The present invention concerns a food supplement comprising *Salvia sclarea* seeds, or flour, oil or pulp or extracts obtained from the seeds as well as finished food products comprising the food supplement. The present invention further concerns a nutraceutical or cosmetic preparation comprising as an active ingredient *Salvia sclarea* seeds, or flour, oil or pulp or extracts obtained from the seeds.
COMPOSITION CONTAINING AS THE ACTIVE INGREDIENT COMPONENTS FROM SALVIA SCLAREA SEED

FIELD OF THE INVENTION

[0001] The present invention relates to food supplements and nutraceutical compositions for raising omega-levels in a subject.

BACKGROUND OF THE INVENTION

[0002] Current research in nutritional medicine indicates that the omega-3 fatty acids are essential components of the human diet. According to studies published in the British scientific journal Lancet, the observed low incidence of arteriosclerosis (fatty plaques development on the inner walls of the arteries which obstructs the blood flow), including coronary artery disease, and chronic inflammatory disease, and diabetes in Greenland Eskimos has been attributed to their traditional ethnic diet, consisting largely of meat from whale, seals, sea birds and fish. This diet is rich in fat and protein low in carbohydrates, but it is extremely rich in omega-3 polyunsaturated fatty acids, and especially rich in two omega-3 fatty acids: C22:6 and C20:5 (DHA) and (EPA).

[0003] The most important Omega-3 fatty acids are eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and α-linolenic acid (ALA).

[0004] EPA is a direct source of an important substance called prostaglandin E3, which is directly responsible for making blood platelets less sticky, thus leading to an easier flow of blood. EPA is, therefore, involved in processes that inhibit blood clots whose presence threaten to obstruct the circulation; this mode of action is particularly important in the small capillaries of the heart.

[0005] DHA (docosahexaenoic acid) is an Omega-3 fatty acid of almost equal importance to EPA. DHA comprises a significant amount of the tissues that make up the human brain as well as a large part of the retina of the eye.

[0006] Some of the most dramatic effects of increased intake of omega-3 fatty acids, are the lowering of high blood pressure, reduction of serum triglyceride levels, and an increase in the clotting time, all positive steps in the prevention of heart and blood vessel diseases. These beneficial effects of omega-3 fatty acids have been noted in both clinical trials and epidemiological studies. Omega-3 fatty acids were found to be extremely useful natural substances powerful enough to normalize the high cholesterol and triglyceride levels that are so extensive in modern populations.

[0007] Omega-3 fatty acids have also been shown to slow down or prevent cancerous tumor growth, prevent blood vessels from closing following vascular surgery, improve inflammatory diseases such as rheumatoid arthritis and relieve symptoms of psoriasis. In addition, omega-3 fatty acids are essential for proper vision and brain development in newborns.

[0008] The average western diet is low in fresh fish and sea food containing EPA and DHA. On the other hand, it is high in refined carbohydrates and saturated fats. This kind of diet can lead to a serious deficiency in the raw materials necessary for proper platelet function in the blood stream.

[0009] Linolenic acid is essential for ensuring healthy skin condition. Moreover, oils containing large amounts of omega-3 fatty acids were shown to be effective in preventing skin wrinkles. The ingestion of these oils markedly lowers the cholesterol content in the blood. α-Linolenic acid is a fatty acid found in some plants and can be converted by the body to EPA and DHA. Plant sources of α-linolenic acid include walnuts and walnut oil, flaxseed, rapeseed (used to make canola oil), soybeans, spinach, mustard greens and purslane.

[0010] α-Linolenic acid is produced in high quantities in several plants, mainly hemp (up to 23% α-linolenic acid is pressed from hempseed) and flax (50%). These oils normally have an “off” flavor and are seldom used as edible oils due to their bad taste and smell. Conventional food oils, such as rape-seed (canola) and soybean contain only small amounts of linolenic acid (11% and 7% respectively).

[0011] Researchers believe that a 1:1 ratio of omega-6 to omega-3 (omega-6 is found primarily in vegetable oils like corn, safflower or sunflower) may be important in preventing heart disease. It seems that omega-3s and omega-6s continually compete for control of important biochemical reactions in the body. When the portion of omega-6 is higher than that of omega-3, it can lead to an overproduction of hormone-like substances called prostaglandins and leukotrienes. Large amounts of these hormone-like substances can disrupt the immune system, initiate the build-up of plaque formations on artery walls, form blood clots and triggers dangerously irregular heart rhythms.

[0012] Currently, the ratio in the American diet is about 10 omega-6 to 1 omega-3, a ratio, some experts say, which is a dangerous oversupply of omega-6 fatty acids.


[0014] Omega-3 fatty acids from vegetable oils could provide all the above health benefits without any of the disadvantages of oil from animal source.

[0015] During ingestion of vegetable oil there is no uptake of cholesterol. Fish oils are a primary source of vitamins A and D. Most marine oils may supply potentially toxic amounts of vitamins A and D, by supplying a sufficient amount of EPA and DHA factors. Also, vegetal omega-3 oil have a clean flavor has a good taste as opposed to bad tasting fish oils. Fish oils are usually contained in preservative-free gelatin capsules for convenience due to their bad taste and smell.

[0016] Aromatic (essential) oil derived from flowers of Salvia sclarea has been used up to date mainly as a perfume; this usage was known from the time of ancient Rome. Other secondary uses for this aromatic oil have been in the tobacco industry, and in herbal remedies to fight infection, and to regulate the digestive system. The natural habitat of the plant...
is in Syria, Italy and Southern France; and its growth requirements in terms of soil content are not particular. Currently, the former Soviet Union, North Africa, and Hungary are the largest producers of this oil, and prices range from $60-90 per liter of oil; The plant can withstand heat, and is found on mountainous terrain, where rainfall is not lower than 400 mm annually. The floral parts alone are used to produce the oil; inclusion of leaves will degrade the oil quality. Typically a single harvest of floral parts is performed. If harvest is performed prematurely, the oil will contain a large percentage of linoleic acid, which lowers the quality of the oil.

No previous use has been made of the seeds of *Salvia sclarea*; previous uses, mainly as a perfume or essential oils, were from plant material derived from the flower.

WO 99/62356 concerns enhanced food for humans which has significantly higher omega-3 content by the use of oil obtained by *Salvia hispanica* seed. *Salvia Hispanic* (Chia) is a summer annual belonging to the Labiate family. It originates in mountain regions extending from west central Mexico to northern Guatemala. Due to its endemic growth restriction to mountain regions of central and southern America and thus its natural habitat is very specific and growth requirements very particular making seed grown from the plant not economical, the plants are not wide spread and has not acquired wide commercial acceptance as a food source.

**SUMMARY OF THE INVENTION**

Seed oil of selected lines of *Salvia sclarea* (Labiate) (also known as “clary sage”) has an average oil content of 25-30%.

The inventors now disclose that the seeds of this plant are a rich source of omega-3-α-linolic acid (about 55%). The other components of this oil are two important fatty acids: Oleic acid (C18:1), which is present in extremely high levels, and linoleic acid (C18:2). Both acids are unsaturated fatty acids and are essential in the human diet.

The present invention hereby discloses whole seeds, or oil, flour/powder, or pulp obtained from *Salvia sclarea* seeds, having all the health benefits of fish oil but none of its drawbacks (notably its bad taste and distinctive smell). The oil or flour/powder has the additional abovementioned benefits over other vegetable oils, and can be used for dietary supplements, as an active ingredient in pharmaceutical and cosmetic compositions, and for industrial uses.

Another important application of this vegetable oil is its use as a drying oil for painting and lubrication, due to its high content of polyunsaturated fatty acids, namely linolenic acid. Up to date, vegetative drying oil has been obtained from crops such as flax seeds and Tung trees. These crops do not lend themselves to mechanical harvesting and cleaning. *Salvia sclarea* seed oil is useful for industry, and is relatively easy to obtain.

The prior art discloses (WO 99/62356) oil, rich in omega-3 obtained from *Salvia hispanica*, which is an endemic plant restricted in its growth to the high mountain area of central and south America. The present invention is based on the surprising finding that seeds obtained from another variant of *Salvia*, i.e. being *Salvia sclarea*, had better nutritional value than oil, or crushed seed, obtained from *Salvia hispanica* as will be shown in the detailed description part of the invention.

Furthermore, the present invention is based on the realization that not only the oil or crushed flour/powder of *Salvia sclarea* has higher nutritional value than the oil of *Salvia hispanica*, but also the growth of the plant of the *Salvia sclarea* variety, as compared to the *Salvia hispanica* variety is more economical. The *Salvia sclarea* plants can grow in any Mediterranean climate such as in the middle east, in Europe, (including southern European countries such as Italy, Spain and Southern France as well as Northern and eastern European countries such as Finland and Russia), North Africa, California and Australia; and its growth requirements in terms of soil content are not particular. The plant can withstand both heat and cold (even snow), and is found on mountainous terrain, where rainfall is even lower than 400 mm annually.

The present invention is further based on the surprising finding that from among several species of different *Salvia* the specific *Salvia sclarea* of the present invention was found to have an extremely high nutritional value.

Thus, the present invention concerns a composition for use as a food supplement comprising as an active ingredient a composition of matter selected from:

- a. *Salvia sclarea* seed;
- b. *Salvia sclarea* seed oil in an essentially pure form;
- c. extracts of *Salvia sclarea* seed;
- d. *Salvia sclarea* seed crushed or milled to form a flour or powder; and
- e. *Salvia sclarea* seed pulp.

The term “composition of matter” refers to several components (fatty acids, proteins, minerals, vitamins, dietary fibers) present as a mixture with specific ratios between the components.

The term “*Salvia sclarea* seed” refers to the whole seed essentially in an unprocessed form as separated from the full plant.

The term “*Salvia sclarea* seed oil in an essentially pure form” refers to oil obtained from the seed which is essentially free from other components. The oil may be obtained by various manners known to separate oil from plant-seeds without damaging their nutritional value.

Examples of manners for separating the oil include:

1) “cold press” achieved by crushing and pressing the seed, centrifugation of the pressed seed for collection of the oily fraction present in the supernatant, and optionally also purification by various means known in the art such as by using filters, collecting sediments etc.;

2) By use of volatile hydrophobic solvents which initially dissolve the oil, and then are evaporated by application of heat and/or vacuum.
[0038] 3) By use of liquid CO₂ or liquid nitrogen in extremely cold temperature ("super-critical extraction").

[0039] The term “Salvia sclarea seed, crushed or milled to form flour or powder” refers to crushing or milling of the seed to fine particles by any mechanical milling means known in the art in order to break the seed into smaller fragments such as crumbs of flour or particles of powder, and in those flour/powder forms, most of the nutrients are more available to the subject than in the whole seed.

[0040] The term “Salvia sclarea seed pulp” refers in fact also to “defatted Salvia sclarea seed flour”. These two alternative terms refer to the seed after the oily fraction has been extracted there from, which pulp is especially rich in dietary fibers, minerals, vitamins and proteins and poor in fatty acids and calories.

[0041] The term “extract of Salvia sclarea seed” refers to any compound that is extracted from the seed by using aqueous or alcohol, or other organic extracts. Typically, where the extracting liquid is water mostly to fibers (dietary fibers).

[0042] By a preferred embodiment of the present invention, the food supplement consists essentially of:

[0043] a. Salvia sclarea seed;

[0044] b. Salvia sclarea seed oil in an essentially pure form;

[0045] C. extract of Salvia sclarea seed;

[0046] d. Salvia sclarea seed crushed or milled to form a flour or powder; and

[0047] e. Salvia sclarea seed pulp.

[0048] Preferably in accordance with a preferred embodiment of the invention the composition of matter is Salvia sclarea oil or Salvia sclarea flour or powder.

[0049] By a more preferred embodiment of the invention the food supplement consists of:

[0050] a. Salvia sclarea seed;

[0051] b. Salvia sclarea seed oil in an essentially pure form;

[0052] c. extract of Salvia sclarea seed;

[0053] d. Salvia sclarea seed crushed or milled to form a flour or powder; and

[0054] e. Salvia sclarea seed pulp.

[0055] By one embodiment, the food supplement further comprises a “carrier” suitable for consumption in food products.

[0056] The carrier is chosen as a carrier known in the art for the specific type of composition of matter of the invention.

[0057] For example where the composition of matter of the invention is oil the carrier may be other types of vegetable oils such as olive oil, rape-seed (canola) oil, corn oil, soy oil, wheat germ oil, coconut oil, peanut oil, sesame oil, palm oil, almond oil, nut oil walnut etc.

[0058] Where the composition of matter of the invention is powder or flour the “carrier” may be other types of flour/powder such as wheat, barley, corn, soy flour, oat flour, rice flour, tapioca, rye flour.

[0059] By another possibility, the food supplement contains only one of the ingredients (a-e) above without any “carrier”.

[0060] The present invention further concerns the use of an agent selected from

[0061] a. Salvia sclarea seed;

[0062] b. Salvia sclarea seed oil in an essentially pure form;

[0063] C. extracts of Salvia sclarea seed;

[0064] d. Salvia sclarea seed crushed or milled to form a flour or powder; and

[0065] e. Salvia sclarea seed pulp.

for the preparation of a food supplement.

[0066] The food supplement above may be used for human or non human consumption, preferably in order to increase the level of at least one omega-3 fatty acid in the subject.

[0067] The non-human animal may be a farm animal such as cattle (cow, goat, and sheep), poultry (hens, ducks, turkeys) as well as fish grown in fish ponds such as carp, bass, tilapia, trout, and pond-raised salmons.

[0068] The food supplement of the present invention is expected to raise the level of at least one omega-3 fatty acid in the meat of the non-human animal (cow, sheep, hens, fish), as well as to raise the level of at least one omega-3 fatty acid in the products of the animals such as milk and eggs.

[0069] Thus, the present invention concerns a method for increasing at least one omega-3 fatty acid level in a subject the method comprising: administering to the subject an effective amount of the food supplement of the present invention.

[0070] The subject may be as defined above and may be a human or non-human animal.

[0071] The term “effective amount” is an amount that increases the level of at least one omega-3 fatty acid, acid in a statistically significant manner as compared to a control subject not fed with the food supplement of the present invention.

[0072] The raise in the animal may be adjusted in accordance with the types of subject, and the desired level but typically for example in egg yolks is a raise of 2 to 10 fold, preferably a raise of more than 4 fold, more preferably a raise of more than 6 fold.

[0073] By another aspect, the present invention concerns a method for increasing the level of at least one omega-3 fatty acid in egg yolks or in the meat of hens, the method comprising: administering to the p hens an effective amount the food supplement of the present invention.

[0074] The term “effective amount” is as defined above.
The present invention further concerns a nutraceutical composition comprising a nutraceutically acceptable carrier and as an active ingredient a composition of matter selected from:

- *Salvia sclarea* seed;
- *Salvia sclarea* seed oil in an essentially pure form;
- extracts of *Salvia sclarea* seed;
- *Salvia sclarea* seed crushed or milled to form a flour or powder; and
- *Salvia sclarea* seed pulp *Salvia sclarea* seed oil in an essentially pure form.

Preferably, the salvia seed oil is prepared by as disclosed above.

More preferably, the nutraceutical composition consists essentially of a composition of matter selected from:

- *Salvia sclarea* seed;
- *Salvia sclarea* seed oil in an essentially pure form;
- extracts of *Salvia sclarea* seed;
- *Salvia sclarea* seed crushed or milled to form a flour or powder; and
- *Salvia sclarea* seed pulp *Salvia sclarea* seed oil in an essentially pure form.

The term “nutraceutical composition” refers to any substance that is a food or a part of a food and provides medical or health benefits, including the prevention and treatment of disease or disorder.

The present invention further concerns a nutraceutical composition as defined above for the treatment of a disease or a disorder wherein a therapeutically beneficial effect may be evident by increasing the level of at least one omega-3 fatty acid.

The term “treatment...therapeutically beneficial effect” may refer to at least one of the following: decrease in at least one undesirable affect of the disease; slowing the deterioration of the disease; increase in the diseased-free time period; or prevention of the disease altogether.

Typically, the disease or disorder is selected from: artherosclerosis, coronary artery disease, chronic inflammatory disease such as rheumatoid arthritis and IBD, diabetes, cancer, prevention of blood vessels from closing after vascular surgery, relieving symptoms of psoriasis, skin wrinkles and depression and mood disorders.

The disease may be any disease or condition which is known scientifically, or is discovered empirically to benefit from the increase in the level of at least one omega-3 fatty acid in the subject.

The nutraceutical composition is typically taken orally for example in the form of gel-capsules containing the oil, liquid formulation containing the oil, tablets containing the flour/powder as known in the art for preparing such compositions, but for several indications such as psoriasis, and other dermal conditions (wrinkles, dry skin) the oil containing formulations (gel-caps, oil) may also be topically applied.

The present invention further concerns a cosmetic composition comprising a cosmetically acceptable carrier and as an active ingredient *Salvia Sclarea* seed oil in an essentially pure form.

Typically the cosmetic composition is for prevention of wrinkles of the skin and/or ensuring skin health.

The term “at least one omega-3 fatty acid” refers to an unsaturated fatty acid with its first double bond at the third carbon atom from the methyl-end. These fatty acids may be such as essential fatty acid, α-linoleic acid (ALA) as well as non essential fatty acids such as docosahexanoic acid (DHA) and eicosapentanoic acid (EPA).

The present invention further concerns a food product comprising the food supplement of the present invention.

Examples of food products are as follows:

1. Food product comprising whole seeds of *Salvia sclarea*: granola-like cereals, granola-like snack bars, food stuff for hens, cows. After soaking in water the whole seeds may be used in whole breads, rolls, crackers, biscuits etc.

2. For *Salvia sclarea* seeds, ground or milled to produce flour/powder: granola-like cereals, granola-like snack bars, and food stuff for hens, cows, whole breads, rolls, crackers, biscuits, pasta and other baked goods. The flour/powder may be used as thickener in gravy, soup, dips dressings and other prepared food that typically contains flour of some sort as a thickener.

3. For *salvia sclarea* oil-formulated into oily pastes or dips (Tehini, Humus) and in oils and paste such as sesame oil or sesame paste, formulated into other vegetable oils or margarine and margarine-like spreads, salad dressings, fish oil, caviar-like products etc.

4. The pulp (defatted seed flour), due to its high fiber content is extremely suitable for the preparation of low calorie (diet) baked products (breads, rolls) and also for the preparations of diet drinks and shakes with high fiber, protein and mineral contents.

### Detailed Description of the Invention

*Saliwa sclarea* has an average oil content of 25-30% in the seeds, with maximum levels of 60% omega-3-linolenic acid of the total fatty acids in the oil. *Salvia sclarea* lines were tested and evaluated as a potential new oil crop for dietary supplement for humans and animals, for use as an active ingredient in pharmaceutical and cosmetic compositions and mixtures and for industrial uses.

Omega-3 fatty acids from vegetable oils could provide all the above health and cosmetic benefits without any of the disadvantages of oil from animal source.

Another important aspect of this vegetable oil is its quality as drying oil, for painting and lubrication, due to the high content of polyunsaturated fatty acids, namely linolenic...
Acid. Up to date, vegetative drying oil is obtained from crops such as flax seeds and Tong trees. These crops do not lend themselves to mechanical harvesting and cleaning.

**[0106]** Comparative Analysis Salvia sclarea and Salvia hispanica

<table>
<thead>
<tr>
<th>General contents</th>
<th>Salvia Sclarea</th>
<th>Salvia hispanica</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test per 100 g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% moisture (g/100 gr)</td>
<td>7.40</td>
<td>7.8</td>
</tr>
<tr>
<td>% protein (g/100 gr)</td>
<td>23.38</td>
<td>21.1</td>
</tr>
<tr>
<td>% Fat (g/100 gr)</td>
<td>26.20</td>
<td>32.3</td>
</tr>
<tr>
<td>% Ash (g/100 gr)</td>
<td>5.77</td>
<td>4.8</td>
</tr>
<tr>
<td>% Crude Fiber (g/100 gr)</td>
<td>20.60</td>
<td>27.7</td>
</tr>
<tr>
<td>mg/100 g Calcium</td>
<td>0.82–0.928</td>
<td>0.680</td>
</tr>
<tr>
<td>mg/100 g Phosphorus</td>
<td>0.70–0.862</td>
<td>0.780</td>
</tr>
<tr>
<td>mg/100 Potassium</td>
<td>1.02–1.29</td>
<td>0.809</td>
</tr>
<tr>
<td>g/100 g Dietary fiber</td>
<td>17.80</td>
<td>N/A</td>
</tr>
<tr>
<td>Saturated fat from total gr. fat</td>
<td>2.50</td>
<td>3.35</td>
</tr>
</tbody>
</table>

**[0107]** As can be seen the Salvia sclarea seeds have a higher protein and dietary fiber contents than Salvia hispanica seeds.

<table>
<thead>
<tr>
<th>Fatty Acid Profile</th>
<th>Range (Salvia hispanica)</th>
<th>Range (Salvia Sclarea)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myristic Acid</td>
<td>C14:0</td>
<td>0.1–0.1</td>
</tr>
<tr>
<td>Palmitic Acid</td>
<td>C16:0</td>
<td>6.6–6.7</td>
</tr>
<tr>
<td>Palmitoleic Acid</td>
<td>C16:1</td>
<td>0.1–0.1</td>
</tr>
<tr>
<td>Heptadecenoic Acid</td>
<td>C17:0</td>
<td>0.2–0.2</td>
</tr>
<tr>
<td>Stearic Acid</td>
<td>C18:0</td>
<td>2.8–3.1</td>
</tr>
<tr>
<td>Oleic Acid</td>
<td>C18:1</td>
<td>6.6–7.0</td>
</tr>
<tr>
<td>Linoleic Acid</td>
<td>C18:2</td>
<td>18.6–18.9</td>
</tr>
<tr>
<td>Linolenic Acid</td>
<td>C18:3(ω-3)</td>
<td>58.2–59.1</td>
</tr>
<tr>
<td>Linolenic Acid</td>
<td>C18:3(ω-6)</td>
<td>0.0–0.1</td>
</tr>
<tr>
<td>Arachidic Acid</td>
<td>C20:0</td>
<td>0.3–0.3</td>
</tr>
<tr>
<td>Gadoleic Acid</td>
<td>C20:1</td>
<td>0.1–0.1</td>
</tr>
<tr>
<td>Eicosadienic Acid</td>
<td>C20:2</td>
<td>0.1–0.2</td>
</tr>
<tr>
<td>Eicosatrienic Acid</td>
<td>C20:3(ω-3)</td>
<td>0.1–0.1</td>
</tr>
<tr>
<td>Behenic Acid</td>
<td>C22:0</td>
<td>0.1–0.1</td>
</tr>
<tr>
<td>Docosatrienoic Acid</td>
<td>C22:4</td>
<td>0.1–0.1</td>
</tr>
<tr>
<td>Lignoeric Acid</td>
<td>C24</td>
<td>0.2–0.2</td>
</tr>
<tr>
<td>Total Fat</td>
<td>32.25%</td>
<td>26.2%</td>
</tr>
</tbody>
</table>

| Ratio:              | omega 3                  | 3.95                  |
| Omega 6            |                           |                       |

**[0108]** As can be seen the omega 3: omega 6 ratio in Salvia sclarea seeds is higher than in Salvia hispanica seeds. Furthermore the oleic acid contents in Salvia sclarea seeds is significantly higher than in Salvia hispanica seeds.

<table>
<thead>
<tr>
<th>mineral profile</th>
<th></th>
<th>Salvia Sclarea</th>
<th>Salvia hispanica</th>
</tr>
</thead>
<tbody>
<tr>
<td>In ( ) the recommended USRDA (mg)</td>
<td></td>
<td>mg in 100 g seeds</td>
<td>mg in 100 g seeds</td>
</tr>
<tr>
<td>Ag</td>
<td>≤0.05</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Al</td>
<td>2.2</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

**[0109]** As can be seen the calcium, potassium and selenium content in the Salvia sclarea seeds are close to the RDA recommended amounts.

<table>
<thead>
<tr>
<th>Fatty Acid Profile</th>
<th>Range (Salvia hispanica)</th>
<th>Range (Salvia Sclarea)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspartic Acid</td>
<td>9.65</td>
<td>9.47</td>
</tr>
<tr>
<td>Metaninf</td>
<td>0.51</td>
<td>0.45</td>
</tr>
<tr>
<td>Threonine (Essential)</td>
<td>3.95</td>
<td>4.25</td>
</tr>
<tr>
<td>Glutamic Acid</td>
<td>17.64</td>
<td>15.37</td>
</tr>
<tr>
<td>Proline</td>
<td>3.18</td>
<td>0.73</td>
</tr>
<tr>
<td>Glycine</td>
<td>6.16</td>
<td>5.23</td>
</tr>
<tr>
<td>Alanine</td>
<td>5.46</td>
<td>5.34</td>
</tr>
<tr>
<td>Valine (Essential)</td>
<td>5.05</td>
<td>6.32</td>
</tr>
<tr>
<td>Methionine (Essential)</td>
<td>0.51</td>
<td>0.45</td>
</tr>
<tr>
<td>Isoleucine (Essential)</td>
<td>3.79</td>
<td>3.98</td>
</tr>
<tr>
<td>Leucine (Essential)</td>
<td>7.78</td>
<td>7.30</td>
</tr>
<tr>
<td>Tyrosine</td>
<td>4.19</td>
<td>3.41</td>
</tr>
<tr>
<td>Phenylalanine (Essential)</td>
<td>6.32</td>
<td>5.86</td>
</tr>
<tr>
<td>Histidine (Essential)</td>
<td>2.63</td>
<td>3.19</td>
</tr>
</tbody>
</table>

**[0109]** As can be seen the calcium, potassium and selenium content in the Salvia sclarea seeds are close to the RDA recommended amounts.
TABLE 4-continued

<table>
<thead>
<tr>
<th>Amino acid contents in 100 g</th>
<th>USRDA</th>
<th>Seeds</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample</strong></td>
<td><strong>Salvia Scarea</strong></td>
<td><strong>Salvia Hispanic</strong></td>
</tr>
<tr>
<td>Lysine</td>
<td>3.69</td>
<td>5.50</td>
</tr>
<tr>
<td>Gamma aminobutyric acid</td>
<td>10.71</td>
<td>11.03</td>
</tr>
<tr>
<td>Total</td>
<td>~98%</td>
<td>~96%</td>
</tr>
</tbody>
</table>

[0110] As can be seen, the amino acid contents in 100 g Salvia Scarea supplies 50-160% of the USRDA essential amino acid contents.

EXAMPLE 1

Effect of Salvia Scarea Seed-Products on Hens

[0111] An experiment was conducted to measure the toxicity of Salvia Scarea seed oil when administered as a dietary supplement to laying hens, and the resultant level of omega-3 fatty acid, as measured in the hens’ body fat and in the resultant egg yolks.

[0112] 11 kg of Salvia Scarea seeds were milled into crude flour, and mixed into standard hen feed at a concentration of 13.75% w/w. Concentrations of 15-17% of the Salvia Scarea flour would also have been appropriate, though they were not included in this experiment. The feed containing the Salvia Scarea flour was stored and used for the duration of the experiment, though typically hen feed is prepared immediately before use.

[0113] 20 hens of the Yarkon variety were selected, having an age of 8.5 months old. At termination of the experiment, the hens numbered 18; this is consistent with the standard mortality rate. The laying capacity was approximately 80-90% at the start of the experiment. The hens were fed once or twice daily by hand, so that each hen received approximately 120-130 gr. of feed, as estimated visually.

[0114] During the first two days, the hens showed classical symptoms seen when feed is changed. These symptoms disappeared thereafter.

[0115] No change was observed in the quantity of feed consumed by the hens, or in the degree of laying, though these values were not physically measured. The quality of the eggs, their size and breakage levels were not measured, but no change was visibly apparent.

[0116] At the start of the experiment, (Day 1), 10 eggs were selected, refrigerated for 4 days, then their yolks were pooled and sent for chemical analysis. Yolks were refrigerated until analysis was performed. The yolk pool had a volume of 30 ml. The fatty acid content, the Total Fat, and the cholesterol levels were analyzed, and are presented in Table 1 below.

[0117] On Day 14 of the experiment, 10 additional eggs were selected and their pooled yolks were sent for analysis.

[0118] On Day 29, 10 yolks were once again pooled and analyzed, and 10 control yolks were likewise pooled and analyzed. The control yolks belong to hens raised in similar conditions, however the control group did not receive Salvia Scarea flour supplement in the feed.

[0119] The experiment was discontinued at Day 34. Two hens were then selected, one being a hen in the experiment group, and one control hen. They were slaughtered, and their body fat content was analyzed. Results are shown in Table 1 below.

[0120] In this experiment, the nutritional value of the Salvia Scarea seed itself was disregarded, though, for instance, feed containing Salvia Scarea flour has a higher oil content than standard feed.

[0121] Referring to Table 5, the percentage of linolenic acid present in the egg contents increased dramatically by 617%. The percentage of DHA increased as well, by 21%.

[0122] Referring to Table 6, the percentage of linolenic acid present in the body fat of hens that consumed Salvia Scarea flour rose dramatically, by 167%.

[0123] No toxicity was observed for Salvia Scarea seed flour.

[0124] These results demonstrate Salvia Scarea seeds are a viable source of Omega-3 fatty acids and that consumption of Salvia Scarea seed flour results in a direct positive effect on the level of Omega-3 fatty acids in the consumer. Dietary supplements containing Salvia Scarea seed flour or oil are thus nutritionally recommended, and could aid in preventing or ameliorating arteriosclerosis and other conditions where high levels of Omega-3 fatty acids have been found to be beneficial.

### TABLE 5

<table>
<thead>
<tr>
<th>Fatty acid</th>
<th>Name</th>
<th>Control</th>
<th>Treated</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>C14:0</td>
<td>Myristic</td>
<td>0.37</td>
<td>0.35</td>
<td>—</td>
</tr>
<tr>
<td>C16:0</td>
<td>Palmitic</td>
<td>24.64</td>
<td>23.36</td>
<td>-6</td>
</tr>
<tr>
<td>C16:1</td>
<td>Palmitoleic</td>
<td>3.18</td>
<td>3.55</td>
<td>+5</td>
</tr>
<tr>
<td>C18:0</td>
<td>Stearic</td>
<td>9.23</td>
<td>7.08</td>
<td>-17</td>
</tr>
<tr>
<td>C18:1</td>
<td>Oleic</td>
<td>42.28</td>
<td>43.26</td>
<td>+2</td>
</tr>
<tr>
<td>C18:2</td>
<td>Linoleic</td>
<td>15.78</td>
<td>15.51</td>
<td>-2</td>
</tr>
<tr>
<td>C18:3</td>
<td>Linolenic</td>
<td>0.57</td>
<td>4.09</td>
<td>+617</td>
</tr>
<tr>
<td>C20:5</td>
<td>EPA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C22:6</td>
<td>DHA</td>
<td>0.57</td>
<td>0.69</td>
<td>+21</td>
</tr>
<tr>
<td>Total fat in</td>
<td></td>
<td>20.93</td>
<td>23.00</td>
<td>+10</td>
</tr>
<tr>
<td>the egg(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P/S ratio</td>
<td></td>
<td>0.47</td>
<td>0.69</td>
<td>+21</td>
</tr>
</tbody>
</table>
TABLE 6

Content of Hen Body Fat after Consumption of Salvia sclarea Seed Flour

<table>
<thead>
<tr>
<th>Fatty acid</th>
<th>Name</th>
<th>Control</th>
<th>Treated</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>C14:0</td>
<td>Myristic</td>
<td>0.52</td>
<td>0.54</td>
<td>+4</td>
</tr>
<tr>
<td>C16:0</td>
<td>Palmitic</td>
<td>18.84</td>
<td>19.55</td>
<td>+4</td>
</tr>
<tr>
<td>C16:1</td>
<td>Palmitoleic</td>
<td>3.71</td>
<td>4.70</td>
<td>+27</td>
</tr>
<tr>
<td>C18:0</td>
<td>Stearic</td>
<td>5.89</td>
<td>5.51</td>
<td>-6</td>
</tr>
<tr>
<td>C18:1</td>
<td>Oleic</td>
<td>37.95</td>
<td>40.88</td>
<td>+8</td>
</tr>
<tr>
<td>C18:2</td>
<td>Linoleic</td>
<td>29.75</td>
<td>23.57</td>
<td>-21</td>
</tr>
<tr>
<td>C18:3</td>
<td>Linolenic</td>
<td>1.44</td>
<td>3.85</td>
<td>+167</td>
</tr>
<tr>
<td>Total hen’s fat (%)</td>
<td></td>
<td>55.3</td>
<td>37.6</td>
<td>-32</td>
</tr>
<tr>
<td>P/S ratio</td>
<td></td>
<td>1.23</td>
<td>1.07</td>
<td>-7</td>
</tr>
<tr>
<td>% S in</td>
<td></td>
<td>14.5</td>
<td>9.03</td>
<td>-32</td>
</tr>
<tr>
<td>Triglycerides</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Based on the nutritional-chemical spectrums of analysis, the general conclusions are that Salvia sclarea seeds can be regarded as almost a nutritionally complete foodstuff.

EXAMPLE 2

Calculations Concerning Salvia sclarea as a Food Supplement for Human Consumption:

According to the analysis shown in tables 1-4 above it is calculated that 100 grams of Salvia sclarea seeds per day will supply approximately 40% to 50% of the required proteins, including all the US RDA for essential Amino Acids (except a too low quantity of Methionine), approx. 40% of the daily recommendations for fats/oils (based on 2000 calories per day diet) with an excellent fatty acid profile that contains approx. 50% Omega-3 ALA, 25% Oleic Acid, and 3.4 to 1 ratio of Omega 3 to Omega 6.

100 grams per day of Salvia sclarea seeds will also supply 75% of the recommended USA daily values for dietary fiber based on a 2000 calories diet (or 100% according to the UK recommendations), 100% of the US RDA for most of the minerals (Ca, Mg, Cu, Se, Mn), 50% of the US RDA for Potassium(K) and Iron (Fe), 33% for Zinc(Zn) and Boron(B) 1.4 mg/100 g.

The Salvia sclarea seeds are also free of trans-fatty acids and gluten, and absorb approx. 8 times their weight in water making them ideal for diet-low calorie foods, as fat replacement products and water binders.

EXAMPLE 3

Production of Salvia sclarea a Flour/Powder

The Salvia sclarea seeds are ground into meal, blended with natural antioxidants to prevent oil oxidation (rancidity) and to prolong the shelf life of the product and then formulated as an ingredient into weight reducing, nutritionally balanced powdered drink mixes, bars and low-cal/low carbohydrates baked goods.

EXAMPLE 4

Production of Cereals Snakes and Pasta

The Salvia sclarea seeds are ground into meal, partially blended with whole seeds, formulated with other grains flours such as wheat barley, soy or corn together with natural binders and fibers, and then extruded by cooking extruders into flakes for breakfast cereals, and other shapes for snacks then flavored, spiced, oil coated and baked (or fried) in oils blended with Salvia sclarea Omega 3 enriched vegetable oils.

For production by “cooking extruders” a dry blend of Salvia meal and other ingredients are cooked together under high pressure, using a single or twin co-rotating screws inside a barrel with injection ports. Water and/or other liquids are injected into the barrel during the cooking and blending process. The extruded product is baked or air-dried, fried, and then flavored.

Formulations for cold extruded pasta products include usage of special natural colorings, dough improvers, spices, flavorings, fibers, etc. that render natural, omega-3 enriched pastas of various shapes and colors.

The extruded products can be used as such (without further processing) or mixed with other ingredients for production of health oriented dry or cooked meals, breakfast cereals, granola mixes, etc. Using state-of-the-art formulations for cold-extrusion systems Omega-3 enriched pasta is obtained in various shapes and colors (using natural colors also with antioxidant activities).

EXAMPLE 5

Production of Low-Calorie Baked Goods

Salvia sclarea whole seeds are pretreated by soaking in water or other suitable liquids or marinades, and then formulated into low-calorie, nutritionally enhanced baked goods. For example, in one embodiment a 250 calorie per 100 gram standard bread has its energy reduced by 40% to a 150 calorie per 100 gram diet bread. Similarly, a substantial reduction in calories applies to buns and rolls, biscuits, bagels. These low-calorie baked goods which are also enriched, Omega 3 enriched, are suitable also for fast food chains (buns for hotdogs or hamburgers), sandwiches, etc.

The Salvia sclarea seeds are marinated in buffer, flavored and naturally colored solutions for varying lengths of time as desired. Temperature and pH are controlled.

The marinated seeds and also Salvia sclarea flour/ powder are mixed into bread dough and other bakery products- and baked accordingly. The marinated seeds will render products containing them low calorie products and also low-carbohydrates (low-carb.) since the bound water marinade will react with the Salvia sclarea fibers to form a soft jelly-type mixture.

EXAMPLE 6

Production of Oil

Salvia sclarea seed oil is extracted from seeds, blended with other oils, vegetable proteins, water, natural emulsifying and stabilizing ingredients and then homogenized by an homogenizer and formed into a butter-margarine like flavored spreads, free of trans fatty acids, very low in saturated fats, and high in Omega-3 and Oleic fatty acids.

Salvia sclarea seed oil is extracted from Salvia seeds by a multi-stage press-extractor. Prior to extraction the seeds are lightly heated and wetted for maximum yields.
The excess water is then removed by a decanting centrifuge. The omega-3 rich and oleic acid rich oil is collected, blended with natural oxidants and bottled as such or blended with other oils (see also Example 8), bottled or blended with other ingredients (emulsifiers, stabilizers, water, etc.) and then homogenized under vacuum to produce high omega-3 and oleic acids butter-like spreads, vegetarian mayonnaise, etc.

**EXAMPLE 7**

Production of Paste

Salvia sclarea seeds, rich in proteins, omega-3 oil and soluble fibers are roasted and ground into a very fine paste by proprietary equipment. The paste may be packed as is, as a high nutritional base that can be used for thickening gravies, soups and preparation of many oriental and Indian type dishes such as meat or vegetarian Satay, curries, Hummus etc.

Additional usage can be to prepare dips such as tehini dip, prepared in conjunction with sesame paste or oil, water, garlic, lemon juice, spices and herbs. The Tehini Dip can be used as is or made into salad dressings, etc.

A sesame/coffee type roasted is used for roasting and controlled temperature heating of the Salvia sclarea seeds, which are then ground and homogenized into an omega-3 rich tehini-type paste.

**EXAMPLE 8**

Production of Omega-3 Enriched Oil Preparations

The treated and drained seeds are blended with Fish oils, and natural marine flavors omega-3 EPA and DHA fatty Acids in desired ratios according to product recipe.

The finished product is packed in glass, plastic or metal packaging and processed to render shelf stable or chilled products with long shelf lives. These products are actually described as vegetarian caviar (fish roe) like products with high nutritional values that include all the nutritional factors of Salvia sclarea seeds, and in addition the full group of omega-3 fatty Acids (ALA, DHA and EPA) from Vegetable and Marine sources.

In this embodiment the Salvia sclarea whole seeds are treated by soaking using a multi-stage battery of variable speed mixers. The differential soaking solutions contain osmotic and acid regulations, and natural antioxidants, flavors and colors. Time and temperatures are controlled and the solutions treated seeds are dewatered by low-speed centrifuges. The seeds are blended as described, and then processed by pasteurization/sterilization (according to pH of product) to yield shelf stable products.

**EXAMPLE 9**

Production of Fish Feed Formulations

Salvia sclarea seeds are milled and blended at various ratios into fish feed formulations.

This embodiment provides sweet water or salty water fish with the entire range of nutritional benefits of Salvia sclarea special oil rich in omega-3 alpha linolenic acid, omega-6 linoleic acid and oleic acid.

The fish formulations are then extruded into floating or sinking pellets according to the type of fish to be fed.

The raised fish will contain in their fillets a relatively higher concentration of omega-3 fatty Acids, which in turn can be controlled by the concentration of ALA (c18:3) which is also a precursor for natural synthesis of DHA (c22:6) in animal, poultry and fish flesh. These feed formulae contain all typical ingredients and added Salvia(x) meal containing high value proteins, minerals and omega-3 oils.

**EXAMPLE 10**

Production of Packaged or Encapsulated Oil

Salvia sclarea seed oil rich in omega-3 ALA is extracted from seeds. The oil is blended with olive and other vegetable oils, rich in monounsaturated and omega-6 fatty acids and fortified with natural proprietary antioxidants that will prevent the oil mixture from oxidation and also will provide beneficial antioxidants (such as Vitamin E Vitamin C and others) to the user.

The ratio of monounsaturated fatty acids to omega-3 9% and omega-6 is calculated to be 1 to 5 to 5, in order to maintain the recommended ratio of ½ monounsaturated 9% poly unsaturated 9% (with a ratio of 1 to 1 between omega-3 9% and omega-6 9%) and ½ saturated fatty acids of vegetable or animal origin (such as palm oil, coconut oil, butter, etc.). All fats and oils should be trans free.

The total fats/oil per daily use is calculated to be 60 gr. Or 75 gr. (i.e. 27% of diets with 2000 calorie/day or 2500 calorie/day respectively).

About 2-3 grams a day of fish oils containing 1000 mg. omega-3 DHA and EPA PUFA, are enclosed separately to the package, in order to supply daily the whole range of omega-3 PUFA: ALA, EPA & DHA.

The entire fatty acids/oils daily portion is packed in a 3 compartment package which will include in comp. 1 the fluid oils blend (to be used in salads, cooking, etc.), in comp. 2a spreadable sat. fatty acids mix (to be used by spreading on crackers, bread slices, etc.) and in comp. 3, the omega-3 PUFA rich, fish oils (to be used with fish salads, dishes, etc. or any other food with a compatible flavor).

The fish oil may also be encapsulated.

Special oil blends including natural herbal and other antioxidants, and rich in omega-3 and oleic acids and compounded to yield nutritionally recommended ratios of omega-6:omega-3, mono-unsaturated poly unsaturated and saturated fatty acids.

1. A composition, for use as a food supplement, comprising as an active ingredient a composition of matter selected from:

   (a) Salvia sclarea seed;

   (b) Salvia sclarea seed oil in an essentially pure form;
(c) extracts from *Salvia sclarea* seeds;
(d) *Salvia sclarea* seed crushed or milled to form a flour or powder; and
(e) *Salvia sclarea* seed pulp.

2. A composition according to claim 1 consisting essentially of a composition of matter selected from:
(a) *Salvia sclarea* seed;
(b) *Salvia sclarea* seed oil in an essentially pure form;
(c) extracts from *Salvia sclarea* seeds;
(d) *Salvia sclarea* seed crushed or milled to form a flour or powder; and
(e) *Salvia sclarea* seed pulp.

3. A composition according to claim 1 further comprising a carrier suitable for consumption.

4. A composition according to claim 1(b) wherein the essentially pure oil is obtained by:
(a) crushing and pressing the *Salvia sclarea* seed;
(b) separating the oily phase of the crushed and pressed seed; and optionally;
(c) purifying the separated oily phase.

5. A composition according to claim 4(b) wherein the separation of the oily phase is obtained by centrifugation of the crushed and pressed seed and collection of the supernatant.

6. A composition according to claim 4(b) wherein the separation of the oil phase is obtained by extraction with volatile solvents, followed by evaporation of the solvents by application of heat or vacuum or a combination of heat and vacuum.

7. A composition according to claim 4(b) wherein the oil is separated by the use of liquid CO$_2$ or liquid nitrogen.

8. Use of a composition of matter selected from:
(a) *Salvia sclarea* seed;
(b) *Salvia sclarea* seed oil in an essentially pure form;
(c) extracts from *Salvia sclarea* seeds;
(d) *Salvia sclarea* seed crushed or milled to form a flour or powder; and
(e) *Salvia sclarea* seed pulp.

for the preparation of a food supplement.

9. A nutraceutical composition comprising a nutraceutically acceptable carrier and as an active ingredient a composition of matter selected from:
(a) *Salvia sclarea* seed;
(b) *Salvia sclarea* seed oil in an essentially pure form;
(c) extracts from *Salvia sclarea* seeds;
(d) *Salvia sclarea* seed crushed or milled to form a flour or powder; and
(e) *Salvia sclarea* seed pulp *Salvia sclarea* seed oil in an essentially pure form.

10. A nutraceutical composition according to claim 9 for the treatment of a disease or disorder wherein a therapeutically beneficial effect may be evident by increase in the level of at least one omega-3 fatty acid.

11. A nutraceutical composition according to claim 10 wherein the disease or disorder is selected from: arthrosclerosis, coronary artery disease, chronic inflammatory disease such as rheumatoid arthritis and IBD, diabetes, cancer, prevention of blood vessels from closing after vascular surgery, relieving symptoms of psoriasis, skin wrinkles and depression and mood disorders.

12. A cosmetic composition comprising a cosmetically acceptable carrier and as an active ingredient *Salvia sclarea* seed oil in an essentially pure form.

13. A composition according to claim 12, wherein said cosmetic composition is designed to prevent wrinkling of skin, or to ensure skin health.

14. Use of *Salvia sclarea* seed oil in an essentially pure form for the preparation of a nutraceutical composition.

15. Use according to claim 14 wherein the medicament is for the treatment of a disease or a disorder wherein a therapeutically beneficial effect may be evident by increase in the level of at least one omega-3 fatty acid.

16. Use according to claim 15 wherein the disease or condition is selected from: arthrosclerosis, coronary artery disease, chronic inflammatory disease such as rheumatoid arthritis and IBD, diabetes, cancer, prevention of blood vessels from closing after vascular surgery, relieving symptoms of psoriasis, skin wrinkles and depression and mood disorders.

17. A food product comprising the food supplement of claim 1.

18. A food product according to claim 17, comprising whole seeds of *Salvia sclarea*, the food product selected from: granola-like cereals, granola-like snack bars, food stuff for hens, food stuff for cattle, whole breads, rolls, crackers and biscuits.

19. A food product according to claim 17 comprising *Salvia sclarea* seeds, ground or milled to produce flour/powder, the food product selected from: granola-like cereals, granola-like snack bars, food stuff for hens, cows, a or fish, whole breads, rolls, crackers, biscuits, pasta and other baked goods; thickener in gravy, soup, dips, dressings and other prepared food.

20. A food product according to claim 17 comprising *Salvia sclarea* seeds oil, the food product selected from: oily pastes or dips, Tehini, Humus, oils and paste in sesame oil or sesame paste, margarine, margarine-like- spreads, salad dressings, fish oil, caviar-like products.

21. A food product according to claim 17, comprising *Salvia sclarea* pulp, the food product selected from: low calorie baked products, low calorie drinks and low calorie shakes.

* * * * *