FDA Approval and Screen Printing Inks
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SGIA and ink manufacturing technical staff receive several customer inquiries each year that involve concerns about FDA Approval for screen printing inks. The United States FDA (Food and Drug Administration) agency cannot and will not approve inks at all; therefore, there is no such thing as an FDA Approved printing ink. The FDA can approve individual ingredients. None of our industry's common screen printing inks are composed of food additives, therefore none of our inks are suitable for regulated direct food contact applications. When used with appropriate barrier technology, some screen printing inks can be used in the decoration of food packaging. Please consult your ink manufacturer directly for application advice.

The FDA is the Food and Drug Administration of the United States government, and it is a federal regulatory enforcement agency. As the name suggests, the FDA is responsible for assuring that the foods and drugs sold to USA consumers will be safe, and in the case of legal drugs, also effective. The FDA also regulates certain other consumer products and medical devices, including cosmetics, pet food and medicine, farm animal food and medicine, and devices which emit radiation, such as microwave ovens. The US Congress has authorized the FDA to monitor the manufacturing, importation, transportation, storage, and sale of these products under the Federal Food, Drug, and Cosmetic Act and several other public safety laws.

A key function of the FDA is to approve and regulate the use of color additives. According to the FDA, a color additive is any dye, pigment or substance that can impart color when added or applied to a food, drug, cosmetic or to the human body.

There are two primary areas where color additives and related components may involve screen printers and printing ink manufacturers. These are cosmetics and food packaging, and we shall discuss each area.

Food packaging is an issue with some printers because of questions about the safety of inks in contact with food. With the exception of approved food-grade pigments and dyes, color additives may not be in direct contact with food. Normally, these other pigments and dyes can be used in packaging food as long as there are proper barriers between the color and the food. Remember the ceramic inks used on the old glass soft drink bottles? They were certainly not approved for use IN foods, but they could be used to decorate the outside of the bottle because they were completely isolated from the food (soft drink) by the bottle. All direct and indirect food contact must be in accordance with strict FDA regulations.

Other food-related items involve printers who produce decorations and image transfers for cake icing and frosting. An example is the finished result of an Edible Image from DecoPac.
Since these are in direct contact with food and are intended to be eaten along with the cake, the color additives must be food-grade, FDA-approved pigments and dyes. The complete lists of these approved color additives is readily available from the FDA. Screen printing inks appear nowhere on the lists! The primary color additive list for food is quite short, and contains nine manufactured color additives subject to batch certification according to Title 21 of the Code of Federal Regulations, Section 74, subpart A. The other list is longer, and contains color additives that are exempt from batch certification. Image transfers are designed to be eaten, and must comply with all regulations pertaining to food items in the US.

Contrary to popular belief, the FDA does not have the authority to approve cosmetics at all, with the exception of color additives. However, the FDA does specifically prohibit and restrict inclusion of certain components that are known to be unsafe, such as mercury in products sold to lighten skin coloring. The very short list of prohibited ingredients for cosmetics include mercury compounds, vinyl chloride, methylene chloride solvent, and several other components which may cause photo-sensitization, neurotoxicity, and/or animal carcinogenicity. A recent addition to the list is methyl methacrylate monomer, which was previously used in some nail varnish products. Some printers have observed that traditional solvent-based vinyl inks may contain some of these components, which of course is one of many reasons why screen printing inks are not recommended for use as cosmetics.

The cosmetic manufacturer must verify that each component and finished product is known to be safe, otherwise the product must carry a warning label indicating that the safety of the product has not been determined. When the FDA takes action against firms involved with cosmetics, the reasons usually include improper labeling, inclusion of dangerous components or unapproved colors, and unproven claims about heath and safety of the product in question. The FDA encourages all cosmetic manufacturers to register their products and ingredients with the FDA’s Voluntary Cosmetic Registration Program, although of course this does not give companies the right to suggest that their products have been FDA Approved!

The cosmetic products of most interest to screen printers include temporary tattoos, such as these flags from Australia. There is no such thing as a temporary tattoo with FDA approval. There are, however, some tattoos which contain the only nine current FDA-approved color additives for use in human food, or the 34 manufactured color additives that are approved for use in cosmetics (21 CFR Section 74, subpart B). Printing inks are not listed on either of the two lists of color additives permitted in cosmetics! While tattoo printers sometimes say that their products have been FDA approved, this is not strictly true. They might more accurately state that all color additives of the temporary tattoos have been approved, and that other components have been allowed for use in cosmetics. The FDA has enforced regulations against several manufacturers of temporary tattoos in Taiwan, United Kingdom, Japan, and Hong Kong for three key reasons, especially the use of unapproved colors, the lack of ingredient declaration, and the use of an “FDA Approved” statement.
There is an American company called Colorcon in Chalfont, PA, whose No-Tox product line is approved for use in contact with food. For example, coupons, recipes, and inserts found inside food packaging would most likely have been printed with Colorcon No-Tox inks. For information on Colorcon, see their website at http://www.colorcon.com/no-tox/index.html.

Some screen printers have observed that FDA-prohibited components do not appear on Material Safety Data Sheets (MSDS) for screen inks, and the simple reason is that MSDS apply to occupational health and safety practices, not to foods, drugs, and cosmetics. It is always a good rule of thumb that under most circumstances, screen printing inks should not be used as foods, drugs, or cosmetics.

For questions or additional information, please contact SGIA Technical Services, or consult the agents of the United States Food and Drug Administration at http://www.fda.gov

ASPT Member Biography

Denise Breard  
Inducted into the Academy in 2003

Denise Breard recently joined the SGIA Technical Services Team following her work as Technical Services Manager for Sericol (Hong Kong) Ltd. Prior to her position in China, she worked as the National Key Account manager for Sericol Australia, and as the Training Manager for Sericol at their US Corporate headquarters in Kansas City, Kansas. While in Kansas City, she developed and presented technical training curricula and served as a resource for Sericol's Technical Department. She is a speaker and workshop leader for industry shows and exhibitions, and contributes to industry publications with over 20 articles in print, in addition to her many special purpose articles for specific training programs.

Denise is a former member of the SGIA Board of Directors and has participated on various SGIA committees, including the Education Committee for which she served as chair. She has served on the Board of Advisors for various printing programs and as adjunct faculty for workshops and training programs, including those offered by the SPTF. Denise has often served as a technical judge in printing competitions including SGIA's Golden Image Competition and Imprinted Sportswear Shows. She has received numerous awards and commendations, but is most proud of the prestigious Key Award, in 1999, from SGIA for her educational contributions to the industry.

Prior to joining Sericol, Denise was a technical sales representative, a regional sales manager, and a product manager for Autotype Americas, Inc. Denise is an amateur naturalist, chef and scuba diver with a particular interest in marine environments.