



**European Directorate for the Quality of Medicines
Division Certification of Substances**

**Certificate of suitability
No. R1-CEP 2000-120-Rev 01**

1 *Name of the substance:*
2 **CASEIN-MEAT PEPTONE E2**
3 Ref. 19501

4 *Name of holder:*
5 **ORGANOTECHNIE SAS**
6 27 Avenue Jean Mermoz
7 F - 93120 La Courneuve

8 *Site of production:*
9 **ORGANOTECHNIE SAS**
10 27 Avenue Jean Mermoz
11 F - 93120 La Courneuve

12 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
13 **R1-CEP 2000-120-REV 00**

14 After examination of the information provided on the origin of raw material(s) and type of
15 tissue(s) used and on the manufacturing process for this substance on the site of production
16 mentioned above, F - 93120 La Courneuve, we certify that the substance **CASEIN-MEAT**
17 **PEPTONE E2** meets the criteria described in the current version of the monograph Products with
18 risk of transmitting agents of animal spongiform encephalopathies no. 1483 of the European
19 Pharmacopoeia, current edition including supplements.

20 - country(ies) of origin of source materials:
21 - nature of animal tissues used in manufacture:

22 The submitted dossier must be updated after any significant change that may alter the quality,
23 safety or efficacy of the substance, or that may alter the risk of transmitting animal spongiform
24 encephalopathy agents.

25 Manufacture of the substance shall take place in accordance with a suitable quality assurance
26 system such as ISO 9001, and in accordance with the dossier submitted.

27 Failure to comply with these provisions will render this certificate void.

- 28 The certificate is valid provided that there has been no deterioration in the TSE status of the
29 country(ies) of origin of the source material.
- 30 This certificate is renewed from **7 March 2006** according to the provisions of Resolution AP-
31 CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any
32 subsequent amendment, and the related guidelines.
- 33 This certificate has 33 lines only.


Dr. A. ARTIGES
Director of the Quality of Medicines

Strasbourg, 13 July 2006

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

ORGANOTECHNIE SAS, as holder of the certificate of suitability

R1-CEP 2000-120-Rev 01 for CASEIN-MEAT PEPTONE E2

hereby authorises
(name of the pharmaceutical company)

to use the above-mentioned certificate of suitability in support of their application(s) for the following Marketing
Authorisation(s): *(name of product(s) and marketing number(s), if known)*

The holder also certifies that no significant changes to the operations as described in the CEP dossier have been
made since the granting of this version of the certificate.

Date and Signature *(of the CEP holder)*: