



Central Agricultural Office
Directorate of Veterinary Medicinal Products

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Certificate No: CG-HU/11V/2011.

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC as amended.

The competent authority of **Hungary** confirms the following:
The manufacturer **Bábolna Környezetbiológiai Központ Kft.**
Site address **Szállás u. 6., Budapest, H-1107, Hungary**

Is an active substance manufacturer that has been inspected in accordance with Art. 80 (1) Directive 2001/82/EC, transposed in the following national legislation:
85. § (1), (2) b), (3) and (4) of Decree 128/2009. (X. 6.) of the Minister of Agriculture and Rural Development on veterinary medicinal products.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **05/05/2011**, it is considered that it complies with the principles of GMP for active substances¹ referred to in Article 51 of Directive 2001/82/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

Part 2

Manufacture of active substance. Names of substances subject to inspection:
(S)-(+)-METHOPRENE

Any restrictions or clarifying remarks related to the scope of this certificate:

This certificate covers the production premises No I. as well as No II. of the Synthesis plant.

15/07/2011

Name and signature of the authorised person of the
Competent Authority of Hungary


Dr. Gábor Kulcsár
Director



¹These requirements fulfil the GMP recommendations of WHO.