Request for an opinion on the equivalence of Noni Juice (juice from the fruit of *Morinda citrifolia* L).

Request made by:
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On Behalf of the:
Pacific Islands Noni Association and other Pacific Islands Noni juice Producers

CAMedica
April 23rd 2004.

Request for an opinion on the equivalence of Noni Juice (juice from the fruit of *Morinda citrifolia* L).

CAMedica Ltd

CAMedica is a healthcare consultancy specialising in EU regulatory issues. In this capacity CAMedica has assembled the data for this application on behalf of 23 producers of Noni juice in the Pacific Islands.

PINA

The Pacific Islands Noni Association (PINA) was set up in 2002. Current membership stands at 9 (see below *), though this is building and it is anticipated that most of the applicant companies will in future work together within the Association.

Applicant Companies

COMPANY	*CONTACT*	*ADDRESS*
Pure Pacific Nin Juice *	Francis Reimers	P.O. Box 786 Majuru, Marshall Islands
Pacific Fabrication	Carmen Bigler	P.O. Box 424 Majuru, Marshall Islands
Noni PNG Ltd.	Brendan Chan	P.O. Box 246 , Lae Morobe Province, PNG
Royale Noni Ltd*.	William Brull	P.O. Box 5842, Navutu Lautoka, Fiji
Herbex Ltd *.	Gerhard Stemmler	P.O. Box 516 Lautoka, Fiji
Bioteknology Ltd.*	Jeff Liew	P.O. Box 13617 Suva, Fiji
Owlfiji Ltd *.	George Patterson	P.O. Box 149 Levuka, Fiji
Frezco Beverages Ltd *.	Mohammed Altaaf	P.O. Box 9303 Nadi, Fiji
Nonu Supplies Fiji Ltd *.	David A. Khan	P.O. Box 10664 Suva, Fiji
Lita Trading Ltd.	T. Takataka	P.O. Box 1584 Nuku'alofa, Tonga
IBC*	Simon Agius	PKF House Port Vila, Vanuatu
Timoteo Panapa		Tuvalu

Cook Islands Noni Marke.	Teava Iro Jnr.	P.O. Box 184 Rarotonga, Cook Islands
Sunline Noni Ltd.	Taura Tukaroa	P.O. Box 295 Rarotonga, Cook Islands
Cook Islands Prem. Noni Nonimana Inc. Ltd.	Danny Mataroa	P.O. Box 78 Rarotonga, Cook Islands
Noni Ltd.	Richard Browne	P.O. Box 144 Rarotonga, Cook Islands
CCK Trading *	Ken Newton	P.O. Box 3043 Apia, Samoa
Wilex	Eddie Wilson	P.O. Box 3428 Apia, Samoa
Nonu Samoan Ent.	Tia Siaosi	P.O. Box 1099 Apia, Samoa
Richard Keil Holdings	Richard Keil	P.O. Box 977 Apia, Samoa
Belau Agro Ind. Dev. Corp	Minoru Ueki	P.O. Box 8013/1197 Koror, Palau
King Solomon Noni *	Morgan Wairiu	P.O. Box 378 Honiara, Solomon Islands
Nauru Noni	Nelson Tamakin	Nauru

Notification

This notification is being submitted to comply with the procedures laid down in Regulation 258/97 and the requirements of the UK Food Standards Agency. This notification follows the Commission Decision of 5 June 2003 addressed to Morinda Inc authorising:-

'Noni juice' (juice of the fruit of *Morinda citrifolia* L may be placed on the market in the Community as a novel food ingredient to be used in pasteurised fruit drinks.'(authorised juice).

The purpose of this notification is to demonstrate that the noni juice used in the fruit juices produced by the applicant companies and those that they intend to market are substantially equivalent within the terms of Article 3 (4) of Regulation 258/97 to the authorised juice.

In submitting this notification and in accordance with Regulation 258/97 the following data will be presented:-

1. The Specification of the Noni Juice

2. The Production process

3. Microbiological and contaminant information

4. Proposed use of Noni juice

Specification of the Noni Juice

Origins

Noni juice is a juice from the fruit of Morinda citrifolia L also known as the 'Indian Mulberry' and the 'awl tree'. Morinda citrifolia L is a member of the genus Rubiaceae.

Morinda citrifolia is a small tree with ovate glossy leaves 15-20 cm long. Clusters of fragrant, white, tubular flowers appear all year followed by irregularly ovoid, cream fruits, to 7.5 cm long which smell like blue cheese when ripe. The tree is native to tropical Asia, Australia and Polynesia. (source: RHS, Encyclopedia of Herbs and their uses 2002).

The tree is now also found in India, Africa and the West Indies where it was introduced.

Botanical Opinion

Morinda citrifolia L used to produce noni juice is widely distributed throughout Polynesia.

The authorised juice is from fruit grown in Tahiti but fruit from Fiji, Samoa, Tonga, Vanuatu, the Cook Islands and other islands in the Pacific all comes from the tree that is botanically recognised as Morinda citrifolia L.

This is supported by Dr A Whistler, from Hawaii, who confirms that 'the plants growing on different Polynesian and Melanesian islands are morphologically indistinguishable from each other'. (See botanist opinion – schedule 1).

Composition and Nutritional information of Noni Juice

The Noni juice produced by the members of PINA is unfermented and pasteurised. It is presented as a 100% juice with no added water neither are any other fruit juices added e.g.: grape juice.

For the purposes of the application a sample 100% juice has been selected that is representative of all applicant producer products. All analytical data submitted refers to this sample (PINA sample) and will serve as the specification for all 100% Noni juices produced by the applicant companies.

The composition of the PINA noni fruit juice is compared with the authorised 89% Tahitian Noni™juice and a 100% Noni juice from Tahiti (for a direct comparison). For a strict comparison the two 100% juices should be compared, one from Tahiti and the other from the other Pacific Islands (PINA). There are, of course, variations as would be expected from natural products. However the compositions are very comparable and support the case for substantial equivalence.

See schedules 2-4 (confidential)

The Production Process

The production process flowchart is shown in Schedule 5 (confidential).

This section is confidential.

Comparison with Authorised juice

Analysis of the PINA noni juice confirms that this production process produces an unfermented juice product with a composition comparable to the authorised noni juice (see schedule 2), allowing for the fact that the authorised juice has other fruit juices added.
In order to investigate whether a degree of fermentation took place during production the levels of ethanol were measured and found to be 0.3% v/v, a level in line with other fruit juices e.g. orange juice and at a similar level (0.2% v/v) to the authorised noni juice (see schedule 2). **It is concluded therefore that the applicant juice is unfermented.**

Clearly pasteurisation arrests any possible fermentation and ensures microbiological safety.

Microbiological and contaminant information on PINA Noni Juice

Microbiological

Schedule 6 confirms that the microbiological status of the sample PINA noni juice is satisfactory.

Contaminants

Analysis of the heavy metal content of the PINA sample Noni Juice shows that the sample is well within international guidelines. (Schedule 7)

A pesticide analysis carried out on the sample did not show any cause for concern, the levels being below the detection limits and below EC maximum residue limits (Schedule 8).

The presence of Anthraquinones in the roots and leaves of Morinda citrifolia have been reported but they are believed to be absent from the mature fruit. Leaves and roots are excluded from the production of the juice in the early stages of the production process, (see schedule 5).

Proposed use of PINA noni juice

Recommended daily intake

The unfermented pasteurised product that is produced is a 100% noni juice, which is not blended with any fruit concentrates. The 100% juice does have a unique taste. Perhaps because of this, a daily intake of 30 ml is recommended. This recommendation has grown up with time and has become standard amongst manufacturers of noni juices.

Exports and global use

Members of the Pacific Islands Noni Association have been exporting their products all around the world including Asia, USA, Australia, Canada and New Zealand for a number of years.

Schedule 1

Letter from Dr A Whistler:-

Art Whistler Ph.D.
ISLE BOTANICA Publishers and Botanical Consultants
2814 Kalawao St., Honolulu, Hawaii. 96822 PH/FAX (808) 945-9334 E-Mail: whistler@hawaii.edu

3 November 2003

Gerhard K. Stemmler
Herbex Ltd.
P.O. Box 516
Lautoka, Fiji - Islands

Dear Mr. Stemmler,

Thank you for your inquiry about *Morinda citrifolia* (noni). I am very familiar with this tree, since I have dealt with it many times during my thirty years of ethnobotanical and taxonomic work on Pacific plants, and it is discussed in a number of my books on Pacific botany, including *Polynesian Herbal Medicine* (1992) *Tongan Herbal Medicine* (1992), *Samoan Herbal Medicine* (1996), and *Plants in Samoan Culture* (2001). The tree grows widely throughout the Pacific islands and is one of the most significant sources of traditional medicines among the local societies. It is native from Southeast Asia (Indonesia) to Australia, but was an ancient introduction throughout Micronesia and Melanesia, and in Polynesia eastward all the way to Hawai'i. In many of these islands it is naturalized and indistinguishable from native species.

Since the tree is naturalized and appears not to have undergone much selection for favorable varieties, no clear sub-populations bearing unique characteristics have been recognized. Only two varieties and one cultivar are currently distinguished: var. *citrifolia* (the wild type found throughout the species' range), var. *bracteata* (a small-fruited variety with conspicuous bracts found in Indonesia and elsewhere east of Oceania), and CV 'Potteri' (an ornamental plant with green and white leaf variegation, distributed throughout the Pacific). Thus the tree is relatively uniform throughout its Pacific range, and plants growing on different Polynesian and Melanesian islands are

morphologically indistinguishable from each other. The noni of Tahiti (it is actually called *nono* there) is virtually indistinguishable from the noni used in Hawai'i (where it is called *noni*) and from the one in Fiji. Thus there is no reason why the chemical composition of noni from Fiji would differ significantly from that in Tahiti or anywhere else in Polynesia, and any conclusions that have been drawn about the Tahitian noni would also apply to noni throughout its range. I hope this elucidates the variability of noni in the Pacific for anyone concerned.

Regards,

Art Whistler, Ph.D.
Isle Botanica
Honolulu, Hawai'i

Schedule 2

Compositional Profile of Tahitian Noni™ juice

Proximate		*Content*	*Unit*
Moisture		89-90	g/100 g
Protein		0.2-0.5	g/100 g
Ash		0.2-0.3	g/100 g
Total fat		0.1-0.2	g/100 g
Total carbohydrate		9.0-11.0	g/100 g
Total dietary fiber		0.5-1.0	g/100 g
Fructose		3.0-4.0	g/100 g
Glucose		3.0-4.0	g/100 g
Sucrose		<0.1	g/100 g
Energy	163-197		kJ/100g
Specific gravity	1.015		g/mL
pH		3.4-3.6	

Vitamins			
Vitamin C		3-25	mg/100 g
Vitamin B_1		0.003-0.01	mg/100 g
Vitamin B_2		0.003-0.01	mg/100 g
Vitamin B_6		0.04-0.13	mg/100 g
Vitamin B_{12}		0.1-0.3	mcg/100 g
Folic acid		7.0-25.0	mcg/100 g
Biotin		1.5-5.0	mcg/100 g
Niacin		0.1-0.5	mg/100 g
Pantothenic acid		0.15-0.5	mg/100 g
Vitamin E		0.25-1.0	IU/100 g
Carotene		(as vitamin A activity)	
Total beta carotene		18-22	IU/100 g
Total carotene		18-22	IU/100 g
Alpha carotene	6.0-7.0	IU/100 g	
All-*trans* beta carotene	6.0-7.0	IU/100 g	
Cis-beta carotene		6.0-7.0	IU/100 g

Minerals			
Calcium		20-25	mg/100 g
Iron		0.1-0.3	mg/100 g
Phosphorus		2.0-7.0	mg/100 g
Magnesium		3.0-12	mg/100 g
Molybdenum		0.3-1.0	mg/100 g
Sodium		15.0-40.0	mg/100 g
Potassium		30.0-150	mg/100 g
Salt (as sodium chloride)		0.09-0.12	%

Amino acids			
Aspartic acid		30-77	mg/100 g
Threonine		8-11	mg/100 g
Serine		9-12	mg/100 g
Glutamic acid		25-44	mg/100 g
Proline	24-33		mg/100 g
Glycine		10-22	mg/100 g
Alanine		17-33	mg/100 g
Cystine	7-11		mg/100 g
Valine		10-22	mg/100 g
Methionine		1-4	mg/100 g

Isoleucine	7-11	mg/100 g
Leucine	10-22	mg/100 g
Tyrosine	6-11	mg/100 g
Phenylalanine	5-8	mg/100 g
Histidine	4-6	mg/100 g
Lysine	7-11	mg/100 g
Arginine	30-44	mg/100 g
Tryptophan	1-3	mg/100 g

NB: Source of compositional details is from the:-

Opinion of the Scientific Committee on Food on Tahitian Noni™ juice,(expressed on 4th December 2002)

In addition a separate analysis conducted on a purchased bottle of Tahitian Noni™juice contained 0.2% ethanol.

Schedule 3

COMPOSITIONAL ANALYSIS OF NONI JUICE FROM TAHITI

A bottled sample of Noni juice produced in Tahiti (100% Organic Noni Tahiti) was supplied for analysis. It was analysed by standard procedures and the results are reported below. The free amino acid profile was sub-contracted. A commentary is provided making comparison with other data provided on the authorised Tahitian product.

Analyte	Results	Units
Moisture	97.2	g/100 ml
Protein	0.8	g/100 ml
Ash	0.6	g/100 ml
Total Fat	<0.1	g/100 ml
Total Carbohydrate	3.5	g/100 ml
Total Dietary Fibre	<0.1	g/100 ml
Fructose	1.8	g/100 ml
Glucose	1.8	g/100 ml
Sucrose	<0.1	g/100 ml
Energy	74	kJ/100 ml
Sodium	25	mg/100 ml
Density	1.021	g/cm^3
PH	3.6	
Vitamin C	<5	mg/100 ml
Carotenoids	Not Detected (<0.1 mg/100 ml)	
Calcium	9.6	mg/100 ml
Iron	0.5	mg/100 ml
Phosphorus	21	mg/100 ml
Magnesium	22	mg/100 ml
Molybdenum	Not Detected (<0.05 mg/l)	
Potassium	124	mg/100ml
Salt (as sodium chloride)	0.2	g/100g
TVC	70	cfu/g
Yeasts and moulds	<10	cfu/g

Amino Acid	Concentration (mg/100ml)
Aspartic acid	12
Threonine	6
Serine	9
Glutamic acid	9
Asparagine	0
Proline	3
Glycine	5
Alanine	21
Cystine	2
Valine	6
Methionine	3
Isoleucine	3
Leucine	9

Tyrosine	7
Phenylalanine	7
GABA	2
Histidine	9
Lysine	7
Arginine	11
Tryptophan	0

Commentary

The pH is typical of a fruit juice and the microbiological status is satisfactory.

The glucose and fructose ratios are consistent with the authorised Tahitian product. The higher absolute level of these in the comparative juice may reflect the known addition of other fruit concentrates.

There were no carotenoids detected in this sample, therefore no vitamin A was present. This is consistent with the fact that this is a filtered juice and no pulp is present.

The mineral levels are similar to any normal fruit juice. The molybdenum level was high in the authorised Tahitian product, but was not detectable here.

The amino acid levels are typical of a fruit juice but lower than in other samples.

Schedule 4

COMPOSITIONAL ANALYSIS OF PINA NONI JUICE

A bottled sample of PINA noni juice was supplied for analysis. It was analysed by standard procedures and the results are reported below. The amino acid profile was sub-contracted. A commentary is provided making comparison with other data provided from the authorised Tahitian product.

Analyte	Results	Units
Moisture	96.7	g/100 ml
Protein	0.5	g/100 ml
Ash	0.8	g/100 ml
Total Fat	0.1	g/100 ml
Total Carbohydrate	4.2	g/100 ml
Total Dietary Fibre	0.1	g/100 ml
Fructose	1.6	g/100 ml
Glucose	1.7	g/100 ml
Sucrose	<0.1	g/100 ml
Energy	82	kJ/100 ml
Sodium	49	mg/100 ml
Specific Gravity	1.025	
PH	3.83	
Vitamin C	20	mg/100 ml
Carotenoids	Not Detected (<0.1 mg/l)	
Calcium	3.9	mg/100 ml
Iron	0.6	mg/100 ml
Phosphorus	2.0	mg/100 ml
Magnesium	20	mg/100 ml
Molybdenum	Not Detected (<0.05 mg/l)	
Potassium	98	mg/100ml
Salt (as sodium chloride)	0.2	g/100g
Alcohols	0.3 (ethanol) 0.2 (methanol)	% v/v
TVC	<10	cfu/g
Yeasts and moulds	<10	cfu/g

Amino Acid	Concentration (mg/100ml)
Aspartic acid	54
Threonine	12
Serine	27
Glutamic acid	24
Proline	8
Glycine	10
Alanine	30
Cystine	1
Valine	13
Methionine	6
Isoleucine	8

Leucine	19
Tyrosine	13
Phenylalanine	11
Histidine	9
Lysine	13
Arginine	21
Tryptophan	0

Commentary

The pH is typical of a fruit juice and the microbiological status is satisfactory.

The presence of ethanol and methanol indicates that slight fermentation and depectinisation has taken place. This is not unusual for a fruit juice and the ethanol level is within the AIJN norm of <0.3%.

The glucose and fructose levels are consistent with the Tahitian product. The higher absolute level of these in the Tahitian juice may reflect the known addition of grape juice.

There were no carotenoids detected in this sample, therefore no vitamin A was present. This is not surprising as the juice was clear and carotenoids are associated with pulp.

The mineral levels are similar to any normal fruit juice. The molybdenum level was unusually high in the authorised Tahitian product, but was not detectable here.

The amino acid levels are typical of a fruit juice. Higher levels of proline and arginine in the authorised Tahitian juice may reflect the known addition of grape concentrate to that sample.

Schedule 5

PINA Noni Juice Production Process

Processing FlowChart

This section is confidential.

Schedule 6

PINA Noni juice – Microbiological Analysis

Results of Microbiological Analysis

Analysis	Result	Units
Total Viable Count	< 10	cfu/g
Bacillus cereus	< 50	cfu/g
Clostridium perfringens	< 10	cfu/g
Coliforms	< 10	cfu/g
Escherichia coli	< 10	cfu/g
Listeria spp	Not Detected	in 25g
Listeria spp	< 20	cfu/g
Salmonella spp	Not Detected	in 25g
Staphylococcus aureus	< 50	cfu/g
Yeasts	< 10	cfu/g
Moulds	< 10	cfu/g

Schedule 7

COMPOSITIONAL ANALYSIS OF PINA NONI JUICE – Heavy Metals

A bottled sample of noni juice produced in the Pacific Islands was supplied for analysis of possible heavy metal content. It was analysed by standard procedures and the results are reported below.

Analyte	Results	Units
Arsenic	<0.005	mg/100ml
Lead	<0.001	mg/100ml
Mercury	<0.002	mg/100ml
Cadmium	<0.001	mg/100ml

Schedule 8

PINA Noni juice – Pesticide Screen

Analytical Results

Aldrin	<0.005	mg/kg
Chlordane	<0.020	mg/kg
DDT (Total Isomers)	<0.050	mg/kg
Dieldrin	<0.005	mg/kg
Endosulphan	<0.050	mg/kg
Endosulphan Sulphate	<0.050	mg/kg
Endrin	<0.010	mg/kg
HCB	<0.005	mg/kg
Alpha HCH	<0.010	mg/kg
Beta HCH	<0.010	mg/kg
Gamma HCH (lindane)	<0.010	mg/kg
Heptachlor	<0.010	mg/kg
Heptachlor Epoxide	<0.010	mg/kg
Tecnazene	<0.050	mg/kg
Permethrin	<0.050	mg/kg
Deltamethrin	<0.050	mg/kg
Fenvalerate	<0.020	mg/kg
Cyfluthrin	<0.020	mg/kg
Cypermethrin	<0.050	mg/kg
Cyhalothrin	<0.020	mg/kg
Acephate	<0.020	mg/kg
Azinphos ethyl	<0.050	mg/kg
Azinphos methyl	<0.100	mg/kg
Bromophos	<0.020	mg/kg
Bromophos-ethyl	<0.050	mg/kg
Carbophenthion	<0.020	mg/kg
Chlorpyriphos	<0.050	mg/kg
Chlorpyriphos-Methyl	<0.050	mg/kg
Chlorfenvinphos	<0.020	mg/kg
Coumaphos*	<0.020	mg/kg
Diazinon	<0.020	mg/kg
Dichlofenthion	<0.020	mg/kg
Dichlorvos	<0.050	mg/kg
Dicrotophos	<0.020	mg/kg
Dimethoate	<0.020	mg/kg
Ethion	<0.050	mg/kg
Ethoprophos	<0.020	mg/kg
Etrimphos	<0.050	mg/kg
Fenamiphos	<0.020	mg/kg
Fenchlorfos	<0.010	mg/kg
Fenitrothion	<0.050	mg/kg
Fenthion	<0.020	mg/kg
Fonophos	<0.020	mg/kg
Malathion*	<0.020	mg/kg
Methacriphos	<0.050	mg/kg

Methadithion	<0.020	mg/kg
Methamidophos	<0.010	mg/kg
Mevinphos	<0.050	mg/kg
Omethoate	<0.020	mg/kg
Parathion	<0.100	mg/kg
Parathion-methyl	<0.050	mg/kg
Phorate*	<0.050	mg/kg
Phosalone	<0.100	mg/kg
Phosmet	<0.010	mg/kg
Pirimiphos-Methyl	<0.050	mg/kg
Propetamphos	<0.020	mg/kg
Quinalphos	<0.020	mg/kg
Tetrachlorvinfos	<0.020	mg/kg
Turbufos*	<0.020	mg/kg
Vinclozolin*	<0.020	mg/kg
Fluemetralin	<0.020	mg/kg
Iprodione	<0.020	mg/kg

Methyl Carbamates	None detected