

23570#3L\_BSz

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-----**ImmiVet**-----

-----**ASSESSMENT REPORT**-----

**Introduction**-----

The marketing authorization applied for registration of the product as therapeutic product do not qualify as drug on the 4th March, 2014.-----

**The new documentation issued**-----

The marketing authorization holder submitted the recommended product guide, the product label and the required documentation.-----

**Product composition**-----

100% Beta 1,3/1,6 glucan (product of the yeast *Saccharomyces cerevisiae*).-----  
The product guide (and planned label at the same time) is proposed to be accepted as enclosed in a corrected form based on an agreement with the applicant.-----

**Indication**-----

For strengthening the natural resistance of the organism, thus for the prevention and supplementary treatment of contagious diseases. By means of increasing the natural reactivity of the immune system the product supports efficacy of the vaccines. It can be also applied for supplementary treatment of allergic symptoms, to increase physical activity and vitality and for supplementary treatment of the neoplastic diseases.-----

**Expert opinion**-----

Based on the above the **ImmiVet** product meets the requirements on other pharmaceuticals do not qualify as drugs, based on the Decree 33/2010 (07 April) FVM of the Minister of Agriculture and Rural Development on modification of the Decree 128/2009 (06 October) FVM on veterinary products.-----

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Budapest,

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For the Director General

Certified translation from Hungarian

**National Food Chain Safety Office [NÉBIH]**-----  
**Directorate of Veterinary Medicinal Products**-----  
**H-1107 Budapest, Szállás u. 8.**-----  
**Tel.: +36/1/433-0330, Fax: +36/1/262-2839** -----  
[www.nebih.gov.hu](http://www.nebih.gov.hu) -----

**Reg. No.** 02.2/01538/0003/2014 -----  
**Re:** Certification on registration-----  
**Official in charge:** dr. Anna HAJÓS -----  
**Appendix:** Product guide, label-----

-----**CERTIFICATION**-----

The National Food Chain Safety Office as the registering authority herewith certifies that the **ImmiVet** product of **Dr. Csaba JUHÁSZ** (H-1112 Budapest, Mikes Kelemen u. 77.) meets the requirements of the operative law, meets the requirements on other pharmaceuticals do not qualify as drugs, thus the National Food Chain Safety Office has registered the product under the **registration number 591/1/2014 NÉBIH ÁTI (50g)**.-----

The National Food Chain Safety Office herewith certifies that the **ImmiVet** product meets the requirements on other pharmaceuticals do not qualify as drugs, based on Sections 114/O – 114/Q. of point a) of Article (2) of Section 15 of Decree 33/2010 (07 April) FVM of the Minister of Agriculture and Rural Development (hereinafter R. by its Hungarian abbreviation) as well as based on the modification of Decree 128/2009 (06 October) FVM.-----

The **ImmiVet** product as a pharmaceutical that does not qualify as drug can be marketed free based on Article (1) of the new paragraph 114/N enrolled by section 9 of the R., and can be marketed for 5 years based on Article (3) of paragraph 114/P of the R.-----

The appendix of the present certification forms the approved product guide and label based on Article (3) of paragraph 114/O. of the R.-----

Dated: Budapest, 22 April 2014 -----  
On behalf of and for -----  
dr. Márton ORAVECZ, President-----

Signature (signed) of dr. Gábor KULCSÁR, Manager -----

Seal -----

To: -----

1. dr Laura HERPAY (H-1025 Budapest, Felsőzöldmáli Str. 88/c) on behalf of Dr.  
Csaba JUHÁSZ -----

2. Archives-----

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Budapest,

\_\_\_\_\_  
For the Director General

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Product guide/label to the 50 g sachet-----  
**IMMIVET** veterinary medicinal product does not qualify as drug-----  
**Composition** 100% Beta 1.3/1.6 glucan (product of the yeast *Saccharomyces cerevisiae*) -----  
**Target animal species:** Swine, cattle, poultry, dog, cat, small rodents and fish. ----  
**Indication:** For strengthening the natural resistance of the organism, thus for the prevention and supplementary treatment of contagious diseases. By means of increasing the natural reactivity of the immune system the product supports efficacy of the vaccines. It can be also applied for supplementary treatment of allergic symptoms, to increase physical activity and vitality and for supplementary treatment of the neoplastic diseases. -----  
**Dosage, application:** -----  
General dose of the product is 10 mg/body weight kg/day. -----  
For supplementary treatment of neoplastic diseases 50 mg/kg bw/day-----  
Perorally, once daily mixed to the individual ratio of the animals. -----  
The product should be applied continually in order to reach the required effect. ----  
The product cannot be applied as mixed feed supplement! It can solely been used for individual supplementary treatment of the animals! -----  
**Contraindication, side effects:**-----  
The product is innocuous; it can be applied for a long period safely. In case of – the extremely rare – hypersensibility, application should be ceased and the animal has to be taken to veterinarian. -----  
The product can be applied in pregnant and nursing animals as well.-----  
**Expiration** -----  
It can be used for 5 years from manufacturing. -----  
**Storage** -----  
Keep on room temperature (below 25°C), keep dry, keep away from light. -----  
**For veterinary purpose only! Keep out of reach of children, locked!** -----  
**Supplied in:** 50 g triplex foil -----  
Unused leftover of the product and the emptied package material should be destroyed in accordance with the requirements of the local authority. -----

**Manufacturer:** Biothera, Eagan, Minnesota, USA. (Supplier: Pharmatéka Bt, / unlimited partnership/, Pusztaberki) -----

**Distributor: Dr. Csaba JUHÁSZ** (H-1112 Budapest, Mikes Kelemen u. 77. Phone.+36 20 988 7766)-----)

**Register number: 591/I/2014 NÉBIH ÁTI (50 g)** -----

**Product No:** see on the package -----

**Manufacturing date:** see on the package -----

Seal -----  
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Budapest,

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For the Director General