# Product Regulatory Information Packet

**Product:** **SE Kola Nut**

**Product ID #:** **2078A**

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## 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), Soy or soy derivatives, Peanuts, Tree Nuts (e.g. almonds, cashews), Egg or egg derivatives, Corn or corn derivatives, Sodium, Cereals (e.g. spelt, rye, barley, oats), Celery, Mustard, Sesame seeds, Lupin, Sulfur Dioxide/Sulfites, Mollusks, Yeast or yeast derivatives.

### The following food allergens are present in this product:

None.

### Cosmetic allergens NOT present in this product:

This product does not contain any of the 83 substances listed in the EU Cosmetics Regulation 2023/1545

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## 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.

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## 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.

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## 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 with the FDA interim rule effective January 12, 2004 (9 CFR Parts 309, 310, 311, 318 and 319) regarding prohibition

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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.

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**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.

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**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.

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**RSPO Statement:**

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

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**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:**

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.

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## 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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## 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.

The material does contain Propylene Glycol, but this ingredient is an accepted component of natural flavors.

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## 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.

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## Phthalate Statement:

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

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## 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.

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## 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.

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**SVHC Statement:**

This is to verify that the above-mentioned product does not contain any of the 240 Substances of Very High Concern (SVHC) identified by the REACH Regulation in their compositions.

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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 |

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

Sophia Imanov

**Sophia Imanov**
Regulatory Affairs Supervisor
Bio-Botanica Inc.