Ensuring Safety and Quality with Low Migration Inks & Coatings

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Abstract

This white paper presents a primer on the manufacture of low migration packaging for food and other sensitive products, with emphasis on the role of low migration inks and coatings in the manufacture of high quality and safe packaging that ensures not only retention of the quality of the product, but more importantly, consumer safety.

By becoming a subject matter expert, in knowledge and in actual practice, on the subject of low migration packaging, packaging converters and commercial printers who manufacture packaging can increase their value within the packaging supply chain and become an even more valuable partner to their brand owner customers.

Packaging designers, converters and distributors bear responsibility for ensuring the design, manufacture and distribution of high quality packaging that complies with regulations and guidelines. This primer is an excellent starting point for new entrants into the market, and is also a good tool for use by experienced packaging converters who wish to review their policies and practices.

Introduction

Brand owners face an increasingly complex environment when it comes to product packaging. There is increased market pressure to reduce time to market, increase shelf appeal, and customize products to address specific geographic, demographic or other target consumer characteristics. This often results in the need to produce and manage smaller lot sizes of a larger number of SKUs. New production technologies are enabling the introduction of a broad range of different types of packaging on a wide variety of materials, and new production tools can make the design, review and production cycle more efficient.

In this often hectic and dynamic environment, one thing brand owners shouldn't have to worry about is the effect that printing inks, coatings and adhesives used in the manufacture of packaging have on sensitive products such as food, cosmetics, pharmaceuticals, tobacco and personal hygiene products. That's why it is important for packaging converters to stay current on compliance with the latest regulations and requirements on behalf of their brand owner clients, taking full responsibility for this aspect of package manufacturing.

This white paper addresses the key challenges faced by the packaging supply chain in the manufacture of low migration packaging that meets FDA and European Union (EU) guidelines for food (including pet food) and other regulated packaging. It offers solutions to the potential for unwanted compounds to migrate into sensitive products via their packaging. It will assist packaging converters and commercial printers who are a critical part of the packaging supply chain in becoming subject matter experts in low migration packaging techniques, positioning themselves as trusted advisors to their brand owner clients on the topic and taking one more worry off the brand owner's plate.

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Low Migration Packaging: A Primer

The term low migration packaging is commonly used to designate materials used in the packaging structure whose components will not migrate, or move, from the packaging into the product. To qualify as low migration packaging, compounds contained in the packaging structure, including printing inks, coatings and adhesives, must not have any deleterious effect on the appearance, flavor, odor, taste, shelf-life or safety of the product contained within the packaging. Low migration guidelines have been published by several brand owners who require compliance by suppliers.
Migration of components from print, adhesive or coating can occur under a number of conditions, including:

- Penetration Migration: Migration from the printed or coated side through the substrate and onto the unprinted side that is in contact with the product.
- Contact Migration: Migration from the printed side of one sheet to the unprinted side of another sheet in a stack or roll, usually referred to as set-off.
- Evaporation Migration: Migration due to the evaporation of volatile materials by heating (e.g., cooking, baking, microwaving or boiling frozen or other food products in their original packaging.
- Condensation Migration: Migration through steam distillation during cooking, baking, microwaving or sterilization.

Proper application of low migration strategies, including the selection of substrates, inks, coatings and adhesives, can act to mitigate many of these conditions to ensure that packaging is in compliance.

Migration Testing

In order to determine the migratory characteristics of various components of the packaging structure, migration testing is generally undertaken by qualified testing labs that use highly sophisticated equipment and techniques, including techniques such as chromatography or mass spectroscopy, to measure substance migration. For best results, these labs require the use of fully commercial and representative production packaging along with control samples of the product that will be contained within the packaging. Migration is measured by determining the identity and amount of materials that move from the packaging sample into the food or other product being tested. Sometimes simulated foods are used to mimic the nature of the food itself in this testing. Results are generally quoted in parts per million (ppm), parts per billion (ppb) or nanograms per milliliter of food stimulant. These metrics are then compared to guidelines to determine if migratory levels are acceptable or fall out of compliance with those guidelines.

Migration testing can take several weeks to complete and should be taken into consideration when planning time to market for a new product, or for new packaging for an existing product.

Acceptable Levels

Acceptable migration levels will vary depending on the toxicity of the specific component being tested. As a general rule of thumb, though, Table 1 provides guidelines in parts per billion for risk assessment of substance migration.

Table 1. Substance migration risk assessment

Measured Level	Description	Note
< 10 ppb	No Effect Level	#1
10-50 ppb	Evaulate Test Results	#2
> 50 ppb	Full Evaulation Needed	#3

Note 1: Even if the level of migration is less than 10ppb (the no concern level) there must be no material detectable with potential carcinogenic activity.
Note 2: Requires test data which demonstrates absence of genotoxicity (typically from 3 negative in vitro mutagenicity tests).
Note 3: The full toxicological profile must be evaluated by a competent expert and approved at this level of migration. For example, one of the migrants may be an approved food additive.

How About Those Hot Pockets?

As mentioned earlier, migration of compounds will vary depending upon the conditions the packaging is subjected to. This is relevant for food packaging, which is likely to be subjected to a wider range of conditions than other types of packaging. This is especially true in an age when convenience foods seem to be the norm. Many foods are designed to be baked, boiled or microwaved in all or part of their original packaging. As a result, packaging—including any inks, coatings or adhesives used in its manufacture—must be designed with a view toward low migration of components even under these more severe conditions.

One development in convenience food packaging that should specifically be considered is the use of susceptors. A susceptor is a piece of metallic film on a package of microwaveable food that helps cook and brown the food by concentrating energy on the food's outer surface.

An example of susceptor use in convenience food packaging is the crisping sleeve used in heating products like Hot Pockets or microwavable containers that crisp the crust of pies. Another example is microwave popcorn, where susceptors rapidly heat the oil that will cause the popcorn to pop.

By absorbing microwaves that penetrate the packaging (or the crisping sleeves), susceptor patch temperatures are raised to levels that can heat the food. If there is an air gap between the susceptor and the food, as in the Hot Pockets example, the susceptor will heat to a much higher temperature, causing a broiling effect that crisps or browns foods.

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Above - Hot Pockets crisping sleeves use susceptors for crisping

While the extra heat is great for the foods, it can also play havoc with compounds used in the manufacture of the packaging or sleeves. When susceptors are used in convenience food packaging, it is important to carefully consider the location of the print, coating and adhesive relative to the susceptors, especially where susceptors will come in direct contact with the food while cooking.

Eliminate or Minimize the Potential for Set-Off

It is also important to ensure minimal set-off during the package printing process so that components from the print are not transferred to the non-printed side of packaging substrates, and the packaging in contact with the packaged product is free from print or coating. Where there is a risk of set-off onto the food contact surface, a functional barrier should be included in the packaging design. Set-off can be controlled to some extent by using approved materials in the manufacturing process, using spray powder and/or water-based coatings with conventional oil-based inks, and ensuring the best possible cure when using UV-curable inks. Fanning or airing the printed stack can also reduce component migration by removing some volatile components, as can creating smaller stacks to reduce the pressure in the stack. In web printing, ensuring maximum drying or curing and, where practical, lowering web tension to minimize pressure in the reel may also help reduce set-off.

It should be noted that the application of coatings or varnish will not normally prevent migration, and in fact, depending upon the products used for coating, could actually increase the risk of component migration.

Low Migration Manufacturing Considerations

As this background information demonstrates, migration issues must be addressed from the point of packaging concept. Packaging converters and commercial printers who are producing packaging should leverage their knowledge of migration issues surrounding printing inks and coatings as they work with their brand owner clients in new product development efforts. To the extent converters can become engaged with brand owners, product managers, packaging engineers, design agencies and other stakeholders in the product development process, they can help those stakeholders make better decisions about package construction, likely saving both the brand owner and the converter time, money and aggravation downstream.

Following is a non-exhaustive list of the types of compounds that are likely to migrate during the life and use of packaging that packaging converters should be aware of. As we will discuss later, there are avariety of low migration products, including inks, coatings and adhesives, that converters can utilize to minimize the migration of unwanted components into package contents.

- Solvents, washes and cleaning compounds
- Oils and greases
- Plasticizers from plastics or inks
- Residual monomers from plastics, inks or coatings
- Breakdown products from inks and/or coatings following curing or drying
- Low molecular weight components from substrates or other raw material sources such as adhesives
- Hydrocarbon distillates, mineral oils and vegetable esters from conventional inks
- Non reacted materials in the case of insufficient UV or EB curing

This list provides some insight into manufacturing processes that can be adjusted in order to minimize migration and to ensure the safety of packaging and compliance with regulations and guidelines in line with good manufacturing and risk assessment practices. By ensuring continuous and full compliance of packaging materials, especially materials used to package human and pet food, and by staying informed about changes in regulations and guidelines, packaging converters can become invaluable subject matter experts their brand owner clients can rely on throughout the process of designing and manufacturing packaging. Knowledgeable packaging converters can assist with:

- Appropriate pack design
- Controlling the composition of the raw materials
- Controlling the migration features of the raw materials
- The use of functional barriers
- Directly testing the intermediate or finished products
- Controlling the process (working hygiene)

It should also be noted that the quality of food products can be affected by the introduction of odors or other taints into the product as a result of poorly manufactured packaging. While these odors or taints may not be harmful, they do affect the overall quality of the product and ultimately, consumer acceptance. Thus, package manufacturing processes should also take into consideration conditions that may cause non-harmful odors or taints to invade package contents.

Printing inks, coatings and adhesives, unless specifically designed for the purpose, should not, under normal circumstances, come into direct contact with packaged food and other sensitive products.

It should also be noted that printing on the contact side of packaging is not recommended, although brand owners may have reasons for wanting to do so. As a subject matter expert, the packaging converter should discourage this practice.

There are two key reasons this is not recommended, especially for food packaging:

1. It puts the packed product in intimate contact with inks or coatings in a confined space, increasing the risk of migration into the packaged product; and,
2. Since the reverse side of many folding carton materials is uncoated, inks are likely to penetrate the reverse side of the board during the printing process. In this case, penetrated inks may not be appropriately dried or cured, and the risk of component migration is significantly increased.

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If printing on the reverse side of packaging material cannot be avoided, use of low migration inks and coatings can mitigate risk. In addition, the location of the printing, especially if susceptors are used, is critical. Keep in mind that the smaller the printed area, the lower the risk. Alternatively, there are a small number of products specifically designed for printing on the direct food contact surface, although they may have some additional technical restrictions and a limited color range.

Color Selection

Not all colors are created equally, especially when it comes to the printing of packaging that will be exposed to high temperatures in cooking or other processes. Packaging converters should closely collaborate with their ink supplier to fully understand which pigments are heat stable. Even with heat-stable pigments, long exposure (in excess of 30 minutes) to temperatures above 390 F (200° C) should be avoided. In addition, there have been reports of isolated instances of a potential fire hazard when containers printed with a printing ink incorporating carbon black pigment are heated in a microwave oven. In this case, if necessary, a trichomatic (CMY) black can be used in place of a carbon-black-based ink.

Packaging Safety Responsibility

It is the responsibility of the packaging designer, packaging converter and distributor to ensure that packaging has been fully tested and meets all applicable regulations and guidelines for its end use prior to proceeding with full production printing, especially in the case of packaging for microwave or ovenable applications. To the extent packaging converters can play a lead role in taking on these responsibilities, their value in the packaging supply chain is increased.

Selection of Materials

The key to the manufacture of high quality, safe packaging for food and other sensitive products lies in good communication among stakeholders across the entire packaging supply chain. This will better ensure that final packaging complies with relevant regulations and guidelines, and ultimately, ensures consumer safety. Stakeholders should be clear about all elements of specification and traceability, as well as what is to be packed and how (i.e., hot filling). Final consumer use of the product and packaging should also be fully understood. Questions to ask include:

- Is the packaging intended for food or other sensitive products?
- If it is for food (including pet food) or sensitive products such as cosmetics, pharmaceuticals, tobacco and personal hygiene products, is the package component destined to be used as primary packaging where the packaged goods are in prolonged direct contact with the non-printed side of the packaging?
- Alternatively, is the component designed as a primary outer wrap, also known as secondary or indirect packaging, where the goods are contained in some form of primary packaging such as a flow wrap or a tray? Is the primary packaging a barrier to migration? If not, low migration inks should be used.
- Will the packaging undergo some form of secondary processing; for example, in boiling water, an oven or a microwave?
- Does the packaged food or other sensitive product contain materials that make it a higher risk for migration, such as high sugar or fat content?

Once the answer to these questions is understood, the packaging converter—and in fact, the entire packaging supply chain—is in a better position to select appropriate materials for the manufacture of the packaging.
There are a variety of low migration inks, coatings and adhesives that can be used in this manufacturing process. These include:

- Low migration UV inks and coatings that avoid the use of low molecular weight raw materials including solvents, use polymeric photoinitiators and are fast curing with a high cross-link density;
- Low migration EB inks and coatings that provide for optimum curing with irradiation by an electronic beam. Curing usually takes place in an inerted chamber, with a Nitrogen atmosphere preferred when producing food packaging;
- Conventional oleoresinous inks designed for food packaging. These are normally based on raw materials such as specially modified resins, high molecular weight polyesters or vegetable oil derivatives. These inks, under normal circumstances, do not migrate.
- Low migration water-based coatings that avoid the use of ingredients that have been identified as potential migrants. Water-based coatings are made from specially selected polymers, but they also contain coalesc ing solvents, slip control agents, anti-corrosion and anti-microbial additives in order to be fully effective.

Other consumables that should be optimized for the manufacture of low migration packaging include fountain solutions and press washes, which could leave migratory residues on the final printed package. This includes the avoidance of products that use isopropyl alcohol, a highly mobile potential migrant.

And it goes without saying that a clean press and a clean working environment are a must in the production of packaging for food and other sensitive products. If a press can be dedicated to the manufacture of low migration packaging, the converter can derive a number of benefits, including:

- Reduced downtime in changeovers
- Reduced cleaning
- Reduced waste
- Optimal dedicated work practices

Adhesives and glues used in the folding and gluing process should also be specialty low-migration products.

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In addition, manufacturers of packaging should:

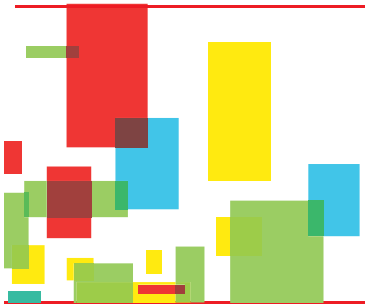
- Avoid strong odors in all storage areas to mitigate airborne migration of volatile components, especially with regard to paper and board.
- Ventilate areas thoroughly after cleaning floors with products that contain volatile components, or avoid the use of those products entirely, substituting cleaning products that do not contain volatile components that could migrate into packaging raw materials.
- Carefully select paint and coatings for use on buildings and signage to avoid inadvertent migration of volatile components to packaging raw materials.
- Do not allow exhaust fumes from vehicles to impact work in progress or print stored in warehouses. Exhaust fumes, especially from engines using fossil fuels, can contain non-burned hydrocarbons and sulfur compounds with potentially significant adverse impacts on migration performance.
- Store and transport packing work in progress at normal temperatures. This is important not only for dimensional stability of the packaging but also for minimizing migration of unwanted volatile compounds.

Summary

By adopting good manufacturing practices and by staying fully informed about industry regulations and guidelines, packaging converters can position themselves well to not only assume responsibility for the manufacture of packaging appropriate to the contents it will contain, but also to act as a key partner and subject matter expert to brand owner customers, from concept through production.

Keep in mind that the use of low migration inks, coatings and adhesives, while critical to good manufacturing processes for food and sensitive product packaging, are not the only consideration for many of the reasons stated in this white paper. This reinforces the need for exceptional communication among all stakeholders in the packaging supply chain. Low-migration products should be acquired from reliable suppliers that have stringent and proven safeguards, analyses and compliance strategies built into their manufacturing and distribution processes.

Even with all of these precautions in place, migration testing is still required and should be performed by an expert third-party accredited laboratory that specializes in this type of work. Once the testing results are received, it is necessary to evaluate them carefully to understand what has actually been tested—the outer packaging itself (printed or non-printed side), or the whole packaging as it will be used including the inner wrap layer, if any. This information is essential, as results could be misleading, depending on the test(s) used and how the results are calculated.



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