



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

July 29, 2009

ITW Thermal Films
14981 32 Mile Road
Romeo, MI 48065

This correspondence is in response to a request from Mr. Bill Herring, on behalf of ITW Thermal Films, for an opinion from the FDA on the regulatory status of the ingredients of an ink formulation to be used to label fresh produce. This ink would be transferred from an initial carrier film to the non-food contact side of a paper label via thermal transfer printing. This paper label is then stuck directly to fresh produce via an adhesive layer on the opposite (i.e. food contact) side of the label. Our correspondence with Mr. Herring on this matter, including the composition of the ink formulation, has been logged into our tracking system as CTS [REDACTED]

We have evaluated the compositional data presented in CTS [REDACTED]. All of the ingredients listed in CTS [REDACTED] are either Generally Recognized as Safe as direct additives to food, prior sanctioned for the intended use, the subject of an applicable food additive regulation, or will not result in migration to food from the intended use (i.e. will not become a food additive). As such these ingredients, as described, are regulated for the intended use. This conclusion applies only to the formulations and use conditions described in CTS [REDACTED]. If these ink formulations, or the intended use, are significantly modified, new data would need to be evaluated.

Please note that FDA does not approve or endorse products manufactured by specific companies. Rather, FDA is a regulatory agency which authorizes the use of substances for food-contact applications under specific conditions. If a product meets the relevant regulatory specifications, it can be marketed without any need for FDA review.

Consumer Safety Officer
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition