INKS & COATINGS

for Food Packaging Applications

INX®

GLOBAL VISION, GLOBAL CAPABILITIES, LOCAL SOLUTIONS.

"At INX, there is nothing more important than the safety and welfare of our employees, customers, and consumers. That is why INX is committed to progress forever, especially as it relates to packaging inks used for food products. All facets of our business, from research and development, product stewardship, manufacturing, and quality work together to ensure that our food packaging inks are of the highest quality and safe for use as intended when applied."

Rick Clendenning
President and CEO of INX International Ink Co.

CONTENT

1 | FOREWORD

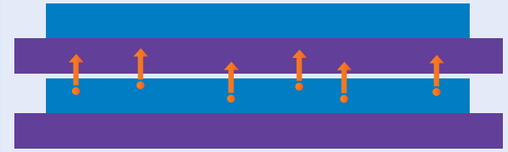
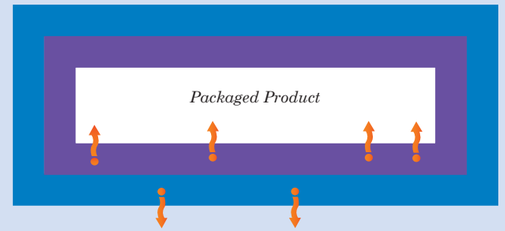
INX is dedicated to achieving industry leadership through excellence in product quality and customer service. Our mission is to meet our customers' needs and goals with technological developments and continuous improvement in manufacturing processes. We strive to produce products that minimize environmental impact.

This guide will give an overview of the issues related to food packaging inks. The intent is to provide printers and packaging converters with a sound understanding of the issues that can arise from the interaction of packaging with the food product. It aims to provide recommendations that will help promote informed choices when printing food packaging in accordance with the most relevant and current legislation.

2 | MIGRATION IN PACKAGING

Migration is the transfer of various components from the finished packaging to the food product. These components can originate from inks, adhesives, varnishes, coatings, substrate, or the environment. Often migration cannot be detected by odor or taste, but instead must rely upon chemical analysis to identify if any migration has occurred.

How ink migration can occur from printing
Three common paths where migration can occur:

1	Physical Migration	Penetration migration from printed side through substrate onto unprinted side.	
2	Physical Migration	Set-Off migration from printed side to unprinted side of another sheet in a stack or roll.	
3	Gas Phase Migration	Evaporation or condensation migration, either due to the evaporation of volatile materials by heating (e.g. cooking, baking, or boiling frozen products in their original packaging) or the condensation through steam distillation.	

Potential sources of Migration from printing

Presses	Substrate	Inks & Coatings	Finishing	Environment
▪ *Changeover contamination* ▪ *Press wash* ▪ *Fountain solution*	▪ *Paper/Film* ▪ *Paper coating* ▪ *Recycled content*	▪ *Mineral oils* ▪ *Unreacted raw materials* ▪ *Lower molecular weight components*	▪ *Adhesives* ▪ *Foils* ▪ *Laminates* ▪ *Equipment* ▪ *Forming release agents*	▪ *Climate* ▪ *Transportation* ▪ *Storage*

How is Migration Measured?

Migration is typically measured using gas or liquid chromatography with mass spectroscopy equipment. These measurements identify and quantify substances which have transferred from the package to the food product. Migration analysis models are typically dependent on the foodstuff, storage conditions, and package design. Results are usually measured in ug/dm² and converted to parts per billion (ppb) over a defined surface area.

To meet your target compliance requirements migration studies should beperformed by an accredited independent laboratory. Depending on risk assessment, ongoing migration testing should be performed to ensure compliance over time in accordance with current industry and government requirements.

What level of migration is acceptable?

The maximum allowable level of migration is based on the toxicological profile of the migrating substance, government regulations for said substance, and brand owner requirements. In every case, the migration profile must first be identified in order to carry out a risk assessment.

< 10 ppb	10 - 50 ppb	> 50 ppb
No Effect Level Required for toxicologically unevaluated substances or substances where not enough data exists to judge toxicity.	**Evaluate test result** Acceptable for substances for which three mutagenicity tests exist and are all negative (i.e. absence of genotoxicity).	**Full evaluation needed** At this level of migration, the full toxicological profile must be evaluated. The migrant may be an approved food additive or otherwise non-toxic. This decision must be made by a competent regulatory and scientific person(s).

3 | SUPPLY CHAIN ROLES

Responsibility for compliance of the packaging does not lie with one single individual member of the packaging supply chain. It is the ownership of all stakeholders, including the package designer, printer/converter, and material suppliers. Ultimate responsibility for ensuring compliance rests with the company placing the packaging in the market.

Achieving safe packaging requires all stakeholders in the packaging design and production chain to work together. A good example of this is outlined in the European Union Good Manufacturing Practice (GMP) regulation (EU Regulation EC 2023/2006/EC). This regulation details the overall requirements regarding selection and use of materials and articles intended to come into contact with food in accordance with EU Regulation EC 1935/2004. It establishes a framework of rules for all stakeholders involved in the development of packaging. Furthermore, it establishes and maintains recommendations for working specifications, quality assurance, control mechanisms, and traceability.

More information on Good Manufacturing Practice (GMP) can be found at www.eupia.org in the “EuPIA Position on Regulation EC No 2023/2006 of 22.12.2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food” document. Brand owners and end users of packaging may also wish to review their printer/converter’s Good Manufacturing Practice procedures and protocols to assure themselves that appropriate measures are in place to produce packaging suitable for its intended use.

Package Design & Pre-Press → **Printer/Converter** → **Material Suppliers** *(inks, coatings, substrates)*

INX International’s food packaging inks are manufactured in accordance with the requirements of Good Manufacturing Practice. Raw materials are carefully selected according to “EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles”. Accordingly, our food packaging inks are formulated without SVHC (Substance of Very High Concern), CMR (Carcinogen, Mutagen or Reproductive Toxin), heavy metals, and toxic or very toxic substances.

Ultimate determination of packaging compliance with migration regulations can only be assured with testing of the complete package as it will go to market.

Roles in Package Production	Areas of focus	Considerations
Package Design & Pre-Press	End-Use Packaging	▪ *Non-food contact* ▪ *Direct food contact* ▪ *Food type*
	End-Use Processing	▪ *Microwaveable/bake-able* ▪ *Retort/Pasteurization*
	Substrate specifications desired for package	▪ *Absolute barrier properties* ▪ *Functional barrier properties* ▪ *Filling, packing, storage, distribution*
Printer/Converter	Set materials specifications for materials suppliers	▪ *Verify materials needed to manufacture desired package* ▪ *Substrates* ▪ *Ink, coating, varnish, adhesives*
	Potential Sources of Contamination	▪ *Press wash* ▪ *Rollers* ▪ *Aniloxes* ▪ *Films* ▪ *Spray powder* ▪ *Press lubricants* ▪ *Fountain solutions* ▪ *Improperly functioning Curing Unit* ▪ *Maintenance chemicals*
	Curing	▪ *Follow all cure/drying specifications* ▪ *Ensure proper handling after printing*
	Follow Regulatory Guidelines and Good Manufacturing Practices	▪ *EU* ▪ *Switzerland* ▪ *U.S. FDA* ▪ *China* ▪ *Japan* ▪ *EuPIA* ▪ *NAPIM* ▪ *Australia/New Zealand* ▪ *CFIA (Canada)*
Material Suppliers *(inks, coatings, substrates)*	Raw Material Verification	▪ *Should meet regulatory guidelines and voluntary industry guidelines*
	Manufacturing	▪ *Follow Good Manufacturing Processes in accordance with government regulations*
	Lab Testing	▪ *Ink compliance* ▪ *Curing/drying parameters*
	Specification Requirements	▪ *Ensure all material properties and requirements meet established printer/converter specifications, including regulatory specifications identified by the printer/converter*

4 | LEGAL AND REGULATORY ENVIRONMENT

In general terms, food packaging regulations exist to prevent the adulteration of food from handling or packaging that could bring about a change in the nature, substance or quality of the food to a point that may endanger human health. INX International takes its product stewardship responsibility seriously. The company works hard to keep abreast of all current and future legislative changes to support customers in managing their compliance on a continuous basis.

Examples of Current Legislation Now in Place

Region/Country	Relevant Legislation	Main Concerns for the Food Packaging Chain
European Union member states	■ Framework Regulation (EC) 1935/2004 ■ Commission Regulation (EU) 2016/1416 amending and correction regulation (EU) No 10/2011 ■ Commission Regulation (EC) No. 2023/2006 (GMP)	▪ *No unacceptable change in food characteristics* ▪ *Setting out migration limits for substances* ▪ *Need to operate to Good Manufacturing Practices (GMP)*
Switzerland	▪ Ordinance of the FDHA on Materials and Articles (817.023.21) (only CH) https://www.blv.admin.ch/blv/de/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/lebensmittelrecht-2017.html	▪ *All ink raw materials for food packaging have to be listed and comply with SMLs*
USA	■ FDA, title 21 CFR ■ FCN (Food Contact Notification) ■ Food safety modernization act (FSMA); Foreign supplier verification program (FSVP) http://www.fda.gov/Food/GuidanceRegulation/FSMA/ ■ FDA Guidance for Industry: Preparation of premarket notification for food contact substances: Chemistry recommendations	▪ *Pre-market clearance required for direct food contact* ▪ *Non-food contact inks may require a functional barrier to eliminate migration*
Canada	▪ CFIA & "Health Canada"	▪ *Setting out food packaging standards* ▪ *Recommended "Letter of No Objection" for any packaging that may come in contact with food (unless functional barrier)*
Australia/NZ	▪ Australian Standard AS 2070-1999	▪ *Strong reference to the EU approach*
Japan	▪ Food Sanitation Law	▪ *Contamination of foodstuff by their packaging must be avoided*
Germany	▪ German Ink Ordinance (GIO)	▪ *Under development, expected to be similar to Swiss with positive lists and SMLs*
China	▪ GB9685 Hygienic Standard for Use of Additives in Food Containers and Packaging Materials	▪ *Comprehensive food safety law*

Definitions and Requirements

UNITED STATES OF AMERICA

Direct food additives are approved by the U.S. Food and Drug Administration for direct addition to food in order to perform a specific function. These are not part of printing ink or packaging.

Indirect food additives are not approved for direct addition to food. However, if they may reasonably be expected to migrate into food, they are then considered a food additive and are regulated by the U.S. FDA 21 CFR Parts 170-189. Compounds in printing inks or coatings that are converted in or on food packaging structures may be potential indirect food additives.

Direct food contact refers to a food contact substance (FCS), such as a printing ink or coating that is intended by design to be in direct contact with a food product. By virtue of this intimate contact, compounds in the printing ink or coating have a high potential to migrate to food and, therefore, must be in compliance with the indirect food additive guidelines at 21 CFR Parts 173-178. An example of this would be a printing ink or coating converted on the inside of food packaging material directly in contact with the packaged food product. A printed or coated surface in direct contact with food is always considered an ***indirect food additive*** unless it can be proven that there is no migration to the food product.

Indirect food contact is a term inappropriately used to describe a printing ink or coating that is not intended by design to be the surface in intimate contact with a food product, but which ***might*** come in contact with a food product. An example of this would be a printing ink or coating converted on the ***outside*** of food packaging structures (bags, boxes, etc.). This type of contact does not in and of itself require compliance with the indirect food additive guidelines. Mere contact of a food product with a converted printing ink or coating does not trigger a compliance need. The contact must be reasonably expected to result in the ink or coating becoming a part of the food. Migration from properly converted and dried ink or coating films generally will not take place by this mere inconsequential contact. Should migration to food occur, migration levels must be within the indirect food additive guidelines as specified at 21 CFR Parts 173-178. Generally speaking, in situations where exterior printing results in significant migration to a food product, root cause analysis should be done to determine the source of migration.

Food Contact Substance (FCS): Is a substance that is in contact with food. A FCS must either conform to 21 CFR Parts 173-178, demonstrated to be under the Threshold of Regulation (21 CFR 170.39), or be approved through the Food Contact Notification (FCN) process.

CANADA

The Canadian Food Inspection Agency (CFIA) and the Health Products and Food Branch of Health Canada are both responsible for food packaging issues. Packaging requirements at federally regulated packaging facilities are enforced by the CFIA. As a best practice, Health Canada recommends that food packaging companies obtain a Letter of No Objection from the Health Protection Branch for any packaging that may come in contact with food. (It is important to note that a Letter of No Objection does not absolve the packager from liability should there be a failure in package design leading to the contamination of the food product.) To obtain a Letter of No Objection, detailed information about the printing and packaging processes is required, along with representative migration test data, where possible. If the food package has a functional barrier between the food and the printed ink film, or the ink is completely dry and there is no ink set-off during stacking/nesting of the packages, then the package is considered to have no direct food contact with the ink film and a Letter of No Objection is not required.

EUROPE

Printing ink manufacturers that are members of EuPIA commit that they will follow the EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles **(http://www.eupia.org)**, which sets out in full, the responsibilities of the ink manufacturers within the packaging chain. As a principle, the Code of Practice agreed to by all EuPIA members, carcinogenic, mutagenic, or reprotoxic substances are generally excluded from use. Food packaging inks are formulated and manufactured taking into account many individual and varying parameters relating to the substrate, application, and end-use. They are designed to minimize the potential for transfer of ink components into food by migration, or set-off, while meeting the end use requirements. Food packaging inks are formulated and manufactured in accordance with the EuPIA Good Manufacturing Practices.

5 | PRACTICAL RECOMMENDATIONS TO MINIMIZE MIGRATION RISK

INKS AND COATINGS FOR FOOD PACKAGING

When inks and coatings are separated from the packaged food by one or more layers of material, the suitability of those inks and coatings are determined by the barrier properties and the extraction properties of the packaged food.

Because there is a wide array of combinations of food types, packaging materials, inks and coatings; there is a lack of clarity on the permeability of various combinations of plastic containers and film substrates. To be sure a packaging material acts as a functional barrier, migration tests with the final packaging construction are recommended. Containers such as pre-formed metal cans and glass bottles are considered low to no risk for migration.

Low migration inks are recommended when it comes to UV/EB and conventional sheetfed printing especially if thin film substrates or paper material with weak barrier properties are used as the primary packaging material. Low migration inks should be tested under standardized conditions to prove that they do not migrate above defined acceptable limits. Because these tests cannot simulate all possible food/substrate combinations, there cannot be 100% safety assurance without a suitable risk assessment.

RISK ASSESSMENT

For every specific packaging and label application, it's advisable to assess the risk of migration. This is especially recommended for packaging where no absolute barrier exists. Organoleptic testing for taste and odor; migration modeling; practical migration tests on the printed packaging material; and calculation of possible worst case scenarios help create a comprehensive analysis of a particular food packaging project and dictate what inks will work best.

CARE WITH ON-PRESS ENHANCEMENTS

For food packaging press runs, converters are advised to install extra controls to prevent the occurrence of visible set-off while maintaining the lowest possible levels of residual solvents and other volatile substances. Such controls should also be employed to ensure sufficient dying occurs to meet requirements.

Low odor and the elimination of any potential adulterant are important. Technical instructions from your consumable and equipment suppliers should be followed in full.

If slow or low evaporating solvents are used for improved printability of solvent-based and water-based inks, care must be taken with these choices as slow solvents have a high potential to be retained in the printed product and could subsequently migrate to the packaged food.

MATERIAL ASSESSMENT AND CONTAMINATION PREVENTION

It is always important to assess all materials that are used throughout the complete food packaging manufacturing cycle. When printing with low migration inks be sure that only specially selected low migration ink additives are used, including adhesion promoters and foam suppressors. To prevent accidents, no other general ink additives should be anywhere near the press. To ensure that migration from inks or coatings in the finished package remains within legislative limits, additional graphic features that might be printed on top of the low migration ink design must also consist of materials that have proven low migration tendencies.

When converting a press from conventional printing ink to a low migration ink, the press must be thoroughly cleaned to avoid any contamination from those previously used high migration materials.

MINIMIZING UV/EB MIGRATION

To meet UV and EB curing needs for food packaging and labels, proper curing is absolutely critical. Careful management of lamp power, print speed and ink film thickness are critical for proper curing to occur. It is essential that all UV lamps be on and fully functioning. It's imperative to use lamps within their specified lifespan or a successful cure will not be achieved.

Cure level should always be checked at the start of a print job, and during regular intervals throughout the run. Maintaining proper color density is also important, as too high of a print density may adversely affect cure.

6 | FREQUENTLY ASKED QUESTIONS

Why measure migration?

To ensure consumer safety it's imperative that packaging comply with the relevant regulations in line with Good Manufacturing Practice and Risk Assessment practices.

How does migration occur?

Migration from printing typically occurs in three different ways:

1. by penetration through the substrate,
2. by set-off transfer to the reverse/food contact side of a stack or reel, or
3. migration via vapor (gas) phase transfer

Is migration time dependent?

The longer potentially migrating components are next to the packaged foodstuff, the greater the risk of migration. There are many additional factors that affect the rate and extent of migration including the type of packaged foodstuff, the temperature at which the packaging is stored and the nature of the packaging itself.

What are 'low-migration' inks? Are they available from INX International?

Low migration inks and coatings are specifically designed and tested for use in food packaging applications sensitive to migration issues. When used correctly for their intended application, the migration of ink is minimized.

INX International offers a wide array of low migration inks and coatings for food packaging applications.

To learn about a low migration product suitable for your specific application please contact your sales rep or visit our website at:
www.inxinternational.com or email info@inxintl.com.

How do I ensure prevention of health hazards where legislation is currently incomplete?

Where legislation is currently incomplete, the best available guidelines and recommendations should be used. These guidelines should be applied to each of the separate components of composite packaging materials. When unsure of a composite material, or where an efficient functional barrier cannot be applied, ensure that the overall migration limit, as well as the individual substance specific migration limit and other limitations when applicable are fully respected. This can be achieved by:

- Appropriate package design
- Controlling the composition of the raw materials
- Controlling the migration features of the raw materials
- The use of functional barriers
- Testing directly the intermediate or finished products
- Controlling the process (GMP)

7 | ABBREVIATIONS, DEFINITIONS AND RESOURCES

CEPI	Confederation of European Paper Industries – www.cepi.org
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations (USA)
CITPA	International Confederation of Paper and Board Converters in Europe – www.citpa-europe.org
CMR	Carcinogen, Mutagen or Reproductive Toxin
ECMA	European Carton Makers Association – www.ecma.org
EFSA	European Food Standard Agency – www.efsa.europe.eu
EuPIA	European Printing Ink Association member of CEPE (European Council of producers and importers of paints, printing inks and artists' colors) – www.eupia.org
FCN	Food Contact Notification (USA)
FCS	Food Contact Substance
FDA	US Food and Drug Administration – www.fda.gov
Absolute Barrier	A layer(s) that prevents materials from migrating through the substrate. Typically glass bottles, pre-formed metal cans and metal pouches. However this barrier will not prevent set-off.
Functional barrier	A barrier consisting of one or more layers of any type of material that ensures the final material or article complies with Article 3 of Regulation (EC) No. 1935/2004 and with the provisions of this regulation. A functional barrier is a food contact substance which forms a protective barrier to the migration of compounds from the packaging structure or outside environment into the food, above FDA allowable limits.
GMP (Good Manufacturing Practice)	Those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to conform with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof (from Regulation 2023/2006/EC, art. 3).
OML	Overall migration limit
Set-off	Transfer from the printed surface, which is not properly dry, to the non-printed surface which can come into contact with food during storage in piles or in rolls.
SML	Specific migration limit
SVHC	Substance of Very High Concern
ppb	Parts per billion or 1 in 1,000,000,000 (1 ug/kg = 1 ppb)
ppm	Parts per million or 1 in 1,000,000
mg/dm²	Milligrams per square decimeter
mg/kg	Milligrams per kilogram (1 mg/kg = 1 ppm)
µg/kg	Micrograms per kilogram (1 µg/kg = 1 ppb)

IN A WORLD OF MANY INKS, THERE IS ONLY ONE INX.

INX International Ink Co.
150 N. Martingale Road, Suite 700
Schaumburg, IL 60173

1.800.233.INKS
www.inxinternational.com

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