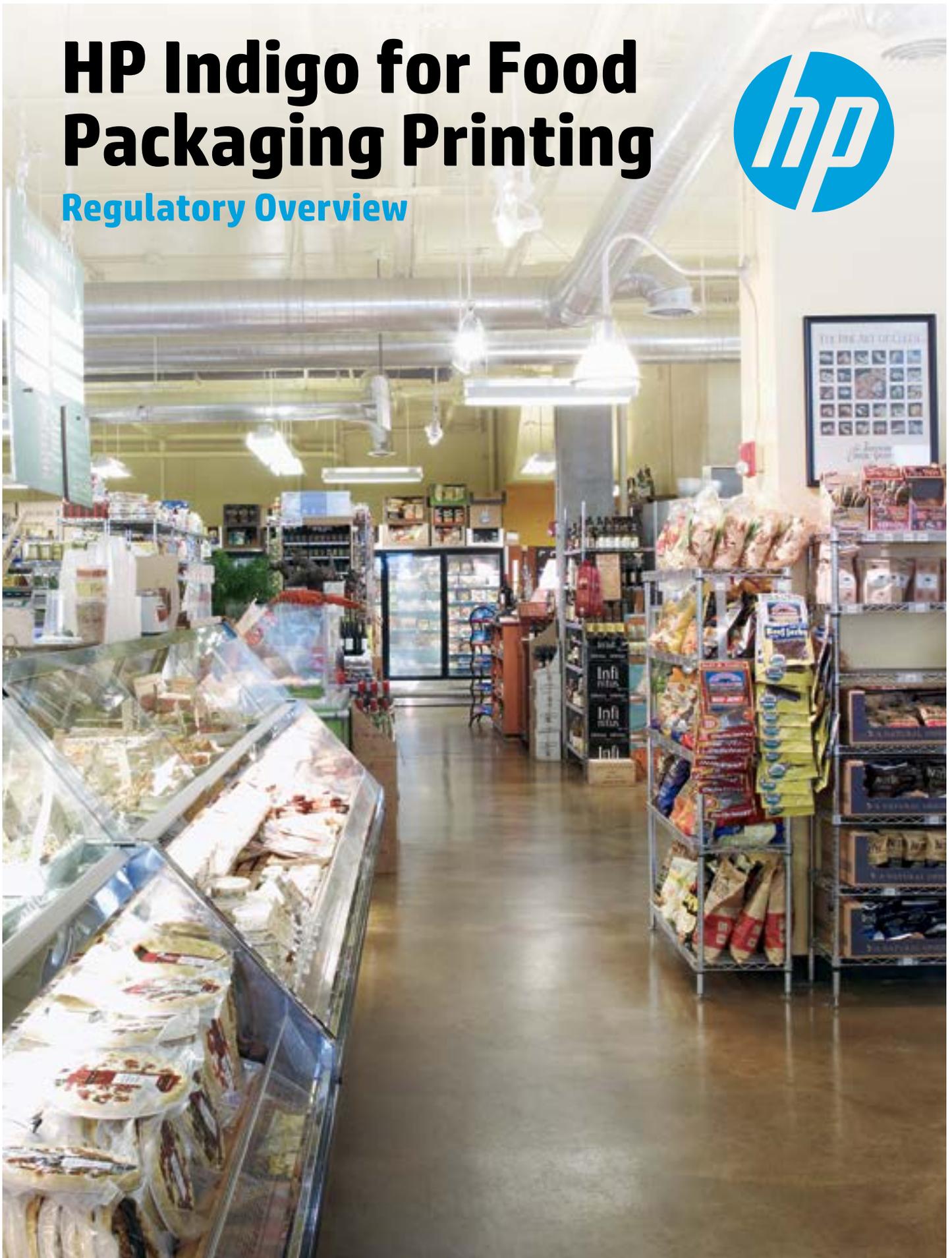


HP Indigo for Food Packaging Printing

Regulatory Overview





Introduction

Converters who print food packaging operate their businesses within a complex and strict set of regulations and guidelines, set forth by both government agencies and industry associations, to help ensure that printed packaging does not negatively impact the products they contain.

HP Indigo develops printing solutions and inks that enable converters to produce food packaging that can comply with regulations and industry standards. This document aims to give an overview of the status of HP Indigo ElectroInk in relation to current food packaging regulations.

HP Indigo ElectroInk is safe and suitable for printing flexible packaging and folding cartons on the non-food contact side of the food packaging, under certain conditions of use and compliance with Good Manufacturing Practices (GMP). GMP is a framework of rules for all parties involved in the development of packaging and provides recommendations and requirements to maintain quality assurance and safety.

Studies have been conducted by HP Indigo to validate the use of ElectroInk for printing on commonly used packaging substrates, and under certain frequently referenced conditions of use. The studies indicate that migration of substances through the packaging substrate to the packaged goods, under the conditions of use assessed, meets US and European regulatory requirements, which are also considered favorably by other countries. Our testing has also shown that set-off, the transfer of ink or its components from the non-food contact side to the food contact side of the package, while in a stack or a roll, meets EU and FDA regulatory requirements and can be further mitigated while printing on HP Indigo solutions by using drying systems and other methods.

HP Indigo seeks to provide customers with the information that they need about HP Indigo ElectroInk and the HP Indigo printing process, so they can compete and differentiate within the ever-changing and increasingly regulated food packaging industry while maintaining the highest standards of safety.



HP Indigo 20000 Digital Press for flexible packaging, labels and other applications.

HP Indigo ElectroInk

HP Indigo sets the benchmark for print quality in the world of digital printing with its unique printing technology. In order to understand how this technology can be used for the production of food packaging, it is important to have a basic knowledge of the HP Indigo printing process and HP Indigo ElectroInk.

HP Indigo ElectroInk, a liquid ink developed by HP Indigo and used exclusively by our presses, contains electrically charged ink particles dispersed in liquid. Precisely controlled electrical fields move the charged color particles, enabling accurate placement on the printing material.

HP Indigo ElectroInk particles are very small, only 1-2 microns, allowing for higher resolution, uniform gloss, sharp image edges and very thin image layers. For more information please refer to the HP Indigo Digital Offset Technology White Paper.



Substrate priming

An important step is substrate priming. The function of the primer is to enhance adhesion of the ink to the substrate. The priming can be performed on-or off- press. Michelman Inc. has developed a range of primers that enhance the adhesion of HP Indigo ElectroInk to the substrates used for packaging. Among these primers are Michem®In-Line Primer 030 and DigiPrime® 050 , 060, and 680.

For additional details, regulatory information and applicable restrictions please contact Michelman directly (www.michelman.com).



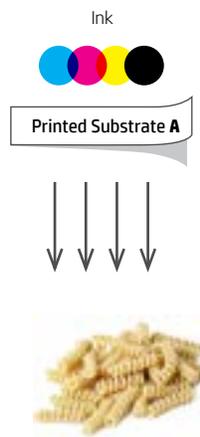
Migration and set-off

Packaging substances can be transferred to packed foods in a variety of ways. The two main types of transfer discussed here in regards to HP Indigo printed packaging are migration and set-off.

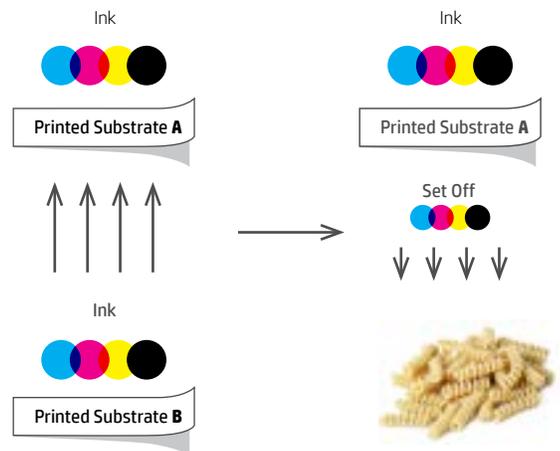
Migration is defined as the transfer of a substance through the packaging material into the food. The concentration of migrants is generally expressed in mg/dm² packaging or mg/kg of foodstuff (package contents).

Set-off can occur post-printing, when packaging is in stacks or rolls. At this phase of the printing process there is a risk of material transfer from the printed side of one substrate to the non-printed side of the substrate that will come into contact with food. Set-off can be visible or invisible. Visible set-off must be avoided and dealt with by the converter by ensuring that proper operating procedures are followed.

Migration



Set-off



Migration limits

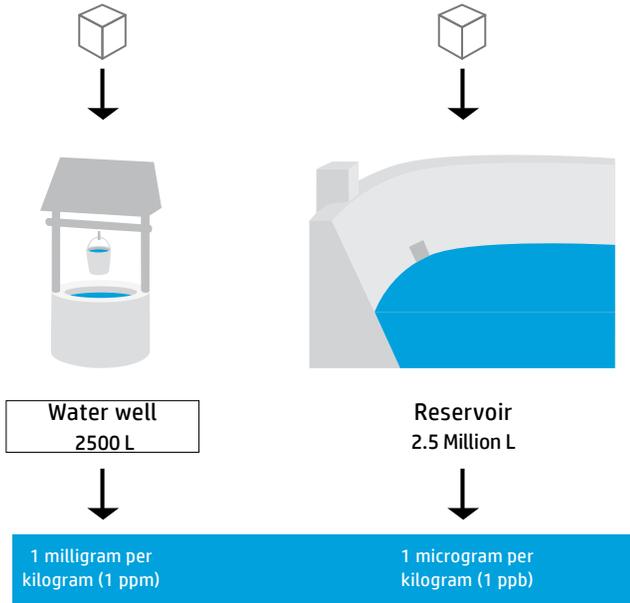
The amount of material that transfers from packaging to the packaged product depends on the starting concentration of migrants in the printed packaging, the nature of the packaging material, the migration rate, the type of food, the solubility of the migrant in the packaging or in the food product, and the conditions of use in general. To regulate within these variable factors, two major migration limits have been established, as follows:

The first limit is the Overall Migration Limit (OML), which is the maximum permitted amount of all non-volatile substances that can transfer from the packaging to the contents. The generally accepted value for OML is 10 mg/dm² or, based on the widely-accepted assumption that 6 dm² contains 1 kg of food, 60 mg/kg of foodstuff, or 60 ppm.

The second limit is the Specific Migration Limit (SML). This defines the maximum permitted amount of a given substance which can be released into the food. In the US, the TDI (tolerable daily intake) is generally used along with various dietary exposure factors to determine the maximum permitted amount which can migrate.

Parts per million (ppm) vs. parts per billion (ppb)

Sugar cube (2.5 g)
dissolved in:



Low migration inks

Many companies and ink manufacturers offer “low migration inks” for food packaging applications. Although there is no universal definition of what low migration inks are, they are essentially inks that are designed and formulated such that any migration that does occur meets regulatory limits. Although not expressly marketed as such, HP Indigo ElectroInk, when used as intended and in compliance with GMP and under certain frequently referenced conditions of use, meets this the industry-accepted description.

Mineral oils (Paraffinic hydrocarbons)

Mineral oils include a wide range of hydrocarbon substances, including paraffinic hydrocarbons. These hydrocarbons are used in many printing applications, such as in inks for newspaper printing. Since newspaper is an important source of recycled fiber for the paper and paperboard industry, some of the hydrocarbons used in newspaper inks end up in recycled boards, which can be used for food packaging applications. Therefore there has been much focus on the identification, characterization and toxicology of paraffinic hydrocarbons in the food packaging context.

HP Indigo ElectroInk also uses paraffinic hydrocarbons as the inert carrier of the ink particles. There are different kinds of mineral oils, which differ vastly in their potential impact on human health. Mineral oils are generally divided into saturated oils (MOSH – mineral oil saturated hydrocarbon) and aromatic oils (MOAH – mineral oil aromatic hydrocarbon). The specific MOSH used by HP Indigo has been shown to be of significantly less health concern than certain types of MOAH. Whereas newspaper printing inks contain both MOSH and MOAH, HP Indigo ElectroInk contains highly purified MOSH.

The specific paraffinic hydrocarbons used by HP Indigo comply with several FDA regulations for use in food-contact applications. Any migration and set-off that might occur involve only these purified paraffinic hydrocarbons. When used as intended, under certain frequently referenced conditions of use, HP Indigo ElectroInk is safe for printing a wide range of food packaging applications.

Direct food contact

Direct food contact of the ink with food in printing applications is rare and limited. Most current regulations refer to indirect contact, or printing on the non-food contact side of the food packaging. HP Indigo ElectroInk is not intended for direct food contact printing.



Testing and assessing migration

HP Indigo has conducted extensive evaluations in consultation with leading experts and according to recognized standards in well-known European and US laboratories, in order to evaluate HP Indigo ElectroInk compliance with food packaging regulations, as discussed in the pages that follow.

These evaluations simulated the contact of packaging with food under well-defined conditions of use, reflecting typical use and storage conditions. Since HP Indigo ElectroInk is intended for printing on the non-food contact side of food packaging, some kind of film or barrier between the printing ink and the food is always present. The food contact layers were selected and tested on the basis of their widespread use. Certain materials are known to be absolute barriers (e.g. glass, pin-hole free aluminum foil). When these materials are present as part of the food package, migration of ink components to the food cannot take place and thus the only concern for the converter and food packager is the small amount of invisible setoff that might occur.

Since paperboards are not generally considered to be effective barriers, when printing on the non-food contact side of paperboards it is advisable as good practice to have a polymeric layer or other layers between the paperboard inner surface and the food, as recommended by government agencies such as the German Federal Institute for Risk Assessment (BfR).

Supply chain responsibility

HP Indigo manufactures ElectroInk under stringent conditions of GMP and uses processes to ensure that our inks meet the compositional requirements of European, US and worldwide regulations. Food packaging applications can be printed safely when our guidelines for conditions of use are followed, the press is operated and maintained as required, and recommended ink coverages are used.



HP Indigo 30000 Digital Press for folding cartons.

The responsibility for ensuring the safety and organoleptic integrity of the printed package lies with the printer and the printer's customers. HP Indigo supports customers and engages with customers' regulatory teams on any questions that might arise. A Statement of Composition (SOC) can be provided, under a Confidentiality Agreement, to allow downstream users in the supply chain to perform a risk assessment of the final package.

HP Indigo ElectroInk regulatory status

- Complies with Article 3 of the EU Framework Regulation No. 1935/2004 when printing on the non-contact side of common polymeric food packaging materials (see below), where the resulting packages may be used to hold all types of food long term at or below room temperature, as well as for hot fill.
- When used as intended, complies with Good Manufacturing Practices (GMP) of the European Union, EU Regulation No. 2023/2006 and corresponding FDA requirements.
- All ingredients are on the Swiss Positive List of the Swiss Ordinance on Materials and Articles in Contact with Food (RS 817.023.21).
- All ingredients are on the Inventory List of the European Printing Ink Association (EuPIA) Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles (December 2013 version) and does not contain any chemical substances as described in the EuPIA Exclusion List for printing inks and related products (2nd edition, March 2016).
- All pigments used in HP Indigo ElectroInk formulations are on either list 1 or list 2 of Technical Document 1 of the Council of Europe Resolution AP (2005)2.
- Does not contain: (1) any of the substances listed on the Candidate List of Substances of Very High Concern (SVHC) for inclusion in Annex XIV of REACH, as published on December 17, 2015; (2) phthalates; (3) bisphenols; (4) materials listed under California Proposition 65.
- Meets the Federal Food Drug and Cosmetic Act 21 U.S.C 201 (FFDCA) requirements for printing on the non-contact side of common polymeric food packaging materials (see below), where the resulting packages may be used to hold all types of food at temperatures up to 100°C.
- Does not contain any materials on the Negative List of the Japanese Printing Ink Manufacturers Association (JPIMA) Voluntary Regulations Concerning Printing Inks (Version May 2015).
- Compositionally compliant with Nestlé Guidance Note on Packaging Inks, version 02-2014.



Regulation overview

United States Food and Drug Administration (FDA) vs. European Systems

The US (i.e. FDA) and European systems have different approaches to the notion of regulatory compliance of substances used for food packaging. The European system is based on a hazard assessment of the substance. The hazard assessment will generate a limit or restriction on migration of the substance to food (expressed as a Specific Migration Limit or 'SML'). In contrast, in the US compliance is predicated on a safety evaluation of the intended uses of a substance in the food packaging construction, with a satisfactory evaluation resulting in a clearance that specifies the upper limit of severity of permitted uses. Compliance requires conformity to the permitted conditions of use.

In both systems similar toxicology data must be evaluated, but the place that the evaluation of migration data takes in the US system differs from the European system. For US FDA, the threshold question is "What is the dietary exposure based on the migration data, for the specified conditions of use?" The dietary exposure then dictates the toxicology data needed to establish the safety of the intended use.

For the European system, however, the threshold question is "How much of the material is migrating into the food?" The migration data dictate the toxicology data needed to establish the safety of the intended use.

A common misconception is that ink brands are approved by either the FDA or European regulatory body. Ink brands are not approved by regulatory bodies. However, specific components of inks can be approved for specific applications and under defined conditions of use. HP Indigo ElectroInk is formulated only with components that are cleared for use in food packaging printing (non-contact side). No prohibited materials are used in these applications.

US regulations and food legislation

FFDCA of the FDA

The Food and Drug Administration (FDA or USFDA) is an agency of the United States Department of Health and Human Services, one of the United States federal executive departments. Among other functions, the FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety. The US legislation surrounding food regulation is rooted in the "food additive" concept. Thus, the Federal Food Drugs and Cosmetics Act defines a food additive as: "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in . . . packaging....)." The FDA compliance of ElectroInk is predicated on meeting the requirements of specific regulations, under specified conditions of use.

US Food and Drug Administration (FDA) Status of HP Indigo ElectroInk for Food Packaging

HP Indigo ElectroInks, Cyan, Magenta, Yellow, Black, White, Orange, Violet FP, Violet for Packaging and Green, have been assessed in relation to the Federal Food, Drug, and Cosmetic Act (FFDCA) and all applicable food additive regulations, and may be used to print on the non-food contact side of the food-contact layer of polymeric multilayer food packaging.

The following food-contact layers were selected for testing on the basis of their widespread use:

- (1) Low-density polyethylene (LDPE) 40 microns thick;
- (2) Polypropylene 20 microns thick;
- (3) Polyester 12 microns thick; and
- (4) Polycarbonate (Lexan) 20 microns thick.

The testing that was conducted took both migration from the package and invisible set-off into consideration. The thicknesses and materials tested are indicative and representative only, and additional film thicknesses and materials may also be suitable subject to appropriate testing or other suitable means of risk assessment.



The resulting packages may be used to hold all types of food at temperatures up to 100°C (also known as FDA's Condition of Use B, "Boiling Water Sterilized", under 21 CFR 176.170). These conclusions are based upon the formulation of the inks, the intended conditions of use, the results of evaluation at a leading laboratory, and the advice and opinion of independent consultants and advisors.

European regulations and food legislation

European Union (EU) regulations

EU framework regulation

Framework Regulation (EC) No 1935/2004, related to materials and articles intended to come into contact with foodstuffs, provides the basis for the assurance of a high level of protection of human health and of consumers' interests in relation to food packaging, whether printed or not. Article 3 of this regulation stipulates that food contact materials must not endanger human health, cause unacceptable changes in the composition of the food, or alter the organoleptic properties of the food.

HP Indigo ElectroInk printed on the non-food-contact side of polymeric multilayer food packaging may properly be described as complying fully with the applicable provisions of European food legislation. Specifically, Indigo's Cyan, Magenta, Yellow, Black, Orange, Violet FP, Violet for Packaging, Green and White, are in compliance with Article 3 of the EU Framework Regulation No. 1935/2004 for food contact materials.

The following food-contact layers were selected for testing based on their widespread use:

- (1) Low-density polyethylene (LDPE) 40 microns thick;
- (2) Polypropylene 20 microns thick; and
- (3) Polyester 12 microns thick.

The testing that was conducted took both migration from the package and invisible setoff into consideration. The thicknesses and materials tested are indicative and representative only, and additional film thicknesses and materials may also be suitable subject to appropriate testing or other suitable means of risk assessment.

The resulting packages may be used to hold all types of food for long term storage at room temperature and below including heating up to 70°C for up to two hours, or heating up to 100°C for up to 15 minutes. These conclusions are based upon the formulation of the inks, the intended conditions of use, the results of evaluation at an accredited European laboratory, and the advice and opinion of independent consultants and advisors.



Good Manufacturing Practices (GMP)

The manufacture of materials intended to come into contact with food must comply with the regulations on good manufacturing practice harmonized for the whole of the European Union (EU), so that these materials do not represent a danger for the consumer, nor change the composition of food nor the organoleptic characteristics thereof. In particular manufacturers must comply with Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, including packaging. This GMP Regulation details rules for all business operators, at all stages of the manufacturing and supply chains to ensure safety, quality, and process control.

The rules that regulate manufacturing processes under the GMP requirements pertain, among other things, to the use of printing inks on the non-food contact side of the substrate under stipulated conditions that aim to limit migration and set-off to levels in the food which are in line with the requirements of Article 3 of the Framework Regulation (EC) No 1935/2004 as well as other safety measures. GMP specifies that detailed documentation must be kept of many aspects of the manufacturing process, including specifications, formulae, processing, performed manufacturing operations, as well as the results of testing and other quality assurance systems. Such a system is also intended to monitor and correct any failure to achieve GMP.

HP Indigo implements GMP by operating state of the art quality control systems, which monitor continuously and in detail the highly automated ink production process and its output, thereby producing and delivering inks of consistent composition and high quality.

Plastics Implementation Measure

Plastics used in food packaging are subject to Commission Regulation 10/2011 of the EU, known as the Plastics Implementations Measure (PIM), which sets out a comprehensive set of requirements for categories of plastic materials used in the production of food packaging. This Regulation provides a Union list of monomers, additives (excluding color additives), and polymer production aids excluding solvents and macromolecules from microbial fermentation that may be used in the production of food flexible packaging. The categories of these materials are:

- a. Exclusively plastic materials, articles and parts
- b. Plastic multi-layer materials and articles held together by adhesives or other means
- c. Materials and articles mentioned in a) and b) that are printed or covered by a coating
- d. Plastic layers or plastic coatings forming gaskets that compose a set of two or more layers of different types of materials
- e. Plastic layers in multi-material, multi-layer materials and articles

Printing inks are not specifically regulated under the PIM, but printed plastic materials used for food packaging must comply with the migration limits as laid out in the regulation, including migration limits for printing ink components which are included in the Union list. The specific HP Indigo ElectroInk components that are included in the Union list meet the required migration limits, under the conditions of use defined in the EU Framework Regulation status section.



Other European regulations

Swiss Ordinance 817.023.21

The Swiss Ordinance of the Federal Department of Home Affairs (FDHA) on articles and materials details certain provisions relating to packaging inks. This ordinance provides a positive list of substances to be used specifically in food packaging inks. Article 26g of this ordinance determines that printing inks used on Food Contact Materials (FCM) may only be manufactured from the substances set out in annex 1 (lists I, II and III of plastics) and in annex 6 (lists I - V of packaging inks).

The lists of permitted substances of annex 6 are: (I) binders (monomers), (II) dyes and pigments, (III) solvents, (IV) additives, and (V) photoinitiators. Each list is divided into two—an A list for evaluated substances and a B list for unevaluated ones. Additionally, the migration limit(s) applicable to the substance(s) must not be exceeded and Good Manufacturing Practices (GMP) for printing ink manufacturing and printing must be used. Substances on a B list must comply with a migration limit of 0.01 milligrams per kilogram, or 10 parts per billion (ppb). This is in line with the EuPIA guidance (see below), which sets a 10 ppb limit for substances with insufficient toxicological data. For components with at least two negative mutagenicity tests, the limit is 50 ppb.

The ingredients of HP Indigo ElectroInk Yellow, Magenta, Cyan, Black, Orange, Green, Violet FP, Violet for Packaging and White are all included on the Positive List (Parts A & B) of the Swiss Ordinance on Materials and Articles in Contact with Food (RS 817.023.21) (Swiss “Bedarfsgegenständeverordnung”) article 26g.



Industry guidelines: The European Printing Ink Association EuPIA

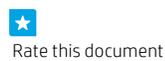
The European Printing Ink Association is a widely recognized industry association that works to give industry members guidance on safe manufacturing, use and handling of printing inks, related products, and their applications—including food packaging production.

HP Indigo ElectroInk Yellow, Magenta, Cyan, Black, Orange, Green, Violet FP, Violet for Packaging, and White comply with the EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles, December 2013 version. Furthermore, HP Indigo ElectroInk does not contain any chemical substances as described in the EuPIA Exclusion List for printing inks and related products.



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