



## Declaration :

### CERTIFICATE US Pharmacopeia Class VI

Wijchen july 2008

### **Teflon® PFA Fluoroadditives in Applications Regulated by the Food and Drug Administration.**

This data sheet pertains to the U.S. Federal Food and Drug Administration (FDA) regulations governing the use of fluoropolymers as articles or components of articles intended for use in contact with food.

### **US Pharmacopeia Class VI**

Representative samples of *Teflon*® PTFE, FEP, **PFA**, and *Tefzel*® fluoropolymers have been tested in accordance with USP protocol, and all meet the requirements of a USP Class VI plastic.

These tests on representative samples may not reflect results on articles made from these fluoropolymers, especially if other substances are added during fabrication.

Testing of the finished article is the responsibility of the manufacturer or seller of the finished product if certification that it meets USP standards is required.

USP testing was done to support use of these fluoropolymers in pharmaceutical processing and food processing applications.

While USP Class VI certification is not required for pharmaceutical processing, many pharmaceutical customers seeking ISO-9000 certification have requested it.

### **Medical Use**

**Caution:** Do not use *Teflon*® or *Tefzel*® fluoropolymers or Zonyl® fluoroadditives in medical applications involving permanent implantation in the human body.

For other medical applications, see "DuPont Medical Caution Statement," H-50102.

DuPont does not make surgical or medical grades of *Teflon*® or *Tefzel*® resins and does not guarantee continuity of process in our manufacturing operations as changes may occur from time to time.

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#### Note:

These statements are quoted from the original document H-22779-5 from DuPont