

GR



Original Submission

000001

MARIGOT  
LIMITED  
GRAS Notification

with respect to

Phymatolithon calcareum  
(Lithothamnium calcareum) &  
Lithothamnium corallioides.

on behalf of

Marigot Ltd.

Trading as Celtic Sea Minerals

Of

Strand Farm,

Currabinny,

Carrigaline,

Co. Cork.

Ireland.

1999 JUL 28 A 11: 05

000002



STRAND FARM, CURRABINNY, CARRIGALINE, CO. CORK, IRELAND  
TELEPHONE . 353 . 21 . 378727 FACSIMILE . 353 . 21 . 378588  
E-Mail: marigot@indigo.ie

V.A.T. No. IE 4654535B COMPANY REGISTRATION No. 110210



## **1.1 Notifier**

**1.1.0** Marigot Ltd, t/a Celtic Sea Minerals, full contact details listed below, wish to submit a GRAS Notice with respect to the use of Maërl or Calcified Seaweed in food.

**Company** Marigot Ltd.

**Trading as** Celtic Sea Minerals

**of Address** Strand Farm, Currabinny,  
Carrigaline, Co. Cork.  
Ireland.

**Telephone (Int.)** +353 21 378727

**Telefax (Int.)** +353 21 378588

**E-Mail** marigot@indigo.ie

**URL** <http://www.celticseaminerals.com>

**Contacts:** Mr. Michael Ryan, Managing Director  
Mr. Michael O'Donohoe, Commercial Manager  
Dr. Bakri Assoumani, Technical Director  
Mrs. Anne Walley, Quality Manager  
-Ms. Joan Murphy, Administration

000003

## **2.1 Name of Notified Substance**

### **2.1.0 Common Names:**

Maërl or Calcified Seaweed.

In this document Calcified Seaweed is the preferred nomenclature but either term may be used interchangeably.

Calcified Seaweed is a naturally occurring photosynthetic product of marine origin which accumulates in submarine banks or deposits over time.<sup>1</sup> Its exact and precise constituents may vary from point to point, season to season or at different depths.

The Celtic Sea Minerals Food Grade Calcified Seaweed product is sold under the trade-name AquaMin<sup>®</sup>.

### **2.1.1 Technical Names:**

Maërl or Calcified Seaweed found in Irish waters may contain a combination of any or all of the following: *Lithophyllum dentatum*, *Lithophyllum fasciculatum*, *Lithophyllum hibernicum*, *Lithothamnium corallioides*, *Lithothamnium glaciale*, *Mesophyllum lichenoides*, *Phymatolithon calcareum*. (Two of the above; *L. hibernicum* and *M. lichenoides*, have not been found this century)<sup>2</sup>

In some literature *Phymatolithon calcareum* is sometimes referred to as *Lithothamnium calcareum* particularly in France. The Taxonomists renamed *Lithothamnium calcareum* as *Phymatolithon calcareum* in 1970 and the species directory notes the continuation of the terminology specifically in France.<sup>3</sup>

The subject of this application is Calcified Seaweed dredged from the seabed off Lonehort Point, Castletownbearhaven, (more often abbreviated to Castletownbear) Co. Cork, Ireland.<sup>4</sup>

The deposit off Lonehort Point is typically comprised of *Phymatolithon calcareum* and *Lithothamnium corallioides*.<sup>5</sup>

<sup>1</sup> The Distribution of Maërl Beds Around Ireland and their Potential for Sustainable Extraction.- Floral Component . Sammy De Grave, Aquatic Services, Helen Fazakerly, Irish Seaweed Organisation, Marine Institute, National University of Ireland, Galway, Lorna Kelly & Michael Guiry, Marine Institute, National University of Ireland, Galway, Article currently being edited prior to publication.

<sup>2</sup> The Distribution of Maërl Beds Around Ireland ....

<sup>3</sup> Species Directory - Christine M. Howson, Bernard E. Picton, Ulster Museum / Marine Conservation Society, 1997, ISBN 09481 50068 - Page 348 Ref ZM236, Page 349 Ref ZM252 & Ref ZM255

<sup>4</sup> JN 165 Lonehort Point Maërl Survey - 1998 Compiled by Aqua-Fact International Services, Kilkerrin

Park, Liosbaum, Galway, Ireland

<sup>5</sup> JN 165 Lonehort Point Maërl Survey

### **3.1 Conditions of Use**

#### **3.1.0 Applicable Levels of Use & Limiting Factors for Consumption**

Natural Calcified Seaweed, AquaMin<sup>®</sup> comprises of 84.2% Calcium Carbonate and 11.4% Magnesium Carbonate. (Total 95.6%)<sup>6</sup> Both Calcium Carbonate and Magnesium Carbonate are GRAS approved. (21 CFR 184,1191, Calcium Carbonate, 21 CFR 184,1425, Magnesium Carbonate)<sup>7</sup>.

The Applicable Level of Use, Limiting Factors for Consumption for Calcified Seaweed, AquaMin<sup>®</sup>, have been set the at the same levels as those for Calcium Carbonate.

In addition it should be noted that the physical properties of Calcified Seaweed, AquaMin<sup>®</sup>, itself can limit palatability or texture of a food into which it may be incorporated. Empirical evidence in snack foods would suggest that concentrations of AquaMin<sup>®</sup> in excess of 2% have an effect in the product texture. Levels in excess of 4% render the food unpalatable.<sup>8</sup>

#### **3.1.1 Commercial Applications to Date by Companies other than Celtic Sea Minerals<sup>9-10</sup>**

##### Water Treatment

The use of Lithothamnium in ponds lakes is a simple and efficient way of combating the problems of acidification, silting up and eutrophication.

##### Toothpaste

The Biolabor society (Federal Rep. Germany) recently [circa 1989] lodged a patent (Wisforth Bruno) for the manufacture of a fluoridated toothpaste with a Maërl base, used because of its supply of carbonate and fluorine.

##### Baths and Packs

Its marine origin, its richness in trace elements and its descaling and absorbent power make Maërl a product highly valued in the preparation of poultices and packs.

---

<sup>6</sup> Seaweed Resources in Europe, Edited by Michael D. Guiry, Associate Professor, Department of Botany and Marine Institute, National University of Ireland, Galway, - Gerald Blunden, Professor of Pharmacognosy, School of Pharmacy and Biomedical Sciences, Plymouth Polytech., United Kingdom. ISBN 0 - 471 - 92947 - 6 Page 89

<sup>7</sup> Source FDA

<sup>8</sup> Section.3.2.1 Empirical Evidence and Ten Examples of Typical Applications

<sup>9</sup> Lithothamnium, A tradition of the Past and Its Role in Tomorrow's Agrochemistry. The Institute of Oceanography, Paris Oceanis Vol. 15 1989, 5 (Partial English Translation).

<sup>10</sup> All examples cited are DIRECT quotations from the above article.

Dietetics

Maërl is used in dietetics as a food complement, sold either directly in powder form or in the form of capsules or tablets. Maërl, therefore plays a part in the treatment of mineral deficiencies in food. .... Carbonate occurs also as an anti-acid agent, thus constituting a remedy for heartburn.

### 3.2.0 Area of Applications - General<sup>11</sup>

Celtic Sea Minerals have widely listed the immediate and the long term potential applications for Calcified Seaweed, AquaMin®.

These applications would be primarily but not exclusively focused on the following products and product types:

- ↳ Biscuits
- ↳ Cereal Based Products
- ↳ Dairy deserts
- ↳ Dairy Yoghurts
- ↳ Dietetic Foods, Invalid Geriatric Foods
- ↳ Flavoured Milks / Yoghurt Drinks
- ↳ Margarine and Spreads
- ↳ Orange Juice Fortification
- ↳ Orange, Grape and Pineapple Juice Cloudifiers
- ↳ Pasta, Noodles
- ↳ Soups
- ↳ Soya Deserts / Soya Products
- ↳ Soya Milk
- ↳ Sweets / Candy

---

<sup>11</sup> Celtic Sea Minerals, Marketing Promotions Flysheet, Ref. AquaMin® 1

## 3.2.1 Empirical Evidence and Ten Examples of Typical Applications<sup>12</sup>

### 3.2.1.1 Biscuits

AquaMin<sup>®</sup> may be incorporated into biscuits at a level of 1.5-2.0% without any adverse effect on the taste/functionality of the biscuits. At this level of fortification up to 50% of the Calcium RDI\* may be administered in one serving of biscuits (3 biscuits / 20g per biscuit). Taste panels could not detect the presence of extra Calcium in the biscuit. Analytical tests, friability, Water Activity and Colour measurement confirmed that the addition of Calcium to the biscuits did not have any negative effects.

### 3.2.1.2 Pasta

Fresh pasta may be fortified with Calcium at levels of 1.2 -1.3 % AquaMin<sup>®</sup>. Up to 70% of the Calcium RDI\* could be obtained in one serving of pasta (150g). Addition of AquaMin<sup>®</sup> to the pasta had positive effects:

- It increased the firmness of the pasta (thus reducing breakage's in the pasta)
- It reduced the stickiness of the pasta (Texture Analyser AACC 16-50 Std. Method)

The organoleptic qualities of the pasta, colour, volume, speckledness, glossiness and bulkiness of the pasta were unaffected by fortification.

### 3.2.1.3 Sweets / Candy

AquaMin<sup>®</sup> may be incorporated into hard candy at a level of 3.0-4.0% AquaMin<sup>®</sup>. Each sweet (3-4g) could contain 4-6% Calcium RDI\*. The inclusion of AquaMin<sup>®</sup> to sweets did not effect taste, colour or the appearance of the sweets.

### 3.2.1.4 Tomato Juice

At 0.3% AquaMin<sup>®</sup> partially dissolves and suspends in the juice. It imparts a slightly sweeter taste.

### 3.2.1.5 Soya Milk

The addition of 0.3% AquaMin<sup>®</sup> does not affect palatability. Due to relatively high pH of Soya milk (7.0 - 7.2), AquaMin<sup>®</sup> does not dissolve. It may suspend in slightly viscous systems but will tend to precipitate at low viscosity.

### 3.2.1.6 Soya Desserts and Soya Yoghurt

AquaMin<sup>®</sup> suspends easily at levels of 0.3%. No negative effect on palatability or pH.

\* RDI based on 800 mg/day

<sup>12</sup> Published Source: Celtic Sea Minerals Internet Site URL <http://www.celticseaminerals.com>

Specific page locations [http://www.celticseaminerals.com/newsletter/981216\\_001.html](http://www.celticseaminerals.com/newsletter/981216_001.html)

<http://www.celticseaminerals.com/applications/index.html>

**3.2.1.7 Dairy Yoghurt**

The low pH allows AquaMin<sup>®</sup> dissolution. However pH is increased and titratable acidity decreases.

**3.2.1.8 Dairy Desserts, Rice Desserts**

0.3% AquaMin<sup>®</sup> had no impact on palatability or pH.

**3.2.1.9 Dietetic Foods, Invalid and Geriatric Foods**

These are usually powdered premixes, supplemented with Calcium often in the form of tricalcium phosphate. AquaMin<sup>®</sup> blended readily with the premixes and was undetectable in the rehydrated products at levels of 0.3%.

**3.2.1.10 Soups**

AquaMin<sup>®</sup> was blended with dried soups and was undetectable on reconstitution. The inclusion level was 0.3% of final volume, i.e. 0.3% of 1 pint, equivalent to 580mg Calcium,  $\frac{1}{3}$  RDI per  $\frac{1}{2}$  pint portion.

### **3.3.1 Area of Applications - Specific**

**3.3.1.0** It is intended that GRAS notice will be based on all the applications

outlined in the above listed section 3.1. Area of Applications - General. The products outlined have a potential global market place and as such may potentially be consumed by a global population.

The following is a listing of the Research and Development Programme currently being undertaken by Celtic Sea Minerals with respect the Calcified Seaweed and its potential application with respect to the food industry. Project status varies from almost complete through ongoing to just initiated or planned for future development. The purpose of this listing is to give a more technical scientific overview as to the potential markets for Calcified Seaweed, AquaMin®.

#### **3.3.2.1 Project Title**

Characterisation of Lithothamnium species to establish physical characteristics linked to functionality.

#### **3.3.2.2 Project Background**

Natural sea calcium is thought to have an unique calcium/magnesium balance as calcium and magnesium carbonates, an optimal ratio of calcium to magnesium and a supply of trace elements. The loose matrix structure of Calcified Seaweed with its large surface area, makes it a highly bio-available source of calcium.

#### **3.3.2.3 Project Objective**

The characterisation of Lithothamnium species, with a view to upgrading the chemical / physical characteristics for use in food applications.

#### **3.3.3.1 Project Title**

Development of a functional Lithothamnium preparation, suitable for use as a mineral supplement in oil based dairy, snack and flour confectionery applications.

#### **3.3.3.2 Project Background**

Low-fat spreads generally have little or no dairy ingredients and there is now a strong trend in the industry towards calcium fortification. The target is to provide 10-20% of the calcium ( $\text{Ca}^{2+}$ ) RDA in a 15g serving of low fat spread. Mineral fortification in extruded snacks, biscuits and cakes is also an area of growing interest.

#### **3.3.3.3 Project Objective**

To develop a mineral supplement from Lithothamnium calcium suitable for incorporation into oil based dairy, snack and flour confectionery applications.

**3.3.4.1.a Project Title**  
To develop a clouding agent from Lithothamnium calcium suitable for incorporation into non and low juice containing beverage applications.

**3.3.4.2.a Project Background**  
Clouding agents or cloudifiers are widely used in the non-juice / low-juice containing beverage market.

**3.3.4.1.b Project Title**  
To develop a functional Lithothamnium preparation suitable for use as a mineral supplement in fruit juices.

**3.3.4.2b Project Background**  
With a significant percentage of the population displaying allergies to milk, the obvious source of calcium in the diet, orange represents a globally acceptable medium for mineral fortification.

**3.3.4.3 Project Objective**  
To develop a clouding agent from Lithothamnium calcium suitable for incorporation into non and low juice containing beverages. To develop a mineral supplement from Lithothamnium calcium suitable for the fortification of pure fruit juices.

**3.3.5.1 Project Title**  
The Development of an alpha-galactosidase / Lithothamnium blend for use in the production of Tofu from Soya Milk.

**3.3.5.2 Project Background**  
The incidence of lactose intolerance is significant in certain areas of the world and Soya Milk is a common first alternative. High consumption of Soya Milk causes digestive problems with other carbohydrates, such as raffinose and stachyose, verbascose, after a switching from cows milk to Soya milk. Such diets are typically lacking in Calcium (50-60% Calcium deficiency) and consumption of nutrient supplements is common.

**3.3.5.3 Project Objective**  
To develop a functional ingredient / nutraceutical from Alpha ( $\alpha$ ) galactosidase for the treatment of Soya Milk and a blend of Alpha ( $\alpha$ ) galactosidase on a carrier of Calcified Seaweed for the production of Tofu.

## **4.1 Basis for GRAS Determination**

### **4.1.1 Chemical Name**

Calcified Seaweed / Maërl typically comprised of *Phymatolithon calcareum* in combination with *Lithothamnium corallioides*.<sup>13</sup>

### **4.1.2 Chemical Abstract Service (CAS) Registry Number**

None

### **4.1.3 Empirical Formula**

None - Complex Compound

### **4.1.4 Structural Formula**

As defined in "Studies on the Maërl Species *Phymatolithon calcareum* (Pallas) nov. comb. and *Lithothamnium corallioides* Crouan in the Ria del Vigo"<sup>14</sup>

### **4.1.4 Quantitative Composition**

84.2% Calcium Carbonate and 11.4% Magnesium Carbonate.  
(Total 95.6%)

Balance is moisture (Typically 0.5-2%) and a complex mixture of trace element structures.

Trace elements include:

Aluminium,	Copper	Molybdenum	Sulphur
Arsenic Inorganic,	Fluoride	Nickel	Tin
Boron,	Indium	Phosphorous	Titanium
Cadmium,	Iodine	Potassium	Zinc
Chromium	Iron	Selenium	
Chloride	Lead	Silver	
Cobalt	Mercury	Sodium	

<sup>13</sup> JN 165 Lonehort Point Maërl Survey

<sup>14</sup> "Studies on the Maërl Species *Phymatolithon calcareum* (Pallas) nov. comb. and *Lithothamnium corallioides* Crouan in the Ria del Vigo" Walter H Adey and Dale L. McKibbin - US National Museum Washington, DC Published Botanica Marina / Vol. XIII / 1970 / Fasc. 2 p100 - 106

## 4.1.4.1.

**Typical Listing of Common and Less Common Elements  
& Analytical Results Obtained<sup>15</sup>**

Element	Presence	Element	Presence
Aluminium	< 5 ppm	Magnesium	3.3 %
Arsenic Inorganic	1.0 ppm	Manganese	70 ppm
Boron	29 ppm	Mercury	< 0.008 ppm
Cadmium	0.1 ppm	Molybdenum	2.25 ppm
Calcium	33.3 %	Nickel	< 5 ppm
Chloride	1190 ppm	Phosphorus	600 ppm
Chromium	3 ppm	Potassium	151 ppm
Cobalt	0.2 ppm	Selenium	0.6 ppm
Copper	2 ppm	Silver	< 2 ppm
Fluoride	192 ppm	Sodium	0.18 %
Heavy Metals Measured as Lead	< 10 ppm	Sulphur	0.2 %
Indium	6 ppm	Tin	< 1.7 ppm
Iodine	< 9 ppm	Titanium	15 ppm
Iron	621 ppm	Zinc	7 ppm
Lead	< 0.9 ppm		

<sup>15</sup> All analysis complies with FCC (Food Chemical Codex) and has been completed by independent accredited laboratories. 15 Laboratories include :- CEVA, France, Consult Us Laboratories, Ireland, Dunn Son & Stone, Australia, Handels Laboratories, Germany, KAFRI, Korea ( Government Research), Korean Food Hygiene Institute, Korea, Martin Ryan Institute, Ireland, Microchem, Ireland, National Food Lab., CA, USA; NLJ Technologies, UK, Oxford Lab., NC, USA, SGS.Natec GmbH, Germany, Teagasc Grange, Ireland, University of Liverpool, UK, WCAS, CA, USA.

#### 4.1.5 Method of Manufacture

Calcified Seaweed or Maërl is dredged in Bantry Bay. During transport to the quay it is further washed using sea water. On arrival at the quay it is transported to the plant where it is further washed, screened, and dried.

All food grade materials are sterilised and deodorised. AquaMin<sup>®</sup> is sterilised and deodorised using 1,000 litres of water per metric tonne of AquaMin<sup>®</sup> in a 3% Hydrogen Peroxide solution heated to 50% in a re-circulation process. The AquaMin<sup>®</sup> dwells for 90 - 120 minutes depending on the rate of Hydrogen Peroxide breakdown. Samples are taken at 30 minute intervals for validation and process monitoring.<sup>13</sup>

The AquaMin<sup>®</sup> is then milled and bagged under sterile conditions. As such AquaMin<sup>®</sup> is nothing other than a Maërl product, refined and processed to food grade standard.<sup>16</sup>

---

<sup>16</sup> Extract from the Celtic Sea Minerals ISO 9000, Quality Manual pertaining to the processing of AquaMin<sup>®</sup>.

## 4.1.6 Characteristic Properties

M.S.D.S. 1 Revision 4

Issued By

4th November, 1998

To conform with ISO 11014-1

Anne Walley

Page 1 of 4

### AquaMin®

#### 1 Product & Company Identification

**BOTANICAL NAME** Lithothamnium Corallioides/Lithothamnium Calcareum  
/Phymatolithon Calcareum.

**SYNONYMS/  
TRADE NAMES** AquaMin®

**SUPPLIED BY** Marigot Ltd t/a Celtic Sea Minerals  
Strand Farm Tel: +353 21 378727  
Currabinny, Co. Cork Fax: +353 21 378588  
Ireland E-Mail marigot@indigo.ie

#### 2 Composition Information on Ingredients

Contains  
Rhodophyta Seaweed principle constituent Calcium Carbonate.

#### 3 Hazardous Identification

Prolonged exposure to powdered products may cause mechanical irritation to eyes and lungs.

#### 4 First Aid Measures

Exposure Route	Symptoms	Treatment
Inhalation	Mild Irritation	Remove from exposure. If recovery is not rapid or complete seek medical attention.
Skin Contact	Mild Irritation	Drench skin with water. If irritation persists seek medical attention.

### AquaMin®

Exposure Route	Symptoms	Treatment
Eye Contact	Irritation	Irrigate thoroughly with water for at least 15 minutes. If irritation persists seek medical attention.
Ingestion	Mild Irritation	Wash out mouth with water. If patients feels unwell seek medical attention.

---

#### 5 Fire Fighting Procedures

Does not support combustion.

Suitable Fire Extinguishing Media	Use an extinguisher suitable to cause of fire.
Hazardous Combustion Products	Not Applicable.

---

#### 6 Accidental Release Measures

Safety Precautions	Use goggles and dust mask in incidences of high dust contamination.
Clean Up Procedure	Shovel, sweep, vacuum.

---

#### 7 Handling & Storage

Avoid the formation of dust. Local exhaust recommended if handling large quantities. Store in a cool dry area.

---

#### 8 Exposure Controls / Personal Protection

##### Personal Protective Equipment

Respiratory Protection:	Approved dust mask in high dust concentrations.
Hand:	Gloves.
Eye:	Goggles.
Skin:	Light overalls.

## AquaMin®

### 9 Physical & Chemical Properties

Appearance AquaMin®	Cream / off white, odourless powder.
Decomposition Temperature	>850°C
Flashpoint	Not Applicable.
Flammability	Does not support combustion.
Solubility	Insoluble in water, alcohol and most organic solvents.

---

### 10 Stability & Reactivity

Stability	Stable under normal conditions.
Potential hazardous reactions	Reacts with acids liberating Carbon Dioxide.
Conditions to avoid	Not Applicable.
Materials to avoid	Acids.

---

### 11 Toxicological Information

Local Effects	Fine powders may irritate the upper respiratory tract. Prolonged skin contact may cause irritation. Can cause mechanical irritation to the eyes. Unlikely to be hazardous if swallowed.
---------------	---

---

### 12 Ecological Information

Environmental Effects separated or	Insoluble in water and can easily be from aqueous systems by sedimentation filtration.
Aquatic Toxicity	Not Applicable.

---

### 13 Disposal Considerations

Landfill	Comply with local authority regulations.
----------	--

## **AquaMin<sup>®</sup>**

### **14 Transport Information**

Not regulated.

---

### **15 Regulatory Information**

No risks or hazards.

Not Regulated.

Conform with local authority regulations.

---

### **16 Other Information**

This product is intended for use as a food ingredient.

The information provided in this M.S.D.S. is correct to the best of our knowledge, information and belief at the date of its publication and is in our opinion consistent with the state of general scientific and technical knowledge at that date but we cannot accept liability for any loss, injury or damage which may result from its use.

In compiling this M.S.D.S. we have taken into account all proper applications of the material of which we are aware. It is the responsibility of any intermediary supplier to ensure that the information contained in this M.S.D.S. is passed to the ultimate user.

If the ultimate user wishes to receive revisions, please notify us and we will make the necessary entry in our records.

## SPECIFICATION

### AquaMin<sup>®</sup>

<b>Description</b>	AquaMin <sup>®</sup> is a white, inert, non-hygroscopic powder, which is almost insoluble in water but soluble in weak acids.	
<b>Typical Analysis</b>	Moisture	< 5.0% (Oven drying S.I. 200 1984)
	Residue on Ignition (550°)	90-94% (S.I. 200 1984)
	Calcium	31-34.0% (AA)
	Magnesium	2.8-3.3% (AA)
	pH (1% Soln.)	9.8/10.1 (CSM1)
	<u>Trace Elements</u>	
	Lead	<0.9ppm (I.C.P)
	Iodine	< 9ppm (Potentiometric)
	Boron	29ppm (I.C.P.)
	Selenium	<0.6ppm (A.A.)
<b>Particle Size</b>	Average 2.5 - 5 micron (maximum 20 micron) [HELOS Lazer]	
<b>Bulk Density</b>	0.6 - 0.7 g/ml (CSM3)	
<b>Packaging</b>	Packed in 25kg brown cardboard boxes with a polyethylene liner.	
<b>Storage</b>	Store indoors in cool, dry area.	
<b>AquaMin<sup>®</sup></b>	AquaMin <sup>®</sup> is a natural photosynthetic product of marine origin. As it is subject to seasonal variation, the foregoing values are typical but may vary.	

600019

#### 4.1.7 Potential Human Toxicants

Countries which have a defined standard for the analysis and use of Seaweed in food with appropriate regulatory authorities in parenthesis: France (CEVA) - USA (FDA)<sup>17</sup>

#### Authorised Heavy Metals and Iodine Contents<sup>18</sup>

in mg/kg [ppm]	France authorised seaweeds	USA authorised seaweeds
inorganic Arsenic	3	3
Cadmium	0.5	-
Mercury	0.1	-
Lead	5	10
Tin	5	-
Total Heavy Metals content	-	40
Iode [Iodine]	5000	1000 - 5000 for brown seaweeds 500 for red seaweeds

#### Combination of French and USA requirements for Seaweed interspersed with certified results for AquaMin<sup>®19</sup>

in mg/kg [ppm]	France Authorised Seaweeds	Certified Results for AquaMin <sup>®</sup>	USA Authorised Seaweeds
Inorganic Arsenic	3	1.0	3
Cadmium	0.5	0.10	-
Mercury	0.1	< 0.008	-
Lead	5	< 0.9	10
Tin	5	< 1.7	-
Total Heavy Metals content	-		40
Iode [Iodine]	5000	< 9	1000 - 5000 for Brown Seaweeds 500 for Red Seaweeds

<sup>17</sup> Seaweed News N° 0 - European Bulletin of the Seaweed Industry. Publisher Centre d'Etude et de Valorisation des Algues, CEVA Jan - Mar 1997

<sup>18</sup> Seaweed News N° 0 - European Bulletin of the Seaweed Industry

<sup>19</sup> A report of analysis on AquaMin<sup>®</sup> (Rapport d'Analyses et d'Essai N° 98/07/01/1) was issued by CEVA on 16/07/98 and received by these offices on 19/07/98.

#### 4.1.8 Specifications for Food Grade Material

As per 4.1.6

#### 4.1.9 Self Limiting Levels

As previously advised the self limiting factors for consumption of Calcified Seaweed have been set to correspond with Calcium Carbonate as Calcified Seaweed is 84.2% Calcium Carbonate.

The use of Calcified Seaweed in food is further limited by its effects on palatability and texture. Typical levels for the incorporation of Calcified Seaweed are below 2%. While a level of 4% has been noted for hard sweets / candy manufacture, this level is viewed to be at the upper limit of the range.

#### 4.2 Scientific Procedures GRAS Determination

Calcified Seaweed and specifically AquaMin® has been determined by CEVA as being appropriate and safe for use as a food ingredient. This determination is the result of analytical testing in accordance with limits as laid down by CEVA and quoted previously.

In Belgium *Phymatolithon calcareum* (*Lithothamnium calcareum*) has been approved for use as a food ingredient under Royal Decree of August 29th 1997.<sup>20</sup> This decree deals with the production and sale of foodstuffs comprised of or containing plant or plant preparations.

#### 4.2.1 Technical Evidence of Safety

At present, the following seaweed species have GRAS status<sup>21</sup> (Code 212 of Federal Regulations part 184) in the "Spices, Condiments and Aromas" category: 16 brown algae

*Analipus japonicus*, *Eisenia bicyclis*, *Hizikia fusiforme*, *Kjellmaniella gyrata*, *Laminaria angustata*, *Laminaria claustronia*, *Laminaria digitata*, *Laminaria japonica*, *Laminaria longicuris*, *Laminaria longissima*, *Laminaria ochotensis*, *Laminaria saccharina*, *Macrocystis pyrifera*, *Petalomia fascia*, *Scytosiphon tomentaria* and *Undaria pinnatifida*.

and 7 red algae:

*Gloiopellis furcata*, *Porphyra crispata*, *Porphyra deutata*, *Porphyra perforata*, *Porphyra suborbiculata*, *Porphyra tenera* and *Rhododymenia palmata* (*Palmaria palmata*)

The approval criteria for such Seaweeds is listed by table (column 4 USA authorised seaweeds) in 4.1.7 Potential Human Toxicants above. Were the same approval criteria to be applied to Calcified Seaweed it would comfortably meet all such requirements.

<sup>20</sup> Seaweed News - N° 4 - Volume 2 - 1998 - European Bulletin of the Seaweed Industry Page 3 - Publisher Centre d'Etude et de Valorisation des Algues, CEVA

<sup>21</sup> Seaweed News N° 0 - European Bulletin of the Seaweed Industry

000021

#### 4.2.1.1 Probable Consumption

**Population:** Calcified Seaweed has a variety of applications. Depending on the application or combination of applications these products may be ingested by any member of the worlds population. Applications could vary from fortified dairy products in under-developed countries to snack and convenience foods in developed countries.

**Individual:** Calcified Seaweed is typically incorporated into foods in concentrations of 0.5 - 1% and a maximum level of 4% by weight. Given that the bulk of the Calcified Seaweed is Calcium Carbonate, Magnesium Carbonate or Moisture (Total 96.1-97.6%), trace element composition is small.

#### 4.2.1.1 Cumulative Effects

The Applicable Level of Use, Limiting Factors for Consumption for Calcified Seaweed, AquaMin<sup>®</sup>, have been set the at the same levels as those for Calcium Carbonate.

#### 4.2.2 General Availability of Information Supporting Safety

The general availability of information with reference to Calcified Seaweed is widespread and unrestricted. The publication by CEVA of regular news bulletins, many of which have been referenced herein, is evidence of this fact.

It should however be noted that Calcified Seaweed, in commercial quantities, is found only in a few places around the world. The information available typically pertains to these sites. Scientific interest tends to be highly localised rather than global.

### 4.2.3 Unfavourable Information

Calcified Seaweed is a natural photosynthetic product of marine origin. As it is subject to seasonal and geographic variation, the composition of Calcified Seaweed may vary from place to place and from season to season.

Seaweed Resources in Europe<sup>22</sup> - cites Blunden et al<sup>23</sup> (1975) and comparative analytical studies of trace element content of Maërl. The sites compared by Blunden et al were Falmouth Harbour, UK and the Glenan Islands, France. The trace element composition of the samples taken from these two sites is completely at variance to certified sample analysis from the Castletownbear Lonehort Point site dredged by Celtic Sea Minerals.

Such significant variances (Lead 50ppm (Blunden) V's 0.5ppm (WCAS, CA, USA)) were they to be applied to AquaMin<sup>®</sup>, would make it totally unsuitable for its intended use.

The variances in trace element content has been attributed in the main to water quality with both Blunden sites being on or adjacent to major shipping routes. The Castletownbear site is unencumbered by such heavy traffic.

Accordingly trace element levels are significantly reduced in some instances by a factor of 100.

---

<sup>22</sup> Seaweed Resources in Europe, Edited by Michael D. Guiry, Associate Professor, Department of Botany and Marine Institute, National University of Ireland, Galway, - Gerald Blunden, Professor of

Pharmacognosy, School of Pharmacy and Biomedical Sciences, Plymouth Polytech., United Kingdom. ISBN 0 - 471 - 92947

<sup>23</sup> Commercial Collection and Utilisation of Maërl, Blunden G., Binns W.W. & Perks F., 1975, Econ Bot. 29: 140-5

**Comparison of Blunden (UK & France)  
and Castletownbear deposits.<sup>\*24</sup>**

<b>Element ppm</b>	<b>Blunden</b>	<b>AquaMin<sup>®</sup></b>
Aluminium	500	< 5
Arsenic	5	1.0
Chloride	0.20%	1190
Chromium	5	3
Cobalt	1.5	0.2
Copper	15	2
Fluoride	50	192
Indium	200	6
Iodine	1200	< 9
Iron	2500	621
Lead	50	< 0.9
Manganese	480	70
Molybdenum	1	2.25
Phosphorus	0.35%	600
Potassium	0.20%	151
Silver	1	< 2
Sodium	0.17%	0.18 %
Sulphur	0.60%	0.20 %
Tin	200	< 1.7
Titanium	25	15
Zinc	15	7

\* The Celtic Sea Minerals Analysis is more comprehensive than that undertaken by Blunden.  
Comparisons only listed where Blunden result is available.

<sup>24</sup> Seaweed Resources in Europe.

#### 4.2.4 Basis for concluding expert consensus

1 Calcified Seaweed, Maërl, AquaMin<sup>®</sup>, is primarily composed of Calcium Carbonate, Magnesium Carbonate and Moisture. (Typically 97%+)<sup>25</sup>

Both Calcium Carbonate and Magnesium Carbonate have GRAS Approval.<sup>26</sup>

2 There are to the best of our knowledge only two standards for Seaweed and its use in food. One standard is issued and controlled by CEVA, France, the other by the FDA.<sup>27</sup>

Calcified Seaweed, Maërl, AquaMin<sup>®</sup>, has been certified by CEVA as being appropriate for use as a food ingredient.<sup>28</sup>

3 The FDA have previously approved 23 Seaweeds under the "Spices, Condiments and Aromas" category.<sup>29</sup>

4 The criteria for assessment of Seaweeds by the FDA have been published and noted herein.<sup>30</sup>

5 Were these criteria for assessment to be applied to Calcified Seaweed, Maërl, AquaMin<sup>®</sup>, the assessment result would be favourable.

6 In Belgium *Phymatolithon calcareum* (*Lithothamnium calcareum*) has been approved for use as a food ingredient under Royal Decree of August 29th 1997.<sup>31</sup>

7 Calcified Seaweed has been used for at least the past 10 years in water treatment, toothpaste, bath packs and rubs and dietetics.<sup>32</sup>

---

<sup>25</sup> Seaweed Resources in Europe, Edited by Michael D. Guiry, Associate Professor, Department of Botany and Marine Institute, National University of Ireland, Galway, - Gerald Blunden, Professor of Pharmacognosy, School of Pharmacy and Biomedical Sciences, Plymouth Polytech., United Kingdom. ISBN 0 - 471 - 92947 - 6 Page 89

<sup>26</sup> Source FDA

<sup>27</sup> Seaweed News N° 0 - European Bulletin of the Seaweed Industry. Publisher Centre d'Etude et de Valorisation des Algues, CEVA Jan - Mar 1997

<sup>28</sup> A report of analysis on AquaMin<sup>®</sup> (Rapport d'Analyses et d'Essai N° 98/07/01/1) was issued by CEVA on 16/07/98 and received by these offices on 19/07/98

<sup>29</sup> Seaweed News N° 0 - European Bulletin of the Seaweed Industry. Publisher Centre d'Etude et de Valorisation des Algues, CEVA Jan - Mar 1997

<sup>30</sup> Section 4.1.7 Potential Human Toxicants - Table Authorised Heavy Metals and Iodine Contents

<sup>31</sup> Seaweed News - N° 4 - Volume 2 - 1998 - European Bulletin of the Seaweed Industry Page 3 - Publisher Centre d'Etude et de Valorisation des Algues, CEVA

<sup>32</sup> Lithothamnium, A tradition of the Past and Its Role in Tomorrow's Agrochemistry. The Institute of Oceanography, Paris Oceanis Vol. 15 1989, 5 (Partial English Translation).

**5.1 Availability of Information**

With the exception of certified results of analysis and extracts from Quality Control manuals, all articles and references quoted herein have either been obtained from published sources or informational material publicly circulated by Celtic Sea Minerals.

Certifying authorities and customers have access to the Quality Control Manuals and production records for validation purposes. Any customer may have access to certified results of analysis.

As such all material quoted herein is in the public domain. Appropriate bibliographic details for independent confirmation have been attached.

**5.2 Statement of Availability**

The data and information that are the basis for this notice are available for review and copying by FDA or will be sent to FDA on request. This availability is unencumbered by any restriction of time lapse or advance notice. Any information requests will be processed and expedited to the best of our ability

Signed of behalf of Marigot Ltd. (T/a Celtic Sea Minerals)

.....

Position .....

This the 2 day of July 1999

Signed of behalf of Marigot Ltd. (T/a Celtic Sea Minerals)

.....

Position .....

This the 9th day of July 1999

End Submission

000027

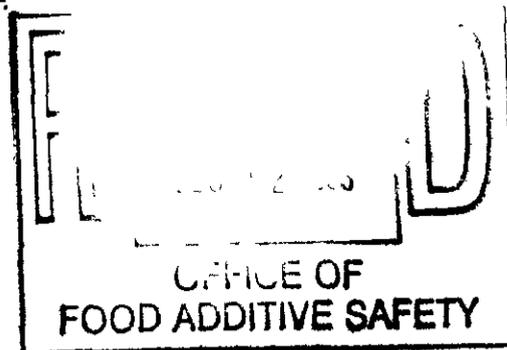
**MARIGOT  
LIMITED**

SU



December 6<sup>th</sup> 2006

Paulette Gaynor,  
Office of Food Additive safety (HFS-200),  
Centre for Food Safety and Applied Nutrition  
Food and Drug Administration,  
5100 Paint Branch Parkway,  
College Park, MD 20740-3835



**Re: GRN No. 000028**

Dear Mr Martin,

This letter is in reference to the substance of seaweed derived calcium as discussed in GRN No. 000028. In Marigot Ltd's original GRAS application in July 1999, a small number of products are listed for which Marigot would like to use seaweed derived calcium as a source of calcium in food products. The products originally listed were biscuits, pasta, hard candy, tomato juice, soya milk, soya desserts, yoghurts, dairy yoghurts, dairy desserts, dietetic foods and soups. Marigot Ltd now wishes to extend the list of products for which seaweed derived calcium is permissible as a source of calcium

We would like to extend the list to include the following food products; ice cream, noodles, bread, confectionary, chocolate, carbonated beverages, non carbonated beverages, cakes, cookies, tofu, cream crackers, flavoured and unflavoured milk, jams and jellies, muffins, ready to eat cereals, cereal breakfast bars, sorbets and sherbets, breakfast juices and dairy spreads.

I would be grateful if you could advise how to proceed with the above amendments. I am contactable by phone or email as detailed below I look forward to hearing from you

Yours Sincerely,

Denis O'Neill,  
Technical Manager,  
Strand Farm,  
Currabinny,  
Carrigaline,  
Co. Cork,  
Ireland.  
E-mail: [d.oneill@marigot.ie](mailto:d.oneill@marigot.ie)  
Telephone: 353.21.4378727  
Facsimile: 353 21.4378588



STRAND FARM, CURRABINNY, CARRIGALINE, CO CORK, IRELAND  
TELEPHONE 353 21.4378727 FACSIMILE 353 21 4378588  
Website [www.marigot.ie](http://www.marigot.ie)

V A T No IE 4654535B COMPANY REGISTRATION No 110210

