

Product Regulatory Information Packet

Product: Nutra Plant Complex II

Product ID #: 3149

Food Allergens:

The following food allergens are NOT present in this product:

Milk/Dairy Products, Fish (e.g. salmon, cod, flounder), Crustacean Shellfish (e.g. shrimp, lobster, crab), Soy or soy derivatives, Peanuts, Tree Nuts (e.g. almonds, cashews), Egg or egg derivatives, Sodium, Celery, Mustard, Sesame seeds, Lupin, Sulfur Dioxide/Sulfites, Mollusks, Yeast or yeast derivatives

The following food allergens are present in this product:

Wheat or wheat derivatives – Cereal Grain: Possible Source of Ethanol

Corn or corn derivatives – Cereal Grain: Possible Source of Ethanol

Cereals (e.g. spelt, rye, barley, oats) - Cereal Grain: Possible Source of Ethanol

Genetically Modified Organisms:

The above-mentioned product contains ethanol that is derived from corn. Due to high refinement used in the manufacturing process of the raw material, no GM or DNA would be detectable in measurable amounts. However, we note the corn used to produce ethanol may or may not be sourced from GM corn.

As a result, we are unable to support a Non-GMO status. To the best of our knowledge, the final product is GMO free.

Vegan/Vegetarian:

The above-mentioned product contains honey that is derived from bees. This product is considered vegetarian as bees are not slaughtered in the making of honey. However, due to certain ethical concerns on the commercialization of honey, this product may not be considered vegan by certain groups of people.

Bee harm is avoided in the extraction process as per the supplier.

This statement is based on supplier information, routinely updated by Bio-Botanica, Inc.



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BSE/TSE Statement:

Bio-Botanica, Inc. certifies that the ingredients in the above-mentioned product is not derived in whole or part from animal sources and does not utilize animal derivatives in its manufacture. Additionally, this material complies with the FDA interim rule effective January 12, 2004 (9 CFR Parts 309, 310, 311, 318 and 319) regarding prohibition of Specified Risk Material (SRM) for human food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle. This product is non-BSE & non-TSE.

Prop 65:

Bio-Botanica, Inc. confirms that the above-mentioned product is compliant with the State of California's Proposition 65; whereas, to the best of our knowledge, this product does not contain any chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

Animal Testing/Cruelty Free:

Bio-Botanica, Inc. confirms that the above-mentioned product has not been subject to animal testing and is considered cruelty free.

GRAS Status:

The Federal Food, Drug, and Cosmetic Act defines a dietary ingredient as a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances.

Section 201(s) of the FD&C Act (21 U.S.C. § 321(s)) exempts dietary ingredients used in dietary supplements from the food additive definition. Although a dietary ingredient used in a dietary supplement must not adulterate the supplement under section 402(f) of the FD&C Act (21 U.S.C. § 342(f)), it does not have to be GRAS for its intended use in the supplement.

Bio-Botanica, Inc. confirms that the above-mentioned product is exempted from GRAS when used in a dietary supplement and/or cosmetic.



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Gluten:

The above-mentioned product contains ethanol that is derived from cereal grains, primarily from corn. Due to high refinement used in the manufacturing process of the raw material, no grain gluten would be detectable in measurable amount that may cause allergic reactions.

CMR Statement:

This is to certify that above-mentioned product manufactured by Bio-Botanica is CMR (Carcinogenic, Mutagenic or Toxic for Reproduction) free.

Natural Certification:

Bio-Botanica, Inc. confirms that the above-mentioned product complies with the FDA's informal definition for "Natural" which states that nothing artificial or synthetic has been included or added.

RSPO Statement:

Bio-Botanica, Inc. confirms that the product mentioned above is made with Glycerin that is derived from RSPO certified Palm Oil.

Non-Irradiation/ETO Statement:

Bio-Botanica, Inc. confirms that the materials used in the manufacture of the above-mentioned product have not been handled by, exposed to, or have been treated with irradiation, Ethylene Oxide (ETO), nor sewage sludge. This statement is based on supplier information, routinely updated by Bio-Botanica.

Phthalate Statement:

Bio-Botanica, Inc. confirms that the above-mentioned is not manufactured or formulated with Phthalates.

PEG-Free Statement:

Bio-Botanica, Inc. confirms that the above-mentioned is not manufactured or formulated with Polyethylene Glycol.



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Preservative-Free Statement:

Bio-Botanica, Inc. confirms that the above-mentioned is not manufactured or formulated with preservatives and is considered preservative-free.

Paraben Statement:

Bio-Botanica, Inc. confirms that no parabens were added to the above-mentioned product during the manufacture, storage, and packaging operations.

To the best of our knowledge, this product is paraben free.

SVHC Statement:

This is to verify that the above-mentioned product does not contain any of the 211 Substances of Very High Concern (SVHC) identified by the REACH Regulation in their compositions.

IFRA Compliance Statement:

Bio-Botanica, Inc. confirms that to the best of our knowledge the above-mentioned does not contain any substances identified in IFRA standards 50th amendment as restricted, prohibited or specified.

Food Grade Statement:

Bio-Botanica, Inc. confirms that the above-mentioned product complies with general principles of food law defined in the European Regulation 178/2002/EC and US Federal Food Drug and Cosmetic Act. Therefore, the ingredients within the formula are food grade quality and can be ingested.

Pesticide Residues Statement

Bio-Botanica, Inc. confirms that the above-mentioned product is confirmed to meet USP <561> requirements for Pesticide Limits. We conduct random pesticide screening as per customer requirements. If the customer requires such testing, a special request must be made. Adequate time must be provided for accurate results.

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Heavy Metal Impurities Report:

Heavy Metal	Specification	Results
Arsenic (As)	10 ppm	< 10 ppm
Cadmium (Cd)	4.1 ppm	< 4.1 ppm
Lead (Pb)	0.5 ppm	< 0.5 ppm
Mercury (Hg)	0.3 ppm	< 0.3 ppm

The above statements are based on supplier information, routinely updated by Bio-Botanica.

Sai Velamakanni

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Raw Material Coordinator

Bio-Botanica Inc.

Version # 1

