

61, rue du Commondant-l'Herminier - ROTHÉNEUF - B.P. 40 - 35404 SAINT-MALO CÉDEX (France)

Teléphone 02 23 18 31 31 - Télécopie 02 23 18 31 32

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

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Dear Sir,

Pursuant the Food and drug Administration regulation 21 CFR § 101.93, please find enclosed the notification of the following dietary supplement:

#### 1-Trade name of the product :

Bronzstarter
PREPARATORY SUN CARE DIETARY SUPPLEMENT

2 -Address of the manufacturer:
Phytomer, part of CODIF INTERNATIONAL
61 rue du commandant l'Herminier,
CS 51749 – 35417 Saint Malo –
FRANCE

Address of USA distributor: PHYTOMER CORP 3350 South Highland Drive SALT LAKE CITY UTAH 84106-3315 USA

#### 3 - Claims:

Zinc

- contributes to reinforce the skin's defense capacities against solar aggressions.\*\*
- prepares the skin for sun exposure \*\*
- gives you a natural glow.\*\*

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

## 4 - <u>Ingredient statement</u>:

Dietary ingredient
Vitamin A (from carrot seed extract)
Vitamin C
Vitamin E
Riboflavin
Niacin
975

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Proprietary blend
Ascophyllum nodosum algae
Rhodymenia palmata algae
Sea water extract
Guava fruit powder

### 5- Intend to use

This product is intended to used by adult.

<u>Direction for Use</u>: Take two tablets in the morning with an 8 oz glass of water, and one in the afternoon with a 4 oz glass of water two weeks before, during and two weeks after exposure to the sun.

Precautions for use: Do not use this product if you are allergic to iodine or have a thyroid disorder or a thyroid problem. Do not use if you are pregnant or nursing a baby. Before taking any dietary supplement, consult with your health care practitioner. Keep out of reach of children. Do not take more than 3 tablets per day

#### 6- Statement of Affirmation

We Phytomer, part of CODIF INTERNATIONAL, affirm that the notifying has substantiation is truthful, not misleading and scientifically valid. The product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended in the label.

Should there any question or comment, don't hesitate to contact us.

Looking forward to hearing from you.

Made out in Saint Malo, December 18<sup>th</sup>, 2002

Antoine GEDOUIN
President

#### **BRONZSTARTER - PREPARATORY SUN CARE DIETARY SUPPLEMENT**

By the presence of specific marine algae extracts with anti-free radicals properties, BronzStarter contributes to minforce the skin's defense capacities against solar aggressions.\*\*

Combined with vitamins and minerals, BronzStarter prepares the skin for sun exposure and gives you a natural glow.\*\*

Direction for use: Take two tablets in the morning with an B oz glass of water, and one in the afternoon with a 4 oz glass of water two weeks before, during and two weeks after exposure to the sun.

Warning: This product does not contain a sunscreen and does not protect against sunburn. Repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer, and other harmful effects to the skin even if you do not burn.

<u>Precautions for use:</u> Do not use this product if you are allergic to iodine or have a thyroid disorder or a thyroid problem.

Do not use if you are pregnant or nursing a baby. Before taking any dietary supplement, consult with your health care practitioner.

Keep out of teach of children. Do not take more than 3 tablets per day.

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Amount per serving	% Daily Value
0.55 IU	$\epsilon_{i}$
46.26 mg	80
10.98 (0	40
0.26 mg	13
12.87 mg	6(
9.83 mg	7(
128.51 mg	
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42,85 mg	1
	serving 0,55 ft/ 46.26 mg 10.98 ft/ 0.26 mg 12.87 mg 9.83 mg 128.51 mg

Other ingredients: Microcrystalline Cellulose, Polyvinylpolypyrrolidone, Maltodextrin, Magnesium Stearate, Artificial Flavor, Litanium Dioxide, Hydroxypropyl Methylcellulose, Stearic Aeid.

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

Manufactured by PHYTOMER - Registered Trademark- CS 51749 - 35417 SAINT-MALO - FRANCE - Made in France Ref. PFCMV205A

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# PHYTOMER



# BRONZSTARTER

OMPLEMENT ALIMENTAIRE SOLAIRE PRÉPARATEUR PREPARATORY SUN CARE DIÉTARY SUPPLEMENT



28g/90 comprimés - 0.98 oz/90 tablets

