

Subject: Swiss Ordinance for Printing Inks Issued: February 2019

The Swiss Ordinance for Printing Inks (817.023.21) contains a positive list in Annex 10 (https://www.blv.admin.ch/dam/blv/en/dokumente/gebrauchsgegenstaende/rechts-undvollzugsgrundlagen/anhang-6-srbedarfsgegenstaende.pdf.download.pdf/130401%20Annex%206_en.pdf) listing all the substances that are allowed to be used in printing inks. This positive list includes two parts:

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

Xeikon hereby states that all the substances that are used in the production process of QA-I, QB-I, QA-IC, QB-IC, QA-CH, QB-CH and SPOT colours toner are listed on Annex 10 of the Swiss Ordinance for Printing Inks.

It is the final responsibility of the manufacturer of the final article to be compliant with the overall migration limit of 10 mg/dm² or 60 mg/kg and any applicable specific migration limits.

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Subject: Nestlé Issued: January 2019

Xeikon hereby states that packaging material printed with QA-I, QB-I, QA SPOT, QB SPOT, QA-IC, QB-IC, QA-CH, or QB-CH toner can be compliant with the requirements of the latest version of the Nestlé Standards on materials in contact with food (version 5.0 – October 2018).

All the substances that are used in the production process of QA-I, QB-I, QA SPOT, QB SPOT, QA-IC, QB-IC, QA-CH, and QB-CH toner are listed on Annex 10 of the Swiss Ordinance for Printing Inks. Moreover, Xeikon also does not use excluded pigments, photo initiators, acrylates or solvents that are listed in the latest version of the Nestlé Guidance Note on Packaging Inks (issued in October 2018) in the production process of these toners for all process and SPOT colours.

It is the final responsibility of the manufacturer of the final article to be compliant with the overall migration limit of 10 mg/dm² or 60 mg/kg, any applicable specific migration limits and to follow local regulations.

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Subject: FDA Compliance Xeikon Dry Toners Issued: January 2018

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
50	Cyan	OK	OK	OK	OK	OK	OK
PROCESS	Magenta	ОК	OK	OK	ОК	ОК	ОК
	Yellow	OK	ОК	ОК	ОК	ОК	OK
	Black	ОК	ОК	ОК	ОК	ОК	ОК

	Toner color	FA toner	QA SPOT toner	QA-IC toner	QA-CH toner	QA-CD toner
SPOT COLORS	White	ОК	ОК	ОК	ОК	ОК
	Clear	ОК	OK	ОК	ОК	ОК
	Super Black	/	OK	/	/	OK
	Extra Magenta	ОК	OK	ОК	ОК	ОК
	Red	ОК	OK	ОК	ОК	ОК
	Green	ОК	OK	ОК	ОК	ОК
	Blue	ОК	ОК	ОК	ОК	ОК
	Orange	ОК	OK	ОК	ОК	ОК
	Palladium Silver	/	OK	ОК	OK	OK
	Matte Silver	/	OK	ОК	ОК	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
(0	Cyan	ОК	ОК	ОК	ОК	ОК	ОК
PROCESS	Magenta	NOK	OK	NOK	OK	OK	NOK
	Yellow	ОК	ОК	ОК	ОК	ОК	ОК
	Black	NOK	OK	NOK	ОК	OK	NOK

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

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

² "/" 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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Subject: Mineral oils Issued: May 2022

According to an opinion of the European Food Safety Authority (EFSA) of 2012, mineral oil hydrocarbons (MOH), or mineral oil products, are considered in the range of 10-50 carbon atoms. Crude mineral oils are by far the predominant source of the MOH considered, but equivalent products can be synthesized from coal, natural gas or biomass. In this opinion, MOH have been divided into two main types, mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH).

From 01.01.2023 the restriction of the use of mineral oils in packaging is enforced in France on a step by step basis. With a grace period of 12 months, the prohibition on the use of mineral oils applies where the concentration in mass in the ink of mineral oil aromatic hydrocarbons (MOAH) is greater than 1 % until 31.12.2024. From 01.01. 2025, the ban on the use of mineral oils applies for mineral oil aromatic hydrocarbons (MOAH), when the mass concentration in the ink of these substances is greater than 0,1 % or the mass concentration in ink of compounds from 3 to 7 aromatic rings is greater than one part per million (ppm). For mineral oil saturated hydrocarbons (MOSH), where the mass concentration in these substances are greater than 0,1 %.

Xeikon hereby states that mineral oil hydrocarbons (MOSH and/or MOAH) are not (and were never) intentionally added in our **toner products** (FA, QB-I, QA-P, QB-IC, QB-CH, QA-CD, QA-SR, QB-T, QC and corresponding SPOT colours), **IDERA**, the **Jetrion** (3824, 4000, 4830, 4900 or 4950 series), and the **PantherCure UV** inks and that these mineral oils are not used during the printing process using Xeikon equipment. However, there is no specific analytical testing performed to check the presence of traces of these substances on the raw materials used, but based on the product formulation and technical data sheets provided by our suppliers, we are convinced that also these substances are not present in the toner raw materials we receive from them. The presence of very small traces of these substances from raw material impurities (NIAS) are not expected but cannot be excluded. In our experience, if detectable amounts of these chemicals are found, the prime cause will be situated in the substrate or varnishes that have been used.

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Subject: AgBB conformity

Issued: August 2014

The committee for health-related evaluation of building products (Ausschuss zur gesundheitlichen Bewertung von Bauprodukten – **AgBB**) has developed criteria regarding (S)VOC emissions from interior-relevant construction products. These criteria are described in the 2012 AgBB Guideline document.

Although these emission criteria relate to the finished construction product, for instance digitally printed wall paper, Xeikon can state that the following compounds are not intentionally added to our toner products, and that independent analysis confirmed their absence (values are mentioned below when analysis was performed):

- Lead < 4.5 ppm
- Mercury below detection limit (DL = 1.4 ppm)
- Cadmium below detection limit (DL = 5 ppm)
- Hexavalent below detection limit (DL = 1.4 ppm)
- Formaldehyde < 1 ppm (after extraction with water)
- Vinyl chloride monomer < 0.1 ppm
- Volatile Organic Compounds (VOC)
- Carcinogenic substances

Given that Xeikon toner is applied on a substrate that is AgBB compliant, Xeikon can state that application of its toner products will have no negative effect on the overall emission. This was already illustrated by Xeikon customers that use its toner products in the preparation of digitally printed wall paper. They were granted AgBB conformity.

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Subject: Compostability and Xeikon toners Issued: May 2020

Concerning compostability and (bio-) degradability, there can be some confusion. Degradation means that the polymeric chain of a material will be cut under certain conditions, for example UV light. Biodegradation means that the polymer chain of a material will be attacked by an organism, resulting in a cut of the polymer chain and a loss of stability and structure. Composting describes a biodegrading process subject to standardized requirements to be suitable for the use in aerobic composting and anaerobic treatment in an industrial waste treatment plant.

There are different standards globally, e.g. DIN EN 13432 (Europe), ASTM D6400 (North-America), BecauseWeCare (Australia), which differ only in some details. In general, a compostable material must meet 4 main requirements: (i) it must be bio-degradable, which is specified to mean it can contain max. 5% total dry weight of non-biodegradable components and each non-biodegradable component may make out max. 1% of the packaging; (ii) it must disintegrate; (iii) it should not have any negative effect on the environment and the treatment process; and (iv) the quality of the compost must not be effected.

Toner must be considered as a non-biodegradable component of a packaging material and be under the 5% limit as a whole, and each toner color must be under the 1% limit. Taking into account the weight of the package, this poses some restrictions on the amount of toner that can be printed on a biodegradable packaging material. Converting from the weight of the toner per m², the total toner page coverage divided by the substrate weight must be equal to or less than 1. The page coverage for each individual toner divided by the substrate weight must be equal to or less than 0.2.

$$\frac{page\ coverage\ of\ total\ toner}{weight\ substrate\ (gsm)} \leq 1$$

$$\frac{page\ coverage\ of\ each\ individual\ toner}{weight\ substrate\ (gsm)} \leq 0.2$$

For example, a typical 80 μ m PLA foil (100 g/m²) can be printed in five colors (CMYKW), with a total page coverage of maximum 100% (or half of the package printed with 200% coverage), and complies with the 5% limit. Each individual toner color can be printed on this PLA foil with a maximal page coverage of 20%, and complies with the individual 1% limit. Of course, the heavier the substrate, the more toner can be printed, without compromising the compostability.

The above guideline is only valid when printing directly on a compostable film. In case the film is subsequentely glued on a compostable flacon the page coverage limitation can be different (less stringent) depending upon the weight of the flacon. This is very difficult to put into a formula and should be investigated and calculated on a case by case scenario. The Xeikon Regulatory Affairs department is willing to help in this assessment.

For the environmental requirements, there are limitations of several elements in the packaging material:

Zn	< 150 ppm	Мо	< 1 ppm	
Cr	< 50 ppm	Se	< 0.75 ppm	
Cu	< 50 ppm	Cd	< 0.5 ppm	
Pb	< 50 ppm	Hg	< 0.5 ppm	
Ni	< 25 ppm	F	< 100 ppm	
As	< 5 ppm			

When subject to the same coverage limitations as above, packaging printed with Xeikon toner (QA-P, QA-I, QA-IC, QA-CD, QA-CH, QA-SR, QB-I, QB-IC, QB-CH) will be compliant with these limits with respect to the toner.

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Subject: Declaration of Paper Recyclability Issued: May 16, 2014

Xeikon Manufacturing NV hereby declares that paper material printed with the V3, FA and QA-toners will give no problem in paper recycling. We hereby refer to the following statement and report:

This first statement comes from the INGEDE organisation (International Association of the Deinking Industry – www.ingede.org)

"In the course of a survey on the deinkability of digital prints that has been conducted in late 2006/early 2007. INGEDE had various samples tested at three research institutes (PMV Darmstadt, PTS München and CTP Grenoble).

The samples that have been submitted to us had been printed with a uniform test file. Before passing them on to the institutes they were made anonymous.

The evaluation of the data showed that the test prints with V3 and FA-toner from the XEIKON 5000 Digital Printing Press did comply with the requirements regarding dirt specks which is the critical requirement for toner based digital prints. The additional requirements as they apply to comparable offset or gravure prints (luminosity ink elimination, chromaticity coordinate, filtrate darkening) are not relevant for dry toners and have been fulfilled without any difficulty.

Thus, as state of the technology and the requirements of the paper industry are now, prints produced with these printers together with the paper tested (UPM Digi Color laser 100 g/m² and 130 g/m² respectively) can be regarded as good deinkable"

In 2013 this procedure was repeated with QA-P toner prints from a XEIKON 8800 Digital Printing Press. In this case, "Digi Finesse Premium Silk", 200 g/m²" paper was used.

"The specified print product was tested according to INGEDE Method 11 and evaluated according to the "Assessment of Printed Product Recyclability – Deinkability Score –" (ERPC 2009). The total scoring is 92% and the deinkability is rated 'good'."

An additional positive test has been performed at the Western Michigan University (USA) studying both PA toner and FA toner. This study was initialised by the IPA (International Prepress Association, now the Association of Graphic Solution Providers) comparing different printing engines from different brands. The complete report of their findings is available from this organisation (www.ipa.org).

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Subject: Animal Origin Issued: May 2020

Xeikon does not add components with a direct animal origin in their toners. However, the source of raw materials further up the value chain is not always easy to determine. Based on the declarations of our suppliers, we have found that one of the additives of the toner has a component which is synthesized from raw materials, one of which is of animal origin. It is a derivative of tallow (rendered form of beef or mutton fat) and is primarily made up of hydrolyzed and derived triglycerides which are then further modified in an inorganic complex.

For all other raw materials, we have the confirmation that these are not of animal origin.

Since the component of animal origin is only a small part of an additive, we can state that 99,7% of Xeikon toners and 99,98% of Xeikon developers is not of animal origin. This is valid for all toners and developers: V3, FA, QA-I, QA-P, QA-IC, QA-CH, QA-CD, QA-SR, QB-I, QB-IC, QB-CH and SPOT colours.

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Subject: Nordic Swan Ecolabel Issued: July 2014

The Nordic Ecolabel is the official Ecolabel of the Nordic countries and was established in 1989 by the Nordic Council of Ministers with the purpose of providing an environmental labelling scheme that would contribute to a sustainable consumption. It is a voluntary, positive Ecolabelling of products and services. The Nordic Ecolabel was also initiated as a practical tool for consumers to help them actively choose environmentally-sound products. It is an ISO 14024 type 1 Ecolabelling system and is a third-party control organ.

For all Xeikon toners/developers (V3, FA, QA-I, QA-P, QA-IC, QA-CH, QA-CD and SPOT colors) Xeikon can state that they received approval from the Nordic Ecolabel in category 41 (Toner – Including Wet and Dry toner, but not ink for digital printing).

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