Product Regulatory Information Packet

Product: **PE Sage**

Product ID #: **4574**

Allergens:

The following food allergens are NOT present in this product:

Wheat or wheat derivatives, Milk/Dairy Products, Fish (e.g. salmon, cod, flounder), Crustacean Shellfish (e.g. shrimp, lobster, crab), Corn or corn derivatives, Soy or soy derivatives, Peanuts, Tree Nuts (e.g. almonds, cashews), Egg or egg derivatives, Cereals (e.g. spelt, rye, barley, oats), Celery, Mustard, Sesame seeds, Lupin, Mollusks, Yeast or yeast derivatives

The following food allergens are present in this product:

Sulfur Dioxide/Sulfites – Caramel color

Cosmetic allergens present in this product:

This product contains Limonene, Linalool, and Geraniol which are naturally occurring in Sage Leaf Extract.

This product does not contain any of the other 79 substances listed in the EU Cosmetics Regulation 2023/1545

Genetically Modified Organisms:

Bio-Botanica, Inc. confirms that none of the ingredients used in its preparation or manufacturing of the above-mentioned product has been subject to or derived from genetically modified sources. It is also free from both genetically modified DNA and the proteins derived from genetically modified DNA.

Therefore, this product is non-GMO.

Vegan/Vegetarian:

Bio-Botanica, Inc. confirms that the above-mentioned product is vegetarian/vegan. No raw materials with animal derivatives have been used in the manufacturing of this product.

BSE/TSE Statement:

Bio-Botanica, Inc. certifies that the ingredients in the above-mentioned product are not derived in whole or part from animal sources and does not utilize animal derivatives in its manufacture. Additionally, this material complies

Product Regulatory Information Packet

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 may contain trace levels of furfuryl alcohol due to the presence of caramel color. To the best of our knowledge, this product does not contain any additional chemicals 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.

Gluten:

Bio-Botanica, Inc. confirms that the above-mentioned product is gluten free and has not been formulated or exposed to gluten-containing grains such as wheat, rye, barley, or oats.

CMR Statement:

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

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Product Regulatory Information Packet

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.

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.

PFA, Microplastics, and Nitrosamines Statement:

Bio-Botanica, Inc. confirms that based on the manufacturing process of the above-mentioned product, the presence of PFAs, microplastics, and nitrosamines is not expected, nor are they intentionally added, even though these substances are not currently measured.

Nanomaterial Statement:

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

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.

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:

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Product Regulatory Information Packet

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.

Pesticide Statement:

Bio-Botanica, Inc. confirms that the above-mentioned product is confirmed to meet USP <561> requirements for Pesticide Limits.

SVHC Statement:

This is to verify that the above-mentioned product does not contain any of the 253 Substances of Very High Concern (SVHC) identified by the REACH Regulation in their compositions.

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.

Alexis Rivelli

Alexis Rivelli
QA and Regulatory Coordinator
Bio-Botanica Inc.