



<p><b>suggested use:</b> 1 to 2 capsules as needed.</p> <p><b>warning:</b> keep out of the reach of children.</p> <p>store in a cool place</p> <p>These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, cure, treat or prevent any disease.</p> <p>Manufactured by ELAN, Ltd., St.Petersburg, Russia. Distributed by Pure Research Products Naturally, LLC. Boulder, Colorado 80302</p>	<p>Pure Research Products Naturally LLC</p> <h1>Preparate</h1> <p>a lysate powder of <i>Lactobacillus delbrueckii ssp. bulgaricus</i></p> <p>immediate immune system support</p> <p>Net Contents: 30 capsules</p>  <p>a dietary supplement from St. Petersburg, Russia</p>	<p><b>supplement facts:</b></p> <table border="1"> <tr><td>servings size: 1 capsule</td></tr> <tr><td>servings per container: 30</td></tr> <tr><td>amount per serving: 125 mg</td></tr> <tr><td>calories per serving: 2</td></tr> </table> <p><b>Active Ingredient:</b> a lysate powder of <i>Lactobacillus delbrueckii ssp. bulgaricus</i></p> <p>other ingredients: brown rice powder</p> <p>natural product chemical free</p> <p>©Pure Research Products Naturally LLC Boulder, Colorado 80302</p>	servings size: 1 capsule	servings per container: 30	amount per serving: 125 mg	calories per serving: 2
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**This attachment (<sup>4</sup>~~6~~ pages) was removed in its entirety because it contained confidential trade information.**

TRANSLATION FROM  
RUSSIAN -

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Preparation of a food supplement  
with curative and prophylactic properties

The producer

As a producer, the strain of *Lactobacillus Debrueckii* Lev., specially selected by the method of successive inoculations on a solid medium and passaging with selection of clones of an increased biostimulating activity is used. The passages were performed on liquid media stimulating the biochemical activity.

Of such media, the MRS was chosen, which was supplemented with microelements and a fermentative hydrolyzate of milk casein in the amount which ensured an optimum amino nitrogen content in that modified medium (MRS-M).

The strain is stored lyophilized and is renewed every year and a half. Before use, the strain viability and productivity are restored by means of passaging under special conditions.

As the seeds of the initial culture inoculation, the 24 hours' culture grown on the modified MRS-M medium at temperature from 35°C to 45°C (optimal 39±1°C) after productivity restoration on the solid mediums was used.

Culture medium

The culture can be done on differently composed mediums containing constituents required for the growth and formation of useful properties.

As possible basic constituents of the medium can be used:

- malt wort;
- a yeast autolyzate
- a casein fermentative hydrolyzate;
- a fermentative hydrolyzate of defatted and desodorized soy-bean flour;
- a corn extract;
- glucose (or enzyme-hydrolyzed starch, or acid-hydrolyzed saccharose);

- macro- and microelements:

ammonium citrate

sodium citrate

$K_2HPO_4 \cdot 3H_2O$

$KH_2PO_4 \cdot H_2O$

$MgSO_4 \cdot 7H_2O$

$MnSO_4 \cdot 5H_2O$

calcium lactate

ascorbic acid (L+)

traces of selenium and potassium iodide

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The medium composition which allows to obtain the biomass yield of 1 to 5 gr per litre of culture medium with stimulating effects of the required level:

1. The malt wort treated with multimuramidase-protease-nuclease complex (MMPNC) for the purpose of clearing and increasing its nutritive value and diluted with water to the carbohydrate content of 5.0 to 7.5% using the separation method or microfiltration.
2. The casein hydrolyzate in amount ensuring the end content of amino nitrogen from 0.3 to 1.0 mg/ml (optimal 0.65 mg/ml).
3. The yeast autolyzate pre-treated with 0.1-0.2% MMPNC in the amount which ensure the amino nitrogen content in the medium from 0.4 to 1.0 mg/ml (optimal 0.75 mg/ml).
4. From 3% to 10% (optimal 7.5%) glucose is added when the carbohydrate content in the malt wort is insufficient.
5. Macroelements:

$K_2HPO_4$  - 2.2 gr/L (from 1 to 4 gr/L)

$KH_2PO_4$  - 1.5 gr/L (from 1 to 3 gr/L)

$MgSO_4$  - 0.2 gr/L (from 0.1 to 0.5 gr/L)

$MnSO_4$  - 0.05 gr/L (from 0.01 to 0.1 gr/L)

ammonium citrate - 2.0 gr/L (from 1 to 5 gr/L)

Treatment of the malt wort

To the malt wort, from 0.050 to 0.075% MMPNC pre-diluted in a small amount of water is added. The wort is maintained with vigorous stirring

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at 40-45°C for 40-30 min., then it is separated or microfiltered, and diluted with water to 5-7% carbohydrate content.

It is better to use a ready caseine hydrolyzate. The caseine hydrolyzate amount is calculated according to the end volume of the medium in such a way that the end amino nitrogen content ensured by the casein hydrolyzate is 0.60-0.65 mg/ml.

The yeast autolyzate is added in the amount that brings the amino nitrogen content to not less than 0.1 mg/ml. The end content of aminonitrogen in the medium is from 0.70 to 0.75 mg/ml. Prior to be added to the medium, the yeast autolyzate is treated with MMPNC (in amount of 0.1-0.2% of yeast autolyzate weight) at 40-45°C for 60-90 min.

All the constituents, i.e., the cleared malt wort, casein hydrolyzate solution, and yeast autolyzate are placed into the blender, supplemented with the macroelements diluted in a small amount of water, sterilized at 120°C for 30 min., then cooled to 40°C and supplemented with a sterile glucose solution in order to reach 7.5% carbohydrate content (if the wort does not ensure such a content), pH being brought to 6.5-7.0. For culture, the 1.0-2.5% 24 hours' seeds are used.

Cultivation at 30-40°C (optimum 39°C) is performed without forced aeration, with mixing for 5-7 min every 2 hours of the culture, after the first 4 hours of growth. The pH value, after its natural decrease to 5.5, is maintained at 6.2-6.5 by the ammonia solution. The fermentation process is stopped when the carbohydrate content reaches 0.3-0.5%, however, not later than after 16-18 hours of growth. Lactobacillus cells are separated by the separator or flowing centrifugation at 10-15000 rpm, after which the biomass is ready for a fermentative treatment.

## 2. Treatment of the biomass

I. Preparation of the working suspension and correction of the pH value.

From 9 to 10 kg of the Lactobacillus biomass (LB) or 1000 gr as cal-

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culated in dry weight are resuspended in 30-60 L of distilled water and 5-20% NaOH solution is added to bring the pH value to 7.0-7.5.

#### 2.1. Treatment of LB biomass with bacteriolytic enzymes (LE)

Ten litres of a lytic enzyme (lysozyme, lysostaphin etc) are dissolved in 500 ml of distilled water. The LE solution is added with stirring to 40 L of the LB suspension (optimal pH 7.0). Lysis continues for 3-10 hours at 30-45°C (optimal 37-40°C).

#### 2.2. Treatment of the lysate suspension with proteases.

Ten gram of a protease (trypsin, pancreatin or microbial proteases) are dissolved in 500 ml of distilled water. The pH is brought to the value which is optimal for the enzyme used. The protease solution is added with stirring to the lysate suspension. The treatment continues, with stirring, for 3-10 hours at 30-45°C (optimal 37-40°C). The pH value is maintained optimal (for trypsin it is 7.5-8.0).

Then the proteases are inactivated by heating the suspension to 85-100°C for 10-30 min after which the suspension is cooled to 40°C.

#### 2.3. Treatment of the suspension with nucleases (RNCase, DNCase, microbial nucleases).

From 10 to 20 gr of a nuclease are dissolved in 500-1000 ml of distilled water. Hydrolysis is performed at 30-45°C (optimal 37-40°C) for 3-10 hours.

#### 2.4. Treatment of the suspension with the enzyme complex.

From 1 to 2 gr of the lytic enzyme is dissolved in 500-1000 ml of distilled water, hydrolysis is performed at 30-45°C (optimal 37-40°C) for 3-10 hours.

### 3. Suspension pasteurization

The suspension is heated to 60-100°C and is maintained at this chosen temperature for 3-10 min.

### 4. Suspension drying

The suspension is dried using a pulverizing equipment or sublimation