Purple Corn Extract: NDI Application
Submitted by Rainforest Botanicals LCC,

February 28, 2005

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CFSAN/FDA

To:

Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
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Submitted by:

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Dear Sir/Madam:

The information provided in the following application shows the basis on which there is reason to conclude that the product "purple corn extract" may be reasonably expected to be safe when used according to label directions.

Attached are copies of all the referenced material including a report on the acute oral toxicity of the product.

Sincerely,

Juan Ferreira

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Product Name:

Purple corn extract (recently named Purple X®)

Product Distributor:

Rainforest Botanicals LLC (formerly Ashaninka Imports, Inc.)
P. O. Box 770065
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Product Manufacturer:

Laboratorios Fitofarma E.I.R.L., Av. Nicolas Arriola 2844, San Luis, Lima, Peru.

Purple Corn (*Zea mays* L.)

Although purple corn extract represents a new dietary ingredient in the United States, corn chips made from purple corn are widely consumed in the United States and other countries. Because of its pigmenting anthocyanin content, purple corn has long been traditionally used in Peru as a natural colorant for local beverages and foods. In addition, a fermented drink prepared from the kernels is traditionally consumed in Peru and known as "chichi morada".[1]

Product Description

Purple corn extract is a solvent (water-alcohol) extract of the whole cobs (without the leaves) of a colored type of *Zea mays* L. from Peru, which is known by the vernacular, "maiz morado" or purple corn. The form of the extract is a water-soluble powder standardized to contain proanthocyanidins (procyanidonic value of 12),[2] approximately 6% anthocyanins,[3] and approximately 25% total phenolic compounds.[4] The taste of the extract is neutral, the odor is characteristic, and the color is a deep purple. The carrier for the extract is non-GMO maltodextrin.[2]

Laboratory tests[5] show that purple corn extract contains the following general components and characteristics:

Ash	10.82%
Fat	0.13%
Protein	2.59%
Sodium	2.58%
Carbohydrates	76.56%
Calcium	620 mg/kg
Magnesium	1906 mg/kg
Manganese	14 mg/kg
Zinc	40 mg/kg
Copper	12 mg/kg
pH	3-4
Moisture	≤8%

Anthocyanins

Naturally occurring anthocyanins are largely responsible for the intense color of purple corn. On a dry weight basis, their content in Peruvian purple corn is comparable to that of blueberries.[6] Individual anthocyanins detected in purple corn cobs from Peru include C3G (cyanidin-3-glucoside, also known as 3-*O*-β-D-glucoside or cyanidin-3-*O*-β-glucopyranoside), peonidin-3-glucoside, and pelargonidin-3-glucoside.[7] The most abundant anthocyanin in purple corn is C3G,[7,8] which is also the most abundant anthocyanin in blackberry extract[9] and blood oranges[10] and is also found in appreciable amounts in red wine.[11]

Suggested Dosage

The dietary supplement containing purple corn (*Zea mays* L.) extract at a level of 250 mg per capsule or tablet will be suggested to be taken two times per day.

Usage Recommendations

Purple corn extract is intended for use as a dietary supplement or an ingredient thereof for the purpose of providing a dietary antioxidant. As a precaution, it is not intended for use by pregnant or lactating women.

Evidence of Safety

A search for evidence of toxicity from "purple corn" and "purple corn extract" was made in PubMed, TOXNET, EMBASE, and BIOSIS in February 18, 2005. No evidence of human or animal toxicity, mutagenicity or cytotoxicity to healthy cells were found.

Heavy Metals, Pesticides, and Caffeine

Arsenic, cadmium, lead and mercury were not found in detectable amounts in purple corn extract and various pesticides were also not present in detectable amounts.[12] Caffeine content of the extract was found to be less than 0.4 mg/capsule and less than 0.1% (wt/wt, based on capsule content weight).[13]

Acute Toxicity

No acute toxicity was found from purple corn extract following oral administration in four groups of five male albino rats at doses of 446.43-3571.43 mg/kg. Because no mortalities occurred, the oral LD_{50} of the extract in mice was estimated to be greater than 3571.43 mg/kg.[14]

The high anthocyanin content of purple corn extract is also reasonably expected to be safe. An extract made from purple corn ("purple corn color") containing 21.5% anthocyanins,[15] or three times the level of anthocyanins found in purple corn extract,[2] is used as a food colorant in Japan. The food colorant includes approximately 7% C3G (the major anthocyanin in purple corn cobs) and has been widely used in Japan in beverages and confections[16] where it has apparently received approval for use in foods from the health authorities of that country.

According to published reports, "purple corn color" failed to cause hepatotoxic or nephrotoxic effects in glutathione-depleted mice following oral administration at an acute oral dose of 4500 mg/kg, as evidenced by a lack of significant increases in SGPT activity and serum urea nitrogen (SUN) concentration.[17] (At 5% of the diet for 32 weeks in two groups of male rats, "purple corn color" also failed to show evidence of adverse effects, despite intakes of 3,484 and 3744 mg/kg/day.[15])

Conclusion

Evidence of toxicity from purple corn extract was not found. At the dosage suggested for use of purple corn as a dietary supplement or ingredient thereof, evidence from animal tests, tests for heavy metals, pesticides, and caffeine levels indicate that purple corn extract may be reasonably expected to be safe.

Contact for Queries:

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Kenneth Jones (President)

References

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