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(54) **Title**: COMPOSITION AND METHOD FOR TREATMENT OF COGNITIVE IMPAIRMENT

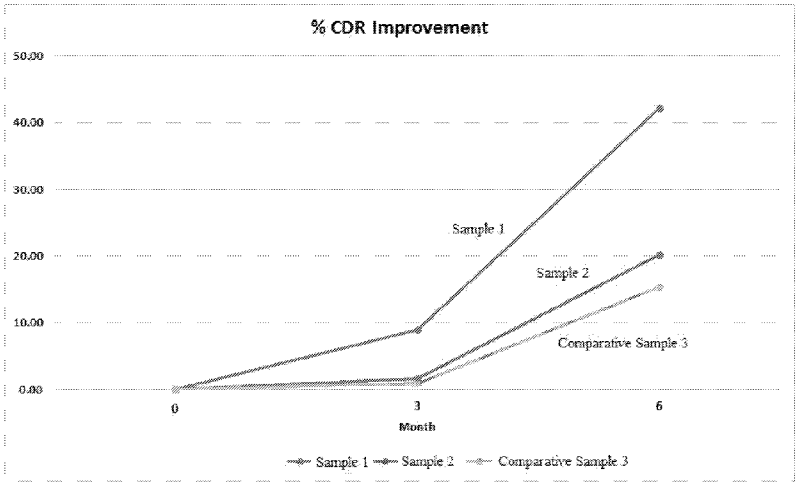

FIGURE 3

(57) **Abstract**: The present invention, in embodiments, is a composition and method of treatment using a composition that includes: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; 4 to 15 weight percent of soy lecithin; 0.05 to 1 weight percent of biotin; and 0.01 to 0.2 weight percent of antiox - idant, wherein the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

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COMPOSITION AND METHOD FOR TREATMENT OF COGNITIVE IMPAIRMENT

DESCRIPTION

RELATED APPLICATION

[0001] This application claims the priority of U.S. provisional application Ser. No. U.S.S.N. 62/307,714, entitled "COMPOSITION FOR TREATMENT OF NEURODEGENERATIVE DISEASES," filed March 14, 2016, which is incorporated herein by reference in its entirety for all purposes

BACKGROUND OF INVENTION

[0002] Neurodegenerative diseases are known.

TECHNICAL FIELD

[0003] The present invention relates to compositions for treatment of neurodegenerative disease.

BRIEF SUMMARY OF INVENTION

[0004] In embodiments, the present invention is a composition that includes: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; 4 to 15 weight percent of soy lecithin; 0.05 to 1 weight percent of biotin; and 0.01 to 0.2 weight percent of antioxidant, wherein the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

[0005] In embodiments, the composition includes 85 to 97 weight percent of the medium chain triglycerides. In yet other embodiments, the composition includes 8 to 15 weight percent of the soy lecithin. In other embodiments, the composition includes 1 weight percent of the biotin.

[0006] In another embodiment, the composition includes 0.1 to 0.2 weight percent of the antioxidant. In yet other embodiments, the composition further includes 0.05 weight percent to 0.11 weight percent of folic acid.

[0007] In yet other embodiments, the composition includes: 85 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon acid esters of glycerol; 5 to 10 weight percent of soy lecithin; 0.05 to 0.2 weight percent of biotin; and 0.01 to 0.2 weight percent of antioxidant, wherein the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

[0008] In other embodiments, the present invention is a method of treatment of cognitive impairment including: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 5% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition includes: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon acid esters of glycerol; and 4 to 15 weight percent of soy lecithin.

[0009] In yet other embodiments, the effective amount includes 15 to 25 grams per dose and two to four doses per day. In embodiments, the effective amount includes 15

grams per dose and three to four doses per day. In other embodiments, the effective amount includes 17 grams per dose and three doses per day.

[00010] In yet other embodiments, the effective amount includes 50 grams per day. In embodiments, the method of treatment includes a composition that further includes at least one of: 0.05 to 1 weight percent of biotin or 0.01 to 0.2 weight percent of antioxidant. In embodiments, the composition includes an antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

[00011] In yet other embodiments, the present invention is a method of treatment of cognitive impairment including: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 25% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition includes: a first component comprising: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon acid esters of glycerol; 4 to 15 weight percent of soy lecithin; and olive oil.

[00012] In embodiments, a weight ratio of the first component to the olive oil is 2:1 to 1:2. In yet other embodiments, the weight ratio of the first component to the olive oil is 1:1.

[00013] In embodiments, the effective amount comprises 15 to 25 grams per dose and two to four doses per day. In yet other embodiments, the effective amount comprises 15 grams per dose and three to four doses per day. In yet other embodiments, the effective amount comprises 17 grams per dose and three doses per day and the weight ratio of the first component to the olive oil is 2:1 to 1:2.

[00014] In embodiments, the method includes a composition that further includes at least one of: 0.05 to 1 weight percent of biotin or 0.01 to 0.2 weight percent of antioxidant. In yet other embodiments, the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[00015] FIG. 1 illustrates a non-limiting method of making embodiments of the present invention.

[00016] FIG. 2 illustrates the results a nematode study of embodiments of the present invention.

[00017] FIG. 3 illustrates the results of a human study of embodiments of the present invention.

[00018] FIG. 4 illustrates the specifications of olive oil used in the human study.

[00019] FIG. 5 illustrates the specifications of olive oil used in the human study.

[00020] FIG. 6 illustrates the specifications of olive oil used in the human study.

[00021] FIG. 7 illustrates the specifications of olive oil used in the human study.

[00022] The figures constitute a part of this specification and include illustrative embodiments of the present invention and illustrate various objects and features thereof. Further, the figures are not necessarily to scale, some features may be exaggerated to show details of particular components. In addition, any measurements, specifications and the like shown in the figures are intended to be illustrative, and not restrictive. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but

merely as a representative basis for teaching one skilled in the art to variously employ the present invention.

DETAILED DESCRIPTION

[00023] The present invention will be further explained with reference to the attached drawings, wherein like structures are referred to by like numerals throughout the several views. The drawings shown are not necessarily to scale, with emphasis instead generally being placed upon illustrating the principles of the present invention. Further, some features may be exaggerated to show details of particular components.

[00024] The figures constitute a part of this specification and include illustrative embodiments of the present invention and illustrate various objects and features thereof. Further, the figures are not necessarily to scale, some features may be exaggerated to show details of particular components. In addition, any measurements, specifications and the like shown in the figures are intended to be illustrative, and not restrictive. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a representative basis for teaching one skilled in the art to variously employ the present invention.

[00025] Among those benefits and improvements that have been disclosed, other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying figures. Detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely illustrative of the invention that may be embodied in various forms. In addition, each of the examples given in connection with the various embodiments of the invention which are intended to be illustrative, and not restrictive.

[00026] Throughout the specification and claims, the following terms take the meanings explicitly associated herein, unless the context clearly dictates otherwise. The

phrases “in one embodiment” and “in some embodiments” as used herein do not necessarily refer to the same embodiment(s), though it may. Furthermore, the phrases “in another embodiment” and “in some other embodiments” as used herein do not necessarily refer to a different embodiment, although it may. Thus, as described below, various embodiments of the invention may be readily combined, without departing from the scope or spirit of the invention.

[00027] In addition, as used herein, the term "or" is an inclusive "or" operator, and is equivalent to the term "and/or," unless the context clearly dictates otherwise. The term "based on" is not exclusive and allows for being based on additional factors not described, unless the context clearly dictates otherwise. In addition, throughout the specification, the meaning of "a," "an," and "the" include plural references. The meaning of "in" includes "in" and "on.

[00028] As used herein, the term “clinical dementia rating” or “CDR” is used to determine the “treatment of cognitive impairment.” CDR is a global assessment instrument used in clinical trials and longitudinal research projects to rate the presence and severity of cognitive problems in Alzheimer disease and related disorders. The CDR rates the severity of Alzheimer disease using a 5-point scale that rates the severity of signs and symptoms as they affect the patient’s ability to function in the 6 cognitive categories of memory, orientation, judgment and problem solving, community affairs/ involvement, home life and hobbies, and personal care. Although designed for use with patients with a probable diagnosis of AD, the CDR is appropriate for use in the assessment of dementia that is associated with other medical disorders (e.g., Lewy body disease). The CDR rating varies as follows:

0 = Normal

0.5 = Very Mild Dementia
1 = Mild Dementia
2 = Moderate Dementia
3 = Severe Dementia

[00029] The CDR is completed by the researcher or a clinician after performing a face-to-face, semi-structured interview with the patient and a reliable informant such as a spouse or other family member/caregiver. The informant is interviewed first, and the results of that interview are used to assess patient recall of events and to confirm the accuracy of patient responses. In each cognitive category the patient receives a score of 0 (no cognitive impairment) to 3 (severe cognitive impairment). The CDR can be scored to obtain a global score by using an algorithm that weights memory more heavily than the other categories, or it can be scored using the sum of boxes (SOB) method in which all categories are weighted equally; in general, the higher the score, the greater the severity of dementia

[00030] The CDR can be administered and interpreted in any setting in which a patient requires evaluation or treatment for AD or other dementia, including inpatient and outpatient healthcare settings and community settings (e.g., during provision of in-home care by a home health nurse; as part of a public health screening program)

[00031] The CDR is administered and interpreted by trained healthcare clinicians who provide treatment to patients with suspected or known dementia and/or medical conditions that are known to correspond with dementia based, at least in part, on the information in Table 1 below:

Table 1

CLINICAL DEMENTIA RATING (CDR):	0	0.5	1	2	3

	Impairment				
	None 0	Questionable 0.5	Mild 1	Moderate 2	Severe 3
Memory	No memory loss or slight inconsistent forgetfulness	Consistent slight forgetfulness; partial recollection of events; "benign" forgetfulness	Moderate memory loss; more marked for recent events; defect interferes with everyday activities	Severe memory loss; only highly learned material retained; new material rapidly lost	Severe memory loss; only fragments remain
Orientation	Fully oriented	Fully oriented except for slight difficulty with time relationships	Moderate difficulty with time relationships; oriented for place at examination; may have geographic disorientation elsewhere	Severe difficulty with time relationships; usually disoriented to time, often to place	Oriented to person only
Judgment & Problem Solving	Solves everyday problems & handles business & financial affairs well; judgment good in relation to past performance	Slight impairment in solving problems, similarities, and differences	Moderate difficulty in handling problems, similarities, and differences; social judgment usually maintained	Severely impaired in handling problems, similarities, and differences; social judgment usually impaired	Unable to make judgments or solve problems
Community Affairs	Independent function at usual level in job, shopping, volunteer and social groups	Slight impairment in these activities	Unable to function independently at these activities although may still be engaged in some; appears normal to casual inspection	No pretense of independent function outside home Appears well enough to be taken to functions outside a family home	Appears too ill to be taken to functions outside a family home
Home and Hobbies	Life at home, hobbies, and intellectual interests well maintained	Life at home, hobbies, and intellectual interests slightly impaired	Mild but definite impairment of function at home; more difficult chores abandoned; more complicated hobbies and interests abandoned	Only simple chores preserved; very restricted interests, poorly maintained	No significant function in home
Personal Care	Fully capable of self-care		Needs prompting	Requires assistance in dressing, hygiene, keeping of personal effects	Requires much help with personal care; frequent incontinence

Score only as decline from previous usual level due to cognitive loss, not impairment due to other factors.

[00032] As used herein, the term "olive oil" means a lipid pressed from ripe olives. A non-limiting example of olive oil according to the present invention is shown in Figures 4 to 7.

[00033] As used herein, the term "Lipidbrain" corresponds to an embodiment of a lipidic blend of the present invention.

[00034] In embodiments, the present invention is a composition that includes: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon acid esters of glycerol; 4 to 15 weight percent of soy lecithin; 0.05 to 1 weight percent of biotin; and 0.01 to 0.2 weight percent of antioxidant, wherein the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

[00035] In embodiments, the composition includes 85 to 97 weight percent of the medium chain triglycerides. In yet other embodiments, the composition includes 8 to 15 weight percent of the soy lecithin. In other embodiments, the composition includes 1 weight percent of the biotin.

[00036] In another embodiment, the composition includes 0.1 to 0.2 weight percent of the antioxidant. In yet other embodiments, the composition further includes 0.05 weight percent to 0.11 weight percent of folic acid.

[00037] In yet other embodiments, the composition includes: 85 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; 5 to 10 weight percent of soy lecithin; 0.05 to 0.2 weight percent of biotin; and 0.01 to 0.2 weight percent of antioxidant, wherein the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

[00038] In other embodiments, the present invention is a method of treatment of cognitive impairment including: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 5% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition includes: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon acid esters of glycerol; and 4 to 15 weight percent of soy lecithin.

[00039] In yet other embodiments, the effective amount includes 15 to 25 grams per dose and two to four doses per day. In embodiments, the effective amount includes 15 grams per dose and three to four doses per day. In other embodiments, the effective amount includes 17 grams per dose and three doses per day.

[00040] In yet other embodiments, the effective amount includes 50 grams per day. In embodiments, the method of treatment includes a composition that further includes at least one of: 0.05 to 1 weight percent of biotin or 0.01 to 0.2 weight percent of antioxidant. In embodiments, the composition includes an antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

[00041] In yet other embodiments, the present invention is a method of treatment of cognitive impairment including: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 25% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition includes: a first component comprising: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6

to 12 carbon fatty acid esters of glycerol; 4 to 15 weight percent of soy lecithin; and olive oil.

[00042] In embodiments, a weight ratio of the first component to the olive oil is 2:1 to 1:2. In yet other embodiments, the weight ratio of the first component to the olive oil is 1:1.

[00043] In embodiments, the effective amount comprises 15 to 25 grams per dose and two to four doses per day. In yet other embodiments, the effective amount comprises 15 grams per dose and three to four doses per day. In yet other embodiments, the effective amount comprises 17 grams per dose and three doses per day and the weight ratio of the first component to the olive oil is 2:1 to 1:2.

[00044] In embodiments, the method includes a composition that further includes at least one of: 0.05 to 1 weight percent of biotin or 0.01 to 0.2 weight percent of antioxidant. In yet other embodiments, the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

[00045] In some embodiments, the present invention is a method of treatment of neurodegenerative disease comprising orally administering an effective amount of a composition to a human of a composition to reduce a rate of onset or magnitude of the neurodegenerative disease when compared to a human administered olive oil alone.

[00046] In some embodiments, the cognitive impairment is a result of a neurodegenerative disease including, but not limited to, Very Mild Dementia, Mild Dementia, Moderate Dementia, Severe Dementia, Alzheimer's Disease, progressive supranuclear palsy; a dementia; Creutzfeldt-Jacob disease, frontotemporal dementia, Pick's disease, Frontotemporal Dementia with Parkinsonism-17 corticobasal degeneration, frontotemporal lobe degeneration; Huntington's Disease; or Parkinson's Disease.

[00047] In some embodiments, the present invention is a composition that may be used for the treatment and/or prevention of neurodegenerative disease. In some embodiments, the composition is a lipidic blend. In some embodiments, the composition can be taken by a subject to improve memory, cognitive performance, and concentration, and could be used as a treatment for or a preventative against neurodegenerative diseases, including Alzheimer's disease.

[00048] In some embodiments, the present invention is a composition, comprising: 75 to 97 weight percent of medium chain triglycerides. In some embodiments, the present invention is a composition, comprising: 75 to 90 weight percent of medium chain triglycerides. In some embodiments, the present invention is a composition, comprising: 75 to 85 weight percent of medium chain triglycerides. In some embodiments, the present invention is a composition, comprising: 75 to 80 weight percent of medium chain triglycerides. In some embodiments, the present invention is a composition, comprising: 80 to 97 weight percent of medium chain triglycerides. In some embodiments, the present invention is a composition, comprising: 85 to 97 weight percent of medium chain triglycerides. In some embodiments, the present invention is a composition, comprising: 90 to 97 weight percent of medium chain triglycerides. In some embodiments, the present invention is a composition, comprising: 80 to 90 weight percent of medium chain triglycerides.

[00049] In some embodiments, the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol. In some embodiments, the medium chain triglycerides comprise 6 to 10 carbon fatty acid esters of glycerol. In some embodiments, the medium chain triglycerides comprise 6 to 8 carbon fatty acid esters of glycerol. In some embodiments, the medium chain triglycerides comprise 8 to 12 carbon fatty acid esters of

glycerol. In some embodiments, the medium chain triglycerides comprise 10 to 12 carbon fatty acid esters of glycerol. In some embodiments, the medium chain triglycerides comprise 8 to 10 carbon fatty acid esters of glycerol.

[00050] In some embodiments, the composition comprises 4 to 15 weight percent of lecithin. In some embodiments, the composition comprises 4 to 13 weight percent of lecithin. In some embodiments, the composition comprises 4 to 11 weight percent of lecithin. In some embodiments, the composition comprises 4 to 9 weight percent of lecithin. In some embodiments, the composition comprises 4 to 7 weight percent of lecithin. In some embodiments, the composition comprises 4 to 5 weight percent of lecithin.

[00051] In some embodiments, the composition comprises 6 to 15 weight percent of lecithin. In some embodiments, the composition comprises 8 to 15 weight percent of lecithin. In some embodiments, the composition comprises 10 to 15 weight percent of lecithin. In some embodiments, the composition comprises 12 to 15 weight percent of lecithin. In some embodiments, the composition comprises 14 to 15 weight percent of lecithin. In some embodiments, the composition comprises 6 to 13 weight percent of lecithin. In some embodiments, the composition comprises 8 to 10 weight percent of lecithin.

[00052] In some embodiments, the lecithin is soy lecithin.

[00053] In some embodiments, the composition comprises 0.05 to 1 weight percent of biotin. In some embodiments, the composition comprises 0.05 to 0.8 weight percent of biotin. In some embodiments, the composition comprises 0.05 to 0.6 weight percent of biotin. In some embodiments, the composition comprises 0.05 to 0.4 weight percent of biotin. In some embodiments, the composition comprises 0.05 to 0.2 weight percent of

biotin. In some embodiments, the composition comprises 0.1 to 1 weight percent of biotin. In some embodiments, the composition comprises 0.3 to 1 weight percent of biotin. In some embodiments, the composition comprises 0.5 to 1 weight percent of biotin. In some embodiments, the composition comprises 0.7 to 1 weight percent of biotin. In some embodiments, the composition comprises 0.9 to 1 weight percent of biotin.

[00054] In some embodiments, the composition comprises 0.1 to 0.8 weight percent of biotin. In some embodiments, the composition comprises 0.3 to 0.6 weight percent of biotin. In some embodiments, the composition comprises 0.4 to 0.5 weight percent of biotin. In some embodiments, the composition comprises 0.05 to 0.08 weight percent of biotin.

[00055] In some embodiments, the composition comprises 0.01 to 0.2 weight percent of antioxidant. In some embodiments, the composition comprises 0.01 to 0.15 weight percent of antioxidant. In some embodiments, the composition comprises 0.01 to 0.10 weight percent of antioxidant. In some embodiments, the composition comprises 0.01 to 0.05 weight percent of antioxidant. In some embodiments, the composition comprises 0.05 to 0.15 weight percent of antioxidant. In some embodiments, the composition comprises 0.1 to 0.15 weight percent of antioxidant. In some embodiments, the composition comprises 0.05 to 0.1 weight percent of antioxidant. In some embodiments, the composition comprises 0.01 to 0.03 weight percent of antioxidant.

[00056] In some embodiments, the composition comprises folic acid. In some embodiments, the composition comprises 0.01 weight percent to 0.2 weight percent folic acid. In some embodiments, the composition comprises 0.03 weight percent to 0.2 weight percent folic acid. In some embodiments, the composition comprises 0.07 weight percent to 0.2 weight percent folic acid. In some embodiments, the composition comprises 0.1

weight percent to 0.2 weight percent folic acid. In some embodiments, the composition comprises 0.15 weight percent to 0.2 weight percent folic acid. In some embodiments, the composition comprises 0.01 weight percent to 0.15 weight percent folic acid. In some embodiments, the composition comprises 0.01 weight percent to 0.1 weight percent folic acid. In some embodiments, the composition comprises 0.01 weight percent to 0.07 weight percent folic acid. In some embodiments, the composition comprises 0.01 weight percent to 0.05 weight percent folic acid. In some embodiments, the composition comprises 0.05 weight percent to 0.11 weight percent folic acid. In some embodiments, the composition comprises 0.07 weight percent to 0.11 weight percent folic acid.

[00057] In some embodiments, the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

[00058] In some embodiments, the composition comprises additional phospholipid compounds. In some embodiments, the phospholipid compounds comprise phosphatidylinositol (PI), phosphatidic acid (PA), phosphatidylethanolamine (PE), phosphatidylcholine (PC) and combinations thereof.

[00059] In some embodiments, the composition comprises emulsifiers. In some embodiments, the composition comprises vitamins.

[00060] In some embodiments, the method of making an embodiment of the composition is detailed in Figure 1. In yet other embodiments, the method of making an embodiment of the composition of the present invention is combining the lipidbrain formed with the process detailed in Figure 1 with olive oil using any commercially acceptable method of combining lipids.

[00061] In other embodiments, the present invention is a method of treatment of cognitive impairment including: orally administering an effective amount per day to a

human in need thereof of a composition to increase a clinical dementia rating of the human at least 5% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition includes: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; and 4 to 15 weight percent of soy lecithin. In embodiments, the composition further includes at least one of: 0.05 to 1 weight percent of biotin or 0.01 to 0.2 weight percent of antioxidant. In yet other embodiments, the composition further includes an antioxidant selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof. In some embodiments, the composition is as described in any embodiment detailed herein.

[00062] In other embodiments, the present invention is a method of treatment of cognitive impairment including: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 0.8% measured after a 3 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 3 month duration; wherein the composition includes: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; and 4 to 15 weight percent of soy lecithin. In embodiments, the composition further includes at least one of: 0.05 to 1 weight percent of biotin or 0.01 to 0.2 weight percent of antioxidant. In yet other embodiments, the composition further includes an antioxidant selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof. In some embodiments, the composition is as described in any embodiment detailed herein.

In some embodiments, the cognitive impairment is a result of a neurological disease. In some embodiments, the cognitive impairment is a result of Aβ toxicity. In some embodiments, the cognitive impairment is a result of a progressive cognitive disorder including, but not limited to, Very Mild Dementia, Mild Dementia, Moderate Dementia, Severe Dementia, Alzheimer's Disease, progressive supranuclear palsy; a dementia; Creutzfeldt-Jacob disease, frontotemporal dementia, Pick's disease, Frontotemporal Dementia with Parkinsonism-17 corticobasal degeneration, frontotemporal lobe degeneration; Huntington's Disease; or Parkinson's Disease.

[00063] In some embodiments, the effective amount comprises 5 grams to 100 grams of the composition per day. In some embodiments, the effective amount comprises 5 grams to 100 grams of the composition per day. In some embodiments, the effective amount comprises 15 grams to 100 grams of the composition per day. In some embodiments, the effective amount comprises 25 grams to 100 grams of the composition per day. In some embodiments, the effective amount comprises 40 grams to 100 grams of the composition per day. In some embodiments, the effective amount comprises 50 grams to 100 grams of the composition per day. In some embodiments, the effective amount comprises 65 grams to 100 grams of the composition per day. In some embodiments, the effective amount comprises 75 grams to 100 grams of the composition per day. In some embodiments, the effective amount comprises 85 grams to 100 grams of the composition per day. In some embodiments, the effective amount comprises 95 grams to 100 grams of the composition per day.

[00064] In some embodiments, the effective amount comprises at least 5 grams of the composition per day. In some embodiments, the effective amount comprises at least 15 grams of the composition per day. In some embodiments, the effective amount comprises

at least 25 grams of the composition per day. In some embodiments, the effective amount comprises at least 40 grams of the composition per day. In some embodiments, the effective amount comprises at least 50 grams of the composition per day. In some embodiments, the effective amount comprises at least 75 grams of the composition per day. In some embodiments, the effective amount comprises at least 85 grams of the composition per day. In some embodiments, the effective amount comprises at least 95 grams of the composition per day. In some embodiments, the effective amount comprises at least 100 grams of the composition per day.

[00065] In some embodiments, the effective amount comprises 5 grams to 90 grams of the composition per day. In some embodiments, the effective amount comprises 5 grams to 70 grams of the composition per day. In some embodiments, the effective amount comprises 5 grams to 50 grams of the composition per day. In some embodiments, the effective amount comprises 5 grams to 40 grams of the composition per day. In some embodiments, the effective amount comprises 5 grams to 25 grams of the composition per day. In some embodiments, the effective amount comprises 5 grams to 15 grams of the composition per day. In some embodiments, the effective amount comprises 5 grams to 100 grams of the composition per day.

[00066] In some embodiments, the effective amount comprises 25 grams to 75 grams of the composition per day. In some embodiments, the effective amount comprises 35 grams to 80 grams of the composition per day. In some embodiments, the effective amount comprises 40 grams to 60 grams of the composition per day. In some embodiments, the effective amount comprises 50 grams of the composition per day.

[00067] In embodiments, the effective amount of the composition is based, at least in part, on the weight of the human in need thereof.

[00068] In other embodiments, the effective amount comprises 15 to 25 grams per dose and two to four doses per day. In embodiments, the effective amount comprises 15 to 25 grams per dose and two doses per day. In other embodiments, the effective amount comprises 15 to 25 grams per dose and three doses per day. In other embodiments, the effective amount comprises 15 to 25 grams per dose and four doses per day.

[00069] In embodiments, the effective amount comprises 15 grams per dose and three doses per day. In embodiments, the effective amount comprises 15 grams per dose and four doses per day.

[00070] In embodiments, the effective amount comprises 17 grams per dose and three doses per day.

[00071] In other embodiments, the present invention is a method of treatment of cognitive impairment comprising: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 25% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition comprises: a first component comprising: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; 4 to 15 weight percent of soy lecithin; and olive oil. In embodiments, the composition further includes at least one of: 0.05 to 1 weight percent of biotin or 0.01 to 0.2 weight percent of antioxidant. In yet other embodiments, the composition further includes an antioxidant selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof. In some embodiments, the composition is as described in any embodiment detailed herein.

[00072] In other embodiments, the present invention is a method of treatment of cognitive impairment comprising: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 20% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition comprises: a first component comprising: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; 4 to 15 weight percent of soy lecithin; and olive oil. In other embodiments, the present invention is a method of treatment of cognitive impairment comprising: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 15% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition comprises: a first component comprising: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; 4 to 15 weight percent of soy lecithin; and olive oil.

[00073] In other embodiments, the present invention is a method of treatment of cognitive impairment comprising: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 10% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition comprises: a first component comprising: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides

comprise 6 to 12 carbon fatty acid esters of glycerol; 4 to 15 weight percent of soy lecithin; and olive oil. In other embodiments, the present invention is a method of treatment of cognitive impairment comprising: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 5% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition comprises: a first component comprising: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; 4 to 15 weight percent of soy lecithin; and olive oil.

[00074] In other embodiments, the present invention is a method of treatment of cognitive impairment comprising: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 5% measured after a 3 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 3 month duration; wherein the composition comprises: a first component comprising: 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; 4 to 15 weight percent of soy lecithin; and olive oil. In other embodiments, the present invention is a method of treatment of cognitive impairment comprising: orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 8% measured after a 3 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 3 month duration; wherein the composition comprises: a first component comprising: 75 to 97

weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; 4 to 15 weight percent of soy lecithin; and olive oil.

[00075] In some embodiments, the cognitive impairment is a result of a neurological disease. In some embodiments, the cognitive impairment is a result of Aβ toxicity. In some embodiments, the cognitive impairment is a result of a progressive cognitive disorder including, but not limited to, Very Mild Dementia, Mild Dementia, Moderate Dementia, Severe Dementia, Alzheimer's Disease, progressive supranuclear palsy; a dementia; Creutzfeldt-Jacob disease, frontotemporal dementia, Pick's disease, Frontotemporal Dementia with Parkinsonism-17 corticobasal degeneration, frontotemporal lobe degeneration; Huntington's Disease; or Parkinson's Disease.

[00076] In embodiments, a weight ratio of the first component to the olive oil in the composition is 5:1 to 1:5. In embodiments, a weight ratio of the first component to the olive oil in the composition is 4:1 to 1:4. In embodiments, a weight ratio of the first component to the olive oil in the composition is 3:1 to 1:3. In embodiments, a weight ratio of the first component to the olive oil in the composition is 2:1 to 1:2. In embodiments, a weight ratio of the first component to the olive oil in the composition is 1:1.

[00077] In some embodiments, the effective amount comprises 5 grams to 100 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 5 grams to 100 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 15 grams to 100 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 25 grams to 100 grams of

the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 40 grams to 100 grams of the composition per day. In some embodiments, the effective amount comprises 50 grams to 100 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 65 grams to 100 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 75 grams to 100 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 85 grams to 100 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 95 grams to 100 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day.

[00078] In some embodiments, the effective amount comprises at least 5 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises at least 15 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises at least 25 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises at least 40 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises at least 50 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises at least 75 grams of the

composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises at least 85 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises at least 95 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises at least 100 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day.

[00079] In some embodiments, the effective amount comprises 5 grams to 90 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 5 grams to 70 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 5 grams to 50 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 5 grams to 40 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 5 grams to 25 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 5 grams to 15 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 5 grams to 100 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day.

[00080] In some embodiments, the effective amount comprises 25 grams to 75 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 35 grams to 80 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 40 grams to 60 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 50 grams of the composition having a weight ratio of the first component to the olive oil of 2:1 to 1:2 per day. In some embodiments, the effective amount comprises 50 grams of the composition having a weight ratio of the first component to the olive oil of 1:1 per day.

[00081] In some embodiments, the olive oil in the composition detailed in one or more embodiments herein, may be replaced, at least in part, by flax seed oil.

[00082] In embodiments, the effective amount of the composition is based, at least in part, on the weight of the human in need thereof.

[00083] In other embodiments, the effective amount comprises 15 to 25 grams per dose and two to four doses per day. In embodiments, the effective amount comprises 15 to 25 grams per dose and two doses per day. In other embodiments, the effective amount comprises 15 to 25 grams per dose and three doses per day. In other embodiments, the effective amount comprises 15 to 25 grams per dose and four doses per day.

[00084] In embodiments, the effective amount comprises 15 grams per dose and three doses per day. In embodiments, the effective amount comprises 15 grams per dose and four doses per day.

[00085] In embodiments, the effective amount comprises 17 grams per dose and three doses per day.

[00086] In some embodiments, the effective amount comprises any dosage amount detailed above and one to three doses per day. In some embodiments, the effective amount comprises any dosage amount detailed above and one to two doses per day. In some embodiments, the effective amount comprises any dosage amount detailed above and one dose per day. In some embodiments, the effective amount comprises any dosage amount detailed above and two doses per day. In some embodiments, the effective amount comprises any dosage amount detailed above and three doses per day. In some embodiments, the effective amount comprises any dosage amount detailed above and four doses per day.

[00087] Traditionally, there are two methods to assess the improvement and/or prevention of neurodegenerative disease. A first method is related to the phenotype of cognitive impairment and the second method is based on genotype associate with this cognitive impairment.

[00088] A first method is based on a method of psychiatric criteria according to American Psychiatric Association. In this method, DSM-IV and classification of mental and behavioral disorders of World Health Organization ICD-10, cognitive decay is diagnosed in accordance with the following four criteria:

[00089] I. Impairment of one or more of the following cognitive areas:

a. Attention/concentration
b. Language
c. Gnosia
d. Praxis
e. Visuospatial abilities
f. Executive function

[00090] II. The cognitive impairment is:

a. Acquired, indicating a decline over previous capabilities of the individual;

b. Reported by the patient or a reliable informant;
c. Focused on neuropsychological examination; and
d. Several months and observed in patients with a normal level of consciousness

[00091] III. The cognitive impairment only interferes minimally in basal or advanced activities of daily living; and

[00092] IV. Cognitive impairment is not associated with disorders at conscience level.

[00093] According to the criteria described above there is an ascending classification of: Mild cognitive impairment, combined Dementia, probable Alzheimer's Disease, possible Alzheimer's Disease, Alzheimer's Disease and confirmed Alzheimer's Disease with associated cerebrovascular disease. An improvement in cognitive impairment is evident at two levels: i) when any of these criteria (ex. concentration, memory, praxis, etc.) evolve positively; ii) the disease suffers a stage change to a minor stage (ex. combined dementia with mild cognitive impairment).

[00094] A second method is a genetic markers method. In the second method, DNA extracted from blood plasma allows the assessment of genetic variants associated to the production of proteins that regulate the neuropathological changes caused by neurodegenerative disease. A decrease in the expression of these genes is directly related to cognitive enhancement.

[00095] As used herein, "CDR" is used to assess the treatment of cognitive impairment.

[00096] Non-limiting Examples

[00097] The following examples are intended to illustrate the invention and should not be construed as limiting the invention in any way.

[00098] Trials consisted in growing transgenic *Caenorhabditis elegans* strain CL4176 at 16 °C and synchronized age with two different doses, 1 and 10mg/mL, of the lipid blends: Lipid Brain and Control Z (negative control). The compositions of Lipid Brain and Control Z are detailed in Tables 2 and 3

[00099]

TABLE 2
LIPID BRAIN

Raw Material	wt%
Medium Chain Triglycerides (MCTs)	93.24
Soy Lecithin	6.67
Biotin	0.07
Ascorbil Palmitate	0.02

TABLE 3
CONTROL Z

Raw Material	wt%
Soybean Oil	69.988
Palm Olein	30.00
TBHQ	0.012

[000100] Once the nematodes reached the larval stage L3, Aß peptide expression was induced by increasing the temperature to 25°C. After induction, paralysis was count on each population until 100 % were paralyzed. The tests included control nematodes maintained at 16°C (Aß peptide expression is not induced), a feed control condition (NG induction medium) and a positive control (extract from Gingko biloba) condition. The curves obtained were analyzed statistically using the software Graph Pad Prism.

[000101] The averaged results are shown in Figure 2. In the non-limiting example, the effect of Lipid Brain and Control Z's blends on body paralysis induced in *Caenorhabditis elegans*strain CL4176 is shown in Figure 2. The figure represents the percentage of non-paralyzed nematodes in each condition versus time. Paralysis curves

obtained indicated a significant protective effect with Lipid Brain at two concentrations tested as compared to the NG. Furthermore, the effect was dose dependent, increasing sample concentration show delay in the paralysis acquisition. The dose of 10 mg / mL delayed significantly the appearance of body paralysis, demonstrating the Lipid Brain effect on reducing of the peptide-induced toxicity. Additionally, this effect was greater than the obtained with the Ginkgobiloba extract EGb 761 (positive control) and the NG.

[000102] Moreover, no positive effect was shown with the Control Z compared to the NG, and both doses tested resulted in curves similar in paralysis. All these results are corroborated with statistical analysis performed with the GraphPad Prism program as detailed in Table 4.

[000103] The data indicated that in control conditions (NG) worm paralysis began at 41h. Although the Control Z shows delayed entry into paralysis (43h), supplementation with the Control Z had no positive effects on paralysis. Lipid Brain, however, had a protective effect at doses of 1 mg / mL (P=0.006) and 10 mg / mL (P < 0.0001) and showed a delay in the entry into paralysis (47h).

Table 4

Condition	Paralysis initial time (h)	Log Rank Test X^2	P-value	Protective Effect
NG	41			
EGb 761 (1µg/mL)	45	26.83	<0.0001	Yes
Control Z (1mg/mL)	43	8.85	0.0029	No
Control Z(10mg/mL)	43	9.98	0.0016	No
Lipid Brain (1mg/mL)	43	7.5	0.006	Yes
Lipid Brain (10mg/mL)	47	69.19	<0.0001	Yes

[000104] The results of the non-limiting examples show the effectiveness of Lipid Brain on reducing body paralysis in the transgenic *Caenorhabditis elegans*strain CL4176. *Caenorhabditis elegans* is a pre-clinical model for determining the neuromolecular basis of cognitive function. *Caenorhabditis elegans* has been used to model aspects of a different number of age-associated neurodegenerative diseases, including Alzheimer's, Parkinson's and Huntington's diseases. These models typically involve a transgenic expression of disease-associated human proteins. Thus, since this model of Alzheimer accumulation can be correlated with toxicity Aß peptide, the results of this study indicate that the administration of the Lipid Brain reduces toxicity in transgenic strain and thus, would be expected to result in a "reduced rate of onset or magnitude of cognitive impairment."

[000105] A human study was further conducted to evaluate the effect of an embodiment of a lipid composition of the present invention. The purpose of the study is to evaluate the effect of an embodiment of a lipid composition of the present invention on 110 patients diagnosed with cognitive impairment or mild-to-moderate Alzheimer´s disease. Study parameters: randomized, double blind, placebo-controlled prospective.

[000106] Table 5 below illustrates the compositions and treatment regimen of the study.

Table 5

Sample	Treatment Regimen
Sample 1 Glass bottle with 25 grams Lipidbrain (described in Table 2) and 25 grams Olive Oil.	Daily intake of one bottle containing Sample 1
Sample 2 Glass bottle with 50 grams Lipidbrain (described in Table 2)	Daily intake of one bottle containing Sample 2
Comparative Sample 3 Glass bottle with 50 grams of Olive oil	Daily intake of one bottle containing Comparative Sample 3

[000107] The density of the Sample 1, Sample 2 and Comparative Sample 3 is 9 milligrams per milliliter. The specifications of the olive oil used in Sample 1 and Comparative Sample 3 are detailed in Figures 4 to 7.

[000108] The targets of the study include the following:

[000109] - Changes in Clinical Dementia Rating (CDR) over a timeframe of 3 months and 6 months and

[000110] The patient eligibility guidelines for the study are detailed in Table 6.

Table 6

Minimum Age	55 Years
Maximum Age	85 Years
Gender	Both
Healthy Volunteers	No
Inclusion Criteria	• Informed consents signed by patients and/or caretaker • The patient has to fulfill dementia clinical criteria. • MMSE score between 18 and 26. • The patient can fulfill all neuropsychologic test, according to investigator. • The patient has to be always with his/her caretaker during monitorization visits • The caretaker has to be in regular contact with the patient, knowing his/her situation and participation in the study. • The caretaker has to check four times per week, at least, the product intake, as well as the routine medication and his/her dietetic habits. • Both caretaker and patient have to be able to complete the product intake during all the length of the study, according to the main investigator.
Exclusion Criteria:	• Patient and/or caretaker not being able to understand and agree in writing their participation in the study. • Patient disability to oral intake of products. • Known allergy to any of the product components (active and placebo) • Evidence of suffering other neuropsychiatric disturbances apart of dementia as: Parkinson disease, psychotic disturbance, bipolar depression. • Regular intake of alcohol higher than 45 g ethanol/day, during the year before study inclusion. • Any known concurrent malignant pathology in the moment of

	study inclusion, or severe metabolic, cardiovascular, renal, hepatic, or gastrointestinal disease that cannot allow the ending of the study according the investigator. • Any analytical abnormality during the screening, apart from: Creatinine no less than 1.7 mg/dL; low levels of Vitamin B12, and TSH abnormal values

[000111] The magnitude of the treatment effect (as percentage) was calculated by the difference between the actual values (in the corresponding 95% confidence interval) from the baseline (which indicates that the treatment had no effect). This magnitude represents percentage of improvement through CDR value. These calculations and results are shown in Table 7 and Figure 3.

Table 7

Composition	**% CDR Improvement**		
	0 months	3 months	6 months
Sample 1	0	8.87	42.11
Sample 2	0	1.66	20.23
Comparative Sample 3	0	0.8	15.29

[000112] According to % CDR improvement, patients taking Sample 1 exhibited an increase in CDR values in comparison to Sample 2 and Comparative Sample 3. The results illustrate the benefits of an embodiment of the lipidic blend of the present invention, alone and in combination with olive oil, in treatment of cognitive impairment compared to olive oil alone.

[000113] Moreover, the CDR correlates and quantifies the level of memory of the patients. Additionally, the inventors expect that the effect of improved CDR will also result in a long term impact on a change in the Mini Mental State Examination (MMSE) and biomarkers in blood. The MMSE is a tool that can be used to systematically and thoroughly assess mental status. The MMSE is an 11-question measure that tests five areas of cognitive function: orientation, registration, attention and calculation, recall, and

language. The maximum score is 30. A score of 23 or lower is indicative of cognitive impairment. The MMSE takes 5-10 minutes to administer.

[000114] While a number of embodiments of the present invention have been described, it is understood that these embodiments are illustrative only, and not restrictive, and that many modifications may become apparent to those of ordinary skill in the art. Further still, the various steps may be carried out in any desired order (and any desired steps may be added and/or any desired steps may be eliminated).

CLAIMS

We claim:

1. A composition, comprising:

   (i) 75 to 97 weight percent of medium chain triglycerides;

   wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol;

   (ii) 4 to 15 weight percent of soy lecithin;

   (iii) 0.05 to 1 weight percent of biotin; and

   (iv) 0.01 to 0.2 weight percent of antioxidant,

   wherein the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

2. The composition of claim 1, wherein the composition comprises 85 to 97 weight percent of the medium chain triglycerides.

3. The composition of claim 1, wherein the composition comprises 8 to 15 weight percent of the soy lecithin.

4. The composition of claim 1, wherein the composition comprises 1 weight percent of the biotin.

5. The composition of claim 1, wherein the composition comprises 0.1 to 0.2 weight percent of the antioxidant.

6. The composition of claim 1, wherein the composition further comprises 0.05 weight percent to 0.11 weight percent of folic acid.

7. The method of claim 1, wherein the composition comprises:

(i) 85 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol;

(ii) 5 to 10 weight percent of soy lecithin;

(iii) 0.05 to 0.2 weight percent of biotin; and

(iv) 0.01 to 0.2 weight percent of antioxidant, wherein the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof

8. A method of treatment of cognitive impairment comprising:
orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 5% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition comprises:

(i) 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol; and

(ii) 4 to 15 weight percent of soy lecithin;

9. The method of claim 8, wherein the effective amount comprises 15 to 25 grams per dose and two to four doses per day.

10. The method of claim 9, wherein the effective amount comprises 15 grams per dose and three to four doses per day.

11. The method of claim 10, wherein the effective amount comprises 17 grams per dose and three doses per day.

12. The method of claim 8, wherein the effective amount comprises 50 grams per day.

13. The method of claim 8, wherein the composition further comprises at least one of:

    (iii) 0.05 to 1 weight percent of biotin or

    (iv) 0.01 to 0.2 weight percent of antioxidant

14. The method of claim 13, wherein the herein the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

15. A method of treatment of cognitive impairment comprising:
    orally administering an effective amount per day to a human in need thereof of a composition to increase a clinical dementia rating of the human at least 25% measured after a 6 month duration when compared to a human that is orally administered an identical amount to the effective amount per day of olive oil for a 6 month duration; wherein the composition comprises:

    a) a first component comprising:

        (i) 75 to 97 weight percent of medium chain triglycerides; wherein the medium chain triglycerides comprise 6 to 12 carbon fatty acid esters of glycerol;

        (ii) 4 to 15 weight percent of soy lecithin; and

    b) olive oil.

16. The method of claim 15, wherein a weight ratio of the first component to the olive oil is 2:1 to 1:2.

17. The method of claim 16, wherein the weight ratio of the first component to the olive oil is 1:1.

18. The method of claim 15, wherein the effective amount comprises 15 to 25 grams per dose and two to four doses per day.

19. The method of claim 18, wherein the effective amount comprises 15 grams per dose and three to four doses per day.

20. The method of claim 15, wherein the effective amount comprises 17 grams per dose and three doses per day and the weight ratio of the first component to the olive oil is 2:1 to 1:2.

21. The method of claim 15, wherein the composition further comprises at least one of:

    (iii) 0.05 to 1 weight percent of biotin or

    (iv) 0.01 to 0.2 weight percent of antioxidant

22. The method of claim 21, wherein the antioxidant is selected from the group consisting of tocopherol, ascorbyl palmitate, Rosemary extract and mixtures thereof.

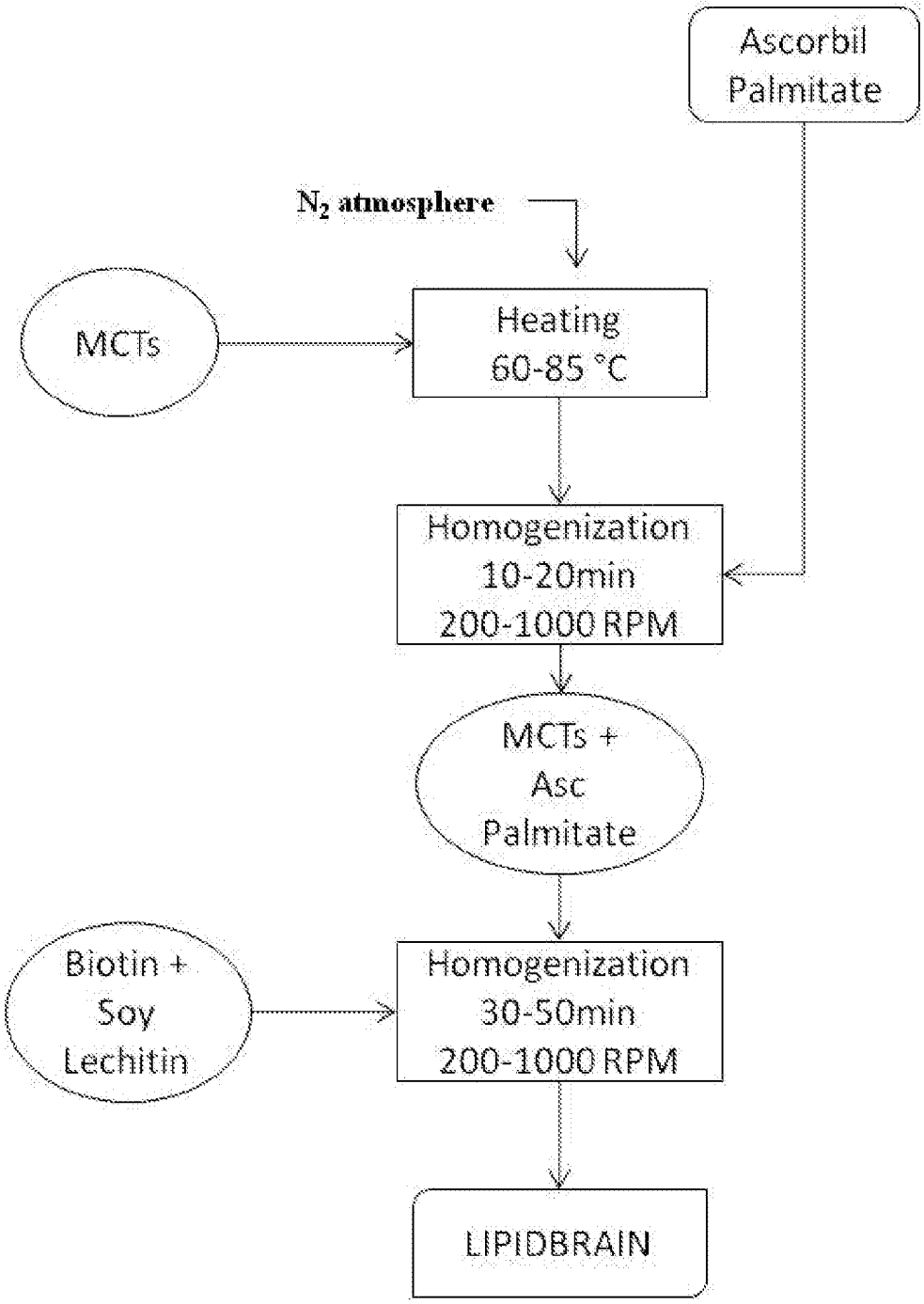
Ascorbil Palmitate
N_2 atmosphere
MCTs
Heating 60-85 °C
Homogenization 10-20min 200-1000 RPM
MCTs + Asc Palmitate
Biotin + Soy Lechitin
Homogenization 30-50min 200-1000 RPM
LIPIDBRAIN

FIGURE 1

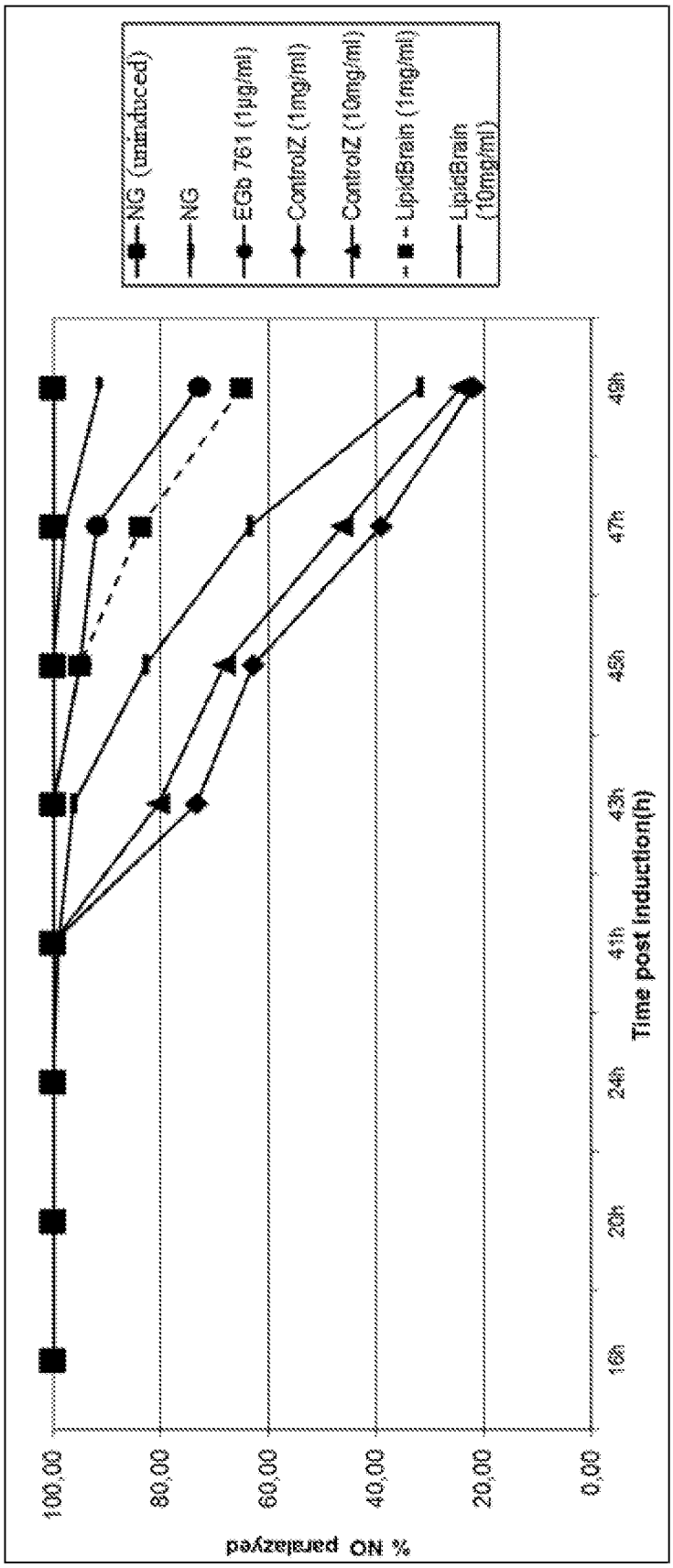
NG (unnduced)
NG
EGb 761 (1µg/ml)
ControlZ (1mg/ml)
ControlZ (10mg/ml)
LipidBrain (1mg/ml)
LipidBrain (10mg/ml)
% NO penalazyed
100,00
80,00
60,00
40,00
20,00
0,00
16h
20h
24h
41h
43h
46h
47h
48h
Time post induction(h)

FIGURE 2

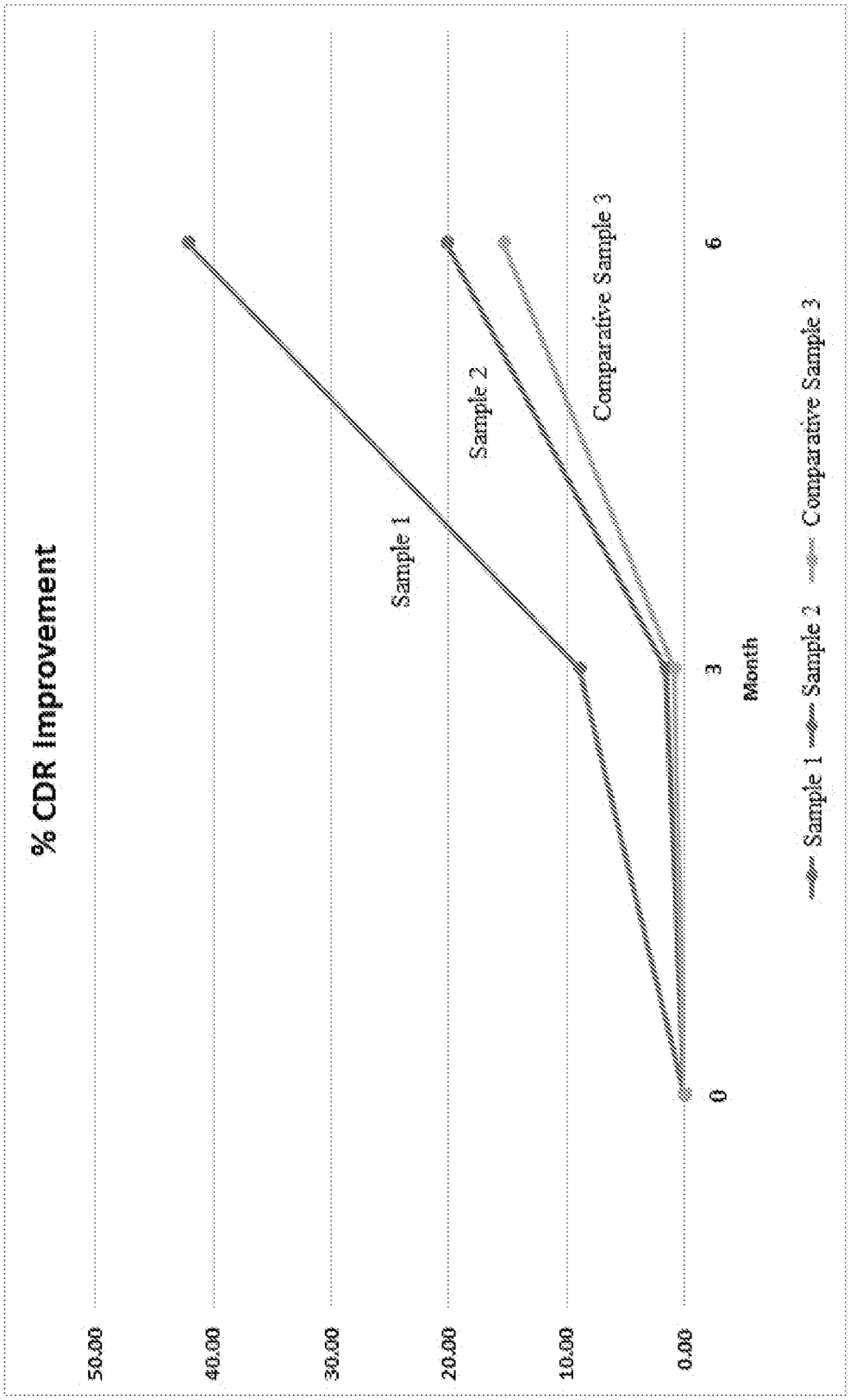
% CDR Improvement
50.00
40.00
30.00
20.00
10.00
0.00
0
3
6
Month
Sample 1
Sample 2
Comparative Sample 3
Sample 1
Sample 2
Comparative Sample 3

FIGURE 3

Acesur INNOVAMOS POR TRADICIÓN	FICHA TÉCNICA DE PRODUCTO / PRODUCT SPECIFICATION	Cod.: EG_AOVE.bi	Rev.: 1.4
		Fecha/Date: 01/03/2011	
		Página/Page 2 de/of 6	
Producto/Product:	ACEITE DE OLIVA VIRGEN EXTRA (INTENSO) MARCA OLIVETTO. FORMATOS: 12X250, 12x500 y 12x750mL, 6x1L		

1.1. Descripción

Aceite de oliva virgen extra, compuesto de aceites de oliva de categoría superior especialmente seleccionados y mezclados para obtener una aceite de un sabor único. Aceite obtenido a partir de aceitunas por procedimientos mecánicos u otros procedimientos físicos en condiciones, sobre todo térmicas, que no impliquen la alteración del aceite y que no hayan sufrido tratamiento alguno distinto del lavado, la decantación el centrifugado y la filtración.

La acidez, expresada en ácido oleico, no podrá ser superior a 0,4gr/100gr y cuyas otras características son conformes a las establecidas para esta categoría.

1.2. Estabilidad

Producto estable a temperatura ambiente. Por debajo de los 10° C puede aparecer cierta turbidez en el aceite. Este proceso de enturbiamiento es perfectamente natural y el aceite volverá a aparecer claro en unas condiciones de temperatura más cálidas.

1.1. Description

Extra virgin olive oil, composed of superior category extra virgin olive oils especially selected and blended to obtain a unique flavour olive oil. This oil obtained from olives by mechanical procedures or other physical procedures in conditions, mainly thermal, that do not imply the alteration of the oil and which they have not undergone treatment some different one from the washing, the movement the centrifuged one and the filtration.

The acidity, expressed in oleic acid, could not be superior to 0,4gr/100gr and whose other characteristics are in agreement to the established ones for this category.

1.2. Stability

Stable product to room temperature. Below 10° C it can appear certain turbidity in the oil. This process of turbidity is perfectly natural and the oil will return to appear clear in warmer conditions of temperature.

1.3. Datos Nutricionales / Nutrition Facts

	Para/for 14 g	*Para/for 100g*	
VALOR ENERGETICO / ENERGY VALUE	126	900	*Kcal*
	518	3700	*KJ*
PROTEINAS /PROTEINS	0	0	g
HIDRATOS DE CARBONO / CARBOHYRATE	0	0	g
GRASAS / FATS	14	100	g
De las cuales / Of which:			
Saturadas / Saturated	1,96	14	g
Trans	0	≤ 0,01	g

FIGURE 4

Acesur INNOVANDO POR TRADICIÓN	FICHA TÉCNICA DE PRODUCTO / PRODUCT SPECIFICATION	Cod.: EG_AOVE.bi	Rev.: 1.4
		Fecha/Date: 01/03/2011	
		Página/Page 3 de/of 6	
Producto/Product:	ACEITE DE OLIVA VIRGEN EXTRA (INTENSO) MARCA OLIVETTO. FORMATOS: 12X250, 12x500 y 12x750mL, 6x1L		

Monoinsaturadas / Monounsaturated	10,78	77	g
Polinsaturadas / Poliunsaturated	1,26	9	g
COLESTEROL / CHOLESTEROL	0	0	mg
Vitamina E/ Vitamin E	2,8	20	mg

1.4. Ingredientes

Aceite Oliva Virgen Extra variedad Arbequina con un mayor porcentaje de virgen extra variedad Picual

1.4. Ingredients

Extra Virgin Olive Oil Arbequina variety with a higher percentage of Picual variety

1.5. Condiciones de uso

Apto para consumir de modo directo.

Para evitar posibles alteraciones y disfrutar plenamente de las cualidades de este alimento conviene tener en cuenta una serie de recomendaciones:

- Debe evitarse que le dé directamente la luz solar o una luz artificial fuerte, así como la cercanía a fuentes de calor. Su conservación en un lugar fresco y al amparo de la luz puede garantizar la calidad del producto durante mucho tiempo

- Conviene tapar bien el envase después de su consumo y mantenerlo en un lugar reservado, a salvo de olores extraños que le puedan transmitir otros alimentos, ya que los absorbe fácilmente

1.5. Use conditions

Ready to be consumed directly.

To avoid possible alterations and fully enjoy the qualities of this food the following recommendations should be followed:

-Avoid direct sun light or strong artificial light as well as heat sources. Its preservation in a cool place protected from light can guarantee its quality for long periods of time.

-It is advisable to close the bottle after use and keep it in a reserved place away from off odours from other foodstuff since it can absorb them easily.

1.6. Características Organolépticas

Normales, con aromas propios y características sin acusar síntomas de rancidez, alteración o contaminación.

Aroma afrutado característico de las aceitunas, medianamente picante.

Color verde amarilleto.

1.6. Organoleptic Characteristic

Normal, with own aromas and characteristic without accusing symptoms of rancidity, alteration or contamination.

Distinctive fruity aroma, characteristic of olives, peppery aftertaste.

Medium yellow/green in color

1.7. Características Físico-Químicas / Physical-Chemical Characteristic

FIGURE 5

Acesur RENOVAMOS POR TRADICIÓN	FICHA TÈCNICA DE PRODUCTO / PRODUCT SPECIFICATION	Cod.: EG_AOVE bi	Rev.: 1.4
		Fecha/Date: 01/03/2011	
		Pàgina/Page 4 de/of 8	
Producto/Product:	ACEITE DE OLIVA VIRGEN EXTRA (INTENSO) MARCA OLIVETTO. FORMATOS: 12X250, 12x500 y 12x750mL, 6x1L		

DETERMINACIONES / DETERMINATIONS

Acidez (% ácido oleico)	Acidity (% oleic acid)	≤ 0,4
Índice de Peróxidos (mEqiv O2/kg.)	Peroxides rate (mEqiv O2/kg.)	≤ 20
Monopalmitato de 2-glicerilo	Monopalmitate 2-glicerile	≤ 0,9 si % ácido palmítico total ≤ 14 ≤ 1,0 si % ácido palmítico total > 14
K-270	K-270	≤ 0,22
K-232	K-232	≤ 2,50
Ceras (mg/kg)	Waxes (mg/kg)	≤ 250
Eritrodiol + Uvaol (%)		≤ 4,5
Diferencia ECN42 HPLC y teórico		≤ 0,2
Humedad y materias volátiles (%)	Humidity and volatile substances (%)	≤ 0,1
Impurezas solubles en éter de petróleo (%)	Soluble impurities in petroleum ether (%)	≤ 0,05
Estigmastadieno (mg/kg)	Estigmastadien (mg/Kg)	≤ 0,10
Jabones	Soap	Negativo / Negative
Delta-ß	Delta-ß	0,01
Esteres metílicos de los ácidos grasos (FAMEs) y esteres etílicos de los ácidos grasos (FAEEs)	Fatty acid methyl sters (FAMEs) and Fatty acid ethyl sters (FAEEs)	Σ FAMEs + FAEEs ≤ 75 mg/kg

*Cumple toda la normativa vigente, CE 2568/91, COI/T.15/NCn3/Rev.2, RD 308/1983. Complies with all current regulations EC 2568/91, COI/T.15/NCn3/Rev.2, RD 308/1983

COMPOSICIÓN EN ÁCIDOS GRASOS / COMPOSITION IN FATTY ACIDS

Laurico	Lauric	C 12	------	Araquidico	Arachidic	C 20	≤ 0,6
Mirístico	Miristic	C 14	≤ 0,05	Gadoleico	Gadoleic	C 20:1	≤ 0,4
Palmítico	Palmitic	C 16	7,5 - 20	Behenico	Behenic	C 22	≤ 0,2
Palmitoleico	Palmitoleic	C 16:1	0,3 - 3,5	Erucico	Erucic	C 22:1	------
Esteárico	Estearic	C 18	0,5 - 5	Lignocerico	Lignoceric	C 24	≤ 0,2
Oleico	Oleic	C 18:1	55 - 83	Transoleico	Transoleic	tC 18:1	≤ 0,05
Linoleico	Linoleic	C 18:2	3,5 - 21	Translinoleico &	Translinoleic &		
Linolenico	Linolenic	C 18:3	≤ 1,0	translinolenico	translinolenic	18:2 y3	≤ 0,05

FIGURE 6

Acesur INNOVAMOS POR TRADICIÓN	FICHA TÉCNICA DE PRODUCTO / PRODUCT SPECIFICATION	Cod.: EG_AOVE.bi	Rev.: 1.4
		Fecha/Date: 01/03/2011	
		Pàgina/Page 5 de/of 8	
Producto/Product	ACEITE DE OLIVA VIRGEN EXTRA (INTENSO) MARCA OLIVETTO. FORMATOS: 12X250, 12x500 y 12x750mL, 6x1L		

ESTEROLES / STEROLS

Colesterol	Cholesterol	≤ 0,5	β Sitosterol	β Sitosterol	≥ 93
Brasicasterol	Brasicasterol	≤ 0,1	Δ7 Stigmasterol	Δ7 Stigmasterol	≤ 0,5
Campesterol	Campesterol	≤ 4,0			
Estigmastero	Estigmasterol	< Campesterol	Esteroles Totales	Total esterols	≥ 1000 ppm

FIGURE 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2017/000337

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K31/22 A61K31/23 A61K31/355 A61K31/365 A61K31/4188
A61K31/685 A61K36/53 A61K31/519 A61K36/63
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 835 750 B1 (HENDERSON SAMUEL T [US]) 28 December 2004 (2004-12-28) column 8, line 63 - column 9, line 1 column 9, line 40 - line 43 column 10, line 15 - line 20 column 11, line 30 - column 12, line 22 column 13, line 59 - line 61 column 17, line 59 - line 66 example 3 claims 1,2	1-22
Y	US 2013/017278 A1 (KELLER ARLENE [CA]) 17 January 2013 (2013-01-17) Paragraphs 007, 0010, 0014, 0016, 0020, 0022, 0025 example 1	1-22

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 July 2017	09/08/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Albrecht, Silke

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2017/000337

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	VOLZ H P ET AL: "[Improvement in quality of life in the elderly. Results of a placebo-controlled study on the efficacy and tolerability of lecithin fluid in patients with impaired cognitive functions].", MMW FORTSCHRITTE DER MEDIZIN 09 DEC 2004, vol. 146, no. Suppl 3-4, 9 December 2004 (2004-12-09), pages 99-106, XP009195075, ISSN: 1438-3276 page 103, column 3, paragraph 2 - page 104, column 1, paragraph 1 page 104, column 3, paragraph 1 page 106, paragraph "Schlussfolgerung" figure 1	1-22
Y	VALLS-PEDRET CINTA ET AL: "Mediterranean Diet and Age-Related Cognitive Decline A Randomized Clinical Trial", JAMA INTERNAL MEDICINE, vol. 175, no. 7, July 2015 (2015-07), pages 1094-1103, XP009195074, page 1099 table 4 figure 2 page 1102, column 2, paragraph 2	15-22
Y	WO 03/002133 A2 (OAKLEA LTD [GB]; KALINOWSKI PIOTR MAREK [GB]) 9 January 2003 (2003-01-09) page 6, paragraph 6 - page 7, paragraph 6	1-7,13, 14,21,22

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Information on patent family members

International application No
PCT/IB2017/000337

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 8445535 B1	21-05-2013
		US 2013225682 A1	29-08-2013
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		WO 03002133 A2	09-01-2003