ORIGINAL

PRE-MARKET NOTIFICATION

NEW DIETARY INGREDIENT NOTIFICATION

CANARIUM INDICUM NUT OIL

PRE-MARKET NOTIFICATION FOR A NEW DIETARY INGREDIENT

1. **NAME AND ADDRESS OF THE DISTRIBUTOR:**

Naturaleaf Inc.
37 Skyline Drive
Groton, CT 06340
Contact: Dr. Serge R. Martinod
Tel: 860-599-3688
Fax: 860-599-3749
E-mail: SMARTINOD@aol.com

2. **NAME OF THE NEW DIETARY INGREDIENT**

Canarium indicum nut oil.

Oil derived from the nuts of a variety of *Canarium indicum L., Canarium indicum* var. *indicum* which is a rain forest tree native to Melanesia and particularly the Solomon Islands.

Canarium is a large genus of trees of the family Burseraceae found in the tropics form Malaysia to Melanesia with one species in the West Indies. They are balsamic, or resinous, trees with edible oily seeds or trees with fleshy fruits which are eaten as olives.

The Australian Approved Name is *Canarium indicum* var. *indicum* seed oil. *Canarium indicum* synonyms include: *Canarium commune* L, *C. amboinense* Hochr, *C. moluccanum* Blume, and *C. zephyrium* Rumphius. Common names include: ngali nut, canarium almond, canarium nut, galip nut, nangai (Thomson and Evans 2004).

3. **DESCRIPTION OF THE NEW DIETARY INGREDIENT**

(a) The nut.

The nutrient profile of *C. indicum* nut resembles that typical of nuts in general with a high fat content (70 – 80% oil, 48% being saturated, 38% monounsaturated and 14% polyunsaturated) with some protein 13% and carbohydrate (7%) with small amount of minerals and vitamins. (Russel and Savage 2005 Food Science, Thomson and Evans, 2004)

(b) Oil Production.

The fruit from *Canarium indicum* are harvested over 2 to 6 month period each year. To extract the oil from the nut, the process involves the following steps.

- harvesting the fruit
- baking or cooking the fresh fruit to loosen the flesh from the nut shell
- cracking and removal of the seed from the nut shell
- grinding and pressing of the seed
- filtering of oil from the pressed seed

The kernel of *Canarium indicum* weighs 3 grams and may contain up to 75% oil.

(c) The oil

The major lipid classes in *C. indicum* nut oil as determined by layer chromatography are summarized in the following table.

Lipid Class	% Wt/Wt
Triglyceride	94.3 - 98.1
Free fatty acid	1.1 - 4
Sterol	0.4 - 0.8
Diglyceride	0.2 - 0.6
Polar lipids	0.3 - 0.4

Fatty acid profiles by gas chromatography showed the major fatty acids in Ngali nut oil to be unsaturated oleic acid (33%) and linoleic acid (13%) with a small quantity of α linoleic acid and saturated (palmitic acid 40%, stearic acid 12%).

	Content %	
Fatty Acid	Literature Evans 1999	Literature Martin and Harris 1993
Lauric (12:0)	0.4	
Myristic (14:0)	0.2	
Palmitic (16:0)	34.3	34.9
Palmitoleic (16:1)	0.4	
Heptadecanoic (17:0)	0.2	
Stearic (18:0)	13.4	12.9
Oleic (18:1 n - 9) (18:1 n - 7)	37.5	41.6
Linoleic (18:2 n – 6)	13.5	10.3
α Linoleic (18:3 n – 3))	0.3	0.4
Arachidic (20:0)	0.3	0.2
Ecosenoic (20:1)	0.1	

(d) Level of the new dietary ingredient in the dietary supplement. The dietary supplements will contain 100% of *Canarium indicum* nut oil (dietary ingredient).

(e) Conditions of use.

Directions: For adults only. 1 drop or 1 capsule (contains one drop) three times a day with each meal. The total daily dose of *Canarium indicum* nut oil is 200 mg.

Warning: The material is derived from nuts. Do not use the product if allergic to nuts.

These statements have not been reviewed by the Food and Drug Administration. This product is not intended to diagnose treat, cure or prevent any disease.

4. HISTORY OF USE OR OTHER EVIDENCE OF SAFETY

(a) History of Use: The western Melanesian region is a centre of domestication of tree species with generic origins in Southeast Asia (Yen 1994). For thousands of years Melanesians have selected and propagated cultivars of *Canarium indicum.* From its distribution it may be surmised that *C. indicum* is the oldest domesticated species in Melanesia. Plant remains of *C. indicum* were found in Papua New Guinea on a 14,000 year-old archaeological site. Shells of the nut were already from a domesticated variety. On the island of Bougainville shells of *Canarium indicum* were discovered with the skeleton of a woman who died 9,000 years ago. Other archaeological sites dating to 6,000 and 12,000 years ago have also yielded *Canarium indicum* shells. (Yen 1994)

There are numerous edible nut tree varieties found in Melanesia which constitute as significant part of the protein portion of the local diet. The *C. Indicum* nut is one of the most important edible nuts. As a consistent source of animal protein in the local diet is not always available (one of the main forms of such protein being fish) the nuts play an essential, as well as traditional, role in a balanced diet for the islanders (Powell 1976).

C. indicum nuts are used by the people of the Solomon's as a traditional food product. (Thomson and Evans 2004) The nuts are traditionally eaten by the islanders either raw, dried or roasted, (FAO, 1991) or added to other dishes as flavoring (such as taro and cassava puddings). The nuts are also ground and used as an ingredient in a ceremonial pudding (Evans 1999). Ngali nuts are considered to be a food of social status and are used in traditional feasts. In some parts of the country, ngali nut harvest time is celebrated by custom rituals, dances and songs. Dried or roasted kernels and nuts-in-shell are frequently given away as presents or exchanged for other goods and money by local people. A strained emulsion of crushed, well-ripened seeds may be used as milk substitute for infants. The present estimated consumption is 70 g/person/day. (FAO nd; Evans 1999).

The oil from the *C. indicum* nut is used as flavored cooking oil in the Solomon Islands and usually preferred to coconut oil. (FAO, nd, Akus, 1994, Maima, 1994)

C. Indicum nuts are exported by Pacific Nuts Limited in 2.5 kg and 300 g plastic bags under modified atmosphere (CO_2, N_2). According to the manufacturer *C. indicum* nuts can replace all kinds of nuts in recipes.

In late 1991, Solomon Airlines started to serve *C. indicum* nuts to business class customers on their international flights.

(b) Other Evidence of Safety: Using a standard rate model, researchers from the University of Queensland, Australia demonstrated that oils used in product like baby bath oil (mineral oil, apricot, kernel), facial skin body oils (soya bean, persic, macadamia nut), up market cosmetics (jojobe bean, avocado) and moisturizers of various types (mineral oil-water emulsion) can induce chronic poly arthritis. In contrast, other oils such as emu and goanna oils (used by Australian Aborigines) and *C. indicum* or Ngali nut oil (used in the Solomon Islands) were non-toxic. (Whitehouse, 2001)

Canarium indicum nut oil is made up essentially of triacylglyerols which contains simple fatty acids. The metabolism of those lipids is well known. The following table is provided to give an indication of the low toxicity that can be expected for *Canarium indicum* nut oil (from RTECS 2004). Total daily dose for an adult is 200 mg.

Fatty Acid	Species	Test	Dose (mg/kg/bwt)
Myristic	Rate	LD_{50}	>10,000
Palrintic	Rat	LD_{50}	>10,000
Stearic	Rat	LDL_0	4,640
Oleic	Rat Mouse	LD_{50} LD_{50}	25,000 28,000
Linoleic	Mouse	LD_{50}	>50,000

LD_{50} lethal dose 50%. LDL_0 lowest published lethal dose.

On October 15, 2004 the Complementary Medicine Evaluation Committee (CMEC), department of health and aging, therapeutic good administration (TGA) of Australia recommended that *Canarium indicum* seed oil is suitable for use as active ingredient in listed medicine subject of a label advisory statement indicated that the material is derived from nuts (CMEC 48, 2004). Notice was published in the Commonwealth of Australia Gazette on April 6, 2005.

Serge R. Martinod
DVM, PhD, MBA