State Health Department

2-6 Gyali St. Budapest, 1097, PO Box 839, Budapest 1437 Tel: (36-1) 215 5331 or 476-1000, 476-1100

Fax: (36-1) 215-5311

Approval Number: OTH 5456-2/2004 Subject: Approval for Citrofresh

disinfectant

Approved by: Dr. Maria Csiki

Tel: 476-1187 **Attachment:** two

Approval

For Dr, Andras Pitz for a product manufactured by GDM Technologies Pty. Ltd. I approve the distribution of Citrofresh according to the following guidelines:

- During the time of distribution of the product, the conditions must be met with the requirements of the Johan Bela's State Epidemiology Institute, stated in the Microbiological testing report, approval number: 7805/97/2004
- 2/ The distributor is responsible to notify every distribution outlet about Labeling requirements and Directions of Use
- 3/ The State Health Department must be notified regarding any changes of the above product and a new application for approval has to be lodged prior to implementation of any changes.
- In case of termination of distribution of the above product, all relevant documentation must be addressed to the State Health Department
- 5/ The Hazardous Material Act XXV/ 2000 must be considered in relation to this approval

One, fully labeled product must be sent to the "Johan Bela" State Epidemiology Institute prior to distribution

Appeal against this approval must be lodged within 15 days with a payment of 84 000 Hungarian Forint.

Reasoning for the Approval

Dr. Andras Pitz (13 Taban St. Vac, 2600) applied for this approval for the distribution of a product in Hungary, called Citrofresh.

The "Johan Bela" State Epidemiology Institute supports the distribution of the above product, based on the scientific documentations, under the approval number 7805/97/2004.

This approval was issued according to the requirements of the following acts:

- XCVI/1999 (superseded the XI/1991/4)
- 7/1991. (IV.26) NM
- 38/2003. (VII.7) ESZCSM-FVM-KvVM/30/ (7)

Notification abuts this approval was sent to:

- 1./ Dr. Andras Pitz (13 Taban St, Vac, 2600)
- 2./ "Johan Bela" State Epidemiology Institute (PO Box 64, Budapest, 1966
- 3./ Archives

20th of January, 2005, Budapest

Signed by: Dr Adam Vass

Head of State Health Department