



FDA and Printing Inks

Are GRAUEL printing inks FDA – compliant?

„A simple question with a complicated answer!(¹)

Lately, we have been asked quite frequently if our printing inks are FDA-tested, FDA – approved or correspond to FDA regulations however?

By the way, what does FDA mean? The acronym FDA means “**Food and Drug Administration**” and is an organisation of the United States of America. The FDA is a government agency charged with the adopting and enforcing the regulations of the Food, Drug and Cosmetic Act. This act regulates ingredients used in products listed in the **Code of Federal Regulations (CFR)**.

The FDA relates to 21 CFR; this title 21 of the Code of Federal Regulations (21 CFR) is comprised of 17 active parts (170-197). (Hopefully, it is not too complicated up to now, otherwise leave this passage out). The sections related to food activities focus on direct and indirect food additives. Printing inks and coatings are regulated under the four *indirect* food additive parts (and subparts within each). They are:

Part 175

Indirect „food additives“

Additives and Components of Coatings

Part 176

Indirect „food additives“

Paper and Paperboard Components

Part 177

Indirect „food additives“

Polymers

Part 178

Indirect „food additives“

Adjuvants, Production Aids and Sanitizers

(e.g. pigments can be found listed in 21CFR 178.3297)



The long and the short of it: If a printing ink or coating will be in contact with a food product (not hazardous), then all the non-volatile ingredients must comply with regulations listed in 21 CFR 170-189!

In practice, FDA information is more specific. For example, one could sell a clear, water-based overprint coating based on components that allow to indicate it complies with 21 CFR 176.180, "Components of Paper and Paperboard in Contact with Dry Food"⁽²⁾. If a customer wanted to use it as a paper coating in an application where it would be in contact with aqueous (melon, cucumber, etc.) or fatty (pizza, french fries) foods its components would have to be reviewed in the context of the regulation section 21 CFR 176.180 "Components of Paper and Paperboard in Contact with aqueous or fatty food"⁽³⁾. It's possible the coating would be suitable. If not, perhaps the coating would be reformulated to satisfy the requirements of that regulation section.

The FDA has issued an opinion that if printing inks or coatings are separated from the food product by an impervious functional barrier (i.e. ink outside, food product inside) then the inks and coatings are not food additives. In this situation, they are not subject to the regulations of 21 CFR 170-197 by the FDA.

Therefore: It has to be pointed out once again: printed or coated surfaces are not meant to get into direct contact with food products!

NO FOOD PRODUCT ON THE PRINTED SIDE !!!!!!!!!!!!!!!!!!!!!!!

¹ Are your inks or coating FDA – compliant?, David Fishman; INK WORLD – Nov/Dec (1996)

² Code of Federal Regulations, Office of the Federal Register and Records Administration, Page 189-193 Washington; USA (1985)

³ Code of Federal Regulations;: Office of the Federal Register and Records Administration, Page 166-189 Washington; USA (1985)