

November 09, 1999

BLASER AG MALTERS
Werkstrasse 5
CH-6102 Malters

Dear Dr. Hoffmann:

This is in response to your facsimile of October 18, 1999, concerning the regulatory status of **Duraflon**[®] intended for use in food-processing and pharmaceutical equipment.

Your say that **Duraflon**[®] surfaces consist of an electrolytically deposited chrome layer in which poly-tetrafluoroethylene (PTFE) is settled.

We do not certify products intended for food-contact use. It is up to the manufacturer to ensure that his products comply with applicable regulations, and it is not necessary for the manufacturer to get approval from FDA prior to marketing products intended for food contact.

We have no regulations specifically on metals intended for food-contact uses, nor do we have specific standards or testing requirements for metals. Rather, we review proposed uses of metals on a case-by-case basis. In the past we have stated that chrome plating is acceptable for repeat food-contact uses such as food-processing equipment. We have no reason to change this opinion at this time. The use of PTFE as a component of repeat-use articles intended to contact food is currently covered under § 177.1550 Nylon resins, and the producer stated that this product complies with that regulation

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely yours,

Ellen M. Waldron
Division of Petition Control, HFS-215
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition