

**Subject: FDA Compliance Xeikon Dry Toners
Issued: May 2016**

The U.S. Food and Drug Administration (FDA) status of the Xeikon dry toners is positive for the following QA and FA-toners when used on the non food-contact side (**INDIRECT food contact**) of packaging materials that are intended to contact food under room temperature and less severe conditions¹, where the packaging material acts as a functional barrier to migration of the toners:

Table 1.
'Indirect' food

	Toner color	FA toner	QA-I toner	QA-P toner	QA-IC toner	QA-CH toner	QA-CD toner
PROCESS COLORS	Cyan	OK	OK	OK	OK	OK	OK
	Magenta	OK	OK	OK	OK	OK	OK
	Yellow	OK	OK	OK	OK	OK	OK
	Black	OK	OK	OK	OK	OK	OK

	Toner color	FA toner	QA SPOT toner	QA-IC toner	QA-CH toner	QA-CD toner
SPOT COLORS	White	OK	OK	OK	OK	OK
	Clear	OK	OK	OK	OK	OK
	Super Black	/	OK	/	/	OK
	Extra Magenta	OK	OK	OK	OK	OK
	Red	OK	OK	OK	OK	OK
	Green	OK	OK	OK	OK	OK
	Blue	OK	OK	OK	OK	OK
	Orange	OK	OK	OK	OK	OK
	Palladium Silver	/	OK	OK	OK	OK
	Matte Silver	/	OK	OK	OK	OK

The U.S. Food and Drug Administration (FDA) status of the Xeikon dry toners is moreover positive for the following QA and FA-toners when used on the food-contact side (**DIRECT food contact**) of packaging materials that will contact dry foods containing no surface fat or oil under room temperature and less severe conditions¹:

Table 2.
'direct' food

	Toner color	FA toner	QA-I toner	QA-P toner	QA-IC toner	QA-CH toner	QA-CD toner
PROCESS COLORS	Cyan	OK	OK	OK	OK	OK	OK
	Magenta	NOK	OK	NOK	OK	OK	NOK
	Yellow	OK	OK	OK	OK	OK	OK
	Black	NOK	OK	NOK	OK	OK	NOK

	Toner color	FA toner	QA SPOT toner	QA-IC toner	QA-CH toner	QA-CD toner
SPOT COLORS	White	OK	OK	OK	OK	OK
	Clear	OK	OK	OK	OK	OK
	Super Black ²	/	OK	/	/	OK
	Extra Magenta	OK	OK	OK	OK	OK
	Red	NAP ³	OK	OK	OK	OK
	Green	NAP ³	OK	OK	OK	OK
	Blue	NAP ³	OK	OK	OK	OK
	Orange	NAP ³	OK	OK	OK	OK
	Palladium Silver ²	/	OK	OK	OK	OK
	Matte Silver ²	/	OK	OK	OK	OK

¹ FDA's Conditions of Use E (room temperature), F (refrigerated) and G (frozen), under 21 CFR 176.170 (= intended use).

² "p" means that this specific color is not available in this toner formulation

³ No Approval Present

Under room temperature and less severe conditions, packaging materials made from polyethylene terephthalate (PET) that is at least 1 mil (25 microns) thick, paper and paperboard that is technologically suitable for the intended use, or aluminum foil are considered functional barriers to the migration of the dry toner components. This being the case, it can be concluded that the potential level of migration of the toner components to food from the non food-contact side of such constructions would be less than 50 parts per billion (ppb).

Since polyolefin films (e.g. polyethylene, polypropylene, ...) generally are more permeable (for the same dry toner components at room temperature) than the materials mentioned above, migration test data would be required in order to make any conclusions on the FDA status of the toners when used on the non food-contact side of packaging material that will contact food.

Several components of the toner formulations currently are cleared for the intended use under an applicable FDA food additive regulation, and we have determined that those components are suitably pure for their intended use.

For the uncleared components of the formulation, Keller and Heckman has used standard FDA assumptions (i.e., that the maximum migration of toner components to dry food containing no surface fat or oil will be 50 ppb, and the appropriate consumption factor (CF) for colorants for polymers is 5%), and they have reviewed the available toxicity data on the substances, to conclude that the uncleared materials may be considered generally recognized as safe (GRAS).

The study was done and the opinion was formulated by the law firm Keller and Heckman LLP (Washington - Brussels), based on the detailed composition of the toner formulations (also taking into account the presence of small amounts of silicon oil in case of simplex fusing). These consecutively opinions were formulated on:

- September 6, 1999
- December 9, 2004
- August 12, 2005
- March 16, 2006
- September 7, 2006
- June 17, 2008
- April 2, 2009
- November 17, 2009
- February 2, 2011
- February 11, 2013
- September 29, 2015
- October 21, 2015

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