

OMEGA 3-FATTY ACID EMULSION

BACKGROUND OF THE INVENTION

This invention relates to an emulsion for use as a food supplement comprising carotenoids, tocopherols, tocotrienols, omega-3 fatty acids, zinc, selenium and manganese. The invention also relates to a method of making such an emulsion.

The benefits of omega-3 fatty acids have been well documented over the years. This, in turn has created a high level of public awareness and acceptance of omega-3 fatty acids. The benefits of these fatty acids are set out below.

Omega-3 fatty acids play a crucial role in brain function as well as in normal growth and development. Extensive research indicates that omega-3 fatty acids reduce inflammation and help prevent risk factors associated with chronic diseases such as heart disease, cancer and arthritis. These essential fatty acids are highly concentrated in the brain and appear to be particularly important for cognitive and behavioural function. Clinical studies also suggest that omega-3 fatty acids may be supportive with the prevention of a variety of other health conditions such as: high cholesterol, high blood pressure, heart disease, diabetes – lowering of blood triglycerides, weight loss - better control over blood glucose levels, osteoporosis, depression, attention deficit/hyperactivity disorder – improvement in reading, spelling and behavior, skin disorders – treatment of acne, reducing the risk of breast cancer and prostate cancer and improving immune function.

Omega-3 fatty acids cannot be manufactured in the human body and are therefore called essential fatty acids. They need to be obtained from the diet of an individual. In addition, nutrients such as zinc, selenium and manganese play a key role in the metabolism of omega-3 fatty acids in the human body and its subsequent metabolic and functional effects on health.

Docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) are two types of omega-3 fatty acids, which are found in cold water fish. Because of the wide range of known health benefits related to EPA and DHA a number of international organizations (see Table below) and agencies proposed recommendations for EPA and DHA as well as fish intake for health promotion and prevention of various chronic diseases.

Name of organisation	Recommendation
International Society for the Study of Fatty Acids and Lipids	500mg of EPA and DHA combined per day to reduce the risk of cardiovascular health 1000mg of EPA and DHA combined per day may help in the secondary prevention of cardiovascular disease (Hanafiah <i>et al.</i>).
The American Heart Association	1g per day of a mixture of EPA and DHA 2 servings per week of oily fish which is approximately 500mg per day of EPA and DHA (Lee <i>et al.</i>).
American Dietetic Association	≥ 2 servings of fish per week. In addition, 500 mg per day of EPA and DHA is recommended (Kris-Etherton & Hill).
United Kingdom Scientific Advisory	2 portions of fish per week and 450

Committee on Nutrition	mg per day of EPA and DHA (Kris-Etherton & Hill).
World Health Organization	1-2 servings of fish per week the equivalent of 200 to 500 mg EPA and DHA (Kris-Etherton & Hill).

Although the intake of omega-3 fatty acids has proven to be crucial, it has been found that omega-3 fatty acids are deficient in the typical Western diet. The omega-3 deficiency situation is even worse among the poor and malnourished. Since omega-3 is vital for brain development it is essential that infants and children from gestational age to teenagers should consume omega-3 fatty acids. Micronutrient deficiencies such as vitamin A, zinc, selenium and others are also common among the malnourished.

One approach to alleviating omega-3 fatty acid deficiencies is through dietary supplementation, which is a convenient way to add them to the diet. As a result, the interest in omega-3 fatty acid supplements has soared. Nutritional supplements are especially useful in individuals who struggle to meet their nutrient needs because of inadequate dietary intakes. At risk groups for poor dietary intakes may include infants and pre-school children, pregnant women, the aged, individuals with compromised nutritional status and those with a limited variety in food selection.

There are several omega-3 fatty acid supplements available. In particular, in South Africa there are approximately 65 pure omega-3 fatty acid supplements in the form of soft gel capsules available. One such supplement, described in WO 2012/049534 is in the form of a capsule and comprises omega-3 fatty acids, carotenoids, tocopherol and tocotrienol. However, some consumers such as infants, young children, older people, or patients with dysphagia may experience difficulty swallowing supplements in the form of capsules or tablets. There are also a few liquid fish oil supplements available to consumers but to improve the taste manufacturers' frequently use the ethyl ester form of omega-3 fatty acids.

Controversy surrounds the use of ethyl esters since the safety and bioavailability thereof in humans are still debated.

A need therefore exists for an omega-3 fatty acid supplement that is not available in a capsule or tablet form, but rather in a form which is convenient and easy to digest by the consumer, which comprises safe ingredients and which is easily absorbed by the body.

SUMMARY OF THE INVENTION

According to one aspect of the invention, there is provided an emulsion comprising water, omega-3 fatty acids, carotenoids, tocopherols, and tocotrienols. Preferably the emulsion also comprises other micronutrients such as zinc, selenium and manganese.

The source of the omega-3 fatty acid is refined fish oil. More preferably, the fish oil comprises at least 18 % eicosapentaenoic acid (EPA) and 12 % docosahexaenoic acid (DHA). The fish oil may also be present in the form of glycerides, ethyl esters and phospholipids.

In a preferred embodiment, the emulsion comprises from about 1 mg to about 4000 mg of fish oil, from about 0.1mg to about 15 mg of carotenoids, from about 0.1 mg to about 200 mg of tocopherol, from about 0.1 mg to about 200 mg of tocotrienol, from about 1.1 mg to about 40 mg of zinc, from about 5.5 mcg to about 400 mcg of selenium and from about 0.23 mg to about 11 mg of manganese per 5 ml of emulsion.

The fish oil provides for about 445 mg omega-3 marine fatty acids consisting of 267 mg Eicosapentaenoic acid (EPA) and 178 mg Docosahexaenoic acid (DHA) per 5 ml single serving.

The carotenoids, tocopherol, tocotrienol, may be obtained from a mixed concentrate. In particular a concentrate that is derived from palm fruit.

Preferably the concentrate may comprise of 3 % of carotenoids, about 2% of tocopherols, about 8% of tocotrienols and about 79% of glycerides per 100 mg of concentrate. The balance of 8% is made up of other phytonutrients.

More specifically, the carotenoids include carotenes, in particular, alpha-carotene, beta-carotene and gamma-carotene. The tocopherols and tocotrienols may comprise alpha-tocopherol, alpha-tocotrienol, beta-tocotrienol, gamma-tocotrienol and delta-tocotrienol.

The concentrate preferably includes the following carotenoid content per 100 mg; (a) alpha-carotene –about 1.91 mg, (b) beta-carotene – about 2.72 mg; (c) lycopene – about 63mcg and (d) other carotenes – about 160 mcg.

The tocopherols and tocotrienols may be available in the concentrate in amounts of about 3.21 mg and 12.99 mg respectively, per 100 mg of concentrate.

The concentrate may further comprise lycopene, glycerides, phytosterols, Co-Enzyme Q 10 and squalene. The phytosterol may be available in an amount of 234mcg, the squalene-66mcg, co-enzyme Q10 – 12mcg and the glyceride – 79mg; per 100 mg of concentrate.

The concentrate may comprise micronutrients that are substantially free of toxic elements such as lead, mercury and arsenic. In particular, the concentrate comprises less than 0.6 parts per million (ppm) of lead, less than 0.05 ppm of mercury and less than 0.1 ppm of arsenic.

The concentrate may also comprise a low content of microorganisms, for example in an amount of less than 10 cfu/g total plate count for bacteria, yeast and mould.

The emulsion may further comprise soy lecithin, glycerol, puratex (invert sugar) and/or artificial sweeteners, citric acid, stabilizer, flavourants, water and preservatives, preferably potassium sorbate.

The components may be of natural origin and of high purity.

The selenium may be in the form of selenium yeast, selenium amino acid chelate, selenium oxide, , selenium sulphide, sodium selenite or sodium selenate.

The zinc may be in the form of zinc amino acid chelate, zinc gluconate, zinc oxide, zinc sulphate, zinc undecylenate, zinc chloride, zinc stearate and zinc acetate.

The manganese may be in the form of manganese amino acid complexes, manganese gluconate, manganese glycerophosphate and manganese sulphate.

Preferably, the selenium, zinc and manganese are each formulated as amino acid complexes.

In a preferred embodiment, the emulsion comprises the range of constituents as provided in Table 5.

According to a second aspect of the invention there is provided a method of making the emulsion of the invention. The method includes the steps of:

- a) providing a source of fish oil containing at least 18% EPA and 12% DHA;
- b) providing a source of a concentrate comprising carotenoids, tocopherols, tocotrienols and glycerides; preferably the concentrate comprises of 3 % of carotenoids, about 2% of tocopherols, about 8% of tocotrienols and about 79% of glycerides per 100 mg of concentrate, the balance of 8% is made up of other phytonutrients;

- c) optionally providing a source of zinc, manganese and selenium, preferably these are provided as amino acid complexes;
- d) blending together the fish oil, concentrate, optional zinc, manganese and selenium with water and homogenizing the resultant solution until a stable omega-3 fatty acid emulsion is formed.

In a preferred embodiment the method comprises;

- a) blending together a fish oil containing at least 18% EPA and 12% DHA and a concentrate comprising carotenoids, tocopherols, tocotrienols and glycerides until a homogenous mixture A is obtained;
- b) blending together water, and a source of zinc, selenium and manganese until a homogenous mixture B is obtained;
- c) blending together mixtures A and B until a homogenous mixture C is obtained, thereby forming a stabilized omega-3 fatty acid emulsion.

Preferably the concentrate comprises of 3 % of carotenoids, about 2% of tocopherols, about 8% of tocotrienols and about 79% of glycerides per 100 mg of concentrate. The balance of 8% is made up of other phytonutrients.

The water is preferably at a temperature of 40°C.

The zinc, selenium and manganese are preferably added as amino acid complexes.

In a preferred embodiment soy lecithin is first added to the fish oil. The mixture of soy lecithin and fish oil is warmed in a water bath at 40 degrees Celcius and mixed until a homogenous mixture is obtained.

The concentrate is then added to the soy lecithin and fish oil mixture. Preferably the concentrate is added to the mixture at 40 °C and the combined mixture of fish oil, soy lecithin and concentrate is mixed until a homogenous mixture is obtained.

In a preferred embodiment, additives such as a stabilizer, citric acid, glycerol, puratex and/or artificial sweeteners, and potassium sorbate are also added to the emulsion. Examples of stabilizers include: lecithin, sodium alginate, cognac glue, polyglycerol, xanthan gum and guar gum. Examples of artificial sweeteners include: acesulfame potassium, aspartame, xylitol, sodium cyclamate, neotame, saccharin, and sucralose. Preferably these additives are first added to the water. The water together with the additives are first mixed together until a homogenous mixture is obtained. This is then warmed to a temperature of 40°C and then mixed with the fish oil, lecithin and concentrate mixture, and homogenized until a stable emulsion is obtained.

Additionally, an appropriate flavourant is added to the emulsion.

According to a further aspect of the invention, there is provided an emulsion according to the invention for use in the treatment or prevention of a micronutrient deficiency selected from: vitamin A, vitamin E, iron, zinc, copper, manganese or selenium and/or in the enhancement of the immune system of a subject.

According to a further aspect of the invention, there is provided a use of the emulsion of the invention in the manufacture of a medicament for use in the treatment or prevention of a micronutrient deficiency selected from: vitamin A, vitamin E, , iron, zinc, copper, manganese or selenium and/or in the enhancement of the immune system of a subject.

DESCRIPTION OF PREFERRED EMBODIMENTS

The current invention provides for a food emulsion for use as a food supplement, which contains a spectrum of fat soluble phytonutrients including carotenoids, tocopherols and tocotrienols; omega-3 fatty acids in the form of fish oil; zinc, selenium and manganese. The emulsion can

contain other micronutrients known to be deficient in the typical Western diet.

Since this emulsion is a unique combination of vital elements in the diet such as omega-3 fatty acids, vitamin A, vitamin E, zinc, selenium and manganese it will surely play an important role in the fight against malnutrition.

The benefit of having all these multivitamins in the form of an emulsion is that it can be added to infant food and infant formula to ensure optimal daily intake. The emulsion and its contents are stable for up to two years.

FUNCTIONAL ROLE OF INGREDIENTS

Provitamin A (carotenoids)

Carotenoids are red, orange and yellow organic colour pigments which naturally occur in the chloroplasts and chromoplasts of plants. Carotenoids absorb light energy for photosynthesis and protect chlorophyll from photodamage. Humans cannot synthesise carotenoids and it should be obtained via the diet. Carotenoids can be split into two classes namely xanthophylls and carotenes. Some carotenes (alpha-, beta-, gamma-carotene and beta-cryptoxanthin) are precursors to vitamin A which is essential for good vision. In general carotenoids also act as antioxidants.

People consuming diets rich in carotenoids from natural foods, such as fruit and vegetables are healthier and have lower mortality from a number of chronic diseases. With the exception of Vietnamese Gac and crude palm oil, most carotenoid-rich fruit and vegetables are low in lipids.

Alpha- and beta-carotene are known to have the following health benefits:

- a. Provitamin A activity in humans
- b. Anti-inflammatory activity
- c. Antioxidant activity

- d. Increase *in vivo* immune response
- e. Improved cell-to-cell communication
- f. Lower the risk for heart disease
- g. Specific anti-cancer activity. Lycopene may reduce the risk for prostate- and breast cancer. Carotenoids also have anti-metastatic activity.
- h. Reduction of skin reactions in light dermatosis
- i. Macula protection from UV light
- j. Long term beta-carotene intake may slow mental decline.

The Nutrient Reference Value for Vitamin A as stipulated in the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act 54 of 1972) R146 is 900 mcg (micrograms) RE (retinol equivalents) per day for individuals 4 years and older. The upper limit intake of vitamin A is 3 000 mcg RE.

Vitamin E (tocopherols and tocotrienols)

Vitamin E is a fat soluble vitamin with anti-oxidant activity and exists in eight different forms, four tocopherols and four tocotrienols. Both tocopherols and tocotrienols occur in alpha-, beta-, gamma- and delta-forms. It has been claimed that alpha-tocopherol is the form of vitamin E with the highest bioavailability. In general, food sources with the highest concentration of vitamin E are vegetable oils, followed by nuts and seeds, including whole grains.

Vitamin E has many biological functions; the antioxidant function being the most important and/or best known. Other functions include enzymatic activities, gene expression and neurological function(s). It's also been suggested that the most important function of vitamin E is in cell signaling. As it is fat-soluble, it is incorporated into cell membranes, which protects them from oxidative damage.

Some of the isomers from tocopherols and tocotrienols have been further investigated through a number of clinical and non-clinical studies for their biological activities. Some research suggests that tocotrienols are more

potent in their anti-oxidant and anti-cancer effect than the common forms of tocopherol due to significant differences in chemical structure.

Tocotrienols are known to have the following health benefits:

- a. Supplementation with tocotrienols may protect against stroke
- b. Tocotrienols may reverse arterial blockage of the carotid artery in carotid stenosis patients
- c. Tocotrienols may reduce platelet aggregation, have anti-inflammatory action and anti-cancer activity.
- d. Gamma-tocotrienol is a potent suppressor of prostate cancer cell proliferation.
- e. Gamma- and delta-tocotrienols were shown to be effective nutritional agents to treat high cholesterol
- f. Vitamin E intake is significantly associated with a reduced risk of type 2 diabetes.

The majority of food supplements available on the market are in the form of synthetic alpha-tocopherol. The vitamin E in this emulsion is plant derived and therefore a natural component.

The Nutrient Reference Value for Vitamin E as stipulated in the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act 54 of 1972) R146 is 15 mg TE (tocopherol equivalents) (milligrams of alpha tocopherol) per day for individuals 4 years and older. The upper limit intake of vitamin E is 1 000 mg TE.

Selenium

Selenium is a component of the antioxidant enzyme glutathione peroxidase which protects cells and membranes against oxidative damage by free radicals. The role of selenium balances with vitamin E. Selenium is also an important component of the protein matrix of teeth and plays a role in activation of the thyroid hormone.

The Nutrient Reference Value for Vitamin E as stipulated in the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act 54 of 1972) R146 is 55 mcg

(micrograms) per day for individuals 4 years and older. The upper limit intake of selenium is 400 mcg.

Zinc

Zinc is an essential mineral and its deficiency is evident among the developing Fworld. Zinc deficiency in children causes growth retardation, delayed sexual maturation, infection susceptibility and diarrhoea. Benefits of zinc include: optimized activity of about 100 enzymes; is a co-factor in the synthesis of DNA and RNA molecules; is important for growth and development; is required to generate the haeme in haemoglobin; assists the pancreas with digestive functions; assists with the metabolism of macro-nutrients; is involved in mobilization of vitamin A from the liver; has been associated with improved behaviour and learning; assists in immune functions; stabilizes membrane structure; is associated with detoxification of alcohol in the liver; assists in the transport of carbon dioxide from cells to lungs; has a role in anaerobic carbohydrate metabolism; is required in bone metabolism; is important for thyroid function and it is involved in vitamin metabolism.

The Nutrient Reference Value for zinc as stipulated in the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act 54 of 1972) R146 is 11 mg (milligrams) per day for individuals 4 years and older. The upper limit intake of zinc is 40 mg.

Manganese

Manganese is an essential nutrient involved in the formation of bone and in amino acid, cholesterol and carbohydrate metabolism. Manganese is an important element in the activation and activities of several enzymes. Signs of manganese deficiency include impaired growth, impaired reproductive function, impaired glucose tolerance and alteration in lipid and carbohydrate metabolism. Furthermore, manganese deficiency interferes with normal skeletal development.

The Nutrient Reference Value for manganese as stipulated in the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act 54 of 1972) R146 is 2.3 mg (milligrams) per day for individuals 4 years and older. The upper limit intake of manganese is 11 mg.

EFFECTS OF OMEGA-3 DEFICIENCIES

The following groups are considered to be prone to omega-3 deficiencies and would form potential target groups for the emulsion of the invention: infants and adolescents; women from the age of menses to menopause; pregnant women; the elderly, in particular those with poor socio-economic status; pesco vegetarians (only eat fish); subjects consuming a mono-cereal diet; individuals with cardiac disease; cancer patients; immune-compromised persons, including persons infected with HIV or with AIDS; diabetic patients; and malnourished people of any age.

APPLICATION OF THE OMEGA-3 FATTY ACID EMULSION

The carotenoids in the Omega-3 FATTY ACID emulsion include carotenes. The carotenoids and tocotrienols are obtained from a concentrate. The concentrate is a natural tocotrienol (Vitamin E) and carotene oil complex derived from palm fruits. The concentrate includes tocotrienols consisting of alpha-, beta-, gamma- and delta-tocotrienols. The concentrate includes a spectrum of carotenes, but consists predominantly of alpha- and beta-carotenes.

A typical quantity of the concentrate to meet at least 50 % of the Nutrient Reference Values (NRV) the minerals zinc, selenium and manganese for individuals 4 years and older will be about 80.1 mg of the concentrate.

The food supplement emulsion according to the invention provides 445 mg omega-3 marine fatty acids consisting 267 mg Eicosapentaenoic acid (EPA) and 178 mg Docosahaenoic acid (DHA) per 5 ml single serving. Each 5 ml of the emulsion contains 1 486 mg marine fish oil. Current

clinical studies have shown that supplemental omega-3 fatty acids increase the levels of these fatty acids in the blood of research participants.

According to the invention the concentrate of carotenoids used in this food supplement emulsion comprise of a spectrum of eleven natural carotenes, with alpha- and beta-carotene contributing approximately 87-92% of the total carotenes.

An intake of up to 6 mg of carotenes per day was decided upon (5 ml / day) for the food supplement emulsion according to the invention.

The concentrate used as our source for tocopherol and tocotrienol is a natural source containing 81% tocotrienols.

The daily intake of tocopherols and tocotrienols from the 5 ml emulsion per day is 3.21 mg and 12.99 mg respectively. The food supplement according to the invention is unique insofar that 80% of the vitamin E content is tocotrienols which is almost absent from oils generally used for cooking purposes where the vitamin E is mainly present as tocopherol.

High grade fish oil is sourced from a supply containing between 10% and 20% Eicosapentaenoic acid (EPA) and between 10% and 14% Docosahexaenoic acid (DHA). The heavy metal content of the oil is within the legal limits. Each 5 ml serving of the emulsion contains 1 486 mg marine fish oil and a micronutrient mixture of concentrate and other micronutrients.

The invention will now be described further with respect to the following non-limiting examples.

Example 1

Each 5 ml (daily dosage) of Omega-3 emulsion may include the following ingredients in the ranges set out in Table 1 below.

Ingredient	Actual content	Range
Marine fish oil	1 486 mg	1 mg – 4 000 mg
Total carotenes	4.86 mg	0.1 mg – 15 mg
Tocopherols and tocotrienols	16.2 mg	0.1 mg – 200 mg
Zinc	5 mg	1.1 mg – 40 mg
Selenium	27 mcg	5.5 mcg – 400 mcg
Manganese	1.2 mg	0.23 mg – 11 mg

Table 1

Example 2

Typical micronutrients, vitamins and phytonutrients contained within 5 ml (daily serving) of the Omega-3 emulsion, which amounts of palm fruit concentrate components may vary between 10 to 15% depending on the batch of palm fruit processed is set out in Table 2 below.

Component	Content
Alpha Carotene	1.89 mg
Beta Carotene	2.75 mg
Lycopene	32 mcg
Other Carotenes	0.22 mg
Alpha Tocopherol	3.21 mg
Alpha Tocotrienol	3.39 mg
Beta Tocotrienol	81 mcg
Gamma Tocotrienol	6.34 mg
Delta Tocotrienol	3.2 mg
Glycerides	2.76 mg
Phytosterols	6.34 mg
Squalene	1.78 mg

Co-Enzyme Q 10	324 mcg
Zinc	6 mg
Selenium	28 mcg
Manganese	1.2 mg
Total omega-3 fatty acids	445 mg
Eicosapentaenoic acid (EPA)	267 mg
Docosahaenoic acid (DHA)	178 mg

Table 2

Example 3

Typical range of micronutrients, vitamins, phytonutrients and fish oil that may be contained within a daily serving (5 ml) of the Omega-3 emulsion, providing about 15 % to about 100 % of the recommended daily intake for carotenes, vitamin E, zinc, selenium and manganese for individuals 4 years and older, is set out in Table 3 below. Amounts of palm fruit concentrate components may vary between 10 to 15% depending on the batch of palm fruit processed.

Component	Range
Alpha Carotene	30 mcg - 1200 mg
Beta Carotene	45 mcg - 1200 mg
Lycopene	7 mcg - 40 mg
Other Carotenes	7 mcg - 160 mg
Alpha Tocopherol	15 mcg - 50 mg
Alpha Tocotrienol	20 mcg - 520 mg
Beta Tocotrienol	0 mcg - 20 mg
Gamma Tocotrienol	45 mcg - 960 mg
Delta Tocotrienol	25 mcg - 480 mg
Glycerides	12.3 mg – 5 g
Phytosterols	500 mcg – 5 000 mcg
Squalene	170 mcg – 2 000 mcg

Co-Enzyme 010	4 mcg – 1 000 mcg
Zinc	8 mcg - 40 mg
Selenium	8 mcg - 400 mcg
Manganese	2 mcg – 11 mg
Total omega-3 fatty acids	1 mg – 4000 mg
Eicosapentaenoic acid (EPA)	1 mcg – 800 mg
Docosahaenoic acid (DHA)	1 mcg – 800 mg

Table 3

Example 4

Each 5 ml (daily dosage) Omega-3 emulsion may include the following as set out in Table 4 below.

	Ingredient	Content
a)	Marine fish oil	1 486 mg
b)	Total carotenes	4.86 mg
c)	Tocopherols and tocotrienols	16.2 mg
d)	Zinc amino acid complex	60 mg
e)	Selenium amino acid complex	13.5 mg
f)	Manganese amino acid complex	12 mg
h)	Soy lecithin	0.35 g
i)	Distilled water	2.16 g
j)	Stabilizer	8 mg
k)	Citric acid	8 mg
l)	Invert sugar and/or artificial sweetener	0.405 g
m)	Glycerides	0.405 g
n)	Potassium sorbate	8 mg
o)	Oil based flavouring	8.1 mg

Table 4

Example 5

Each single serving (5 ml) emulsion includes substantially the following:

	Ingredient	Content	Range
a)	Marine fish oil	1486 mg	1 mg – 4 000 mg
b)	Total carotenes:	4.86 mg	0.1 mg – 15 mg
	a. Alpha-carotene	1.91 mg	30 mcg – 1 200 mg
	b. Beta-carotene	2.76 mg	45 mcg – 1 200 mg
	c. Other carotenes	0.190 mg	7 mcg – 160 mg
c)	Vitamin E:	16.2 mg	0.1 mg – 200 mg
	a. Tocopherol	3.21 mg	15 mcg – 50 mg
	b. Tocotrienol	12.99 mg	20 mcg – 960 mg
d)	Other micronutrients:		
	a. Zinc amino acid complex	60 mg	1.1 mg – 240 mg
	b. Selenium amino acid complex	13.5 mg	5.5 mcg – 8 000 mcg
	c. Manganese amino acid complex	12.0 mg	0.23 mg – 110 mg
e)	Other ingredients:		
	a. Soy lecithin	0.35 g	-
	b. Distilled water	2.17 g	-
	c. Stabilizer	5.4 mg	-
	d. Citric acid	5.4 mg	-
	e. Invert sugar and/or artificial sweetener	0.41 g	-

	f. Glycerides	0.41 g	-
	g. Potassium sorbate	5.4 mg	-
	h. Oil based flavouring	8.2 mg	-
e)	Omega-3 fatty acids:	1 486 mg	195 mcg – 800 mg
	a. Eicosapentaenoic acid (EPA)	267 mg	100 mcg – 800 mg
	b. Docosahexaenoic acid (DHA)	178 mg	95 mcg – 400 mg

Table 5

Example 6

Preparation of emulsion to provide a month supply of Omega-3 emulsion

1. Weigh 13 g of soy lecithin into an Erlen Meyer flask.
2. Add to the same flask 55 g of the required fish oil containing 18% EPA and 12% DHA.
3. Warm the mixture in a water bath at 40 degrees Celsius and mix until a homogenous mixture is obtained.
4. Add 6 g of concentrate to the above mixture at 40 degrees Celsius and keep mixture in water bath. Swirl gently until a homogenous mixture is obtained.
5. Weigh 80 g of distilled water in a separate Erlen Meyer flask.
6. Add 150 mg stabilizer and stir well until dissolved.
7. Add 150 mg Citric Acid and stir well until dissolved.
8. Add 15 g Glycerol and 15 g Puratex and/or artificial sweetener and mix until homogenous mixture is obtained.
9. Add 2.22 g Zinc Amino Acid Complex.
10. Add 500 mg Selenium Amino Acid Complex.
11. 444 mg Manganese Amino Acid Complex
12. 150 mg Potassium sorbate
13. Warm the water mixture in a water bath at 40 degrees Celsius. When mixture has reached the water bath temperature, this mixture is slowly poured into the mixture containing the fish oil, lecithin and

concentrate and homogenized with a politron at medium speed (3000rpm) for three minutes.

14. After homogenization, the required flavour is added at a rate of 0.2-0.3 % and the mixture is again homogenized at slow speed for 30 seconds.

CLAIMS

1. An omega-3 fatty acid emulsion comprising at least the following components:
 - a) omega-3 fatty acids,
 - b) carotenoids,
 - c) tocopherols,
 - d) tocotrienols,
 - e) zinc,
 - f) selenium, and
 - g) manganesewherein the carotenoids, tocopherols and tocotrienols are obtained from a palm fruit oil mixed concentrate, and wherein the concentrate comprises about 3% of carotenoids, about 2% of tocopherols, about 8% of tocotrienols and about 79% of glycerides per 100 mg of concentrate, the balance being made up of other phytonutrients.
2. The omega-3 fatty acid emulsion according to claim 1, wherein the source of the omega-3 fatty acid is refined fish oil.
3. The omega-3 fatty acid emulsion according to claim 2, wherein the fish oil comprises at least 18 weight% eicosapentaenoic acid (EPA) and 12 weight% docosahexaenoic acid (DHA).
4. The omega-3 fatty acid emulsion according to claim 2, wherein the fish oil is present in the form of glycerides, ethyl esters or phospholipids.
5. The omega-3 fatty acid emulsion according to any one of claims 2 to 4, comprising from about 1 mg to about 4000 mg of fish oil, from about 0.1mg to about 15 mg of carotenoids, from about 0.1 mg to about 200 mg of tocopherol, from about 0.1 mg to about 200 mg of tocotrienol, from about 1.1 mg to about 40 mg of zinc, from about 5.5

mcg to about 400 mcg of selenium and from about 0.23 mg to about 11 mg of manganese per 5 ml of emulsion, the balance being water.

6. The omega-3 fatty acid emulsion according to claim 5, wherein the fish oil provides for about 445 mg omega-3 marine fatty acids consisting of 267 mg Eicosapentaenoic acid (EPA) and 178 mg Docosahaenoic acid (DHA) per 5 ml of emulsion.
7. The omega-3 fatty acid emulsion according to claim 1, wherein the carotenoids are selected from alpha-carotene, beta-carotene and gamma-carotene.
8. The omega-3 fatty acid emulsion according to claim 1, wherein the tocopherols and tocotrienols are selected from alpha-tocopherol, alpha-tocotrienol, beta-tocotrienol, gamma-tocotrienol and delta-tocotrienols.
9. The omega-3 fatty acid emulsion according to claim 7, wherein the concentrate comprises about 1.91 mg of alpha-carotene, about 2.72 mg of beta-carotene, about 63 mcg of lycopene and about 160 mcg of other carotenes, per 100mg of concentrate.
10. The omega-3 fatty acid emulsion according to claim 1, wherein the concentrate comprises about 3.21 mg of tocopherols and about 12.99 mg of tocotrienols, per 100mg of concentrate.
11. The omega-3 fatty acid emulsion according to any one of claims 1 to 10, wherein the concentrate further comprises lycopene, glycerides, phytosterols, Co-Enzyme Q 10 and squalene.
12. The omega-3 fatty acid emulsion of claim 11, wherein the concentrate comprises about 234mcg phytosterol, about 66mcg squalene, about

12mcg co-enzyme Q10 and about 79mg glyceride, per 100 mg of concentrate.

13. The omega-3 fatty acid emulsion according to any one of claims 1 to 12, wherein the concentrate is free of toxic elements, selected from lead, mercury and arsenic.
14. The omega-3 fatty acid emulsion according to claim 13, wherein the concentrate comprises less than 0.6 ppm of lead, less than 0.05 ppm of mercury and less than 0.1 ppm of arsenic.
15. The omega-3 fatty acid emulsion according to any one of claims 1 to 14, wherein the concentrate comprises microorganisms in an amount of less than 10 cfu/g total plate count for bacteria, yeast and mould.
16. The omega-3 fatty acid emulsion according to any one of claims 1 to 15, further comprising any one or more of soy lecithin, glycerol, puratex (invert sugar) and/or artificial sweeteners, citric acid, stabilizers, flavourants, and preservatives.
17. The omega-3 fatty acid emulsion according to claim 16, wherein the preservative is potassium sorbate.
18. The omega-3 fatty acid emulsion according to any one of claims 1 to 17, wherein the selenium is in the form of selenium yeast, selenium amino acid chelate, selenium oxide, selenium sulphide, sodium selenite or sodium selenate.
19. The omega-3 fatty acid emulsion according to any one of claims 1 to 18, wherein the zinc is in the form of zinc amino acid chelate, zinc gluconate, zinc oxide, zinc sulphate, zinc undecylenate, zinc chloride, zinc stearate or zinc acetate.

20. The omega-3 fatty acid emulsion according to any one of claims 1 to 19, wherein the manganese is in the form of manganese amino acid complexes, manganese gluconate, manganese glycerophosphate or manganese sulphate.
21. The omega-3 fatty acid emulsion according to any one of claims 1 to 20, wherein the selenium, zinc and manganese are present as amino acid complexes.
22. The omega-3 fatty acid emulsion according to any one of claims 1 to 21 having the composition comprising:
 - a) Marine fish oil in the range of 1 mg – 4,000 mg;
 - b) Carotenes in the range of 0.1 mg – 15 mg comprising:
 - a. Alpha-carotene in the range of 30 mcg – 1200 mg
 - b. Beta-carotene in the range of 45 mcg – 1200 mg
 - c. Other carotenes in the range of 7 mcg – 160 mg
 - c) Vitamin E in the range of 0.1mg – 200 mg comprising:
 - a. Tocopherol in the range of 15 mcg – 50 mg
 - b. Tocotrienol in the range of 20 mcg – 960 mg
 - d) Other micronutrients comprising:
 - a. Zinc amino acid complex in the range of 1.1 mg – 240 mg
 - b. Selenium amino acid complex in the range of 5.5 mcg – 8000 mcg
 - c. Manganese amino acid complex in the range of 0.23 mg – 110 mg
 - e) Omega-3 fatty acids in the range of 195 mcg – 800 mg comprising:
 - a. Eicosapentaenoic acid (EPA) in the range of 100 mcg – 800 mg
 - b. Docosahexaenoic acid (DHA) in the range of 95 mcg – 400 mg

and further comprising ingredients from the group consisting of:

- f) Other ingredients comprising:
 - a. Soy lecithin
 - b. Distilled water
 - c. Stabilizer
 - d. Citric acid
 - e. Invert sugar and/or artificial sweetener
 - f. Glycerides
 - g. Potassium sorbate
 - h. Oil based flavouring.
23. A method of producing an omega-3 fatty acid emulsion, the method comprising the steps of:
- a) providing a source of fish oil containing at least 18% EPA and 12% DHA;
 - b) providing a source of palm fruit oil mixed concentrate, wherein the concentrate comprises about 3% of carotenoids, about 2% of tocopherols, about 8% of tocotrienols and about 79% of glycerides per 100 mg of concentrate, the balance being made up of other phytonutrients;
 - c) providing a source of zinc, manganese and selenium,
 - d) optionally providing a source of additives,
 - e) blending together the fish oil, concentrate, zinc, manganese, selenium and the optional additives with water and homogenizing the resultant solution until a stable omega-3 fatty acid emulsion is formed.
24. The method according to claim 23, wherein step e) further comprises the following steps:
- a) blending together the fish oil and the concentrate until a homogenous mixture A is obtained;
 - b) blending together the water, and the source of zinc, selenium and manganese until a homogenous mixture B is obtained;

- c) blending together mixtures A and B until a homogenous mixture C is obtained, thereby forming a stabilized omega-3 fatty acid emulsion.
- 25. The method according to claims 23 or 24, wherein the zinc, selenium and manganese are added as amino acid complexes.
 - 26. The method according to any one of claims 23 to 25, wherein soy lecithin is first added to the fish oil and warmed in a water bath at 40°C and mixed until a homogenous mixture is obtained.
 - 27. The method according to claim 26, wherein the concentrate is then added to the soy lecithin and fish oil homogenous mixture and mixed until a homogenous mixture is obtained.
 - 28. The method according to any one of claims 23 to 27, wherein the additives are selected from a stabilizer, citric acid, glycerol, puratex and/or artificial sweeteners, and potassium sorbate.
 - 29. The method according to claim 28, wherein the stabilizer is selected from lecithin, sodium alginate, guar gum, xanthan gum, cognac glue and polyglycerol.
 - 30. The method according to any one of claims 26 to 29, wherein the additives are first added to the water until a homogenous mixture is obtained.
 - 31. The method according to claim 30, wherein the water and additive mixture is warmed to a temperature of 40°C and then mixed with the fish oil, lecithin and concentrate mixture, and homogenized until a stable emulsion is obtained.

32. An omega-3 fatty acid emulsion according to any one of claims 1 to 22, for use in the treatment or prevention of a micronutrient deficiency selected from: vitamin A, vitamin E, , iron, zinc, copper, manganese or selenium and/or in the enhancement of the immune system of a subject.
33. Use of an omega-3 fatty acid emulsion according to any one of claims 1 to 22, in the manufacture of a medicament for use in the treatment or prevention of a micronutrient deficiency selected from: vitamin A, vitamin E, , iron, zinc, copper, manganese or selenium and/or in the enhancement of the immune system of a subject.
34. The omega-3 fatty acid emulsion according to any one of claims 1 to 21 having the composition comprising:
 - a) Marine fish oil in the amount of about 1486 mg;
 - b) Carotenes in the amount of about 4.86 mg comprising:
 - a. Alpha-carotene in the amount of about 1.91 mg
 - b. Beta-carotene in the amount of about 2.76 mg
 - c. Other carotenes in the amount of about 0.190 mg
 - c) Vitamin E in the amount of about 16.2 mg comprising:
 - a. Tocopherol in the amount of about 3.21 mg
 - b. Tocotrienol in the amount of about 12.99 mg
 - d) Other micronutrients comprising:
 - a. Zine amino acid complex in the amount of about 60 mg
 - b. Selenium amino acid complex in the amount of about 13.5 mg
 - c. Manganese amino acid complex in the amount of about 12.0 mg
 - e) Omega-3 fatty acids in the amount of about 1486 mg comprising:
 - a. Eicosapentaenoic acid (EPA) in the amount of about 267 mg

- b. Docosahexaenoic acid (DHA) in the amount of about 178 mg

and further comprising ingredients from the group consisting of:

- f) Other ingredients comprising:
 - a. Soy lecithin in the amount of about 0.35 g
 - b. Distilled water in the amount of about 2.17 g
 - c. Stabilizer in the amount of about 5.4 mg
 - d. Citric acid in the amount of about 5.4 mg
 - e. Invert sugar and/or artificial sweetener in the amount of about 0.41 g
 - f. Glycerides in the amount of about 0.41 g
 - g. Potassium sorbate in the amount of about 0.54 mg
 - h. Oil based flavouring in the amount of about 8.2 mg