

[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.

and other non-steroidal inflammatory drugs (NSAIDs) is associated with the reduced incidence of colon and breast cancer. The main target of NSAID activity is the cyclooxygenase (COX) enzyme. Two isoforms of COX have been identified: COX-1, the constitutive isoform, and COX-2, the inducible form of the enzyme. COX-2 can undergo rapid induction in response to chemical carcinogens. It has been suggested that COX-2 overexpression may lead to increased angiogenesis and inflammatory reaction. Therefore, the inhibition of COX-2 might have a general cancer preventive effect via anti-inflammatory activity and decrease angiogenesis.

[0011] Some studies suggest that physical activity, good nutrition, and the administration of certain drugs may lower a woman's risk of getting this deadly disease. Although progress has been achieved in the treatment of breast cancer, an effective way to prevent or inhibit the development of breast cancer is not available. Therefore, seeking a natural way to prevent human breast cancer becomes a top priority for the scientists who work in this field.

SUMMARY AND OBJECTS OF THE INVENTION

[0012] The present invention advances prior art techniques, formulations, and methods for treating breast cancer during its initial phases, as well as for preventing and inhibiting breast cancer, by providing a safe, nutraceutical formulation comprising *Morinda citrifolia*, methylsulfonylmethane (MSM), and other ingredients. The preferred exemplary embodiments of the present invention improve upon existing systems and methods, and can, in some instances, be used to overcome one or more problems associated or related to such existing systems and methods.

[0013] In accordance with the invention as embodied and broadly described herein, the present invention features a nutraceutical formulation for treating and inhibiting mammary breast cancer comprising processed *Morinda citrifolia* present in an amount between about 0.001 and 99.9 percent by weight. In one preferred exemplary embodiment, the nutraceutical formulation further comprises methylsulfonylmethane (MSM) present in an amount between about 0.001 and 99.9 percent by weight.

[0014] These and other features and advantages of the present invention will be set forth or will become more fully apparent in the description that follows and in the appended claims. The features and advantages may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims. Furthermore, the features and advantages of the invention may be learned by the practice of the invention or will be obvious from the description, as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The foregoing and other objects and features of the present invention will become more fully apparent from the accompanying figures when considered in conjunction with the following description and appended claims. Although the figures depict only typical embodiments of the invention, and are thus not deemed limiting of the invention scope, the accompanying figures help explain the invention in added detail.

[0016] FIG. 1 is a graphical representation of the effectiveness of certain *Morinda citrifolia*-containing compounds on the prevalence of tumors in accordance with the present invention.

[0017] FIG. 2 is a graphical representation of the preventative effects of *Morinda citrifolia*-containing compounds on mammary gland tumorigenesis induced by estrogen in female ACI rats in accordance with the present invention.

[0018] FIG. 3 is a graphical representation of the relative body weight of rats that have been implanted with estrogen to induce tumorigenesis, wherein certain rats have been treated with *Morinda citrifolia*-containing compounds to counteract the effects of estrogen-induced tumorigenesis in accordance with the present invention.

[0019] FIG. 4 is a graphical representation of the relative size of tumors in rats treated with various compounds.

[0020] FIG. 5 is a graphical representation of the conversion of Dimethyl Sulfoxide to Methyl Sulfonyl Methane in accordance with certain embodiments of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0021] The present invention relates to techniques, formulations, and methods for treating breast cancer during its initial phases, as well as for inhibiting breast cancer, by providing a safe, nutraceutical formulation comprising *Morinda citrifolia*, methylsulfonylmethane (MSM), and other ingredients. The preferred exemplary embodiments of the present invention improve upon existing systems and methods, and can be used to overcome one or more problems associated or related to such existing systems and methods.

[0022] The following disclosure of the present invention is grouped into three subheadings, namely "General Discussion of *Morinda citrifolia* and the Methods Used to Produce Processed *Morinda citrifolia* Products," "Formulations and Methods of Administration" and "Preventing, Inhibiting and Treating Breast Cancer." The utilization of the subheadings is for convenience of the reader only and is not to be construed as limiting in any sense.

[0023] It will be readily understood that the elements of the present invention, as generally described and illustrated in the figures herein, could be combined and used in a wide variety of different formulations and methods. Thus, the following more detailed description of the embodiments of the system and method of the present invention is not intended to limit the scope of the invention, as claimed, but is merely representative of the presently preferred embodiments of the invention.

[0024] 1. General Discussion of *Morinda citrifolia* and the Methods Used to Produce Processed *Morinda citrifolia* Products

[0025] The Indian Mulberry or Noni plant, known scientifically as *Morinda Citrifolia* L. (*Morinda citrifolia*), is a shrub or small tree up to 10 m in height. The leaves are oppositely arranged with an elliptic to ovate form. The small white flowers are contained in a fleshy, globose, head-like cluster. The fruits are large, fleshy, and ovoid. At maturity, they are creamy-white and edible, but have an unpleasant

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-

