

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

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Request made by:

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On behalf of:

Mi GmbH Switzerland and Mi EU Ltd. United Kingdom (amended 24 March 2005)

Mi GmbH Switzerland and Mi EU Ltd. United Kingdom

Mi GmbH Switzerland and Mi EU Ltd. (which from this point forward shall be referred to as “Mi”) is a manufacturer and distributor of fruit juices, based in Switzerland. Traditionally fruit juice has been purchased, imported from New Zealand under licence and then bottled in Switzerland.

In an effort to bring higher quality products to the market, Mi intends to import “Flash Frozen” whole fruits directly from the South Pacific Islands, to create freshly squeezed products in Europe. The intension is to juice, process and bottle these imported whole fruits in Switzerland and the Europe Union, thus producing juices that fully meet European and Swiss standards bringing both freshness and quality to our customers which we believe to be essential with any Noni product.

Notification

This notification is being submitted to comply with the procedures laid down in Regulation 258/97 and the requirement of the UK Food Standards Agency. This notification follows the Commission Decision of the 5th of 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).

It is also being submitted to comply with the procedures laid down in Regulation 258/97 and the requirement of the UK Food Standards Agency. This notification follows the Commission Decision of the 1st of November 2004 addressed to Cook Island Noni Juice produced by Natures Products who in turn supply GSE Vertrieb.

The purpose of this notification is to demonstrate that the Noni fruits and subsequent juice created after pressing by Mi, and those that they intend to market are substantially equivalent within the terms of Article 3 (4) of the Regulation 258/97 to the authorised juices.

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

- Specification, and sources of the Noni fruit
- Specification regarding harvesting, and transportation of Noni Fruit
- Production Process
- Specification of the Noni Juice
- Contaminate information
- Proposed use of Noni juice

Specification and sources of the Noni fruit

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 avate glossy leaves 15-20 cm long. Clusters of fragrant, white tubular flowers appear all year followed by irregularly ovoid cream fruits up to 7.5 cm long which have a pungent smell when ripe.

Morinda citrifolia L used to produce our Noni juice is widely distributed throughout Polynesia. As per Botanical Opinion in schedule 1 of PINA application approved 16th of December 2004 one can see that the fruit from Tahiti, Fiji, Samoa, Tonga, Vanuatu, Cook Islands and other islands of the Pacific all come from the same tree botanically recognised as *Morinda citrifolia* L.

All Noni fruit used in production by Mi is from the Pacific island groups to include Tahiti, Fiji, Samoa, Tonga, Vanuatu and Cook Islands.

Specification regarding Harvesting, and Transportation of Noni Fruit

Fruits are selected from Pacific Islands to include Tahiti, Fiji, Samoa, Tonga, Vanuatu and Cook Islands.

At present due to infrastructure, and quality guarantees, all fruit used by Mi is harvested and supplied by the same supplier as Natures Products who in turn supply GSE-Vertrieb. This will remain the situation for the foreseeable future or until we find a supply that exceeds our existing standards both in quality and reliability.

Cook Islands

Other Pacific Islands that are equal to or exceed current harvest process

Stage One:

- Ripe Noni fruit is hand picked from orchard or forest
- Fruit is then sorted with all debris (leaves and twigs) removed. Fruit is also graded for quality & size
- Fruit is passed through a "VinEquip" custom built fruit washing/drying machine on site
- Fruit is dried, then inspected with random fruit being sent for heavy metal analysis etc.

Stage Two:

- Fruit then:
 - Packed into 20kg clear plastic bags and sealed when full
 - Milled (pulped) into 1000kg IBC (food grade) such as Combo Life 285 Containers (Bulk Bladder)
- Product is then frozen to -18 to -22 Degrees Centigrade
- Full sealed 20 foot refrigerated containers (16,000kg with Plastic bags 21,000kg with IBC's) is shipped to Switzerland or EU production plant (end 2005)

Please note that the freezing of Noni fruit has no major impact on the composition characteristics of the final juice, providing defrosting is conducted in a controlled manner hence the slicing into sections of our 1000kg blocks of ice. Appendix 3 lab data confirms equivalence of Mi Juice using this process to Morinda, Natures Products and GSE.

Please see Appendix 1 for flow chart of harvesting and transportation process

Production Process

Switzerland and EU

All equipment and process used to squeeze Noni Juice for Natures Products who in turn supply GSE-Vertrieb are very similar to Mi with the exception of our ultra filtrated product, which is exclusive to Mi. Product is processed.

All facilities are fully certified by the appropriate authorities, as well as local Organic (Bio) organisations.

Stage One:

- Sealed containers are moved from North Port (Hamburg/Rotterdam/Antwerp by train and then truck (last few km's) direct to processing facility in Switzerland or EU facilities
- Fruits (both whole and milled) are defrosted within controlled environmental conditions
milled fruit is sliced into sections to help control defrost
- Fruit is inspected for quality, and random samples taken for lab tests

Stage Two:

- Fruit is then loaded into fruit press for juice extraction
- Juice is then pumped into 15,000 litre or 35,000 litre holding tanks
- Samples are again taken to the lab for quality control

Stage Three:

- Juice is pumped from the holding tank, passed through another filter (policeman sterile filter) then:
 1. Pasteurised and then Bottled
 2. Pasteurised and Filled into 1000L IBC's (septic)
 3. Concentrated, Pasteurised and filled into 1000L IBC's (septic)
 4. Concentrated, Pasteurised and Bottled
- Samples from each batch are sent to the lab for analysis as a final quality check before shipment

Pasteurisation and Bottling: Pasteurisation at 87.5 degrees centigrade for at least 3 seconds or equivalent (Standard and within EU regulations). The juice is then filled into washed and sterilised bottles using recognised and approved Swiss and EU techniques.

Bottles are then labelled and packaged. Random bottles are removed from production for quality control inspection.

IBC's: Juice is pasteurised septic filled into 1,000ltr food grade bulk shipping bladders (IBC)

Concentration: Juice is concentrated to 30 brix, using an EU approved process. The pasteurised concentrate is then filled into 1,000ltr IBC's

Concentrate is also filled into bottles using the above procedures.

All products have organic status, therefore all product is complete by having a full audit trail from harvest to sale.

Please see Appendix 2 for flow chart of production process

Specification and Equivalence of Noni Juice

All Mi Noni Products are based on unfermented, pasteurised juice, sold in ways described in section "Proposed use of Noni juice".

For the purpose of this application Mi has submitted two samples which are representative of the two Noni juices produced and used by Mi to create all products.

The first sample Appendix 3 is analytical data from our Direct Squeeze pasteurised juice, which all our juices are based on.

Our Fresh Squeeze pasteurised juice is based on our Direct Squeeze juice (same composition as Appendix 3) however it is passed through a very fine filter. The juice is then pasteurised and bottled. Appendix 3.1 is analytical data from our Fresh Squeeze juice which indicates no composition change except to colour and taste.

All products for the European Union are pasteurised to both EU and Swiss regulations.

Appendix 3.2 is composition analysis of Natures Products and GSE Vertrieb using the same lab, with the same techniques as the Mi samples for the lab report outlining equivalence between the two products found in appendix 3.4.

Appendix 3.3 is a lab test done on Natures Products and GSE Vertrieb product in New Zealand 18th of May 2004.

As outlined by our independent lab report found in Appendix 3.4, there are of course variations between the samples, as one would be expected from natural products. However the compositions are very comparable, and support the case for substantial equivalence all Mi Noni Juice products to Natures Products and GSE Vertrieb Noni products.

Contaminate information

Appendix 3 and 3.1 confirms that the microbiological status of both Mi Noni Juice's are well within European guidelines.

Contaminants

As all Mi Fruit is from the same supplier as Natures Products, a pesticide analysis done for Natures Products has been submitted. This analysis shows that the sample submitted did not show any cause for concern, and that levels being below the detection limits are below EC maximum residue limits. (Appendix 4.0).

On receiving our next container in March, we will run our own contaminates test, which if requested can be supplied to the commission.

Before using a new supplier, or fruit from another region, rigorous testing will be conducted to ensure the compliance of the fruit to all EU regulations. However Mi does not envisage changing supplier for the foreseeable future, we will, if requested submit lab data on the new supplier.

The presence of Anthraquinones in the roots and leaves of the Morinda citrifolia has 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.

Proposed use of Noni juice

The unfermented pasteurised Noni juice produced by Mi is based on 100% Noni fruit. Mi recommends a daily intake of 30ml on all products as with all manufacturers.

Mi sells juice in the following ways:

- | | |
|-------------------------|----------------------------|
| 1-Direct Squeeze | pasteurised |
| 2-Fresh Squeeze | pasteurised |
| 3-Concentrate | pasteurised |
| 4-Frozen Concentrate | pasteurised (for industry) |
| 5-Frozen Direct Squeeze | pasteurised (for industry) |

Mi also sells blended juice to select customers. These juices are based on our Direct Squeeze pasteurised product blended with Kiwi, Pineapple and other selected fruits creating fruit juice blends produced in the same way as other European fruit juice produces.

We are also looking at flavouring our Fresh Squeeze Noni juice with natural flavours, however this is still being explored, for release late 2005. The FSA will be fully notified before releasing this product to market.