

**Memorandum**

*Rec'd 8/18/06  
JB*

Date: AUG 9 2006

From: Consumer Safety Officer, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Extramel- cantaloupe melon extract

Firm: Seppic, Inc.

Date Received by FDA: May 11, 2006

90-Day Date: August 9, 2006

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Victoria Lutwak

1995S-0316

RPT353



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740

JUL 20 2006

Mr. Robert McKay, Vice President  
Seppic, Inc.  
30 Two Bridges Road, Suite 210  
Fairfield, New Jersey 07004

Dear Mr. McKay:

This is to inform you that the notification, dated April 28, 2006, that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on May 11, 2006. Additional information incorporated into a revised notice, dated June 7, 2006, was received on June 14, 2006. Your notification concerned the substance that you identified as "Extramel," cantaloupe melon extract, *Cucumis Melo* L, that you intend to market as a new dietary ingredient.

Your notification states that you intend to market a product consisting of a powder. Under conditions of use stated in your notice you state: "10 mg of "Extramel" is the recommended daily dose, equivalent to 142 I.U. of antioxidant enzymes (superoxide dismutase and catalase) and 1.8 µg of other antioxidants."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b (a) (2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f) (1) (B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement

containing "Extramel" will reasonably be expected to be safe. Your notification did not provide a description of your extraction process except in very general terms and did not provide details of the manufacturing process. Additionally, you did not provide a history of use or other safety about the material that is the subject of the notice, whole cantaloupe including the rind, establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Extramel" when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of May 11, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-1775.

Sincerely yours,



Linda S. Pellicore, Ph.D.  
Supervisory Team Leader, Senior Toxicologist  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety and Applied Nutrition



**SEPPIC**

SEPPIC, Inc.  
30 Two Bridges Road, Suite 210  
Fairfield, New Jersey 07004  
Phone : 973 882-5597 - Fax : 973 882-5178

8 June, 2006  
Amending 28 April, 2006

Office of Nutritional Products (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
510 Paint Branch Parkway  
College Park, MD, 20740-3835

Rec'd 6/14/06

Re : notification of a new dietary ingredient

Pursuant to 21CFR, Part 190, Subpart B, Sec. 190.6 notification is hereby provided of a new ingredient.

**1. Name and complete address of distributor of the new dietary ingredient**

SEPPIC Inc.  
30 Two Bridges Road  
Suite 210  
Fairfield, New Jersey, 07004  
USA

**2. Name of the new dietary ingredient**

EXTRAMEL

**3. Description of dietary supplements that contain the new dietary ingredient;  
Level of new dietary ingredient in the dietary supplement.**

Cantaloupe melon (*Cucumis Melo* L.-Carl Linneaus) extract rich in antioxidants.  
EXTRAMEL is sold in powder form and is recommended as an antioxidant dietary supplement.

**Ordinary conditions of use of the supplement**

10 mg of Extramel is the recommended daily dose, equivalent to 142 I.U. of antioxidant enzymes (superoxide dismutase and catalase) and 1.8 µg of other antioxidants (as vitamins A, E, C, carotenoids). Due to the fact that the recommended daily dose of EXTRAMEL contains less than a normal daily serving of Cantaloupe, the extract may be considered to be entirely safe.

## **History of use and evidence of safety**

Cantaloupe melon is a widely and commonly consumed fruit either eaten raw or served in deserts such as ice cream, yoghurt, etc.

Cantaloupe melons are a rich dietary source of antioxidants as antioxidant enzymes, vitamins and carotenoids.

A quarter of fresh cantaloupe melon contains 142,000 IU of antioxidant enzymes (superoxide dismutase and catalase) and 18 mg of other antioxidants (as vitamins A, E, C, carotenoids).

The recommended daily dose of the new dietary ingredient Extramel cantaloupe melon extract rich in antioxidants contains 142 IU of antioxidant enzymes (superoxide dismutase and catalase) and 1.8 µg of other antioxidants (as vitamins A, E, C, carotenoids), which correspond to a tea spoon of fresh Cantaloupe melon.

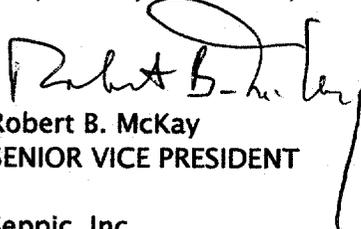
To ensure the protection of antioxidant in Extramel, 20% of Cantaloupe melon extract is coated with 80% of hydrogenated palm oil. The palm oil is a common excipient.

### **The manufacturing process is as follows:**

The melons are selected and washed, then crushed, and the pulp is recovered. The juice is clarified, centrifuged and filtered, then concentrated. The result is freeze dried and coated with palm oil as a protective excipient. Rinds, seeds and pulp are not included. No catalysts or other chemicals are added.

An oral toxicity study (rat) is included.

Respectfully submitted,



Robert B. McKay  
SENIOR VICE PRESIDENT

Seppic, Inc.  
30Two Bridges Rd.  
Suite 210  
Fairfield, NJ 07004

Enclosure :

Technical data sheet of Extramel  
Specifications of Extramel  
Certificate of analysis of Extramel  
ACUTE ORAL TOXICITY TEST IN THE RAT



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www.seppic.com

Date : November 2000  
Update : December 2002

## SPECIFICATIONS

Product : EXTRAMEL® microgranules

Product code : 11024H

Description : Melon pulp extract coated with vegetal fat matter

Characteristics	Standards
Aspect	Non soluble microgranules
Colour	Cream
Odour	Characteristic
Dry matter	Min. 95 %
Proteins	Max. 2 %
Melon pulp extract	20 %
Hydrogenated fat matter of vegetal origin	80 %
Superoxide dismutase activity	14 U <sup>1)</sup> / mg
Conservator	None
Total germs	Max. 10 000 CFU / g
Yeast & Mould	Max. 100 CFU / g
Enterobacteria	Max. 100 CFU / g
Escherichia coli	Absence / g
Salmonella	Absence / g
Pseudomonas aeruginosa	Absence / g
Staphylococcus aureus	Absence / g

(1) SOD activity is measured according to the Oberley and Spitz method 1985 based on the activity of SOD to inhibit the reduction of NBT by O<sub>2</sub><sup>-</sup> generated by a xanthine/xanthine oxidase system ( $\Delta DO_{500}$  initial = 0,025).

One unit of SOD gives 50 % inhibition of the reduction of NBT.

Packaging                      500g in opaque plastic flacons  
Storage                         To store in a dark and dry place  
Shelflife                        18 months

*Product manufactured by BIONOV (France)*

Société d'Exploitation de Produits Pour les Industries Chimiques  
S.A. à Directoire et Conseil de Surveillance au capital de 3.050.640 euros  
Siret : 552 016 487 00407 - N° TVA UE / EU VAT Number : FR 95 552016487

Une société du groupe AIR LIQUIDE



le concentré d'innovation

<http://www.bionov.fr>

## EXTRAMEL®

Micro-granules

### BATCH NUMBER

M 03.01

### Manufacturing date

02/2003

### Physical characteristics

- . Aspect
- . Color
- . Odor

Microgranules  
Cream  
Characteristic

### Physicochemical characteristics

- . Dry matter
- . Proteins  
(BRADFORD method)
- . SOD activity<sup>(1)</sup>
- . Preservative

95 %  
2,1 %  
14 000 UI / gr D.M.  
none

### Microbiological analysis

- . Total germs
- . Yeast and mould
- . E. Coli
- . Salmonella
- . Staphylococcus aureus
- . Pseudomonas aeruginosa

< 10 000 cfu / gr  
< 100 cfu / gr  
absence / gr  
absence / gr  
absence / gr

### Shelf Life / Storage Conditions

- . Shelf Life: 18 months in unopened original packaging.
- . Store in a cool, dark and dry place.
- . Recommended storage conditions: 68 F (20 C) and 50 % Relative Humidity

Date of Issue: 30/04/2003

Quality control  
Jean-Michel COSTE

(1) SOD activity is measured according to the Oberley and Spitz method 1985 based on the activity of SOD to inhibit the reduction of NBT by O<sub>2</sub> generated by a xanthine/xanthine oxidase system ( $\Delta DO_{560}$  initial = 0,025).  
One unit of SOD gives 50 % inhibition of the reduction of NBT.  
GBSA laboratory - University of Montpellier (France)

BIONOV Sarl au capital de 100 000 Euros

Siège social et administratif : Site Agroparc - 755 Chemin des Meinajaries - B.P. 1202 - 84911 AVIGNON Cedex 9 - Tél. 33 (0)4 90 84 31 70 - Fax. 33 (0)4 90 84 00 47  
Atelier de production : ZAC Les Moutouses - Route de Graveson - 13630 EYRAGUES - Tél. 33 (0)4 90 24 91 91 - Fax. 33 (0)4 90 24 91 85  
SIREN 350 675 856 - R.C.S. Avignon B 350 675 856 - Code APE 244 A - N° TVA: FR 153 506 758 56



# **EXTRAMEL<sup>®</sup> microgranules**

***Antioxidant melon extract***

- **Source of SOD, a powerful antiradical compound**
- **Optimal action thanks to a specific coating**
- **Natural complex of antioxidants**



## 1 - DESCRIPTION

EXTRAMEL® microgranules is a natural melon extract, rich in various antioxidants, including superoxide dismutase). It is obtained by a physical process and protected by a coating of vegetable fat matters (80%).

Aspect	Microgranules
Colour	Cream
Taste / Odour	Characteristic

## 2 - SPECIFICATIONS

Characteristics	Standards
Aspect	Non soluble microgranules
Colour	Cream
Odour	Characteristic
Dry matter	Min. 95 %
Proteins	Max. 2 %
Melon pulp extract	20 %
Hydrogenated fat matter of vegetal origin	80 %
Superoxide dismutase activity	14 UI(1) / mg
Conservator	None
Total germs	Max. 10 000 CFU / g
Yeast & Mould	Max. 100 CFU / g
Enterobacteria	Max. 100 CFU / g
Escherichia coli	Absence / g
Salmonella	Absence / 10 g
Pseudomonas aeruginosa	Absence / g
Staphylococcus aureus	Absence / g



### 3 - ANALYSIS

#### 3.1 - Active ingredients

Ingredients	Results (mg/100g of powder)
<b>SOD (activity /mg)</b>	
Catalase (activity / mg)	
Co-enzyme Q10 (/100g)	
Carotenoids (/100g)	
Vitamin A (/100g)	
Vitamin E (/100g)	
Vitamin C (/100g)	
Selenium (/100g)	
Lipoic acid (/100g)	
Glutathione (/100g)	

#### 3.2 - Minerals

Calcium	/100g
Magnesium	/100g
Sodium	/100g
Potassium	/100g

#### 3.3 - Nutritional facts

Characteristics	Results
Protein (N x 6.25)	1.8 %
Fat	80 %
Carbohydrate (by subtraction)	15.2%
Ashes	1.94 %
Recommended daily dosage	10 mg/day



## 4 - PHYSICAL DATA

Loss on drying

Solubility

Temperature

## 5 - TOXICOLOGICAL AND REGULATORY DATA

### 5.1 - Toxicology

Acute dermal test/rabbit

Acute toxicity : LD0 and LD 50 orally/rat

### 5.2 - Regulatory data

Extract of melon pulp, **EXTRAMEL® microgranules** is a food derivative product coated with food approved fat matter. It is not an additive and could be use freely in nutraceutical and health food products.

## 6 - PACKAGING AND STORAGE

Packaging	500 g in opaque plastic flacon
Storage	Before opening the packing, store in a dark and dry place
Shelflife	18 months
Transport - labelling	Product not under the transport regulations



## **7 - USES**

**EXTRAMEL® microgranules** is used as a nutritional ingredient for its health benefits in dairy products and desserts, cereal based products (biscuits, bars, ...) sport foods and dietary/nutraceutical supplements.

*Product manufactured by BIONOV (FRANCE)*



### **Nota**

The analytical specifications warranted are only those mentioned on the certificate of analysis supplied with each delivery of the product.

Except as set forth above, SEPPIC\* makes no warranties, whether express, implied or statutory, as to the product which is the subject of this document . Without limiting the generality of the foregoing, SEPPIC\* makes no warranty of merchantability of the product or of the fitness of the product for any particular purpose. Buyer assumes all risk and liability resulting from the use or sale of the product, whether singly or in combination with other goods. The information set forth herein is furnished free of charge and is based on technical data that SEPPIC\* believes to be reliable. It is intended for use by persons having technical skill and at their own discretion and risk. Since conditions of use are outside SEPPIC\*'s control, SEPPIC\* makes no warranties, express or implied, and assumes no liability in connection with any use of this information. Nothing herein is to be taken as a license to operate under or a recommendation to infringe any patents.

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and, depending on the country :

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**Subsidiary of the AIR LIQUIDE group**

**P/1837/GB/03/November 2002**