforesaid fluid communications and which comprises the aforesaid antireflux valve.

[0094] Preferably, the present apparatus also comprises a flow meter 9 arranged between the oxygen generator-synthesizer 1 and the ozone generator 2, as illustrated in figure 2.

[0095] The flow meter 9 can possibly be equipped with a humidifier in the figures, not shown.

[0096] Preferably, the aforesaid first and second detection units consist of a first and a second spectrophotometer, still indicated with 3 and 6, which preferably are arranged on respective branches of the duct 8.

[0097] In such case, the present apparatus comprises related first 10 and second 11 deflection valves for directing the insufflation gaseous flow and respectively the residual gaseous flow into such branches of the duct 8 towards the spectrophotometers 3 and 6, as illustrated in the example of figure 2.

[0098] In particular, in the section comprised between the ozone generator 2 and the tank 4, the present apparatus

comprises a pair of first deflection valves, hermetically sealed and ozone-resistant, which interrupt the flow in turn towards the tank 4 or towards the first spectrophotometer_3, alternatively deflecting the gaseous flow either towards the first spectrophotometer for measuring the concentration, in particular of ozone, of the gaseous flow entering the tank (insufflated gaseous flow), or towards the tank containing the oil for its ozonification.

[0099] Preferably, one of the aforesaid two first deflection valves, and in particular the valve directly upstream of the tank 4, coincides with the aforesaid anti-reflux valve 5, or in any case constitutes a single valve block therewith, in ozone-resistant material, as illustrated in the example of figure 2.

[0100] Analogous to that illustrated above with reference to the first spectrophotometer 3, a second pair of deflection valves are also provided, hermetically sealed and ozone-resistant, positioned downstream of the tank 4, and respectively a second deflection valve 11a positioned upstream of the ozone removal unit 7, and the aforesaid second deflection valve 11 arranged upstream of the second spectrophotometer 6 at the aforesaid branch of the duct 8, which interrupt the gaseous flow either towards the ozone removal unit or towards the second spectrophotometer, deflecting the gaseous flow either towards the second spectrophotometer, for measuring the concentration, in particular of ozone, of the gaseous flow exiting from the tank, or towards the removal unit of the residual ozone (figure 2).

[0101] Preferably, the ozone removal unit 7 consists of a catalyst filter for the conversion of residual ozone into oxygen.

[0102] Preferably, the present apparatus also comprises ozone indicators 12 (chemical nose) for indicating possible dispersions of the gaseous flow, thus of ozone, both in the insufflated gaseous flow and in the residual gaseous flow, as illustrated in the example of figure 2.

[0103] In particular, the aforesaid ozone detectors 12 are three in number and are arranged downstream of the ozone generator 2, upstream of the ozone removal unit 7 and downstream of the same ozone removal unit 7.

[0104] In accordance with one feature of the invention, the containment tank 4 of the pre-established oil-based (oil) vehicle is of the so-called vertical type, for example a column or drum with vertical axis, with height preferably equal to or greater than 200 cm.

[0105] Still in accordance with the invention, the aforesaid openings of the tank are specifically an inlet opening 13 and an opposite outlet opening 14 placed at related end portions of the tank, for the coupling respectively in inlet and in outlet of the gaseous flow transport duct 8.

[0106] For such purpose, it should be specified that the transport duct 8 of the gaseous flow is a connector duct between the different units or components of the present apparatus and therefore a duct which can be defined discontinuous, and which in the above-considered case does not physically cross the tank 4, as illustrated in the example of figure 2.

[0107] Preferably, the inlet opening 13 is formed at a base of the tank 4, i.e. the lower base or bottom of the vertical tank, while the ozone generator 2 is placed substantially at the same height as such inlet opening 13 in order to reduce to a minimum the resistances of the internal empty spaces of the duct 8 and of the entire apparatus.

[0108] Preferably, the present apparatus comprises two to four ozone generators arranged in series and actuatable independently from each other, such ozone generators being represented in the figures as single block 2.

[0109] Preferably, the present apparatus also comprises a controlling-governing PLC capable of automating the functioning, and thus all of the steps and functions previously described with reference to the production method of the ozonized oil according to the present invention.

[0110] In this manner, the production of a saturated oil-based vehicle is allowed at the maximum possible ozone and peroxide concentration.

[0111] In accordance with one embodiment of the present apparatus, described with particular reference to the example of figure 3, the tank 4 comprises an inlet opening 22 placed at an upper end portion thereof, advantageously at an upper base or head of the same tank, in which an outlet opening 23 is also provided.

[0112] The inlet 22 and outlet 23 openings allow the coupling in inlet and outlet of the transport duct 8 of the gaseous flow insufflated into the oil and residual gaseous flow, respectively.

[0113] In this case, the gaseous flow transport duct 8 also comprises an inner portion 28, inside the tank 4, which physically crosses the entire oil head contained in the tank 4.

[0114] In accordance with such embodiment, the portion 28 of the duct 8 has a closed and sealed end, in particular the lower end placed at the bottom of the tank 4, while it is distally provided, i.e. at the same lower end and for a length preferably comprised between 15 and 20 cm, with a series of lateral holes/nozzles 29, for the exit of the gaseous flow in the form of the smallest possible bubbles.

[0115] Also in this case, the ozone generator 2 is positioned at the same height as the inlet opening of the tank, thus at the head of the tank 4, in order to reduce to a minimum the internal empty spaces and the related resistances to the gaseous flow passage, as illustrated in the example of figure 3.

[0116] In practice, in such embodiment, the transport duct 8 of the gaseous flow is coupled in the tank 4 at the upper portion thereof, and crosses it with the aforesaid inner portion 28 immersed in the oil head, but the actual insufflation and bubbling of the gaseous flow in the oil head occurs in any case from the bottom towards the top by means of the aforesaid holes/nozzles 29 (figure 3).

[0117] Analogous to the embodiment previously described and illustrated with reference to figure 2, also the embodiment of the apparatus described with reference to the example of figure 3 is completed by a generator-synthesizer 1, detection units 3 and 6, an antireflux valve 5 and an ozone removal unit 7. In addition, possibly always analogous to that described above, such embodiment can comprise deflection valves 10, 11 and 11a, a flow meter 9 and ozone detectors, the latter not specifically illustrated.

[0118] In accordance with the invention, the apparatus described above in its different embodiments is possibly provided with a first piston 34 slidable in the tank 4 for drawing the saturated and stabilized oil, which prevents an excessive remixing of the oil and thus prevents the dispersion of the ozone contained therein, along with other possible alterations of the oil.

[0119] This is of considerable importance if one desires, as is the case here, to preserve the organoleptic characteristics and saturation of the oil obtained according to the present method and in accordance with the above-described apparatus.

[0120] For such purpose, as illustrated with particular reference to the embodiment of figure 4, wherein the present apparatus is partially represented, the tank 4 provides, at the bottom, at least one discharge opening 30, provided with hermetic shutter closure, housed in a threaded external pipe union 31 (male or female), of suitable caliber, from which it is possible to make the saturated and stabilized oil exit.

[0121] The pipe union 31 is in turn connected, by means of the screw thread, with a draw duct 32, it too provided with a corresponding screw terminal (not represented in the figures), which inserts the oil directly in pre-set suitable storage containers 33.

[0122] The aforesaid slidable piston 34, of the same caliber as the cylindrical tank 4, is hermetically sealed on the side wall of the tank, and is adapted to be pushed by a rear force from the top towards the bottom, allowing upon process completion the "squeezing" of the oil from the tank 4.

[0123] The aforesaid rear force can be obtained in various modes, for example by means of manual pushing, by pressure provided from suitably growing adjusted weights, correctly placed on the upper part of the piston 34, or by means of an electrical or mechanical hydraulic pump.

[0124] This permits extracting the saturated and stabilized oil by means of a uniform, slow and progressive squeezing, without there being whirling remixing, and above all so as to always maintain the surface of the oil in close contact with the containment walls of the tank 4, up to the filling of the storage containers 33.

[0125] In addition, since it should be considered useful to provide an ozonized oil lacking aldehydes and undesired by-products, and at the same time with ozone concentration less than that of saturation, in particular with reference to the use of the oil as medicament for the treatment of several specific pathologies, the present invention provides the possibility to mix/ dilute the oil at the suitable and desired ozone percentage.

[0126] In this case, a final product is obtained that is not completely ozonized, but whose ozonized aliquot is in any case ozonized to saturation.

[0127] Therefore, the present apparatus can possibly comprise a suitable mixing/dilution duct, in practice a sort of automatic mixing/dilution system, as illustrated with reference to the example of figure 5, wherein the present apparatus is partial represented.

[0128] In such case, a mixing duct 40 is provided, interposed between the tank 4 and the storage containers 33, wherein the ozonized oil coming from the tank 4 by means of the drawing duct 32 and a different diluent vehicle, for example a natural non-ozonized oil contained in a respective second tank 42 and conveyed by means of a dilution duct 43, are mixed.

[0129] In particular, the mixing duct 40 comprises respective portions of the aforesaid drawing 32 and dilution 43 ducts therein; such ducts independently convey therein, and extend counter-rotating spiral paths, one dextrorotary and one levorotary, in a number at least equal to ten.

[0130] The respective portions inside the mixing duct 40 of the aforesaid drawing 32 and dilution ducts 43 comprise, distributed along the aforesaid spirals, surface openings of progressively growing width which the duct 40 extends towards the storage containers 33.

[0131] The aforesaid openings of progressively growing size make, inside the mixing duct 40, a progressively growing fluid communication between the saturated ozonized oil and the non-ozonized dilution oil.

[0132] In practice, in the mixing duct 40 and in particular in the path of the counter-rotating spirals, the drawing duct and the dilution duct are initially isolated from each other, then in fluid communication by means of respective surface openings of reduced size, then in fluid communication by means of respective surface openings of increasing size, until there is a single common outflow or outlet mouth, coinciding with the outflow or outlet mouth of the mixing duct suitable for the direct communication with the storage tanks (figure 5).

[0133] In such a manner, the saturated ozonized oil and the non-ozonized oil are progressively mixed by the counter-rotating whirling path by means of a progressively growing contact, also maintaining at the same time a close contact with the walls respectively of the drawing duct and dilution duct, then as a single mixed and diluted oil of the mixing duct.

[0134] That stated above prevents there being a dispersion of ozone and peroxides during the mixing/dilution of the ozonized oil in accordance with the invention.

[0135] Advantageously, the diameters of the drawing ducts and dilution ducts can be provided with proportional caliber according to the dilution percentage that one wishes to obtain.

[0136] For example, the following may be provided:

a drawing duct 32 having a diameter of 5 mm for drawing the saturated oil, and a dilution duct 43 having a diameter of 5 mm for drawing the diluent oil, for obtaining a 50% dilution;

or

a drawing duct 32 having a diameter of 4 mm for drawing the saturated oil, and a dilution duct 43 having a diameter of 6 mm for drawing the diluent oil, for obtaining a 40% dilution; etc.

[0137] Also in this case, the present apparatus is preferably governed by a PLC, which advantageously can be the same type previously considered for the production process of the saturated and stable ozonized oil according to the invention.

[0138] That set forth above with reference to the mixing/dilution of the saturated and stable ozonized oil-based vehicle with a non-ozonized oil is also valid if one wishes to obtain a saturated oil comprising further compounds of therapeutic interest.

[0139] For example, the already considerably regenerating capacities of the present oil can be improved for the topical application in the treatment of specific pathologies, by means of addition of liposoluble vitamins, such as for example retinoid.

[0140] Retinoid is a compound chemically connected to Vitamin A, regulator of the growth of the epithelial cells, of cellular differentiation and proliferation, of bone tissue growth, of immune function as well as activator of tumor suppressor genes.

[0141] A further liposoluble vitamin compound, also of synthetic origin, which advantageously can be added to the saturated and stabilized oil according to the invention, is the menadione, or Vitamin K3.

[0142] Menadione is active in blood coagulation mechanisms.

[0143] For this reason, infective inflammatory lesions of the teguments with hemorrhage risk are positively affected by a treatment via topical use with saturated and stable ozonized oil according to the invention.

[0144] It is useful to remark once again that in any case the addition to the saturated and stable oil according to the invention of any compound or substance is in any case only and exclusively carried out at the end of the saturation and stabilization process of the oil itself.

[0145] Further details of the present invention are discussed below, such as the use of the actuation apparatus of the present method, experimental and technical data, specific embodiment examples and related advantages.

[0146] The present invention was advantageously made through the use of ozone derived from the ultrafiltrate oxygen with percentages not less than 92%.

[0147] As previously anticipated, the ozone derived by electrification of the atmospheric air is always polluted and is also produced with an unsatisfactory concentration percentage (too low).

[0148] The pollution, due to the production of nitrogen monoxide and other harmful substances, activated by the electrification of the atmospheric air comprising nitrogen, does not permit to obtain an ozonized oil free of risks for topical application on the human and animal body.

[0149] Moreover, the possibility to use high pressure oxygen bottles has also been excluded, due to the considerably dimensions possibly affected, due to the high operating pressure possibly used, for the limited autonomy of one such source, and also for the lack of safety in producing an ozonized oil lacking aldehydes without a specific supply source of noble or inert gases.

[0150] The present invention, therefore, is advantageously actuated by means of the use of an oxygen generator-synthesizer, since this solution ensures quite limited risks, if not nearly entirely absent, both since an oxygen synthesizer constitutes an inexhaustible source of oxygen, thus an absolute freedom of use, and also since it permits the production of a saturated and stable ozonized oil which is particularly suitable for human use.

[0151] The oxygen synthesizer or concentrator is an ultrafiltration apparatus which allows the extraction of a gaseous mixture containing 94 +/- 2% oxygen from the atmospheric air.

[0152] The ultrafiltrating or ultrafiltration apparatus allows the passage of oxygen molecules and that which, in the atmospheric air, has a molecular weight or size equal to or less than the oxygen itself.

[0153] For this reason, the gas exiting from the oxygen synthesizer is purified from the presence of nitrogen, which as considered above, in the passage into the ozone generator, would transform into nitrogen monoxide due to the excitation provided by the electrodes of the generator itself, with consequent pollution of the final oil-based vehicle , production of nitrates, and negative effects on the health of the patient in the topical use as medicament.

[0154] It should also be observed that the ultrafiltration also allows eliminating further undesired substances, such as

micro-particulates of various nature and other polluting gases present in the ambient air which have a molecular weight or size greater than that of the oxygen molecule (O_2).

[0155] The oxygen synthesizer also supplies the operating pressure of the insufflated gaseous flow (up to 185 kPa), and is suitable for supplying an oxygen flow with purity of not less than 96% for a gaseous flow up to 20 liters/minute and continuously supplied.

[0156] Regarding the generation of ozone, it should be added that the present apparatus preferably comprises two to four ozone generators arranged in series, each prearranged for the independent production of a specific hourly quantity of ozone.

[0157] Between the oxygen synthesizer and the first of the ozone generators, the flow meter is preferably arranged which regulates the speed of the oxygen flow (in liters/minute) that passes through the ozone generators.

[0158] Based on the principle that, within certain limits, the ozone concentration in gaseous mixture is inversely proportional to the speed of the oxygen flow which crosses the ozone generators, it is possible, by regulating the flow meter, to vary such speed and consequently control the ozone concentration available at the outlet in the gaseous flow which is insufflated into the oil.

[0159] Regarding the oil tank, it should be considered that the oil head contained therein preferably reaches 200 cm, since such height has been shown to be particularly suitable, at the method operating pressure, for obtaining a complete and quick saturation with ozone and stabilization of the oil.

[0160] In addition, an oil head of 200 cm, thus a tank of at least 200 cm, also allows a facilitated timing of the residence time of the gaseous flow through the oil-based vehicle, and a facilitated calculation of the related speed of transit, as well as a residence of the gaseous flow (per unit of volume flow) in the oil-based vehicle sufficient for ensuring that all of the ozone is dissolved, without there being ozone dispersions, at least until the start of the saturation step.

[0161] In other words, by providing a head of 200 cm of oil, the ozone quantity insufflated into the oil per unit of gaseous flow volume is completely dissolved, and it is not possible to detect the rate of residual ozone if not at the start of the saturation step.

[0162] In accordance with the invention, it has shown to be advantageous, in addition to reliable, to measure the speed of transit of the oil by means of timing, and in particular:

- in case of transparent type tank with ozone generator arranged at the base of the tank (insufflation from the bottom as in figure 1), the measurement is carried out by means of detection at the time when the gaseous flow - gas bubble - enters in the lower position of the tank, hence into the oil volume, and at the time when it exits from the top of the oil head.

[0163] A tank of this type particularly facilitates the observation for carrying out the aforesaid operation.

[0164] In this case, the internal path of the insufflation duct of the gaseous flow is reduced to a minimum and the unidirectional antireflux valve always exerts the same resistance to the "rear power" of the gaseous flow pushed by the oxygen synthesizer.

[0165] The "timing" therefore only and exclusively regards the residence time of the gaseous flow (gas bubble) through the oil head, from the entrance time to the outlet time in the same head.

- In case of transparent type tank and ozone generators arranged at the top of the tank (so-called top insufflation, as in figure 2), thus with insufflation duct having a portion inserted in, and of length equal to, the oil head, the timing is carried out from when the gas bubble exits from the distal holes/nozzles of the immersed portion of the insufflation duct to when it reaches the surface at the top of the oil head.

[0166] The transparency of the container is well adapted for carrying out this timing maneuver.

[0167] It should be observed that in this case the insufflation duct in its portion inside the oil head (immersed in the oil head) provides for being sealed at the top and laterally and distally perforated for a length of 15-20 cm with a plurality of nozzles with smallest possible caliber.

- In case of non-transparent tank but for example of opaque type and so-called bottom insufflated analogous to the example of figure 1, for the "timing" of the residence time taken by the gaseous flow for crossing the oil head, it is also necessary to calculate the residence time of the gaseous flow through the internal empty spaces and the moving time (transit time) through the unidirectional antireflux valve placed upstream of the oil tank.

[0168] In this case, the beginning of the timing is detected upstream of the aforesaid unidirectional antireflux valve.

[0169] A visual inspection from above allows detecting the time at which the gaseous flow penetrates into the oil-based vehicle to be saturated contained in the tank, after traveling through the hollow interior of the duct transporting the gaseous flow and moving through the antireflux valve.

[0170] The above is initially detected by the bubbling of the non-saturated oil (treatment start or sol phase), then by the expansion towards the top of the saturated oil (continuation of the treatment or gel phase).

[0171] From here, the gas bubble begins its path inside the tank and the timing of the time when it penetrates in the tank itself, shown from that stated above, up to the time when it reaches the surface, gives the residence time of the gas through the oil head.

[0172] The two data (residence time through the hollow transport interiors plus the residence time of the bubble through the oil head) tend, as said, to progressively expand as the saturation process advances and is completed. When these data reach the maximum limit, and when this maximum time limit is repeated several times, there is the proof both of the saturation and stabilization of the ozonification process of the oil-based vehicle according to the present invention.

- In case of the (opaque) non-transparent tank, with insufflation of the gaseous flow by means of insufflation duct having a portion immersed in the oil head (top insufflation) of length equal thereto, the closure by means of unidirectional antireflux valve is redundant and it is possible to calculate the speed of transit of the gaseous flow through the oil by starting the timing from the moment when the gaseous flow leaves the ozone generator, thus downstream of the same ozone generator, until the exit of the gas bubble from the liquid oil head.

[0173] Also in this case, the portion of the insufflation duct immersed in the oil head is sealed at the top and laterally and distally perforated for a length of 15-20 cm, with several nozzles of the smallest possible caliber.

[0174] A visual inspection from above allows detecting the time at which the gaseous flow penetrates into the containment tank, after traveling through the hollow interior of the insufflation duct, detected at the start by the bubbling of the non-saturated liquid (treatment start or sol phase), and then of the upward expansion of the saturated liquid (treatment continuation or gel phase).

[0175] From this moment (bubbling or upward expansion), the gas bubble starts its travel (residence) inside the tank and the timing from the time mentioned above to the time when the bubble reaches the surface of the oil head gives the speed of transit, and consequently, as a function of its increase, the density of the liquid (saturation index).

[0176] The two data (residence time through the hollow interior of the insufflation duct and the residence time of the gas bubble inside the oil head) tend to progressively expand as the saturation process is completed. When these data reach the maximum limit, and when this datum is repeated several times, the stabilization of the medium is obtained.

[0177] In such case, it should be observed that the speed of the gaseous flow does not remain constant in the path of the duct portion immersed in the oil, since even if the thrust provided by the synthesizer remains unchanged, it is opposed by the resistance force due both to the weight per cm^2 of the liquid head to be crossed and to the density of the same.

[0178] In this case, therefore, there is an increase of the related residence times of the gaseous flow through the oil head, in particular caused by the increase of the viscosity of the oil, which the denser it becomes, the slower the movement of the gas bubble, and by the interior residence time of the gaseous flow, i.e. the residence time through the duct portion immersed in the oil which in such case is affected by the weight of the liquid head, which lies on the bottom of the container, and by the resistance to the passage of the gaseous flow due to the increase of the surface tension forces of the oil (thickening from sol to gel).

[0179] In summary, in practice the decrease both of the speed of transit (crossing speed) of the gaseous flow through the oil-based substrate and the decrease of the ozone concentration difference between the gaseous flow entering into the oil head and that exiting from the oil head attest both the stabilization index and the saturation index.

[0180] In the second case (saturation), the data must reach zero, in the first case (stabilization) they must be repeatedly superimposed for several measurements (preferably at least 3, carried out at time intervals of 24 hours from each other).

[0181] Since the method requires the use of considerable quantities of high concentration ozone, it is suitable to provide for an apparatus which is overall hermetically sealed, and an ozone removal unit, so as to reconvert the residual ozone into oxygen, of proven effectiveness.

[0182] As stated above, for improved safety, it is preferably to provide in the apparatus, at critical points thereof, i.e. downstream of the external zone of the ozone generator, upstream and downstream of the ozone removal unit, respective ozone detectors calibrated for detecting the ozone rate, preferably equal to 10 parts per billion. Such measurement attests the perfect seal of the apparatus and the effectiveness of the ozone removal unit for inserting a residual gaseous flow into the atmosphere that substantially lacks ozone.

[0183] That stated above also advantageously allows standardizing the present saturation and stabilization process of an ozonized oil, precisely calculating the total quantity (amount) of ozone necessary for the saturation and stabilization of a certain quantity of a specific oil.

[0184] Such standardization is possible from the knowledge:

- of the concentration in grams per cubic meter of the ozone present in the gaseous flow insufflated into the oil;

- of the flow unit.

[0185] Based on the aforesaid parameters, it is possible to calculate the quantity of insufflated ozone (expressed in grams) necessary for saturating the measurement unit (expressed in liters) of oil.

[0186] For example, a gaseous flow comprising oxygen, ozone and noble gases of 1.5 liters per minute, with ozone concentration of 31 grams x m^3, in the span of 24 hours (1.5 liters/minute for 1440 minutes, number of minutes in 24 hours) corresponds with 2160 liters of gaseous mixture insufflated into the tank.

[0187] If for every m^3 of mixture, 31 grams of ozone (31/1000 gr/m^3 concentration) are insufflated into the oil, in the span of one day (24 hours), 66.96 grams of ozone were insufflated (2160 : 1000 = x : 31, so that 2160x31/1000 = 66.96).

[0188] Knowing the time necessary in the present case, according to that described above, for the saturation and stabilization of the oil (which in the specific case of the example reported here is a sunflower oil having characteristics as illustrated in table 1 of figure 6-6a, and with 45 days as minimum) and the exact quantity of the saturated oil (12,400 liters), it is possible to calculate how much total ozone is necessary for carrying out the saturation and stabilization method according to the invention:

45 (number of days) x 66.96 (quantity of ozone per day) = 3.0132 (total ozone quantity in kg),

dividing such quantity for the total oil quantity:

3.0132 (total ozone quantity in kg: 12,400 (total oil quantity in liters) = 243 g (ozone quantity per liter) = 243 grams of ozone per liter of oil.

[0189] Then, knowing the total quantity of ozone necessary for treating a liter of a specific oil, at predetermined temperature and pressure values it is possible to infer how much ozone is necessary for the saturation and stabilization of any amount of that specific oil type.

[0190] Of course, possible concentration variations in the insufflated flow can allow the completion of the process in a quicker or slower manner (within certain limits), as a function of the above proportions.

[0191] In particular, the present method on the aforesaid sunflower oil, carried out for experimental purposes as a non-limiting descriptive example, lead to the obtainment of saturated and stable ozonized oil with characteristics as illustrated in table 2 of figure 7.

[0192] In detail, the aforesaid experimentation is characterized for the following parameters:

- total capacity of the oil containment tank: 14 liters
- height of the oil containment tank: 220 cm
- height of the oil column: 190 cm
- amount of oil treated: 12,400 liters

[0193] Oxygen Source:

- synthesis oxygen generator (synthesizer)
- concentration range: with 1-2 liters/min flow, 94 +/- 2% oxygen concentration; with 2-5 liters/min flow, 92 +/- 4% oxygen concentration
- incorporated flow meter: range from 0 to 5 liters per minute

[0194] Ozone Source:

- two ozone generators, 500 mg/hour when supplied with atmospheric air, connected in series;
- an additional ozone generator, 500 mg/hour when supplied with atmospheric air, which starts functioning at the end of the saturation process, for the purpose of stabilization.

[0195] With the first two generators connected in series, without obstacles downstream of the O_3 generators, we obtain the following concentrations:

O_2 flow liters/minute	O_3 concentration grams/m^3
1.0	43
1.5	32
2.0	24
2.5	20
3.0	17
3.5	15
4.0	13
4.5	11
5.0	10
With the addition of the third O_3 generator, always without obstacles downstream of ozone generators, we obtain the following parameters:	
O_2 flow liters/minute	O_3 concentration grams/m^3
1.0	52
1.5	38
2.0	29
2.5	24
3.0	20
3.5	18
4.0	16
4.5	14
5.0	12

[0196] The measurement was carried out with spectrophotometer calibrated for a concentration range from 0 to 123 grams/m^3. The process took place at a constant temperature of 19°C. We established this sequence order for the start of functioning of the oxygen generators due to the fact that the stabilization method required a supply of ozone greater and at high concentration than that necessary for the saturation process.

[0197] The experimentation started on 28/04/2008 at 11.24am. Sunflower oil is used whose composition is attached to the producer chart. Ozone is inserted in the column; such ozone is generated by a continuous 24 hour a day flow of oxygen for 1.5 liters/minute made to pass through the first two O_3 generators for 33 days and afterward through the three O_3 generators until the 46^{th} day. The average of the ozone concentrations inserted in the liquid during the entire process, equal to 31 grams of oxygen per m^3, results from the sum of the O_3 percentage inserted in the first part of the treatment with that inserted in the second part of the treatment. (32 +/- 3 and 38 +/- 4 : (30 x 33 = 990) + (34 x 13 = 442) / 46) = about 31

Date	Time	Timing of the gas residence time in seconds	Ozone concentration at the outlet, the average inlet concentration being established at 31 grams/liter
30/04/2008	14.10	10.14	0.00
30/04/2008	19.43	11.51	0.00
01/05/2008	11.55	10.79	0.01
02/05/2008	11.35	11.21	0.01
03/05/2008	9.05	11.60	0.02
04/05/2008	12.15	11.64	0.02

(continued)

Date	Time	Timing of the gas residence time in seconds	Ozone concentration at the outlet, the average inlet concentration being established at 31 grams/liter
05/05/2008	9.30	11.62	0.03
06/05/2008	14.10	11.59	0.03
07/05/2008	11.15	12.07	0.03
08/05/2008	11.45	12.28	0.03
09/05/2008	12.05	12.12	0.02
10/05/2008	12.02	11.19	0.00
11/05/2008	11.45	12.02	0.00
12/05/2008	13.30	12.50	0.01
13/05/2008	11.50	12.60	0.01
14/05/2008	11.35	12.56	0.01
15/05/2008	11.20	12.55	0.01
16/05/2008	11.20	12.99	0.00
17/05/2008	11.30	12.94	0.00
18/05/2008	12.40	13.07	0.00
19/05/2008	13.20	13.92	0.00
20/05/2008	12.30	14.47	0.00
21/05/2008	12.45	15.19	0.00
22/05/2008	11.45	16.02	0.00
23/05/2008	11.50	18.40	0.00
24/05/2008	12.00	21.11	0.00
25/05/2008	19.30	23.63	0.00
26/05/2008	14.15	21.56	0.00
27/05/2008	12.00	27.00	0.00
28/05/2008	12.00	23.21	0.00
29/05/2008	14.10	29.11	0.00
30/05/2008	10.50	30.96	0.00
31/05/2008	9.10	31.03	0.00
01/06/2008	15.17	37.86	0.00
3rd ozone generator turned on for stabilization			
02/06/2008	11.50	35.01	0.00
03/06/2008	9.15	36.54	0.02
04/06/2008	11.20	34.94	0.04
05/06/2008	11.35	39.63	0.05
06/06/2008	11.45	42.03	0.09
07/06/2008	11.55	46.54	0.10

(continued)

3rd ozone generator turned on for stabilization			
08/06/2008	12.30	55.49	0.14
09/06/2008	11.00	48.90	0.21
10/06/2008	11.25	51.34	0.28
11/06/2008	11.30	49.14	0.34
12/06/2008	11.40	49.52	0.35
13/06/2008	12.40	48.95	0.34
14/06/2008	10.05	49.21	0.34

End of treatment

[0198] The advantages of the present invention, already clear during the above description, can be briefly summarized by noting that the invention provides a method and a related apparatus for making a saturated and stabilized ozonized oil-based vehicle as considered above, free of undesired substances including mainly aldehydes, carried out at low pressure and room temperature, therefore particular safe, easy to carry out and economical.

[0199] The saturated ozonized oil obtained by means of the present method has shown to be particularly effective in releasing ozone and peroxides passing from a temperature comprised between +4 and +10°C, at which it can advantageously be better preserved, to a temperature comprised between +30 and +37°C, which advantageously corresponds to the normal application temperature (body temperature).

[0200] The topical application of the oil (pure and impure) on the human organism leads to a heating of the oil, which slows the cohesion forces (surface tension), passing from sol to gel and allows the on-site *[in situ]* release of the dissolved ozone.

[0201] The biocide capacity of the oil has its logical explanation in this method (ozone release) and the oxidizing action of ozone.

[0202] In practice, the oil is "loaded" with ozone, since later, under specific conditions, the ozone is "unloaded" (when necessary).

[0203] Along with this disinfectant action, there is another extraordinary property of the present oil, i.e. the neoangiogenetic and fibroblastogenetic properties.

[0204] Ozone is a strong oxidizing agenty; nevertheless, at specific concentrations and in specific administration modes, it paradoxically acts as an antioxidant.

[0205] This is because the target organism, when it comes into contact with ozone, only under specific conditions, reacts by initiating all of its antioxidant mechanisms.

[0206] This reaction is called "reaction via adaptation to the oxidative stress" and also leads to a violent excitation of the immune system.

[0207] The sum of the two properties of the oil-based vehicle (biocide capacities, added to the stimulation by adaptation to the oxidative stress) explains the powerful disinfectant and tissue regenerator capacities of the present oil.

[0208] The action of the present oil is extremely specific and is briefly exhausted on the target tissues, without directly or indirectly involving other apparatuses, due to the capacity of the ozone to bind itself to the electron donors in very short time periods.

[0209] The preferred clinical indications of the present oil, given its organoleptic characteristics, used at the most suitable dilution concentration established from time to time according to the treated pathologies, are the following:

1) Torpid ulcers from blood circulation reduction: phlebitis, thrombophlebitis etc., gaseous gangrene, diabetes, from hypothermia with septic complications.

2) 2nd and 3rd degree burns, infected and non-infected. In these cases, the present oil can be employed:

- for direct aspersion, as spread with sterile spatula directly on the lesion, which is then covered with sterile protection medicament;
- with the affixing of gauzes drenched with oil, pre-packaged in sealed and sterile containers.

3) Infections of the terminal section of the urinary tracts: a good treatment system of infectious urethritis and cystitis is that of sprinkling the evacuation catheter with which the patient is treated with the present oil, before the insertion of the same in the urethral canal.

4) Hemorrhoids - anal rhagades - infected proctitis: the oil is applied by directly aspersion with sterile spatula or by intra-anal insertion with suitable thrust pump.

5) Skin diseases in general: in these cases, the present oil is applied directly on the lesion by means of direct spreading with sterile spatula and with application of ozone-resistant medicated gauze soaked with the present oil, pre-packaged in sealed and sterile containers.

6) Fistular passages (in oral cavities, in perianal region, at the ano-coccygeal raphe, residues from surgery operations). In this case, the present oil is squeezed directly into the fistular passage by means of sterile pressure pump.

7) Herpes simplex, impetigo or not, or otherwise, rhagades of the labial commissure. In this case, the present oil is sprinkled directly on the lesion by means of a small single-use spatula, preferably sterile, left in-situ without cover.

8) Skin mycosis. In this case the present oil is sprinkled directly on the mycosis with sterile spatula, then covering the part with sterile breathable closure bandage.

9) Skin parasitosis. In this case the present oil is sprinkled directly on the mycosis with sterile spatula, and then covering the part with non-breathable sterile closure bandage.

10) Skin smoothing. In case of skin smoothing applications, the present oil is sprinkled directly on the part as a common cream, drawing it from the package with a preferably sterile single-use small spatula.

11) Cellulite. In case of application for cellulite reabsorption, the present oil is applied directly on the part with sterile spatula, and then covering the skin with non-breathable closure bandage. In this case, since the application can regard extensive body parts, with consequent absorption of a considerably amount of ozone (since the ozone has a direct action on the fatty acids), it is appropriate the therapy is carried out under the direct control of a particularly qualified physician, at least for the first few applications.

12) Inflammatory infective pathologies of the oral cavity:

a: ONJ (osteonecrosis of the mandible from biphosphonate use). In all the infected or non-infected mucous-osteonecrotic lesions caused by the use of biphosphonates, which appear in the oral cavity, the present oil is applied by direct aspersion on the lesion by means of sterile syringe, and waiting ten minutes before drug action, or by direct aspesion through negative impression of the dental rima and soft and hard supporting tissues sprinkled with the present oil. The impression, carried out with ozone-compatible material, applied in oral cavity, after medicament aspersion acts as a waterproof container, allowing the liberated gas to penetrate even into the deepest recesses without there being dispersion in the air. The effects of the present oil on the mucous-osteonecrotic lesions of the oral cavity from biphosphonate use are the subject of an in-depth study by several excellent Italian hospitals (IRCSS), observed by the Italian Ministry of Health.

The action of the present oil has led patients who had been deemed incurable to make incredible recoveries. The direct aspersion on the lesions with negative impression, as reported above, of the present ozonized oil, brought the ozone contained and dissolved therein in direct contact with the exposed necrotized bone parts and the infected parts of the surrounding mucus membranes. Here, the ozone transported by the oil carried out the following actions:

- biocide action, with a strong disinfectant and cleansing effect;
- regeneration action, with a concrete action of biostimulation to the tissue and vasal regeneration;
- chelating action, which allows the transformation of the necrotizing agent (biphosphonate) into an amorphous compound.

It has been shown that the biphosphonate, entering into the bone metabolism, in certain areas of the body reaches concentrations such that it loses its characteristic biocide action aimed towards the osteoclasts, in order to become

an indiscriminate necrotizing agent.
It has also been shown that the effusion of the bone tissue of the maxilla by this agent (biphosphonate) lasts for years. It has finally been shown that the in-situ residence of the biphosphonate causes the lesion, and above all it does not permits curing the lesion, by inhibiting the organism's cicatricial reparation processes.
In such situation, the ozone comes into contact with this necrotizing agent and eliminates it by chelating it, and thus the organism's expulsion and reparation processes - up to now inhibited - can finally begin.
In fact, the healing of the lesions occurs with a sequester mechanism of the necrotized tissues and expulsion of the same, with regeneration of the underlying and perilesional tissue. It should be stressed that the absence of the aldehydes of the fatty acids from the oil-based vehicle according to the present method facilitates the reparation and cicatricial action of the ozonized oil, since the astringent mechanism typical of the aldehydes is not present (this would otherwise compete with the oil's reparation action).
Endodontics:

- In devitalizations, it is opportune to spread the present oil on the canal tools, such that the oil penetrates into the canals, having the treatment be followed with the normal canal closure procedure.

- Acute and gangrenous pulpitis are treated in the following manner: remove the inflamed or necrotic pulp, then push the oil into the canals with a smoothed point syringe. Leave in-situ with closed or open medication, depending on the putrefactive processes for several days. Repeat the procedure if necessary. Upon healing, the normal canal closure procedure is carried out.

- The canal retreatments, also in the presence of apical lesions, must be treated in the following manner: after having removed the canal contents, insert the present oil and proceed with the tool cleaning of the canal. Leave the oil in-situ for several days with closed or open medication, depending on the putrefactive processes for several days. Upon healing, the normal canal closure procedure is carried out.

- Also apical granuloma can heal by applying this procedure: opening the canal, piercing the apex and injecting the present oil into the lesion through the apical aperture. Repeat the operation until the lesion is reabsorbed and apex closed.

- The abscesses are treated with: opening of the lesion, draining, and then in-situ infiltration of the present oil with smoothed point syringe. Repeat the operation until healing.

c. Implantology

- Implants can be positively affected by the following treatment: after having prepared the cavity for the positioning of the implant, infiltrate the same with the present oil and then position the implant.

- Also the peri-implants can heal by: infiltration with the present oil into the lesion with smoothed point syringe. Repeat the operation for 3-4 days until healing.

d. Periodontology

- Acute gingivitis is treated with: cleaning with tartar removal from the gingival recesses, then brushing the present oil on all the gingival rings and waiting 8/ 10 minutes before rinsing. Possibly repeat the brushing after 3-4 days.

- Acute purulent serum gingivitis can be treated with: cleaning with tartar removal. Impression of the dental rima with silicon paste which covers the gingival border. Removing the impression from the impression opening, brushing the impression with the present oil.

Repositioning the oil-brushed impression in the oral cavity. Waiting 10 minutes, then removing the impression and rinsing. Repeat the operation every 3-4 days for 3 or 4 times until healing.

- the gingival pockets are treated in the following manner:

    1. single: infiltration of the present oil into the lesion with smoothed point syringe, after such syringe has been carefully cleaned. Waiting 5/6 minutes and rinse. Repeat the operation every 3-4 days for 4-6 times.

2. multiple: tartar removal, impression of the dental rima with silicon paste which covers the gingival border. Removing the impression from the impression opening. Brushing the impression with the present oil, infiltration of the lesions with the present oil with syringe with smoothed needle. Repositioning the oil-brushed impression in the oral cavity. Waiting 10 minutes. Removing the impression and rinsing. Repeating the operation every 3-4 days for 8/10 times until healing.

- Periodontal disease is treated in this manner: tartar removal, impression of the dental rima with silicon paste which covers the gingival border. Removing the impression from the impression opening. Brushing the impression with the present oil. Repositioning the oil-brushed impression in the oral cavity. Waiting 10 minutes. Removing the impression and rinsing. Repeating the operation every 3-4 days for 8/10 times.

- The periodontal surgery operations are positively affected by the following treatment: once the surgery operation has concluded, before suture, infiltrate the present oil into the wound with smoothed point syringe, and then suture. After the suture, infiltrate the oil once again on the borders of the wound and on the stitches, cover with surgical compress. Remove after 7 days.

e. oral surgery: avulsions, apicectomies, surgical removal of neoformations of various type etc. are treated in the following manner: at the end of the operation, before suture, infiltrate the present oil into the lesion, and then suture. After suture, sprinkle with the present oil. Along with the present oil, allo- and hetero-plastic materials can be employed.

f. Aphthae are brushed, with single-use cotton flock or brush directly on the lesion, with the present oil, to be left in-situ for 10 minutes.

13) Eye symptoms: carefully evaluating the concentration-dilution use percentages established from time to time, depending on the infectious pathologies to be treated, the present oil can be used as anti-infective ophthalmic ointment, squeezed directly in the conjunctival sac.

14) Gastro-esophagus pathologies: in this case, the use of the present oil must occur with the assumption by the patient of capsules filled with oil, which can be dissolved inside the gastric sac. Given the preparation characteristics, the preferred indications are the following:

- Gastro-esophagus ulcers from biphosphonate use

- Gastro-duodenal ulcers sustained by the presence of Helicobacter Pylori.

Treatment of cavities.

[0210] To the present invention in its illustrated and described embodiments, in order to satisfy specific and contingent needs, a man skilled in the art can make numerous modifications, all of which moreover contained within the scope of protection of the invention, as defined by the following claims

Claims

1. Method of production of a saturated and stable ozonized oil-based vehicle, comprising:

providing a pre-established amount of a pre-established unsaturated oil-based vehicle inside a tank;
a first insufflation step wherein a continuous gaseous flow comprising oxygen, ozone and at least one noble or inert gas is insufflated into said oil-based vehicle, until said oil-based vehicle is saturated with ozone;
a second insufflation step wherein a continuous gaseous flow comprising oxygen, ozone and at least one noble or inert gas is insufflated into said oil-based vehicle saturated with ozone, until a constant ozone concentration value is obtained in said oil-based vehicle for at least a pre-established time interval or number of measurements, with the stabilization of said saturated oil-based vehicle.

2. Method according to claim 1, wherein said gaseous flow insufflated in said first and second insufflation step comprises at least one noble or inert gas in a quantity between 4 and 8% by weight.

3. Method according to claim 1 or 2, wherein said at least one noble or inert gas is chosen from the group comprising helium, neon, argon, krypton, xenon, radon or their mixtures.

4. Method according to any one of the preceding claims, wherein said gaseous flow is obtained via electrical discharge of a gaseous flow comprising ultrafiltrate oxygen in an amount equal to at least 92% by weight.

5. Method according to any one of the preceding claims, wherein said first and second insufflation steps are carried out consecutively, without interruption.

6. Method according to any one of the preceding claims, wherein said first and second insufflation steps are carried out in a manner such that the respective insufflated gaseous flows bubble from the bottom towards the top in said tank.

7. Method according to any one of the preceding claims, wherein said first and second insufflation steps are carried out at a pressure less than or equal to 185 Kpa.

8. Method according to any one of the preceding claims, wherein said first and second insufflation steps are carried out at substantially constant temperature.

9. Method according to any one of the preceding claims, wherein the temperature of said oil-based vehicle in said first and second insufflation steps is comprised between 16 and 22°C.

10. Method according to any one of the preceding claims, wherein the ozone concentration in said gaseous flow insufflated in said second insufflated step is greater than the ozone concentration insufflated in said first insufflation step.

11. Method according to any one of the preceding claims, wherein said ozone saturation of said oil-based vehicle is indicated by an ozone concentration value measured in said gaseous flow at the outlet of said tank substantially corresponding to an ozone concentration value measured at an inlet point of said tank.

12. Method according to any one of claims 1 to 10, wherein said ozone saturation of said oil-based vehicle is indicated by a maximum value of the residence time, or minimum value of the speed of transit through the liquid oil-based vehicle head inside said tank.

13. Method according to claim 11 or 12, wherein said stabilization of the ozone content in said saturated oil-based vehicle is indicated by a constant value, measured for a predetermined time interval or number of measurements, of the differential percentage of said ozone concentration detected in the gaseous flow upstream and downstream of said tank.

14. Method according to claim 12, wherein said stabilization of the ozone content in said saturated oil-based vehicle is indicated by a constant value, measured for a pre-established time interval or number of measurements, of said maximum value of the residence time, or said minimum value of the speed of transit, through said head.

15. Method according to any one of claims 1-10, wherein for a given oil-based vehicle, the time for reaching said constant ozone concentration value is based on a pre-established quantity of ozone insufflated into said oil-based vehicle.

16. Method according to any one of claims 1-10, wherein for a given oil-based vehicle, said constant ozone concentration value is reached on the basis of a pre-established total amount of ozone insufflated into said oil-based vehicle in a pre-established time interval, and wherein said number of measurements is equal to zero or one.

17. Apparatus for carrying out the method according to any one of the preceding claims, comprising:

at least one oxygen generator-synthesizer (1);
at least one ozone generator (2) arranged downstream of said oxygen generator-synthesizer (1) and in fluid communication therewith;
a first detection unit (3) for measuring an ozone concentration value in a gaseous insufflation flow coming from said ozone generator (2), arranged downstream of said ozone generator (2);
a containment tank (4) of a pre-established oil-based vehicle arranged downstream of said first detection unit (3), provided with inlet (13) and outlet (14) openings for a gaseous flow, in unidirectional fluid communication with said ozone generator (2);

an antireflux valve (5) arranged between said first detection unit (3) and said tank (4) for the aforesaid unidirectional fluid communication from said ozone generator (2) to said tank (4);
a second detection unit (6) for measuring an ozone concentration value in a residual gaseous flow, arranged downstream of said tank (4) and in fluid communication therewith;
an ozone removal unit (7) arranged downstream of said second detection unit (6) and in fluid communication therewith;
a gaseous flow transport duct (8) which achieves said fluid communications, comprising said antireflux valve.

18. Apparatus according to claim 17, further comprising a flow meter (9) arranged between said oxygen generator-synthesizer (1) and said ozone generator (2).

19. Apparatus according to claim 17 or 18, wherein said first and second detection units consist of a first and a second spectrophotometer.

20. Apparatus according to claim 19, wherein said first and said second spectrophotometers are arranged in respective branches of said transport duct (8), and said apparatus comprises respective deflection valves upstream of said first and said second spectrophotometer.

21. Apparatus according to any one of claims 17-20, wherein said ozone removal unit (7) consists of a catalyst filter for converting residual ozone into oxygen.

22. Apparatus according to any one of claims 17-21, wherein said tank is of so-called vertical type.

23. Apparatus according to claim 22, wherein said tank consists of a drum, preferably of height $\geq$ 200 cm.

24. Apparatus according to any one of claims 17-23, wherein said inlet and outlet openings are respectively arranged at a lower end and at an upper end of said tank (4), and wherein said ozone generator (2) is arranged substantially at the same height as said inlet opening (13).

25. Apparatus according to any one of claims 17-23, wherein said inlet (13) and outlet (14) openings are arranged at an upper end of said tank (4), and wherein said gaseous flow transport duct comprises a inner portion inside said tank, said inner portion having a closed end distally provided with a plurality of superficially arranged holes/nozzles (29).

26. Apparatus according to any one of claims 17-25, comprising two to four ozone generators arranged in series, which can be actuated independently from each other.

27. Apparatus according to any one of claims 17-26, further comprising a piston (34) slidable in said tank (4).

28. Apparatus according to any one of claims 17-27, further comprising a drawing duct (32) for the transport of said oil-based vehicle from said tank (4) and a dilution duct (43) for the transport of a further vehicle from a second tank (42), said drawing and dilution ducts being at least in part contained in a common mixing duct, inside of which they are provided with respective surface openings of increasing width, in which counter-rotating spiral paths develop.

29. Apparatus according to any one of claims 17-28, further comprising a controlling-governing PLC for the automation of the functioning of said apparatus.

30. Use of an ozonized oil-based vehicle obtained by means of the method according to any one of claims 1-16 for the production of a medicament for the topical treatment of a disease comprised in the group including phlebitis, gaseous gangrene, thrombophlebitis, diabetes, from hypothermia, infected and non-infected bums, urinary tract infections, hemorrhoids, anal rhagades, infected proctitis, skin infections in general, fistulas in oral cavity, in perianal region, at the ano-coccygeal raphe, residues from surgery operations, herpes simplex, impetiginous or otherwise, rhagades of the labial commissure, skin mycosis, skin parasitosis, inflammatory infectious diseases of the oral cavity including osteonecrosis of the jaw from biphosphonate use, cavities, acute and gangrenous pulpitis, apical granuloma, abscesses, gingivitis, periodontal disease, aphthae, eye diseases, gastro-esophagus pathologies, gastro-esophagus ulcers from biphosphonate use, gastro-duodenal ulcers sustained by the presence of Helicobacter Pylori.

31. Use of an ozonized oil-based vehicle obtained by means of the method according to any one of claims 1-16 for the

topical treatment of skin blemishes, such as cellulite, and for skin smoothing.

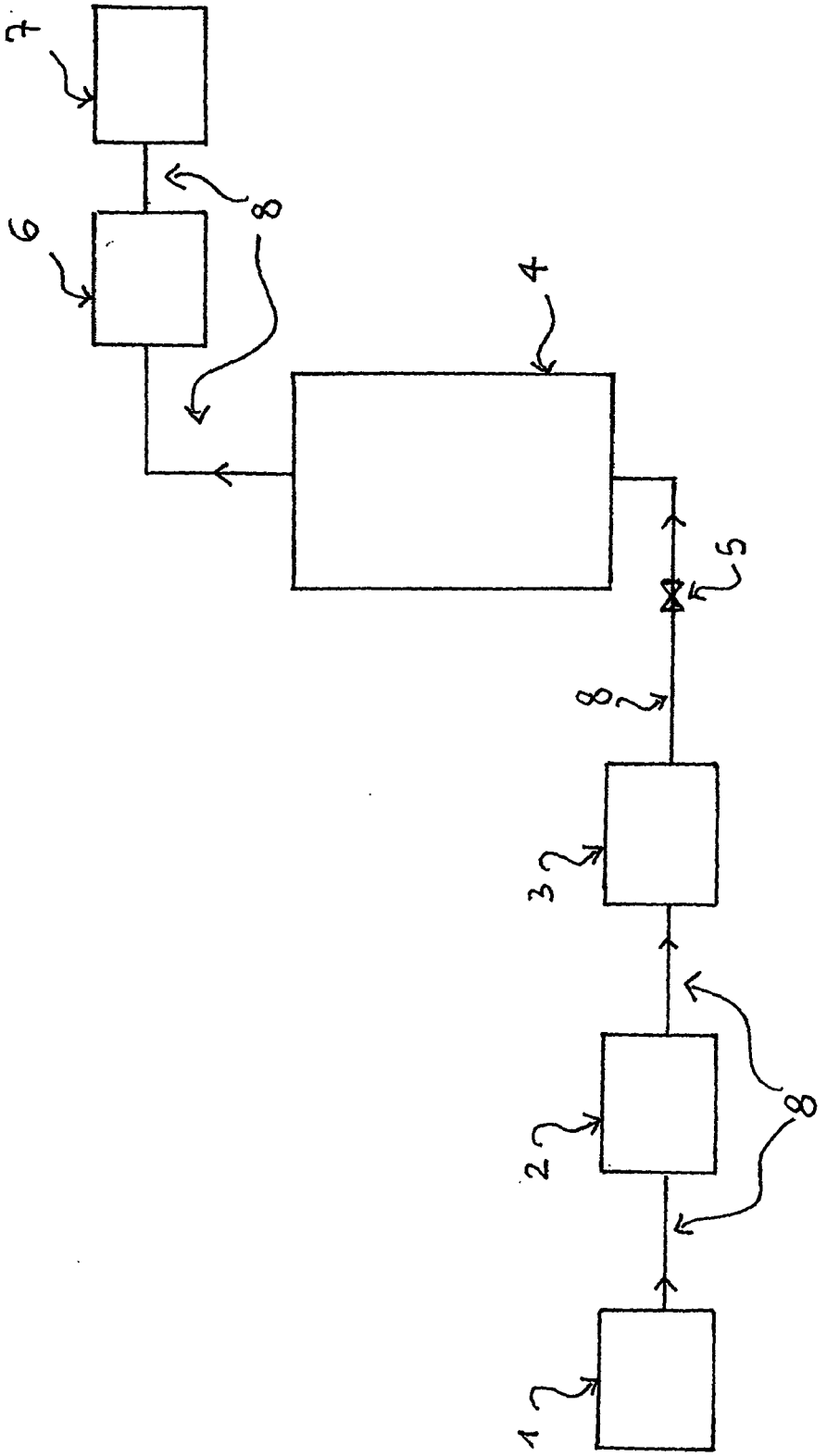

Fig. 1

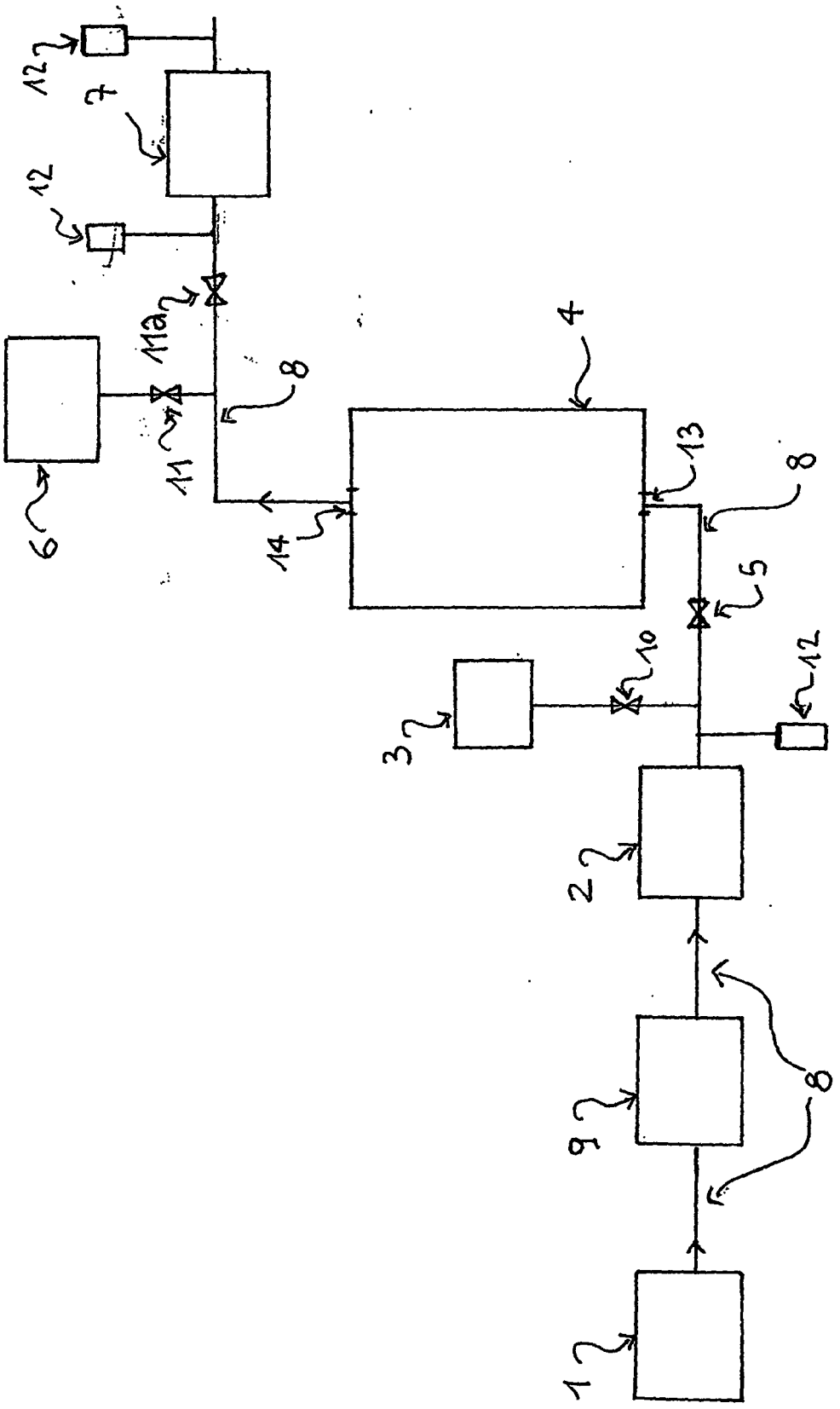

Fig. 2

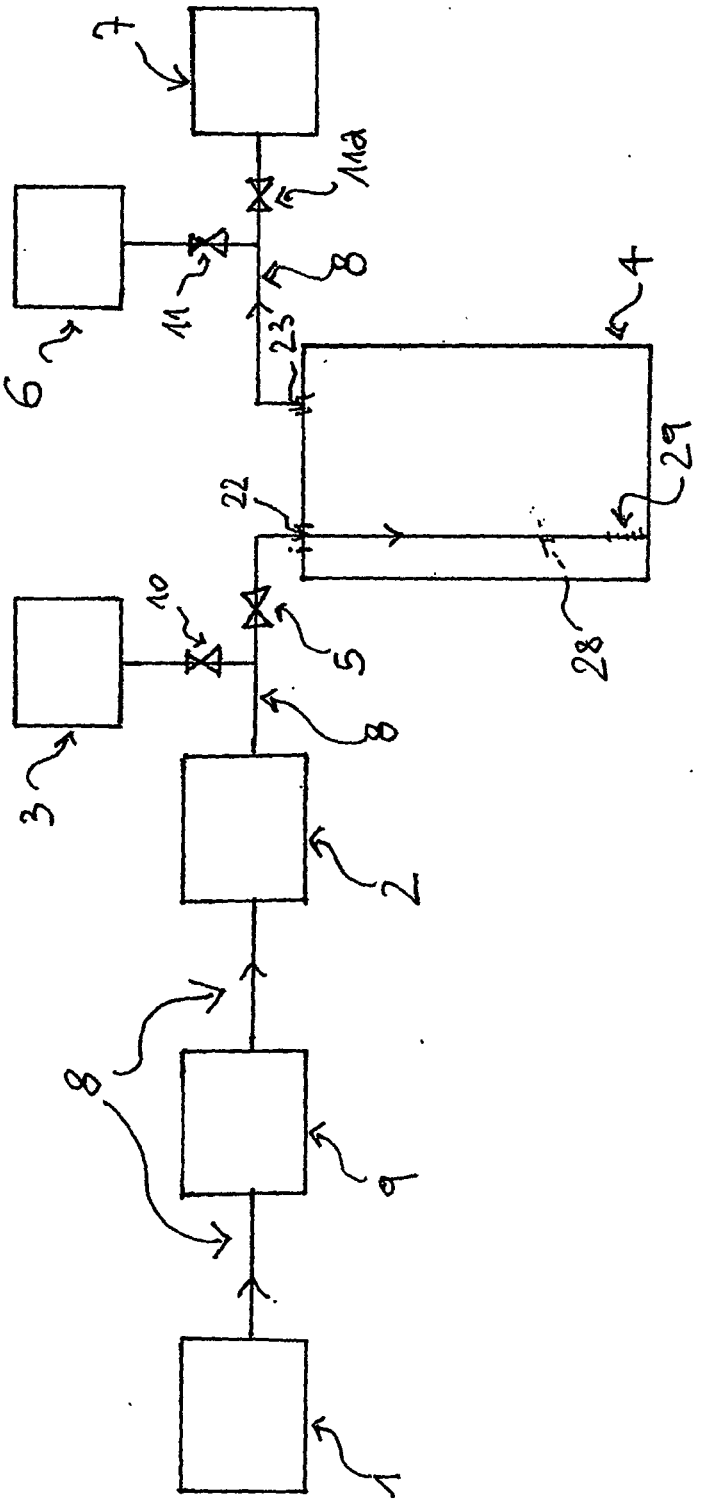

Fig. 3

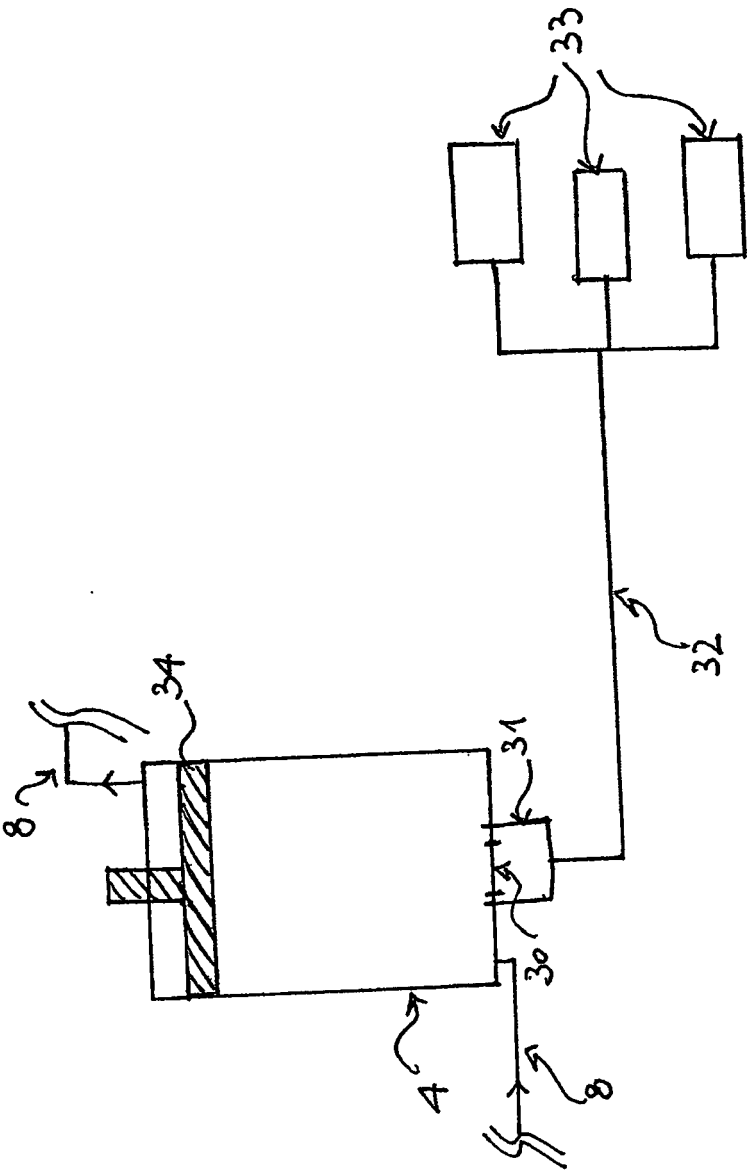

Fig. 4

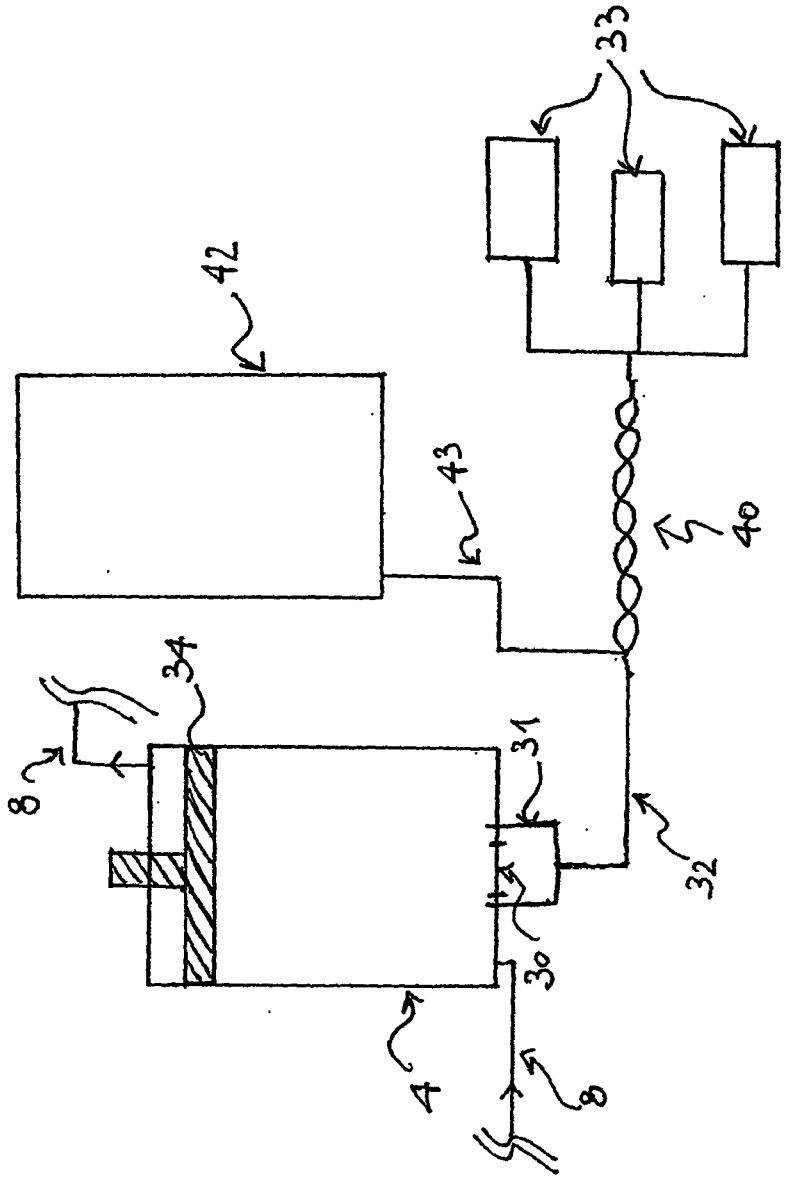

Fig. 5

Table 1

Sunflower oil

description: for refined sunflower oil it is intended the oil extracted from the seeds of Helianthus Annuus with high linoleic acid content, and subjected to the refining process

flavor and smell: neutral, typical of sunflower oil, without outside flavors

Chemical-physical characteristics

	measurement unit	Min	Max	used method
relative density at 20/20°C	Kg/dm^3	0,918	0,923	NGD C18
absorption 420 nm			0,20	(1/1 V/V in n-exane)
			0,10	(1/1 V/V in n-exane)
number of iodine (Wijs)	gr I_2/100gr	118	141	(NGD C32 - 1976)
(oleic) acidity	%	—	0,15	(NGD C10 - 1976)
number of peroxides	meqO_2/Kg		7	(NGD C35 - 1976)
impurity (petroleum ethers)	%		0,05	(ISO 663 - 1992)
soaps (sodium oleate)	mg/Kg		10	(NGD C8 - 1976)
solvents: hexane	mg/Kg		1	(ISO9832 - 1992)

Composition of the fatty acids

fatty acid	measurement unit	Min	Max	Metodo impiegato
myristic acid	%	ND	0,2	ISO5508
palmitic acid	%	5,0	7,6	ISO5508
palmitoleic acid	%	ND	0,3	ISO5508
heptadecanoic acid	%	ND	0,2	ISO5508
heptadecanoic acid	%	ND	0,1	ISO5508
stearic acid	%	2,7	6,5	ISO5508
oleic acid	%	14,0	39,4	ISO5508
linoleic acid	%	48,3	74,0	ISO5508
linoleic acid	%	ND	0,3	ISO5508
arachidic acid	%	0,1	0,5	ISO5508
eicosenoic acid	%	ND	0,3	ISO5508
behenic acid	%	0,3	1,5	ISO5508
erucic acid	%	ND	0,1	ISO5508
lignoceric acid	%	ND	0,5	ISO5508

Fig. 6

continued

Table 1

Metals				
Metal	measurement unit	Min	Max	used method
iron	mg/Kg		1,5	ISO 8294 - 1994
copper	mg/Kg		0,1	ISO 8294 - 1994
lead	mg/Kg		0,1	ISO 12193 1994
arsenic	mg/Kg		0,1	A.O.A.C 963.21 (1990)
Sterol composition				
Sterols	measurement unit	Min	Max	used method
cholesterols	%	ND	0,5	NGD C71
brassicasterol	%	ND	0,2	NGD C71
24-methylene cholesterol	%		§	NGD C71
campesterol	%	6,5	13,0	NGD C71
campestanol			§	NGD C71
stigmasterol	%	6,0	13,0	NGD C71
delta 7-campesterol	%		§	NGD C71
delta 5,23-stigmastadienol	%		§	NGD C71
chlerosterol	%		§	NGD C71
β-sitosterol	%	50,0	70,0	NGD C71
sitostanol	%		§	NGD C71
delta 5-avenasterol	%	ND	6,9	NGD C71
delta 7,9(,11)-stigmastadienol	%		§	NGD C71
delta 5,24-stigmastadienol	%		§	NGD C71
delta 7-stigmastenol	%	6,5	24,0	NGD C71
delta 7-avenasterol	%	3,0	7,5	NGD C71
sterol content	mg/Kg	1700	5000	NGD C72
smoke point	200° C	flash point		> 230°C
antioxidants	deadening agent NITROGEN	aromatizers		not used

ND: indeterminable (less than 0.05%)

§: the components indicated with such symbol, for which no limit was set,

must not be taken under consideration for the purposes of the purity evaluation

Fig. 6a

Table 2

Parameters			
test	test result	measurement unit	test method
pH	4,0	pH unit	APAT CNR IRSA 2060 Man. 29:2003
acid composition			
capronic acid	17,8	%	NGD C41:1976 + NGD C42:1976
hexanoic acid	7,3	%	NGD C41:1976 + NGD C42:1976
caprylic acid	9,6	%	NGD C41:1976 + NGD C42:1976
heptanoic acid	2,3	%	NGD C41:1976 + NGD C42:1976
azelaldehyde acid	8,0	%	NGD C41:1976 + NGD C42:1976
azelaic acid	38,2	%	NGD C41:1976 + NGD C42:1976
pentanoic acid	0,1	%	NGD C41:1976 + NGD C42:1976
palmitic acid	8,9	%	NGD C41:1976 + NGD C42:1976
stearic acid	5,0	%	NGD C41:1976 + NGD C42:1976
oleic acid	2,7	%	NGD C41:1976 + NGD C42:1976

Controlled parameters			
test	test result	measurement unit	test method
pH	4,0	pH unit	APAT CNR IRSA 2060 Man. 29:2003
acid composition :			
caproic acid	8,3	%	NGD C41:1976 + NGD C42:1976
caprylic acid	1,4	%	NGD C41:1976 + NGD C42:1976
azelaldehyde acid	9,4	%	NGD C41:1976 + NGD C42:1976
azelaic acid	27,9	%	NGD C41:1976 + NGD C42:1976
palmitic acid	13,0	%	NGD C41:1976 + NGD C42:1976
myristic acid	0,2	%	NGD C41:1976 + NGD C42:1976
stearic acid	8,2	%	NGD C41:1976 + NGD C42:1976
behenic acid	1,4	%	NGD C41:1976 + NGD C42:1976
margaric acid	0,2	%	NGD C41:1976 + NGD C42:1976
lignoceric acid	0,4	%	NGD C41:1976 + NGD C42:1976
pelargonic acid	10,0	%	NGD C41:1976 + NGD C42:1976
Others:			
nonanal acid	7,4	%	NGD C41:1976 + NGD C42:1976
octanal dimethyl acetal acid	12,2	%	NGD C41:1976 + NGD C42:1976

Fig. 7

Europäisches Patentamt
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EUROPEAN SEARCH REPORT

Application Number
EP 08 42 5531

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	8 January 2009	Saettel, Damien

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 08 42 5531

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08-01-2009

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EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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