

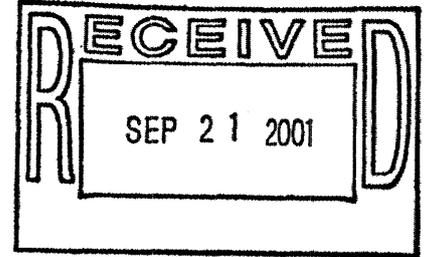
September 13, 2001

77853

**Advitech Solutions inc.**  
**Nutra • Pharma • Derma**

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Canada G1M 3T2  
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http://www.advitech.com

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, DC 20204  
U.S.A.



**STRUCTURE/FUNCTION CLAIM NOTIFICATION - REVISION 1**

**Manufacturer of supplement :**

Advitech Solutions inc.  
650, boul. Père-Lelièvre, bureau 170  
Vanier (Québec) Canada  
G1M 3T2

The supplement will be **distributed** in U.S.A. by :  
Advitech Corp.  
Williston, VT 05495

**Name of Supplement :** Casein Derivative

**Trade Name :** Stressless

**Descriptive Name :** Casein Derivative Dietary Supplement for  
Stress and Anxiety Management

**Description of active ingredient :** F-222 Casein Derivative. See enclosed  
Product Bulletin.

**Label and Supplement Facts :** See enclosed draft label in English. The final  
label will be in two languages : English and Spanish.

**Other ingredients :** gelatin, water, glycerin and titanium dioxide.

**Directions for use :** Take one capsule daily.

97S 0162 LET 8601

**Quantity and Package :** 15 capsules per bottle.

**Structure/Function Claim :** Stressless contains a bioactive milk peptide derived from casein which contributes to manage stress and anxiety.

**Disclaimer :** The following disclaimer will be printed on the package : «This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.»

**Accuracy and truthfulness of the claim :** studies have been conducted by the manufacturer of F-222 to establish a relationship between usage of F-222 and anxiety and stress feelings, at different usage levels.

**Expected launching date :** mid-October 2001

If any other informations are required, we will be pleased to supply them to your office.

Regards,

Signature :



Michel Painchaud  
Development Director  
Advitech Solutions inc.

Signature :



Paul Paquin, Ph.D.  
Scientific Advisor  
Advitech Solutions inc.

USA

September 13, 2001

**Directions for use :** take one capsule daily.

**Keep out of reach of children.**  
Keep in a cool dry place, tightly closed.

Stressless contains a bioactive milk peptide derived from casein which contributes to manage stress and anxiety.\*

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

PROMEDIS®

Stressless

**Casein Derivative  
Dietary Supplement for  
Stress and Anxiety Management**

15 capsules

### Supplement Facts

Serving Size 1 Capsule  
Servings per container : 15

Amount Per Capsule

Casein Derivative 190 mg\*

\*Daily value not established

OTHER INGREDIENTS : Gelatine, Water, Glycerin and Titanium Dioxide.

PRODUCT OF CANADA

Distributed by :  
ADVITECH CORP.  
WILLISTON, VT, USA 05495

[www.advitech.com](http://www.advitech.com)

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## PRODUCT BULLETIN

### F-222

### CASEIN DERIVATIVE IN POWDER

#### Product description

F-222 contains naturally a bioactive peptide which contributes to reduce stress effects.

#### Physical

#### Typical analysis

Solubility at 70°C (ADMI)	2 ml
Scorched particles (ADMI)	A-B
Colour	White cream
Form	Fine homogeneous powder

#### Chemical

Moisture	6 % max
Fat	< 1 %
Protein (N x 6.38) dry matter	80 %
Ash	12 %

#### Minerals

Calcium	0.3 %
Sodium	3.8 %

#### Microbiological

Total plate count	30,000/g
Coliform organisms	negative/0.1 g
E.Coli	negative/g
Clostridium spores S.R. (24 h at 46°C)	9/g maximum
Staphylococcus aureus	negative/0.1 g
Salmonella	negative/25 g
Yeasts - Moulds	30/g maximum

#### Storage and Packaging

Shelf life: typically 24 months when stored in a dry cool place. The maximum storage temperature is 25° and the maximum relative humidity is 70%. Packaged in polythene lined paper bags.

Customs Code: 35 01 90 90 000 0A  
(01/01/2000 - with possibilities of modification)

09/01