



IMAGE PRINTING PRODUCTS INTERNATIONAL

2284 Speers Road, Oakville, Ontario L6L 2X8

Phone: 905 / 825-5600 Fax: 905 / 825-8833

info@ippi.ca

www.ippi.ca

Food and Drug Administration (FDA) Status of Imageflex PPT and PVC Inks

This is in response to your request for regulatory information applicable to our IMAGEFLEX PPT and PVC series inks.

The FDA indirect food additive guidelines apply to packaged pet foods as well as human foods.

As you are aware, the FDA has developed guidelines for products which are considered to be either direct or indirect food additives. Printing inks or coatings printed on a packaging substrate which, by design, are intended to be in direct contact with the food product, are potential indirect food additives. Printing inks/coatings used for direct food contact applications must comply with the requirements of the indirect food additive guidelines found at 21 CFR Sections 170-189 of the Federal Food Drug and Cosmetic Act.

While the indirect food additive guidelines are fairly liberal with regard to resins and certain additives used in conventional printing ink formulations, there are only a few colorants listed in these guidelines. Because of this restriction, very few printing inks are acceptable as indirect food additives.

In addition to the indirect food additive guidelines, the FDA has taken the position that printing inks/coatings converted on the exterior of food packaging materials (or laminated between film substrates) are not food additives as defined under Section 201 (s) of the Food Drug and Cosmetic Act, provided the substrate serves as a suitable functional barrier preventing any migration of the printing ink/coating components to the food product. Inks/coatings used for these applications are not regulated by the FDA guidelines at 21CFR and there is no legal requirement to comply with the requirements of the indirect food additive sections.

Therefore, the Imageflex PPT and PVC series inks may be utilized in food related applications subject to good manufacturing practices and limited to exterior surface printing or laminated between film substrates where the substrate will constitute a functional barrier between the applied ink/coating film and the food to prevent food adulteration. These printing inks are not acceptable for use in direct food contact applications (human or pet food) under any section of 21 CFR of the Federal Food Drug and Cosmetic Act.

Sincerely,

A handwritten signature in black ink that reads 'Derrick Kurz'.

Derrick Kurz
President
Image Group
FDA 001