

**Subject: FDA approval QA-I, QA-P, FA-toners
and Durable Clear Toner - issued : March 31, 2014**

The U.S. Food and Drug Administration (FDA) status of the FA, QA-I and QA-P toners is positive for the following QA and FA-toners when used on

- (1) the non food-contact side of packaging materials that are intended to contact food under room temperature and less severe conditions, where the packaging material acts as a functional barrier to migration of the toners, and
- (2) the food-contact side of packaging materials that will contact dry foods containing no surface fat or oil

Toner color	FA toner	QA-I toner	QA-P toner	QA SPOT
Cyan	OK	OK	OK	
Magenta	Not OK	OK	Not OK	
Yellow	OK	OK	OK	
Black	OK	OK	OK	
White	OK			OK
Clear	OK			OK
Extra Magenta	OK			OK
Orange	Not OK			OK
Red	Not OK			OK

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

Toner color	FA toner	QA-I toner	QA-P toner	QA SPOT	Durable Clear
Cyan	OK	OK	OK		
Magenta	OK	OK	OK		
Yellow	OK	OK	OK		
Black	OK	OK	OK		
White	OK			OK	
Clear	OK			OK	OK
Extra Magenta	OK			OK	
Red	OK			OK	
Green	OK			OK	
Blue	OK			OK	
Orange	OK			OK	

The opinion formulated regarding the suitable FDA status of the FA, QA-I and QA-P toner when used on the non food-contact side of packaging materials that are intended to contact food under room temperature and less severe conditions was based on the determination that, 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 all would act as functional barriers

to the migration of the toner components. This being the case, we can conclude 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).

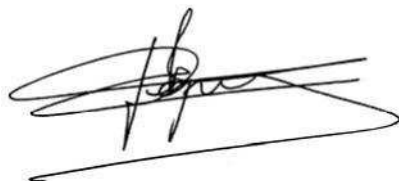
Since polyolefin films generally are more permeable than these other materials, migration test data would be required in order for us make any conclusions on the FDA status of the toners when used on the non food-contact side of polyolefin films.

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

- 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

Several components of the toner formulation 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).

Dr. Lode Deprez



Vice President
R&D Consumables and Process Group

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Statement about QA-I compliance with Swiss Ordinance and latest Nestlé Guidelines

The Swiss Ordinance (EDI 817.023.21 ; <http://www.admin.ch>) includes two parts :

- Part A which lists the substances that have been toxicologically evaluated and for which a Specific Migration Limit (SML) has been set.
- Part B which lists the non-evaluated substances for which the default SML has been set at 0.01 mg/kg (= 10 ppb)

The QA-I CMYK composition (total of 18 ingredients) has been checked versus Annex 6 of the Swiss Ordinance and hereby we can state :

- that 10 ingredients are in the list A (= evaluated list, with known SML),
- 8 ingredients are on list B (known, but not evaluated, so SML = 10 ppb)


For the QA spot colour toners (ORGBCWEm) the 20 ingredients also have been checked and here we can state :

- that 9 ingredients are in the list A (= evaluated list, with known SML),
- 11 ingredients are on list B (known, but not evaluated, so SML = 10 ppb)

From the last Nestlé guidelines for food packaging (different versions can be downloaded from <http://www.xeikon.com/downloads>) we learn that only ink ingredients that are listed in the Swiss Ordinance on Materials and Articles can be used, BUT in addition, this document specifies the components, listed in the Swiss Ordinance, which must be excluded from ink formulations.

We can state that the QA-I toner system (CMYKW) is compliant with the latest version of Nestlé guidelines for food packaging, on condition that all the Specific Migration Limits are met as mentioned in the Swiss Ordinance.

Dr. Lode Deprez



Vice President Consumables & Process Group
Xeikon Manufacturing NV,
Duwijckstraat 17
2500 Lier – Belgium