

[0046] Aqueous suspensions contain the *Morinda citrifolia* in admixture with excipients suitable for the manufacture of aqueous suspensions. Such excipients are suspending agents, for example, sodium carboxymethyl-cellulose, methylcellulose, hydroxy-propylmethylcellulose, sodium alginate, polyvinyl-pyrrolidone, gum tragacanth and gum acacia; dispersing or wetting agents may be a naturally-occurring phosphatide, for example lecithin, or condensation products of an alkylene oxide with fatty acids, for example polyoxyethylene stearate, or condensation products of ethylene oxide with long chain aliphatic alcohols, for example heptadecaethylene-oxycetanol, or condensation products of ethylene oxide with partial esters derived from fatty acids and a hexitol such as polyoxyethylene sorbitor monooleate, or condensation products of ethylene oxide with partial esters derived from fatty acids and hexitol anhydrides, for example polyethylene sorbitan monooleate.

[0047] 2. Formulations and Methods of Administration

[0048] The present invention provides nutraceutical formulations and methods for preventing, inhibiting and treating breast cancer with a *Morinda citrifolia*-based nutraceutical formulation without any significant tendency to cause side effects. The *Morinda citrifolia* is incorporated into various carriers or nutraceutical compositions suitable for in vivo treatment of a patient. For instance, the processed *Morinda citrifolia* may be ingested, introduced through an intravenous injection or feeding, or otherwise internalized as is appropriate and directed.

[0049] Methylsulfonylmethane ("MSM") is a sulfur donor compound occurring in nature and has been found in plants, milk, and urine of bovines and humans. MSM is a normal oxidative product of dimethylsulfoxide (DMSO). Sulfur is the sixth most abundant macro-mineral in breast milk and the third most abundant mineral in the human body based upon the percentage of total body weight and is an essential element for the structure of every living cell. MSM possesses a broad range of health benefits including analgesic, anti-inflammatory, anti-allergy, while enhancing immune function by providing nutritionally essential organic sulfur and methyl groups. A scientific study has reported that ³⁵S-labelled MSM was incorporated into essential sulfur-containing amino acids such as in methionine and cysteine of guinea pig serum protein; thus MSM may provide a source of sulfur for essential sulfur-containing amino acids in animals and humans.

[0050] In one exemplary embodiment, the nutraceutical composition of the present invention comprises one or more of a processed *Morinda citrifolia* product present in an amount by weight between about 0.01 and 100 percent by weight, and preferably between 0.01 and 95 percent by weight combined with methylsulfonylmethane ("MSM"), present in an amount between about 0.001 and 99.9 percent by weight. Several embodiment of formulations are provided below. However, these are only intended to be exemplary as one ordinarily skilled in the art will recognize other formulations or compositions comprising the processed *Morinda citrifolia* product.

[0051] The processed *Morinda citrifolia* product is an active ingredient or contains one or more active ingredients, such as Quercetin and Rutin, and others, for effectuating the prevention, inhibition and treatment of breast cancer. The effects of the processed *Morinda citrifolia* product are

synergistically enhanced by the presence of methylsulfonylmethane ("MSM") in formulation. One embodiment of the present invention comprises a processed *Morinda citrifolia* product combined in formulation with MSM that prevents, inhibits and or treats breast cancer. Active ingredients may be extracted out of various parts of the *Morinda citrifolia* plants using various alcohol or alcohol-based solutions, such as methanol, ethanol, and ethyl acetate, and other alcohol-based derivatives using any known process in the art. The active ingredients of Quercetin and Rutin are present in amounts by weight ranging from 0.01-10 percent of the total formulation or composition. These amounts may be concentrated as well into a more potent concentration in which they are present in amounts ranging from 10 to 100 percent.

[0052] The processed *Morinda citrifolia* product may be formulated with various other ingredients to produce various compositions, such as a nutraceutical composition, an internal composition, or others. The ingredients to be utilized in a nutraceutical composition are any that are safe for introduction into the body of a mammal, and particularly a human, and may exist in various forms, such as liquids, tablets, lozenges, aqueous or oily solutions, dispersible powders or granules, emulsions, syrups, elixirs, etc. Moreover, since the nutraceutical composition will most likely be consumed orally, it may contain one or more agents selected from the group consisting of sweetening agents, flavoring agents, coloring agents, preserving agents, and other medicinal agents as directed.

[0053] The ingredients to be utilized in a topical dermal composition are also any that are safe for internalizing into the body of a mammal and may exist in various forms, such as gels, lotions, creams, ointments, etc., each comprising one or more carrier agents. The ingredients for systemically administered formulations may also comprise any known in the art.

[0054] In one exemplary embodiment, the present invention further features a method of administering a nutraceutical composition to a mammal for the prevention, inhibition or treatment of breast cancer. The method comprises the steps of (a) formulating a nutraceutical composition comprising in part a processed *Morinda citrifolia* product present in an amount between about 0.01 and 95 percent by weight and methylsulfonylmethane ("MSM"), present in an amount between about 0.001 and 80 percent by weight, wherein the composition also comprises a carrier, such as water or purified water, and other natural or artificial ingredients; (b) administering the nutraceutical composition into the body such that the processed *Morinda citrifolia* product is sufficiently internalized; (c) repeating the above steps as often as necessary to provide an effective amount of the processed *Morinda citrifolia* product.

[0055] The step of administering the nutraceutical composition into the body comprises ingesting the composition orally through one of several means. Specifically, the nutraceutical composition may be formulated as a liquid, gel, solid, or some other type that would allow the composition to be quickly and conveniently digested. Once sufficiently internalized, the administered nutraceutical composition may then begin to act prevent, inhibit or treat breast cancer in the subject. In addition, the step of administering the nutraceutical composition may include injecting the composition into the body using an intravenous pump.

taste and odor. The plant is native to Southeast Asia and has spread in early times to a vast area from India to eastern Polynesia. It grows randomly in the wild, and it has been cultivated in plantations and small individual growing plots. The *Morinda citrifolia* flowers are small, white, three to five lobed, tubular, fragrant, and about 1.25 cm long. The flowers develop into compound fruits composed of many small drupes fused into an ovoid, ellipsoid or roundish, lumpy body, with waxy, white, or greenish-white or yellowish, semi-translucent skin. The fruit contains "eyes" on its surface, similar to a potato. The fruit is juicy, bitter, dull-yellow or yellowish-white, and contains numerous red-brown, hard, oblong-triangular, winged 2-celled stones, each containing four seeds.

[0026] When fully ripe, the fruit has a pronounced odor like rancid cheese. Although the fruit has been eaten by several nationalities as food, the most common use of the *Morinda citrifolia* plant was as a red and yellow dye source. Recently, there has been an interest in the nutritional and health benefits of the *Morinda citrifolia* plant, further discussed below.

[0027] Because the *Morinda citrifolia* fruit is for all practical purposes inedible, the fruit must be processed in order to make it palatable for human consumption and included in the nutraceutical used to prevent, inhibit and/or treat breast cancer. Processed *Morinda citrifolia* fruit juice can be prepared by separating seeds and peels from the juice and pulp of a ripened *Morinda citrifolia* fruit; filtering the pulp from the juice; and packaging the juice. Alternatively, rather than packaging the juice, the juice can be immediately included as an ingredient in another food product, frozen or pasteurized. In some embodiments, the juice and pulp can be pureed into a homogenous blend to be mixed with other ingredients. Other process include freeze drying the fruit and juice. The fruit and juice can be reconstituted during production of the final juice product. Still other processes include air drying the fruit and juices, prior to being masticated.

[0028] The present invention also contemplates the use of fruit juice and/or puree fruit juice extracted from the *Morinda Citrifolia* plant. In a currently preferred process of producing *Morinda citrifolia* fruit juice, the fruit is either hand picked or picked by mechanical equipment. The fruit can be harvested when it is at least one inch (2-3 cm) and up to 12 inches (24-36 cm) in diameter. The fruit preferably has a color ranging from a dark green through a yellow-green up to a white color, and gradations of color in between. The fruit is thoroughly cleaned after harvesting and before any processing occurs.

[0029] The fruit is allowed to ripen or age from 0 to 14 days, with most fruit being held from 2 to 3 days. The fruit is ripened or aged by being placed on equipment so it does not contact the ground. It is preferably covered with a cloth or netting material during aging, but can be aged without being covered. When ready for further processing the fruit is light in color, from a light green, light yellow, white or translucent color. The fruit is inspected for spoilage or for excessively green color and hard firmness. Spoiled and hard green fruit is separated from the acceptable fruit.

[0030] The ripened and aged fruit is preferably placed in plastic lined containers for further processing and transport. The containers of aged fruit can be held from 0 to 120 days. Most fruit containers are held for 7 to 14 days before

processing. The containers can optionally be stored under refrigerated conditions or ambient/room temperature conditions prior to further processing. The fruit is unpacked from the storage containers and is processed through a manual or mechanical separator. The seeds and peel are separated from the juice and pulp.

[0031] The juice and pulp can be packaged into containers for storage and transport. Alternatively, the juice and pulp can be immediately processed into a finished juice product. The containers can be stored in refrigerated, frozen, or room temperature conditions.

[0032] The *Morinda citrifolia* juice and pulp are preferably blended in a homogenous blend, after which they may be mixed with other ingredients, such as flavorings, sweeteners, nutritional ingredients, botanicals, and colorings. The finished juice product is preferably heated and pasteurized at a minimum temperature of 181° F. (83° C.) or higher up to 212° F. (100° C.).

[0033] Another product manufactured is *Morinda citrifolia* puree and puree juice, in either concentrate or diluted form. Puree is essentially the pulp separated from the seeds and is different than the fruit juice product described herein.

[0034] Each product is filled and sealed into a final container of plastic, glass, or another suitable material that can withstand the processing temperatures. The containers are maintained at the filling temperature or may be cooled rapidly and then placed in a shipping container. The shipping containers are preferably wrapped with a material and in a manner to maintain or control the temperature of the product in the final containers.

[0035] The juice and pulp may be further processed by separating the pulp from the juice through filtering equipment. The filtering equipment preferably consists of, but is not limited to, a centrifuge decanter, a screen filter with a size from 0.01 micron up to 2000 microns, more preferably less than 500 microns, a filter press, reverse osmosis filtration, and any other standard commercial filtration devices. The operating filter pressure preferably ranges from 0.1 psig up to about 1000 psig. The flow rate preferably ranges from 0.1 g.p.m. up to 1000 g.p.m., and more preferably between 5 and 50 g.p.m. The wet pulp is washed and filtered at least once and up to 10 times to remove any juice from the pulp. The wet pulp typically has a fiber content of 10 to 40 percent by weight. The wet pulp is preferably pasteurized at a temperature of 181° F. (83° C.) minimum and then packed in drums for further processing or made into a high fiber product.

[0036] The processed *Morinda citrifolia* product may also exist as a dietary fiber. Still further, the processed *Morinda citrifolia* product may also exist in oil form. The *Morinda citrifolia* oil typically includes a mixture of several different fatty acids as triglycerides, such as palmitic, stearic, oleic, and linoleic fatty acids, and other fatty acids present in lesser quantities. In addition, the oil preferably includes an antioxidant to inhibit spoilage of the oil. Conventional food grade antioxidants are preferably used.

[0037] The *Morinda citrifolia* plant is rich in natural ingredients. Those ingredients that have been discovered include: (from the leaves): alanine, anthraquinones, arginine, ascorbic acid, aspartic acid, calcium, beta-carotene, cysteine, cystine, glycine, glutamic acid, glycosides, histi-

49. A method for preventing, inhibiting and treating breast cancer, comprising the steps of:

adding one or more processed *Morinda citrifolia* products to an alcohol-based solution;

isolating and extracting an active ingredient of *Morinda citrifolia* from said solution;

combining said extracted active ingredient with about 100-2000 miligrams of methylsulfonylmethane to form a nutraceutical composition

exposing said nutraceutical composition to an area afflicted by one or more carcinogenic cells, wherein said extracted active ingredient inhibits, prevents, and destroys the growth of said carcinogenic cells.

50. A method as in claim 49, wherein said processed *Morinda citrifolia* product is comprised of one or more of the following: *Morinda citrifolia* fruit juice, *Morinda citrifolia* oil extract, *Morinda citrifolia* dietary fiber, *Morinda citrifolia* puree juice, *Morinda citrifolia* puree, *Morinda citrifolia* fruit juice concentrate, *Morinda citrifolia* puree juice concentrate.

51. A method as in claim 49, wherein said nutraceutical composition is used with a carrier medium.

52. A method as in claim 49, wherein said composition is administered by process comprising one or more of the following methods: orally, transdermally, injection, intravenously, topically or administered systemically.

53. A method as in claim 49, wherein said composition is comprised of about 100-2000 milligrams of methylsulfonyl-

methane, 50-90% *Morinda citrifolia* fruit juice by weight, 0.1-50% water by weight and 0.1-30% non-*Morinda citrifolia* based fruit juices by weight.

54. A method as in claim 49, wherein said composition is comprised of about 100-2000 milligrams methylsulfonylmethane by weight, 50-90% *Morinda citrifolia* fruit juice by weight, and 0.1-30% non-*Morinda citrifolia* based fruit juices by weight.

55. A method as in claim 49, additionally comprising 0.1-50% water by weight.

56. A method as in claim 49, wherein one fluid ounce or more is administer to the patient daily.

57. A method as in claim 49, wherein at least three fluid ounces are administered to the patient daily.

58. The method of claim 49, wherein said alcohol-based solution is selected from the group consisting essentially of methanol, ethanol, and ethyl acetate, and other alcohol-based derivatives.

59. A method for inhibiting, preventing, and destroying carcinogenic cells within the mammary region of the breast, said method comprising the steps of:

orally administering at least one ounce of a food product comprising processed *Morinda citrifolia* fruit juice and methylsulfonylmethane on an empty stomach in the morning; and

administering one ounce of said food product prior to sleeping at night.

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