August, 2022

Energy Curable Flexographic Inks for Low Migration Applications

ACTEGA has received many requests for inks with low migration properties from the packaging industry. Low migration inks are especially important for food packaging, cosmetics, and pharmaceutical applications. This whitepaper focuses on migration definitions, regulatory authorities, and other important considerations when selecting energy curable flexographic inks for packaging.

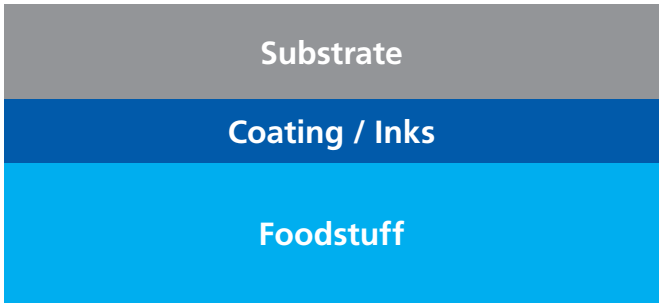
Migration Definitions

Migration represents the transfer of substances to the filled package good from the substrate, printing inks, or coating. Migration mainly depends on four aspects:

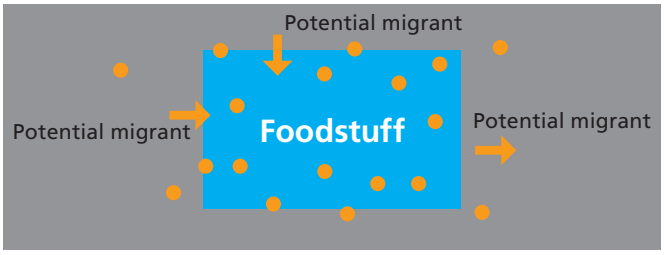
- Barrier properties of the packaging
- Products used in the package construction
- Conditions in the printing process
- Filled good characteristics (e.g. dry, fat containing, etc.)

There are four overall types of migration:

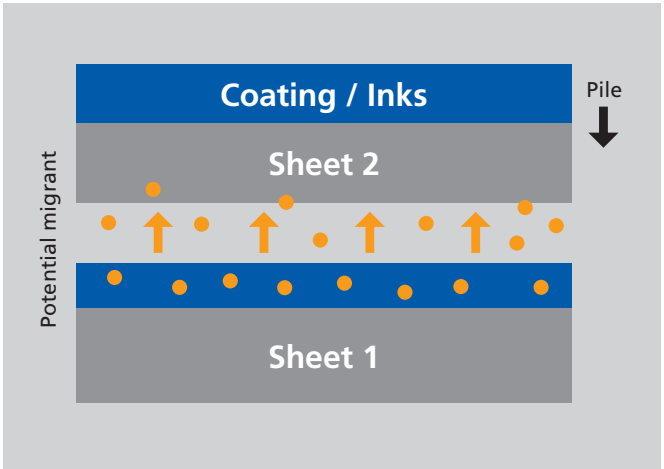
Direct Migration occurs when the print materials come in direct contact with the food.



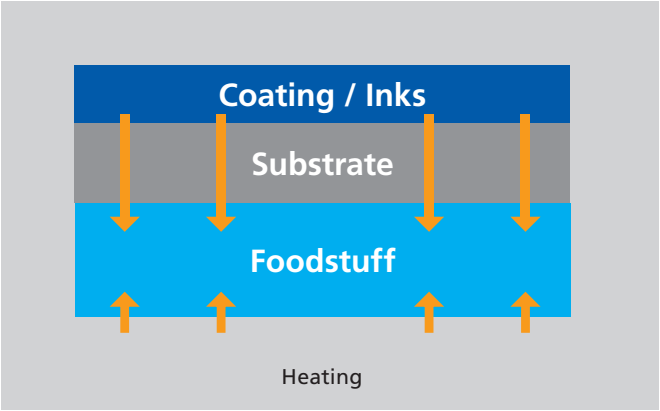
Through Migration occurs when the packaging substrate is not a functional barrier and materials penetrate through the substrate into the foodstuffs on the reverse side of the print. Through migration can be avoided by proper substrate construction or polymer type. For films, PET (Polyethylene Terephthalate) is a functional barrier, however BOPP (Biaxially oriented polypropylene) is not a functional barrier for through migration.



Set Off Migration is caused by the contact of print sheet's printed side with the unprinted side of another print sheet. This may happen in the sheet pile or when rolling up.



Vapor Phase Migration happens through heating conditions that cause the inks to migrate through the packaging. One example is a microwave meal that is heated while still in the original printed packaging. Specific raw material selection to avoid vapor phase migrants in the product development process can eliminate this type of migration.



The safety of foodstuffs in packaging printing has become more and more important. There are many regulations and guidelines to be considered. Applied food contact materials (FCM) must correspond to applicable food law regulations. Unintended substances that may transfer from the packaging must be harmless to health. The responsibility of fulfilling food packaging regulations rests upon those who bring the packaging to market.

Regulatory Overview

The technical feasibility improvements of safer, less hazardous, and more environmentally friendly packaging chemistries have compelled various government, corporate, and non-profit entities to begin to develop standards addressing the chemicals used in packaging applications. At present (2022), much of the chemical regulations are championed in Europe and North America, however, there is increasing regulatory scrutiny from South America, Japan, and China. Large brand owners have also developed compositional statements related to high-profile incidents or general trends of consumer perception, regardless of whether these perceptions are based on good scientific assessments.

Low Migration Regulatory Landscape

The regulatory landscape surrounding food packaging is largely composed of governmental jurisdictions, individual corporate guidance, and non-profit organizations. While governments and corporations dictate the exact guidance that is to be formulated to, in many instances the language of that guidance originates from the non-profits. In consideration of the governmental jurisdictions, western Europe contains the most clearly defined and articulated regulation. In the US, the FDA regulations can be more difficult to navigate, and Mercosur, Japan, and China have similar but unique regulatory styles as in western Europe. When considering food packaging guidance, the Nestle guidance note on packaging inks is one of the more notable ones as it has historically had periodic updates every two years.

European Regulation

Europe has a more complicated regulatory space because in addition to several individual countries having specific and unique regulations, there is the larger European Union regulation which all the individual countries must abide by. For coatings and inks in particular, ECHA or the European Chemicals Agency, which is the main chemical repository of chemicals for the European Union was the main resource location. A chief consideration when selling into European Union countries is that all individual raw materials must be REACH (Registration, Evaluation, and Authorization of Chemicals) registered. The REACH status as well as other chemical information is maintained by ECHA. REACH registration is a complicated and expensive process for raw material suppliers which may present an obstacle to new chemicals entering that geographic marketplace.

Another important topic related to European regulations are Substances of Very High Concern (SVHC). A chemical is given a SVHC status by ECHA if it has “serious and often irreversible effects on human health and the environment.” During the low migration portfolio development, two photoinitiators were recently reclassified as SVCHs and one of the photoinitiators that was being used had to be substituted. Because of this reclassification, a series of alternate photoinitiators were evaluated and a database was compiled to anticipate possible regulatory adjustments that may occur.

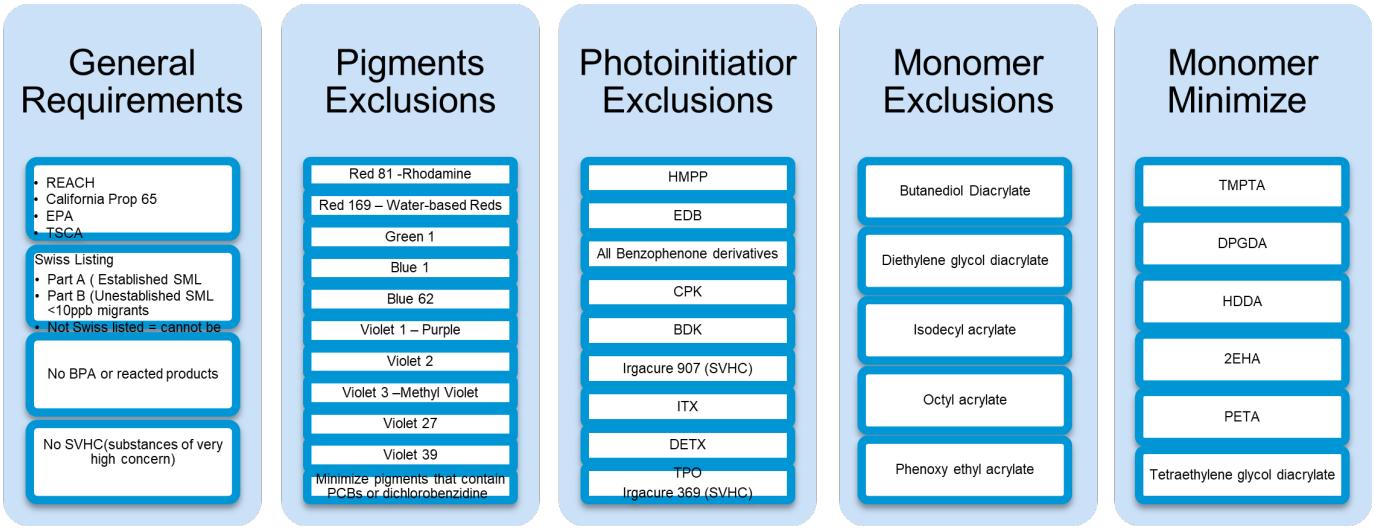
Swiss Annex 6 Listing

Within Europe, the Swiss Annex 6 is also a significant regulatory requirement for Nestle. In the latest Nestle Guidance (2018), one of the requirements is that all chemicals in an ink formula must be listed on Swiss Annex 6. This list is comprised of two groupings of chemicals, part A and part B. The part A chemicals have been evaluated and have a listed specific migration limit (SML) and the part B chemicals have not been evaluated and have a default specific migration limit (SML) of 10 parts per billion (ppb). The part A chemicals migration limits will vary based on the health hazard and can range from several parts per million (ppm) to the 10 parts per billion (ppb). For context of the scale of 10 parts per billion, this volume is 1 ½ tablespoons (25 ml) into an Olympic size swimming pool that contains 660,000 gallons (2,5 million liters).

Nestle Packaging Guidance 2018

In addition to the Swiss listing requirement, there are other compositional requirements such as pigments, photoinitiators and monomers that are prohibited for use. Specifically Nestle prohibits the use of rhodamine, methyl violet and purple pigments that are used in the current (2022) ACTEGA ink lines.

There is also an indication that pigments that have the possibility to generate PCBs (green) or are based on 3'3'-dichlorobenzidine linkages, which include, yellow, red and orange shade pigments should be minimized or phased out. This guidance would largely limit the pigment selection to high performance lightfast pigments. The list of prohibited photoinitiators is the oldest part of the Nestle guidance that originated out of the ITX detected in baby milk in Italy. This list has continued to be updated and more photoinitiators have been added and a few listed on the 2018 guidance have now been reclassified as SVHC by the EU. The monomer prohibition list is mainly monofunctional monomers that have a greater possibility to migrate. The minimize list of monomers was also avoided due to possibility of prohibition in the future. TMPTA was on the 2018 minimize list and has since been listed by the California Proposition 65 as a suspected carcinogen. While the Nestle guidance specifically references the Swiss Ordinance Annex 6 and includes the several positive lists reviewed here, there is also the statement that to comply with the Nestle guidance the inks must comply with "other local regulations such as environmental laws." Examples are given such as California's Proposition 65, US-EPA, TSCA, etc.



California Proposition 65

Packaging guidance is also driven from a compositional side in the US by the California EPA (Environmental Protection Agency) Proposition 65. Proposition 65 was originally targeting drinking water (Safe Drinking Water and Toxic Enforcement Act of 1986). The main implication for the brand owners if the commercial good is known or tested and contains a chemical on the Proposition 65 list, then a warning label must be attached to the product. The warning label indicates through various labeling statements that the product may cause cancer. The Proposition 65 listing is largely informed by IARC (World Health Organizations International Agency for Research on Cancer) as well as California state experts tasked with carcinogen or reproductive toxin identification. These committees include the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant Identification Committee (DARTIC). Since there is no "de-minimis" or minimum value for chemical concentration with regards to migration limits any detectable value will trigger the labeling requirement. Effectively there is no migration limit. If the material can be detected analytically, then the product containing the target chemical will have to be labeled.

United States - FDA

In the United States, The Food and Drug Administration is the agency that regulates food packaging. The list of indirect food contact substances (FCS) are specified in Title 21 of the U.S. Code of Federal Regulations (21 CFR) parts 175-178,179.45, and 180.22. The FDA does specify migration conditions and testing parameters.

Currently, the general interpretation is that there are no approved direct food contact UV curable systems outside of specific Food Contact Notifications. The legal interpretation is that each formula composition is unique, and that the specific composition would have to be evaluated and approved.

One example related to UV curing for packaging is a coating submitted in Food Contact Notification (FCN) 772. The composition of FCN 772 included an epoxy-acrylate, TMPTA, and Esacure One photoinitiator. All of these materials are now restricted materials in consideration of various global regulatory guidance standards. With regards to food packaging, if the application does not intend that the package be consumed and the migration results demonstrate that there are no residual chemicals migrating in the food, then the packaging would not be regulated by the FDA and would be suitable for use.

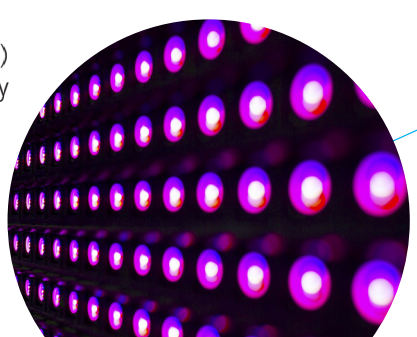
UV vs. LED Curable Inks

UV Curable Inks for Low Migration Packaging

UV curable technology offers many advantages in low migration applications. A key health and environmental attribute is that a UV curable ink can be formulated without any residual solvents. The polymer films formed with UV cure technology often have performance advantages over other chemistry polymer types used for inks. Two important attributes to UV cure technology to press operators are the controlled drying and associated low maintenance of the ink.

UV Curable Inks for Low Migration Packaging

LED curable technology has grown in many packaging applications as several suppliers have advanced the technology in product offerings in the printing market. While there are still a significant number of installations of existing mercury-based UV curing lamps in the field, many companies are transitioning to LED curing lamps for their new press purchases. The adoption of the LED lamp technology is accelerating by the chemistry product portfolio offerings like ACTEGA has developed for low migration applications.



LED for Printing Applications

The most critical point concerning press operation is the proper cleaning of a printing press to achieve below parts per billion level contamination in the finished construction. Another important consideration when using UV and LED low migration OPVs, primers, and adhesives is the proper ambient light conditions. Many standard commercial light sources, especially LED lights, emit light in the UV spectrum that can begin the polymerization process or otherwise impact the rheology. The current state of the art for LED chemistry does not allow the formulation of a coating that will not polymerize under 395nm ambient light but will cure at your top speed under press with the same 395nm light!

Pigments

Regulatory Compliant Pigments

The most important attribute of packaging inks is color, and the color of most packaging inks is obtained by using pigments. Both pigments and dyes are the results of multiple-step chemical synthesis, that generate a solid colorant. Pigments are differentiated from dyes as colorants in that a pigment is insoluble in the medium or fluid it is dispersed into whereas a dye is completely soluble and dissolves into the liquid.

Pigment Overview

The chemical type of the pigment and the synthesis process are critical attributes of packaging inks. Pigments must be milled in an energetic process to reduce the particle agglomerates to a specific particle size distribution to be used in an ink. Many companies add proprietary chemicals or surface treatments to pigments to assist in the dispersion process. The chemistry of the pigment, residual synthesis reagents, and proprietary additives can impact the suitability of pigments for sensitive applications.

Pigment Selection

One of the most important attributes of a regulatory compliant ink system is to ensure that the pigments meet the relevant regulatory requirements. The ACTEGA low migration ink line has specifically selected pigments that meet the current (2022) regulatory guidance across many global jurisdictions. This includes most notably the positive lists of Swiss Annex 6 and the negative list of the 2018 Nestle Guidance.

Pigment Analytical Testing

Beyond the chemical composition of the pigments, ACTEGA currently partners with a supplier that actively monitors the chemical composition of the pigments as well as the associated surface treatments used in the inks for sensitive packaging applications. ACTEGA has also confirmed through external laboratory testing that residual PCBs were below the analytical limit of detection (LOD) in a specific pigment that had the potential for residuals based on the synthesis pathway.

Pigment Specific Regulatory Challenges

One regulatory challenge related to pigments is the use of carbon black and titanium dioxide in packaging inks. Both carbon black and titanium dioxide have similar and recently (2022) updated global SDS hazard labeling requirements. California Proposition 65 and the European Chemicals Agency CLP (Classification, Labeling, & Packaging) (EC 1272/2008) require GHS codes that communicate both carbon black and titanium dioxide are suspected carcinogens. The carcinogen hazard is related to the inhalation hazard associated with the particulate dust and respiratory exposure that is demonstrated to be carcinogenic. However, in the ink products being sold, the pigments should be adequately dispersed such that the pigment particle is continuous with the liquid phase and therefore does not pose a respiratory hazard. It is also not common in flexographic printing that the ink would result in a respiratory hazard, such as "misting" in offset printing. Also, a critical technical performance detail is that there are currently (March 2022) no alternate pigments for carbon black or titanium dioxide white that can achieve the equivalent color characteristics of these two materials. ACTEGA is currently investigating potential alternative materials that will meet the technical requirements for both materials.

Good Manufacturing Practices (GMP) in Low Migration Packaging Applications

Good Manufacturing Practices (GMP) is a critical component in assuring the quality of products designated for food packaging. In order to provide the end consumer with a safe product, the entire supply chain must communicate the required regulatory documentation. The communication should flow in both directions at every link in the supply chain. Because analytical techniques have improved significantly contamination in the earliest point in the supply chain can track through the entire process and ultimately contaminate the final product.

EuPIA GMP

The European Printing Ink Association (EuPIA) provides an excellent resource that discusses some of the highlights of GMP concepts that specifically relate to the manufacturing of printing inks. The highlights of this document are similar to the ISO 9001 and the importance of documentation throughout the manufacturing process. This includes raw material traceability and batch management as well as documentation of manufacturing procedures and site management. The EuPIA GMP guidance for packaging inks also addresses topics such as customer product inquiries, product communication packages, product development, purchasing, and recall guidelines that are unique to printing ink applications. The ACTEGA product line conducted due diligence evaluations before (the raw materials used in the ink formulas), during the manufacturing, and after (the printing/converting of packaging constructions) our position in the supply chain.

GMP Considerations During Product Development

During the development process a significant effort was given to organizing the raw material documentation. The raw materials selected for use in formulation had to follow the various global regulation targeted. Additional regulatory letters were also obtained from multiple suppliers stating the raw material composition conformity to regulatory requirements. All the raw materials were benchmarked by analytical instruments to confirm the supplier claims as well as to benchmark the materials for future reference.

Manufacturing GMP

Manufacturing of the printing inks or coatings designed for food packaging applications must be conducted at a higher level than for standard printing ink applications. The raw materials must be batch managed to ensure the raw material traceability in the event of a recall. Additional raw material evaluations are required in accordance with the EuPIA GMP guidance.

UV LED Press Application GMP

The inks, coatings, and adhesives in the low migration portfolio were trialed and tested on a Mark Andy P5 six station press located in the Ink Technology Center location in Charlotte, North Carolina. Through these press evaluations, the suitability of use of the portfolio was established. One of the critical learnings from the two-year press investigation into printing for low migration, was the necessity of cleaning! In fact, it would be nearly impossible to switch between non-low migration and low migration activities on a printing press and consistently achieve a low migration profile by analytical instrumentation verification. Many idler rolls that have set-off transfer would need to be cleaned between each changeover would make it impractical to switch back and forth between compliant and non-compliant chemistries.

Raw Material Advancements

The source of future advancement lies in the development of new, safer polymer technologies. However, in order to avoid widespread contamination of toxic chemistries, the regulatory burden of new polymer technologies has expanded dramatically. This has necessarily slowed polymer development significantly. It used to be that a preliminary manufacturing notice (PMN) with the US EPA would take 6 months to process for TSCA registration, now the wait even pre-Covid is significantly longer 18-24 months. The REACH polymer registration is also equally onerous in time and cost. As the raw material feed stream becomes increasingly commoditized, this is where ACTEGA claims a unique position as a member of ALTANA to leverage both BYK and ELANTAS polymer synthesis expertise to begin to backward integrate into the raw material supply chain. Already, some basic oligomer synthesis as well as photoinitiator investigations projects are underway with a much longer time horizon. There are also long-term projects that have investigated the next generation of UV curable low migration polymer technologies with university partners around the world.

LED Manufacturing Optimization

LED curable inks exhibit extreme sensitivity to ambient light. To address this topic, yellow light filters may be installed in the manufacturing areas to prevent ambient light from reacting LED curable formulas. Pan covers or chambered doctor blade systems are critical for LED coatings. A handheld spectral light meter provides the ability to benchmark the ambient light conditions and measure the light source as well as the filter reduction efficiency to establish suitability in manufacturing.

Cleanliness, GMP, and the threat of Contamination

The cleanest ink system can be contaminated at any stage during the supply chain. ACTEGA has actively sought to mitigate the liability of contamination through raw material quality control protocols as well as analytical verification for intentionally added substances as well as non-intentionally added substances in the manufacturing environment. Even though the inks may be clean when they arrive unopened, contamination on press or in the ink ready at a converter is an ever-present threat.

About ACTEGA

ACTEGA develops, produces and distributes specialty coatings, inks, adhesives and sealing compounds with a focus on the packaging industry. The portfolio includes solutions for food, beverages, pet food, cosmetics, pharma and household products along with industrial applications. Our products do not only fulfil numerous functions around the protection of the filling good, but also provide the packaging with a high-quality appearance. Production facilities in Europe, the Americas and China ensure that the portfolio is available worldwide.

Legally compliant products, specially tailored to the high safety standards of the food, pharmaceutical and toy industries, determine our innovation roadmap and activities. ACTEGA is a division of the internationally operating specialty chemicals group ALTANA.

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