

FDA Compliance and Printing Inks

Often Printers have questions concerning the Food and Drug Administration (FDA) and compliance of the inks used to print on food packaging applications. The FDA permits the use of inks (e.g. solvent base, water base and UV) as components of food packaging under certain conditions.

Several items must be understood before one can determine if a printing ink is suitable for use on food packaging applications:

“Direct Food Additives” are substances directly and intentionally added to foods, including, but not limited to, ingredients, preservatives, colors and stabilizers.

“Indirect Food Additives” generally refer to substances that are not intended to, but can become, components of food as a result of use in articles that contact food (e.g. ink on food packaging applications).

Both “Direct and Indirect Food Additives” require complex petitions and filings with the FDA that can be very costly, burdensome and time consuming.

Nazdar inks are not designed to be and are not approved as Direct or Indirect Food Additives. However, if an ink on food packaging applications is not expected to become a component of the food under its intended conditions of use, it is not a food additive by definition and, therefore, may be used without the need to obtain any FDA clearance.

A properly conducted migration study is considered to be a sound basis for concluding that the substance is not a food additive. This study should be performed in accordance with FDA’s guidance document, entitled; *Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations*
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-premarket-submissions-food-contact-substances-chemistry>

Another method of concluding that a substance is not a food additive is the use of a functional barrier. An ink that is not part of the food-contact surface of a package, and is separated from the food by a barrier that does not permit migration would not be considered a food additive subject to FDA review. The only significant question for a food packager with respect to non-contact substances is whether a true functional barrier exists.

It is up to the end user to conduct these types of tests/determinations due to the multitude of processes and uses in food packaging and printing applications.

Summarizing, substances used in food contact food packaging applications must follow food additive regulations if they are reasonably expected to migrate to food under the intended conditions of use. However, if the ink on food packaging applications is not reasonably expected to become a component of food under the intended conditions of use, it is not considered to be a food additive, and may be used without the need for a permissive food additive regulation.

The following is a good information source for food packaging applications:
<http://www.packaginglaw.com/>

If there are any questions concerning food packaging applications, please email Nazdar’s Regulatory Compliance Department at regcomp@nazdar.com.

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